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COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council

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{SWD(2017) 469 final} - {SWD(2017) 470 final}

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1. WHAT IS THE PROBLEM AND WHY IS IT A PROBLEM?

1.1 Introduction

This initiative is announced in the **Single Market Strategy**, *Upgrading the Single Market: more opportunities for people and business*, adopted by the Commission on 28 October 2015[1] and constitutes one of the main initiatives of the 2017 Commission Work Programme.[2] It is part of the "Goods Package". It should be set in the context of the fourth priority policy area to be tackled under President Juncker's Agenda for Jobs, Growth, Fairness and Democratic Change, i.e. a **deeper and fairer internal market** with a strengthened industrial base.

The Single Market Strategy aims, inter alia, at strengthening the Single Market for Goods. It notes that the increasing number of illegal and non-compliant products on the market distorts competition and puts consumers at risk. According to the Strategy, *'many economic operators disregard the rules either through lack of knowledge or intentionally to gain a competitive advantage. More deterrence is needed […]The Commission will therefore introduce an initiative to strengthen product compliance by providing the right incentives to economic operators, intensifying compliance checks and promoting closer cross-border cooperation among enforcement authorities, including through cooperation with customs authorities'.*

However the Single Market can only function well and be **fair for people and businesses if all market players play by the rules**. It is therefore essential that such EU legislation is correctly implemented by everyone on the ground to maintain the highest level of protection and to safeguard the competitiveness of businesses across the EU.

1.2 Context

1.2.1 Regulatory context

The Single Market has been a frontrunner in EU economic integration. The most important legislative obstacles have been eliminated through EU harmonisation legislation[3]. The objective of this legislation is twofold, first ensuring that industrial products placed on the European market guarantee high levels of protection for health and safety and the environment and secondly, ensuring the free movement of industrial products by replacing national rules with a single harmonised set of conditions for placing these products on the market.

The basic product rules are set out in **Union harmonised legislation, which covers the great majority of industrial products** such as toys, machinery, radio equipment, electrical and electronic devices, cosmetics, gas appliances, measuring instruments, pressure equipment, chemical substances that could be found in products belonging to a wide range of sectors, energy using products and many others[4]. The rules are applicable to both consumer products and products used in the context of professional activities, regardless of whether traded in physical 'brick- and mortar' shops or online and regardless of whether produced domestically or imported from third countries, as long as they are offered on EU markets. On the other

1 Communication from Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Upgrading the Single Market: more opportunities for people and business*, COM(2015)550/2.
2 COM(2016) 710 final: http://ec.europa.eu/atwork/key-documents/index_en.htm
3 For a glossary of terms and abbreviations see Annex, page 85.
4 Annex 7 Section 1 contains a non-exhaustive list of product sectors covered by Union harmonisation legislation potentially affected by this initiative.

hand, products manufactured in the EU for exports to third countries are not subject to these rules.

Union harmonised rules set specific requirements relating to product technical characteristics and/or other mandatory information or documentation that should accompany the products or be made available to authorities upon request. The main aim of these rules is to protect European citizens from health, safety, environmental and other risks and to improve the competitiveness of businesses by eliminating unjustified barriers to trade. In addition Union product rules, due to harmonisation, benefit businesses in terms of increased opportunities to exploit economies of scale. When products available on the market effectively comply by the harmonised rules, consumers will find it easier to compare products and their prices and will therefore also benefit in terms of lower search and transaction costs. The specific product requirements set out in the legislation depend on the nature and purpose of products and may vary greatly between different areas of legislation and from sector to sector. For instance, in the case of toys the rules cover all (mechanical, chemical, etc.) characteristics of the products so to ensure they will not endanger the health of children. In other cases however relevant rules focus exclusively on one aspect of products (e.g. level of noise emissions of equipment for use outdoors, electrical hazards or chemical substances contained in products, labelling on the composition of textile and footwear, amount of energy consumption implied by a domestic appliance, electro-magnetic compatibility of products using radio frequencies).

Furthermore, the purpose of these rules is often the protection of health and safety but it could also cover other relevant public interests: for instance in the case of measuring instruments (gas, petrol, electricity, taxi meters, scales, etc.) rules cover a number of product (mechanical, software-related, etc.) aspects intended to guarantee the accuracy of measurement and therefore the fairness of transactions between buyers and suppliers of goods to be measured; rules concerning restriction on the use of chemical substances in batteries are also intended to prevent pollution of the environment; rules on electromagnetic compatibility intend to ensure the correct use of spectrum by electronic products. In the case of some products, different sets of rules (i.e. different piece of Union harmonisation legislation) containing complementary requirements are applicable (e.g. to address electrical hazards, electromagnetic compatibility, and energy consumption aspects).

Products covered by Union harmonisation legislation must comply with it, in order to be legally marketed in the EU. In order to strengthen the enforcement of product requirements the New Legislative Framework was adopted in 2008. This is a package of measures that aims to improve market surveillance and creates a toolbox of measures for use in product legislation. The New Legislative Framework consists of:

- Regulation (EC) 765/2008 setting out the requirements for accreditation and the market surveillance of products to be fulfilled by Member States,

- Decision 768/2008/EC on a common framework for the marketing of products, which includes reference provisions to be incorporated whenever product legislation is revised. In effect, it is a template for future product harmonisation legislation.

In particular, according to Regulation (EC) No 765/2008 Member States must ensure effective surveillance of their market. They are required to organise and carry out the monitoring of the products made available on the market or imported. Member States have to take appropriate measures to ensure that the rules set out in Union harmonisation legislation,

are respected in the EU and, in particular, to prevent the making available on the market and use of non-compliant and/or unsafe products[5]. For that purpose Member States must:

- Correctly implement the provisions of the relevant legislation and allow for sanctions proportional to any infringements;

- Control the products (whatever their origin) introduced on their market in order to ensure that they have been subjected to the necessary procedures, that the marking and documentation requirements have been respected and that they have been designed and manufactured in accordance with the Union harmonisation legislation requirements. In the case of products imported from third countries, customs authorities should be closely involved in the market surveillance activities.

- Organise market surveillance according to minimum common requirements (appointment of competent authorities, resources, market surveillance programmes, reviews and assessment of market surveillance, etc.).

- Cooperate with authorities in other member states by sharing information on products controlled and activities carried out, in particular by making use of the common database (ICSMS) and taking part in the Rapex Rapid Alert mechanism (RAPEX) for products presenting a serious risk.

Annex 6 provides an extensive description of market surveillance requirements laid out in and exchange tools made available by the Regulation.

Furthermore, on the basis of Decision 768/2008/EC the EU legislators committed to review applicable Union harmonisation legislation according to the reference provisions identified, including among other the following aspects relevant for market surveillance:

- definitions of relevant economic operators (i.e. manufacturer, importer, distributor) and corresponding responsibilities concerning product compliance and traceability depending on their role in the supply chain, and

- provisions on specific market surveillance procedures (so-called 'safeguard procedures') to be applied when authorities have reasons to believe that a product does not comply with common rules.

At the time of writing an important part of EU harmonisation legislation has been reviewed and now incorporates those reference provisions.[6]

The following box provides an overview of market surveillance rules applicable to products subject to EU product rules depending on whether they now incorporate the reference provisions of Decision 768/2008/EC.

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5 According to Article 16 of Regulation (EC) No 765/2008 "Market surveillance shall ensure that products covered by Union harmonisation legislation which, when used in accordance with their intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained, are liable to compromise the health or safety of users, or which otherwise do not conform to applicable requirements set out in Union harmonisation legislation are withdrawn or their being made available on the market is prohibited or restricted and that the public, the Commission and the other Member States are informed accordingly. Member States shall ensure that effective measures can be taken in relation to any product category subject to Union harmonisation legislation".

6 https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

Box 1: Architecture of main market surveillance rules applicable to products subject to EU product rules

1) For products subject to Union harmonisation legislation aligned to Decision 768/2008/EC:

- definitions and **obligations of relevant economic operators** depending on their role in the supply chain
- procedures to determine the **steps to be followed by market surveillance** notably **when they have reasons to believe that a product presents a risk**, i.e.: assessing conformity of the product and level of risk, requesting businesses to take corrective action, communicating relevant measures to other Member States and the Commission, follow-up by authorities in other Member States, in case of objection by another authority Commission decision confirming the measure notified by the initiating Member State was justified or, to contrary, considering it unjustified.

2) For all products subject to Union harmonisation legislation (Regulation (EC) 765/2008):

- obligation for Member States to **appoint market surveillance authorities** (MSAs) and entrust them with the powers, resources and knowledge necessary for the proper performance of their tasks
- obligation to draw up either a general **market surveillance programme** or sector-specific programmes covering the sectors in which they conduct market surveillance, communicate those programmes to the other Member States and the Commission and make them available to the public
- obligation to **periodically review and assess the functioning of their surveillance activities** (at least every four year) and communicate the results to the EC, other Member States and to the public
- obligation for MSAs to **perform appropriate checks** on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples
- **power of MSAs** to require economic operators to make documentation and information available for the purpose of carrying out their activities, and, where it is necessary and justified, enter the premises of economic operators and take the necessary samples of products. MSA may destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary.
- obligation to ensure that **products which present a serious risk** requiring rapid intervention, including a serious risk the effects of which are not immediate, are **recalled, withdrawn** or that their being made available on their market is prohibited, and that the Commission is informed without delay and that relative **measures** are **notified in** the **Rapex Rapid alert system**
- obligation to share information on non-compliances via an EU general database (**ICSMS**)
- obligation for customs (or other authorities in charge of controls at the border) to **check imported products** and to refuse their release for free circulation if found to be non-compliant.

In 2013, the European Commission adopted proposals for new rules improving the safety of consumer products and market surveillance for all non-food products, in the so-called Consumer Product Safety and Market Surveillance Package[7]. The proposals intended to address the need to streamline, simplify and improve market surveillance rules and procedures to make it easier for national authorities and economic operators to apply and follow them. Specifically, at that time the Commission stressed that market surveillance rules

7 COM(2013)75: Proposal for a Regulation of the European Parliament and of the Council on market surveillance of products; and COM(2013)78: Proposal for a Regulation and of the European Parliament and of the Council on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC.

are spread across three separate 'tiers' - Regulation (EC) N° 765/2008, the General Product Safety Directive and various pieces of product harmonisation legislation (not aligned with reference provisions set out in Decision 768/2008/EC) and that the relationship between the three tiers is often unclear, particularly as many consumer products are covered by all three. The new proposals were also seizing the opportunity to align *mutatis mutandis* the definitions of the relevant economic operators and market surveillance procedures laid down in the General Product Safety Directive to the reference provisions of Decision 768/2008/EC. Last but not least, the proposals contained an obligation for manufacturers and distributors to indicate the origin of products.

However, the negotiations between the European Parliament, the Council and the Commission are stalled since long. In its session of 26-27 May 2016, the *'Council took note of a request made by eleven member states to renew efforts with a view to moving forward negotiations on the Consumer Safety/Market Surveillance package (8985/16). The package is currently blocked in the Council* […]. *The presidency verified that positions within the Council remain unchanged*[8].' The discussions on the proposals were not resumed and it is reasonable to assume that any progress on the proposals in view of its adoption by the co-legislator is highly unlikely.

Meanwhile, the Commission evaluated Union harmonisation legislation in 2014[9]. One of its main outcomes was that market surveillance is considered to be the weakest part of the implementation system, partly due to the inherently difficult nature of the task and in part due to varying levels of resources and technical expertise available in different countries[10].

Because of the urgency to address major gaps in the enforcement of Union product harmonisation legislation the Commission launched the new initiative under the Single Market Strategy. This aims at introducing changes to the EU rules on market surveillance that concern aspects not specifically targeted from the 2013 Package (e.g. controls in the context of e-commerce) or go beyond the solutions proposed at that time (e.g. as regards cross-border cooperation). In addition the new initiative takes into account the latest legislative developments of Union sector specific legislation, in particular the fact that an increasing number of product harmonisation directives or regulations have been incorporating the reference provisions of Decision 768/2008/EC.

The initiative has the ambition to step up enforcement of product requirements set out in a very broad range of Union legislation[11] by setting up horizontal rules applying across the board on top of sector-specific rules.

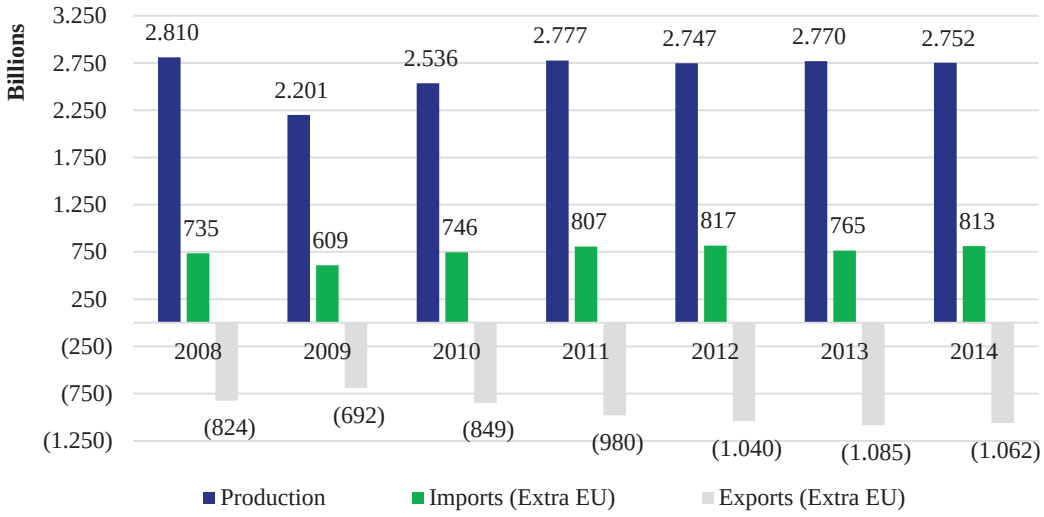
This impact assessment examines options to improve the legal framework for market surveillance of harmonised products and constitutes and ex-ante assessment in the meaning of article 30 of the Financial Regulation to the extent that funding and resourcing of market surveillance by the EU budget could be significantly affected[12].

8 http://www.consilium.europa.eu/en/meetings/compet/2016/05/26-27/
9 COM(2014)25 and SWD(2014)23.
10 SWD(2014)23, section 4.8.
11 More than 60 pieces of legislation are listed in Annex 7 Section 1.
12 Chapter V of Regulation (EC) N° 765/2008 sets out funding provisions for all aspects of the Regulation, including market surveillance.

1.2.2 Economic context

The **value of EU harmonised products** amounted on average to more than 2 400 billion euro per year during the period 2008-2014, and corresponds to about 69% of the overall value of manufacturing products in the EU[13]. Around 1.2 million businesses are involved in the manufacturing of industrial products (65% of all businesses active in the EU manufacturing sector). Furthermore, the value added of wholesale and retail traders whose sales are likely to include harmonised products during the 2008-2015 period is estimated around 850 billion euro per year. The number of enterprises active in the distribution of products in these sectors is estimated around 4 million and the number of their employees over 22.5 million people[14].

Figure 1: Trade of harmonised products: sold production and trades with non EU countries (2008-2015, EU-28), € billions



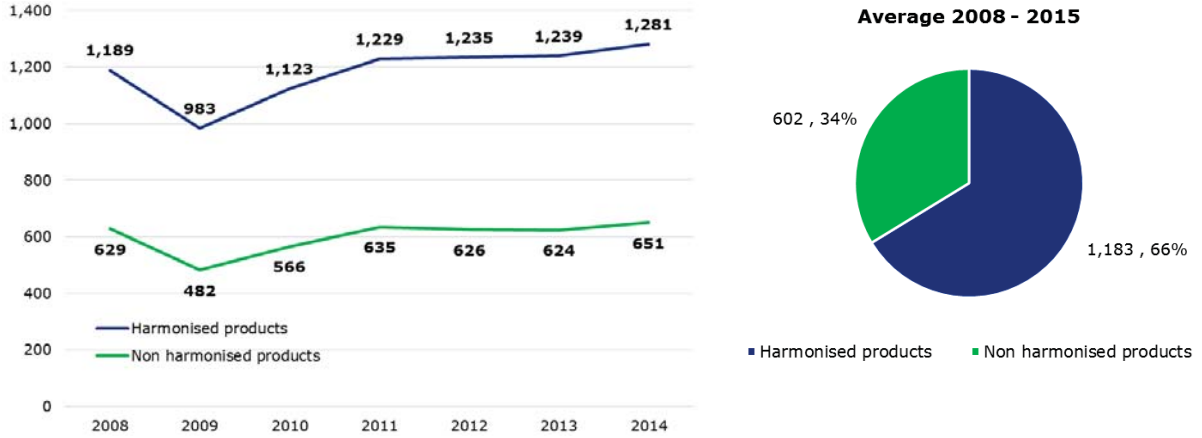
Source: Prodcom – statistics by product, EUROSTAT (2016)

Furthermore, the **intra EU imports** of products for which harmonised product rules exist represent also 66% of the value of the overall (intra-EU) imports of manufacturing goods (€1,183 billion).

13 This value has been calculated considering the value of sold production – value of extra EU exports + value of extra EU imports at product level; the analysis at sectorial level estimates the turnover of harmonised products manufactures in the EU to be around 4 500 billion euro (see Annex 5).

14 Annual detailed statistics for industry and trade (NACE Rev. 2, B-E) [sbs_na_dt_r2 and sbs_na_ind_r2] - EU 28 (Last update: 13.01.17 - Source of data: Eurostat). It should be noted that a precise breakdown between wholesale and retail trade in harmonised products and non-harmonised products is not available. An attempt has been made to identify those wholesale and retail sub-sectors that are likely to be involved in the sale of harmonised products but their sales are likely to include non-harmonised products as well. The added value is therefore likely to be overstated.)

Figure 2: Value of intra EU imports: harmonised products vs non-harmonised products (annual value and annual average 2008-2015, EU-28, EUR billion) [15]



Source: EU trade since 1998 by SITC, EUROSTAT (2016); Average: Harmonised products 1,183 EUR billion, non-harmonised 602 EUR billion.

1.3 What is the problem?

Many products on the EU market do not comply with the rules on industrial products set in Union harmonisation legislation. This means that their substantive characteristics are not in line with what is prescribed by EU rules and/or that mandatory markings, warnings, labels and other information are lacking, incomplete or incorrect.

Non-compliant products cause harm to buyers and law-abiding undertakings alike. In practice, non-compliance means that citizens are exposed to potentially dangerous products or that the environment is put at risk. The following box provides some examples of non-compliant goods recently notified to the Commission by national authorities that are likely to seriously endanger the health and safety of their users. However the type and the seriousness of harm (e.g. injury to buyers, injury to workers, property loss, unfair transactions, pollution, and security problems) suffered as a consequence of non-compliance depend on the specific product at stake and the degree of the non-compliance presented by the product. Non-compliance with substantive or technical product requirements (e.g. physical properties of a product) is often expected to bring about more serious consequences than non-compliance with requirements of formal nature (e.g. mandatory warnings, labels or documentation accompanying the products or to be provided upon request), however the latter may also have serious implications (e.g. buyers using the product improperly lacking instructions). Non-compliance with formal aspects or mandatory markings is also important. It may be spotted more easily than technical non-compliance and cannot be disregarded as it may signal the likelihood of technical non-compliance: in particular the lack of CE marking signals that the manufacturer was not aware of applicable product legislation and that possibly the product was not intended for the EU market.

15 Annex to the REFIT Evaluation on the application of the market surveillance provisions of Regulation (EC) No 765/2008, section 7 Market analysis. NACE sectors and PRODcom codes were selected to target as closely as possible only harmonised goods that come under the scope of the Regulation (EC) No 765/2008. A conservative selection was made for certain sectors (e.g. food, agriculture, pesticides, certain chemicals were excluded or only partially taken on board); the results obtained in this evaluation study are therefore lower for harmonised goods than if a wider selection of (sub)sectors are compared for trade in harmonised and non-harmonised products (market study on non-harmonised good and mutual recognition).

Furthermore, non-compliance means that undertakings selling compliant products face distorted competition from those undertakings which cut corners or deliberately flout the rules to gain a competitive edge. According to some stakeholders non-compliant imports from 3rd countries have a negative (indirect) effect on employment in Europe [16]. More details on the consequences of the problem are provided in section 1.5 below.

Box 2: Examples of non-compliant products presenting a serious risk for their users

- **Mobile phone**: The battery cell may overheat due to an internal short circuit occurring as a result of thin separator and misaligned negative electrode. The product does not comply with the requirements of the Radio Equipment Directive and can provoke burns. Product notified by the UK. The product was also found in other 16 Member States.
- **Travel steam iron:** The mains cable is too short and could consequently deteriorate as a result of mechanical force leaving live parts accessible. Due to the way the product is constructed, the user's hand could come into contact with parts that reach high temperatures. The product does not comply with the requirements of the Low Voltage Directive and can provoke burns or electric shock. Product notified by Spain.
- **Gas burner:** The gas appliance produces a large amount of carbon monoxide in the combustion products during normal use. People in the proximity of the gas appliance could suffer from carbon monoxide poisoning. The product does not comply with the requirements of the Gas Appliances Directive and can cause asphyxiation. Product notified by The Netherlands.
- **Angle grinder:** The guard does not protect the user properly. The tool can restart after an interruption of the mains supply without the user releasing and re-actuating the switch. The product does not comply with the requirements of the Machinery Directive and can provoke cuts. Product notified by Poland.

Although non-compliance often passes unnoticed and the exact share of non-compliant products on the market cannot be quantified with precision across all the product sectors, the problem of non–compliance appears to be rather widespread and even in some sectors the majority of products checked turn out to be non-compliant.

In 2014, 2015 and 2016 respectively a total of 2 435, 2 123 and 2 126 notifications of dangerous products were submitted by Member States through the European rapid alert system for dangerous non-food products 'RAPEX'[17].

In the public consultation organised by the European Commission 89% of all respondents considered the products in their 'sector"[18] as affected to some extent by non-compliance (for 26% of total respondent non-compliance concerns *most* products in the sector, for 42% of them concerns *some* and for 21% it concerns *few* products), only 4% answered that this was not the case, while 7% answered "I do not know" (see Figure 3). When asked to indicate the approximate proportion of non-compliant products in their sector 45% of respondents chosen declared themselves as unable to estimate it, while the rest indicated different estimates

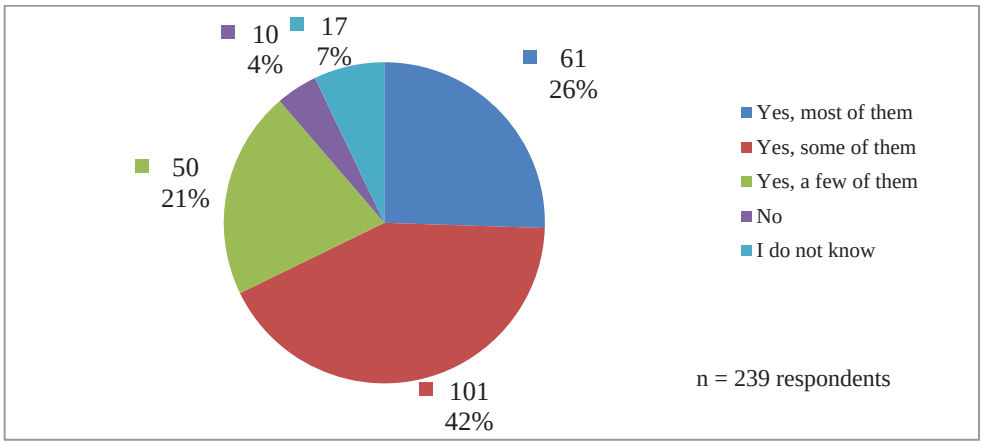
16 "Non-compliant products destroy industrial jobs!", http://www.industriall-europe.eu/Committees/IP/PolBrief/PB2016-08-MarketSurveillance-EN.pdf

17 The system only registers information on non-compliances expected to lead to a serious risk, excluding than products presenting a relatively lower level of risk (i.e. high, medium, low) and non-compliance with administrative requirements when they are not expected to bring out a risk. Furthermore, most Member States de facto record in this system only serious risk concerning the safety of consumers' products so most of non-compliance linked to professional products and other types of public interests are not reflected.

18 This was defined as being the "sector of activity" for businesses supplying products and for conformity assessment bodies, the "sector of responsibility" for national authorities, "sector in which they purchase products" for citizens, consumers, end users, and "sector for which studies have been conducted or expertise gained" for academics or other legal experts.

ranging from close to zero up to "more than 50%". The answers provided more frequently were: "0 to 5%" (given by 14% of respondents), "6 to 10%" (11%) and "11 to 20%" (11%). Additional details can be found in Annex 2 section 2. It is noted that the representation of respondents in terms of activity sectors and Member State origin is well balanced. The findings of the consultation therefore support the thesis that non-compliance of products with applicable requirements cannot be considered as a problem that affects exclusively specific sectors or countries.

Figure 3: Are the products in your sector(s) affected by non-compliance with product requirements laid down in EU harmonisation legislation?



Source: public consultation

The levels of non-compliance vary by Member State and by product sector. Estimates at sector level are hardly available. However, for instance, in the case of the Ecodesign Directive dealing with products such as electric equipment, air-conditioning systems, machines tools etc., a 2009 study estimated non-compliance to be 10% - 20%[19]; as concerns the Energy Labelling Directive a stakeholder mentions non-compliance rates of 20 to 50%[20]. In the area of gas appliances existing studies indicate non-compliance levels of 5% - 10%[21]. In a consultation conducted by the European Commission in 2010 in ten sectors[22], 92% of businesses considered that their sector is affected by non-compliance.

The closest proxy for the level of non-compliance in different sectors is given by shares of products found to be non-compliant during inspections carried out by market surveillance authorities jointly or individually which shows a fairly gloomy picture, although it is noted that authorities focus checks on areas where infringements of products legislation are more likely and that the figures might overestimate average non-compliance rates. For instance, on the basis of **data reported by Member States in the period 2010-2013**[23] non-compliance was found on average in 32% of inspections conducted in the field of toys, 47% in the field of construction products, 34% in the field of low voltage electrical equipment, 58% in the field of electromagnetic and radio equipment and 40% in the field of personal protective

19 European Commission, 'Evaluation of the Ecodesign Directive (2009/125/EC) - Final Report', 2009.

20 See position paper by trade-union federation "IndustryAll" quoting Ecofys, 2013. See also Annex 7 section 2 containing figures on findings of Deutsche Umwelthilfe e.V. (Environmental Action Germany) in Eastern Germany, p 4.

21 European Commission, Impact Assessment study on the review of the Gas Appliances Directive (2009/142/EC)- Final Report', 2009.

22 Commission Staff Working Paper 'Impact Assessment 10 Proposals to Align Product Harmonisation Directives to Decision No 768/2008/EC'. The consultation concerned the following sectors: Low Voltage, Electromagnetic Compatibility, ATEX, Lifts, Pressure Equipment, Simple Pressure Vessels, Measuring Instruments, Non-automatic Weighing Instruments, Civil Explosives and Pyrotechnic Articles.

23 The data were included in national reports published according to Article 18(6) of Regulation (EC) No 765/2008.

equipment.[24] The complete overview on non-compliance found by national authorities during national inspections in 30 different groups of sectors can be found in section 5 of Annex 9. The table below provides a summary view.

Table 1: Percentage on non-compliant products found in sectors inspected (averages for all Member states having reported information)

% of non-compliant products	No of sectors inspected
0-17%	7[25]
23-28%	6[26]
30-40%	8[27]
41-50%	3[28]
> 50%	6[29]

Source: national reports and Commission elaboration.

In the case of REACH and CLP Regulations, whose data were not included in previously mentioned reports, concerning chemicals, more than 200 000 controls per year were reported by the EU Member States from 2007 until 2014. The average level of compliance calculated is reported to be 86%[30]. Conversely the average level of non-compliance is estimated at 14%.

Furthermore, 74% out of the 38,946 investigations (with specified risk) recorded by Members States in the Information Communication System for Market Surveillance (ICSMS) during the period 2008 – 2016 concern non-compliant products. Unlike figures contained in Table 1, these data allow capturing the seriousness of the consequences on the non-compliance found. In particular 2,209 (6%) of these investigations showed products presented a serious risk, 6,214 (16%) a high risk, 8,590 (22%) a medium risk, 12,617 (32%) a low risk, while for 9,316 (24%) investigations no non-compliance was identified.[31]

Estimates based on shares of products found to be non-compliant in the course of **joint inspections** by market surveillance authorities are reported in the following table. They show that in all campaigns but one between 35% and 90% of product tested were found to be non-compliant in some regard. Often products were also non-compliant in relation to different aspects. In all cases substantive or technical non-compliance affects a sizeable share of products (at least 46% of toys tested, 77% of LED lighting equipment, at least 27% of energy and heating meters, respectively 44% and 67% of solar panel inverters in two subsequent years, 68% of repeaters for mobile phones and 51% of drones).

24 According to data provided by Member States on number of inspections carried out and on number of findings of non-compliance in the context of national reviews and assessment of market surveillance activities according to Article 18(6) of Regulation (EC) No 765/2008. This figure represents the weighting average of percentages at national level.

25 Simple pressure vessels and Pressure Equipment; Transportable pressure equipment; Lifts, Cableways; Measuring instruments, Non-automatic weighing instruments and Pre-packaged products; Marine Equipment; Non-road mobile machinery.

26 Machinery; Noise emissions for outdoor equipment; Electrical and electronic equipment under RoHS, WEEE and batteries; Chemicals (Detergents, Paints, Persistent organic pollutants); Ecodesign and Energy labelling; Motor vehicles and tyres.

27 Toys; Cosmetics; Personal Protective Equipment; Aerosol dispensers; Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres; Electrical appliances and equipment under LVD ; Recreational craft; Other consumer products under GPSD

28 Medical devices; Construction Products; Appliances burning gaseous fuels.

29 Pyrotechnics; Explosives for civil use; Electrical equipment under EMC; Radio and telecom equipment under RTTE; Efficiency requirements for hot-boilers fired with liquid or gaseous fuels; Fertilisers.

30 According to data provided by Member States and ECHA under Art 117 (1), (2) of REACH and Art 46(2) of CLP.

31 Data from the Information Communication System for Market Surveillance (ICSMS) (see Annex 7). It is noted that the notifications where the risk is not specified have not been included in the analysis. Furthermore, the information recorded in ICSMS is not representative of all inspections carried out by member States (see Annex 11 for more details on the degree of use of the system).

Table 2: Estimates of non-compliance based on results of joint market surveillance authorities in specific sectors

Toys intended for children under 3 years[32]						
Period	**Participating authorities**	**Total of products checked**	**Non-compliance on warnings, markings and instructions for use**	**Non-compliance as to physical and mechanical requirements**	**Non-compliance as to migration of certain elements**	**Non-compliance as to phthalate content**
2014-2016	10	1850	40% of approx. 608 samples tested	46.4% of 265 samples tested	1.5% of 200 samples tested	13.2% of 228 samples tested

LED lighting equipment[33]					
Period	**Participating authorities**	**Total of products checked**	**Fully compliant**	**Non-Compliance with CE marking requirements[34]**	**Non-Compliance with the Declaration of Conformity requirements[35]**
2011	18	168	17.3%	76.8%	39.9%

Active electric energy meters[36]				
Period	**Participating authorities**	**Total of products checked**	**Fully compliant**	**Non-compliance**
2015-2016	11	22	< 60%	Non-compliant products: > 40% (Formal aspects: 27.3%; Software aspects: 27.3%; Sealing aspects: 9.1%)

Heating meters[37]				
Period	**Participating authorities**	**Total of products checked**	**Fully compliant**	**Non-compliance**
2015-2016	10	18	39%	Non-compliant products: 61% (Formal aspects: 5.5%; Software aspects: 27.8%; Sealing aspects: 5.5%; Functional aspects: 38.9%; Other aspects: 5.5%)

Electromagnetic Compatibility	
2013	Switching power supplies for laptop computers (September 2012 - March 2013)[38]
2014	Solar panel inverters (January 2014 - June 2014)[39]

32 http://www.prosafe.org/images/Documents/JA2013/JA2013_Toys_Final_Technical_Report_24-02-2016.pdf

33 Electromagnetic Compatibility - Report on the Fourth Joint Cross-Border EMC Market Surveillance Campaign on LED lamps (2011), http://ec.europa.eu/DocsRoom/documents/9868

34 Much EU harmonisation legislation requires manufacturers to place a CE mark on the product to demonstrate its compliance with the applicable product laws to market surveillance authorities.

35 A Declaration of Conformity is a document attesting to the compliance of a product with applicable legislation.

36 Final report - MARKETSURV MID - A Joint project for market surveillance in the field of measuring instruments http://ec.europa.eu/DocsRoom/documents/20422

37 Final report - MARKETSURV MID - A Joint project for market surveillance in the field of measuring instruments http://ec.europa.eu/DocsRoom/documents/20422

38 Electromagnetic Compatibility - Report on the Fifth Joint Cross-Border EMC Market Surveillance Campaign on switching power supplies (2012/2013), http://ec.europa.eu/DocsRoom/documents/9869

39 Report on the Sixth Joint Cross-Border EMC Market Surveillance Campaign on solar panel inverters - performed in 2014, http://ec.europa.eu/DocsRoom/documents/8064

Period	Participating authorities	Total of products checked	Fully compliant	Formal non-compliance	Technical non-compliance
2013	19	136	23%	69%	44%
2014	14	55	9%	62%	67%
Radio and Telecommunications Equipment					
2013	5 GHz WLAN (November 2012 - March 2013)[40]				
2014	Repeater for mobile telephones (January 2014 - May 2015)[41]				
2015	Drones (January 2015 - June 2015)[42]				
Period	**Participating authorities**	**Total of products checked**	**Fully compliant**	**Formal non-compliance**	**Technical non-compliance**
2013	21	101	28%		
2014	14	47	6%	90%	68%
2015	18	79	8%	82%	51%
REACH and CLP[43]					
2011	REF1. Registration, pre-registration and safety data sheets				
2013	REF2. Obligation of downstream users - formulators of mixtures				
2015	REF3. Inspection and enforcement of compliance with registration obligations by manufacturers, importers and only representatives in close cooperation with customs				
Period	**Participating authorities**	**Total of companies checked ***	**Fully compliant**	**Non-compliance**	
2011	26	2400	78%	22%	
2013	29	1200	33%	67%	
2015	28	1169	66%	34%	

* The duties checked under the first three projects were duties related to manufactures, importers, distributors, downstream users or only representatives. It is common that one company is checked for more than one duty. For example for REF2 close to 16 000 duties were checked for all 1200 companies inspected.

Source: mostly reports from joint actions

Additional information on no-compliant products provided by stakeholders can be found in Annex 7 section 2.

As mentioned above product requirements set out in a very broad range of Union legislation vary greatly between different areas of legislation and from sector to sector. As a result findings presented on non-compliance concerning one specific sector cannot be 'summed' to analogous findings in other sectors to provide a general quantification of the degree of non-compliance with EU product legislation as a whole.

40 R&TTE directive - Report on the Fifth Joint Cross-Border R&TTE Market Surveillance Campaign (2013) - WLAN 5 GHz http://ec.europa.eu/DocsRoom/documents/9922

41 Report - The Sixth Joint Cross Border R&TTE Market Surveillance Campaign on mobile phone repeaters - 2014 , http://ec.europa.eu/DocsRoom/documents/7718

42 Report - The Seventh Joint Cross Border R&TTE Market Surveillance Campaign on remotely piloted aircraft systems , http://ec.europa.eu/DocsRoom/documents/13343

43 https://echa.europa.eu/about-us/who-we-are/enforcement-forum/forum-enforcement-projects

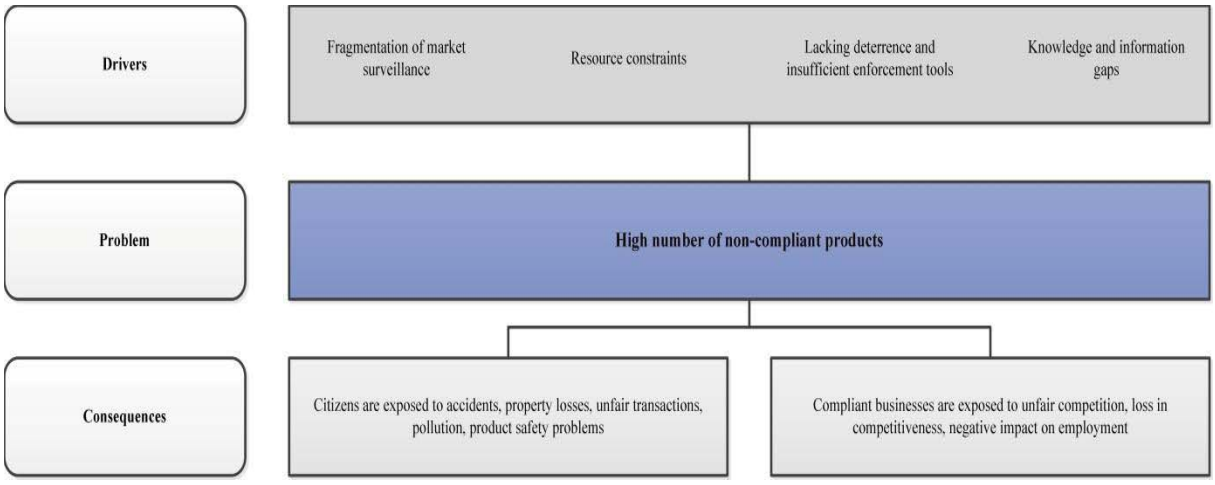
Furthermore, it is a fact that despite the broad scope of this initiative that aims at rules applicable horizontally to several product areas, evidence available focuses on only a sub-set of products for which national authorities were able to report information on the outcomes of their controls carried out individually or jointly. Nevertheless, **for all sectors/product groups where information is available, it consistently points to the presence of a non-negligible number of non-compliant products**. Similarly feedback from the public consultation and regular contact with stakeholders confirms the perception that the problem of compliance of Union product rules in the Single Market is of general nature and does not affect exclusively a few sectors.

1.4 Problem drivers

The **problem of non-compliant products** within the Single Market **is driven by four main factors**, namely (1) **fragmentation of the organisation of market surveillance in the EU**, (2) **resources constraints for market surveillance authorities**, (3) **low deterrence** of the current enforcement tools, notably with respect to imports from third countries and e-commerce and (4) **important information gaps** (i.e. lack of awareness of rules by businesses and little transparency as regards product compliance).

These problem drivers result mainly from the evaluation of the market surveillance provisions of Regulation (EC) 765/2008, which highlighted certain weaknesses in the regulatory framework that need to be addressed in order to improve the functioning of the Regulation. In the description of the problem drivers below, references are included to the findings of the evaluation where relevant.

Figure 4: Problem tree



1.4.1 Fragmentation of market surveillance (within EU/ on products entering EU) hampers effectiveness and uniformity of controls

Market surveillance in the Single Market is fragmented in particular along national borders, within the EU and at the external borders. As explained in the evaluation of Regulation (EC) No 765/2008 the current legal framework does not set explicit obligations on how market surveillance shall be organised at the national level, this being left to Member States' prerogative. Therefore, market surveillance is differently organised at the national level in terms of sharing of competences and powers between market surveillance authorities.

In this regard, three types of overall models (centralised; decentralised at the sectoral level; decentralised at the regional/local level)[44] have been implemented by Member States, although with a number of additional country-specific nuances. As a result for each set of products falling within EU harmonisation rules (e.g. cosmetics, toys, pressure equipment) a specific national authority (or even several local or regional authorities) is appointed in each Member State.

Overall, more than 500 market surveillance authorities exist in the EU[45]. Each authority is competent exclusively for products made available in the part of the single market that corresponds to the national territory of a Member State or a smaller part within the Member State. Furthermore, controls of products entering the EU requires the involvement of customs authorities, i.e. yet a further set of actors. Conversely, businesses often supply products from outside the jurisdiction of the market surveillance authority where the end customer is located. Overall, harmonised products represent about 65% of intra-EU trade in goods[46], although the percentage depends on the specific sector[47]. Furthermore, recent developments in the online market show an increasing proportion of retail sales with a cross-border dimension[48].

The fragmentation of competences has important **consequences on the efficiency and effectiveness of controls**. First of all, when restrictive measures are ordered, market surveillance authorities find it is difficult to enforce their decisions in other Member States due to the territorial scope of administrative decisions, their enforceability and language issues. Respectively 52% and 55% of authorities participating in the consultation confirmed that businesses located in another Member State do not reply to requests for information/documentation and for corrective actions[49],[50]. Thus, in practice authorities can effectively address non-compliance issues only with businesses located in their national territory (e.g. national or local distributors)[51]. Second, this atomisation of competences implies that authorities focus on products available in their jurisdiction and therefore a product that is found to be non-compliant in one Member State may in practice still be made available in another Member State.

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44 See section 5.1 of the evaluation .

45 See Annex 9 section 2 for an overview of the organisation of market surveillance at national level. The detailed list of authorities competent in the EU for the surveillance of products falling under specific legislation is available at: http://ec.europa.eu/DocsRoom/documents/12802 and http://ec.europa.eu/DocsRoom/documents/12803.

46 See Annex 5.

47 58% of participants to the public consultation found difficult to estimate the share of products placed on the market by businesses located in another EU Member State in their respective sector; however when estimates (based on product volumes were provided these pointed to a sizeable share of the market: more than 50% of the market (according to 18% of participants), between 21 and 40% (12% of participants); between 41 and 50% of the market (7% of participants).

48 According to the research by the European Multi-channel and Online Trade Association, 14% of online sales in 2014 were non-domestic business-to-consumer sales (including both EU and non-EU sales). From 2013 to 2018, with a compound annual growth rate of 12%, the online retail market is expected to be worth ca. EUR 234bn by 2018 - Forester Research Online Retail Forecast, 2013-2018, summary available here: http://ecommercenews.eu/online-sales-in-europe-will-grow-to-e233-9bn-by-2018/

49 Taking action against non-compliant products traded by businesses located in another EU Member State was considered difficult businesses do not reply to requests for information/documentation (**52%** of authorities agreed/strongly agreed, 22% disagreed/ strongly disagreed, 26% no opinion/no experience /no answer) and for corrective actions (**55%** of authorities agreed/strongly agreed, 19% disagreed/ strongly disagreed, 26% no opinion/no experience /no answer). Furthermore **57%** of authorities declared no experience in imposing penalties on businesses located in another Member State, while 25% of authorities agreed/strongly agreed enforcement of penalties is difficult, 7% disagreed/ strongly disagreed, 12% provided no answer. The previous percentages are based on the total number of participants to the consultation, including those not replying to this particular question.

50 It is also noted that major high costs components for market surveillance authorities are collecting/assessing information from businesses, interacting with authorities from other member states perceived often to lead to a dead end (study on the impact of digital compliance, VVA 2017, annex 14.

51 Interestingly, 26% of authorities participating in the consultation believe they are not even entitled to contact a business outside its jurisdiction.

In order to address these issues the current regulatory framework includes a number of legal, administrative and financial tools (e.g. common database ICSMS[52] for exchange of information on results of inspections, notifications of restrictive measures based respectively on RAPEX and safeguard clause procedures[53], mutual assistance[54], administrative cooperation groups called 'AdCos'[55], joint actions[56] and Customs Union principles[57]) allow coordination among market surveillance authorities in different Member States.

However, the findings of the evaluation of Regulation (EC) No 765/2008 show that despite the clearly positive role played by these different cross-border cooperation tools, they are not exploited to an extent sufficient to trigger effective coordination and efficient work sharing among surveillance authorities in the Single Market[58]. For instance: the ICSMS database is only used and to different degrees by a subset of Member States (see Annex 11.1.1); the systems for notifying restrictive measures are not systematically used by national authorities and the response provided by recipient authorities is fairly weak both in terms of official 'reactions' and follow-up measures taken (Annex 11.1.2); mutual assistance among authorities willing to contact economic operators located in another Member States only takes place occasionally (Annex 11.1.3); the degree of active participation in administrative cooperation groups is still unsatisfactory (Annex 11.1.4); joint market surveillance actions are carried out only in some sectors and on an-hoc basis and, in most cases, are triggered by EU funding; yet, even EU funding is not sufficient if authorities cannot rely on some administrative framework for the management of the joint projects (Annex 11.1.4-1.6), customs risk management systems are still managed to a large extent nationally. As a result the overall degree of **cross-border cooperation remains fairly weak and** so it is **not sufficient to address the limitations of jurisdiction** described above**.** Market surveillance is still seen to a large extent as a 'national matter' and authorities continue to focus mainly on domestic priorities. Due to national organisation of market surveillance and pressures on staff resources, cross-border cooperation projects may seem more burdensome and their benefits more diffuse and not delivered in the short term.

Furthermore, the evaluation of Regulation (EC) No 765/2008 notes that the relevant EU provisions are drafted in such general terms[59] that Member States have implemented the Regulation in many different, specific forms. Differences emerge not only in terms of distribution of competences, but also in terms of internal coordination mechanisms, level of deployed resources (financial, human and technical), market surveillance strategies and approaches, powers of inspection and sanctions (including for border controls) and penalties for product non-compliance.[60] The heterogeneity existing across Member States in the implementation of the Regulation allows concluding that the **level of market surveillance is certainly not uniform**, given that Member States with more resources and powers have - at least - more tools for a proper enforcement. This lack of uniformity allows inferring that market surveillance might also be more rigorous in some Member States than in others. Potential effects are a less effective deterrence power, an unequal playing field among

52 Annex 11.1.1 and 11.1.6.
53 Annex 11.1.2 and 11.1.6.
54 Annex 11.1.3 and 11.1.6.
55 Annex 11.1.4 and 11.1.6.
56 Annex 11.1.4-6.
57 Annex 11.2.
58 See section 6.1.1 in the Evaluation SWD.
59 For example, the market surveillance provisions oblige Member States to *'entrust market surveillance authorities with the powers, resources and knowledge necessary for the proper performance of their tasks'* while market surveillance authorities must *'perform appropriate checks on the characteristics of products on an adequate scale*'.
60 See section 6.1.2 of the Evaluation SWD.

businesses in some Member States and also potentially imbalances in the level of product safety across Europe.

1.4.2 Resources constraints limit the rigour of controls (within the EU/ on products entering the EU)

Information available and the findings of the evaluation of Regulation (EC) No 765/2008 show that **resources for controls are limited[61].** The availability of limited resources (staff, budget, laboratory capacity) for market surveillance is often mentioned by stakeholders as a factor reducing authorities' ability to detect and punish non-compliance. In their national reports concerning market surveillance activities carried out between 2010 and 2013, authorities indicated that the lack of sufficient resources affected enforcement action in at least 12 Member States. On the other hand, in most Member States the exact amount of resources allocated to market surveillance is not clear. This is because market surveillance is not identified as an activity with a clearly identified budget: in many cases authorities responsible for market surveillance have at the same time to carry out tasks of another nature and the budget of those authorities does not earmark funds for market surveillance.

The analysis carried out during the evaluation shows that according to available data:

- Resources allocated to market surveillance amount on average to a few euros per thousand inhabitants (with the exception in particular of medical devices, cosmetics and toys) and from 0 to maximum 0.5 inspectors per million inhabitants[62].

- The total budget available to all Member States' authorities having reported the information, in nominal terms[63] decreased during 2010-2013 period (from €133.4m to €123.8m); also it is concentrated in a limited number of countries and large differences could be noted in terms of budget available to each country during the four year-period[64].

- A similar trend was noted for human resources: over the period 2010-2013, a reduction of staff available to MSAs can be observed together with a concentration of staff in a small number of Member States[65].

61 See Annex 12 ; Chapters 6.1 and 6.2 of the evaluation and sections 6.1 and 6.2 of Annex 4 of the evaluation.
62 See sections 5, 6.1 and 6.2 of Annex 4 of the evaluation
63 Not all EU28 Member States provided reliable data for this indicator. Therefore, figures do not include Austria, Cyprus, Estonia, Greece, Croatia, Luxembourg, Slovenia, the United Kingdom and Hungary.
64 See section 5.2.1 of Annex 4.
65 See section 5.2.1 of Annex 4.

Figure 5: Total budget available to 19 MSAs in nominal terms during 2010-2013, € M

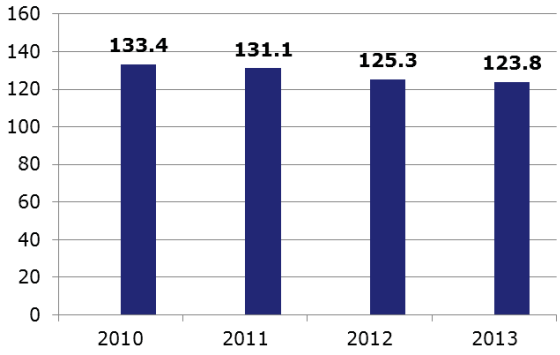
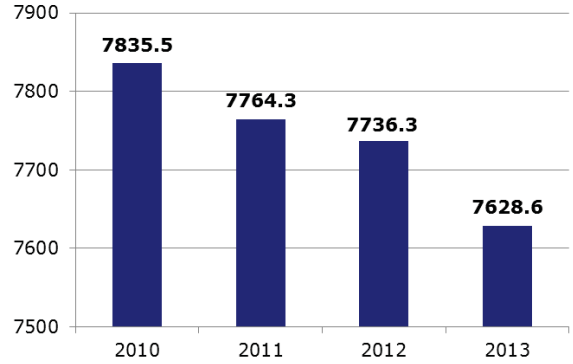
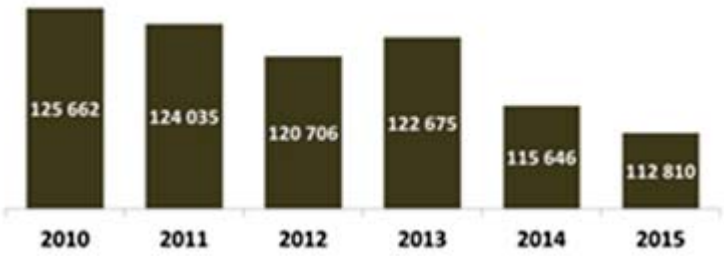


Figure 6: Total staff resources available to MSAs (FTE units) during 2010-2013 at EU level[66]



Similarly also the number of customs officials has seen a continuing downward trend of about 10% since 2010[67]. This explains at least partially the fact that product compliance checks by customs remains fairly limited in relation to the number of imports[68] [69]. Stakeholders often report that the order of magnitude of controls in one of one of the biggest harbours is only 0.1%.

Figure 7: Total staff resources available to customs during 2010-2015 at EU level[70]



The perception about limited resources and the difficulties in providing concrete figure is mirrored by the results of the public consultation: 51% of respondents reported having experience or knowledge of instances where market surveillance authorities lacked sufficient financial or human resources to carry out specific tasks in at least a given sector; however only 18% were able to provide an estimate of the approximate financial gaps; those estimates range from 1 to more than 50%. Furthermore, respondents establish a clear link between current level of deterrence of market surveillance in their sectors and authorities resources as deterrence is expected to improve by giving authorities more resources (72% of respondents) and through more efficient use of existing resources (73%). As mentioned in the evaluation the amount of resources available for controls cast doubts on the ability of market surveillance

66 The analysis includes: BG, CZ, DE, DK, EE, ES, FI, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SK; the other MS have not provided complete and reliable data.

67 See also Annex 11 section 2.2.

68 DGTAXUD - Customs and MSA limited Report on customs controls in the field of product safety and compliance in 2015, July 2016 providing partial information on import controls from a selection of Member States.

69 See also annex 9: in absolute numbers controls are low compared to import volumes and on average 8% of controls are prompted by customs as reported by Member States for the period 2010-2013. Controls are concentrated in 6 product sectors (of 30). Moreover inspection coverage is low in the main entry points to the EU, the sea ports and Rotterdam in particular (Public consultation Position papers; Dutch Court of Auditors, Producten op de Europese markt: CE-markering ontrafeld, January 2017)).

70 The analysis includes: BG, CZ, DE, DK, EE, ES, FI, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SK; the other MS have not provided complete and reliable data. When interpreting these figures, it should be taken into consideration that not all the MS are able to provide the exact data on the allocation of their staff. This could be due to merged organisations where the customs are mixed together with tax administrations, etc. In such cases, data was only estimated by the MS.

authorities to perform appropriate checks on the characteristics of the products on an "adequate scale". Besides risk profiles of products, market surveillance authorities and customs confirm that in first instance they determine the “adequate scale” of controls mainly on the basis of financial and human resources available. Data available show that in many Member States the number of inspections is rather low in comparison with total population and that the average correlation with the number of enterprises in every country is very low[71].

1.4.3 Current control systems lack deterrence and enforcement tools are insufficient to respond to evolving markets and business models

Lack of willingness to comply with applicable requirements for products marketed in the EU constitutes another explanation for non-compliance[72]. This was confirmed by the public consultation where 78% of participants considered that the lack of willingness to comply was among the top three reasons for non-compliance. 33% considered it the main reason for non-compliance.

Box 3: Academic research about deterrence and incentives to comply

Deterrence and incentives to comply have been the subject matter of abundant academic research[73]. According to the traditional literature on deterrence what motivates compliance are economic incentives. A strong enforcement programme and a considerable risk of detection of infringements can discourage non-compliant behaviour. More recent developments in the academic research on compliance and enforcement focus on the concept of 'responsive regulation' according to which corporate compliance and deterrence of non-compliance are not primarily the result of fear of legal sanctions; it rather stems from a combination of the intrinsic motivation to behave responsibly (i.e. goodwill, dialogue with the regulator and with interested third parties, trust in the regulator), and external influences, such as stakeholder pressure or fear of sanctions. For these reasons responsive regulation advocates that: 1) firms should be initially addressed by regulators with a cooperative, persuasive strategy; 2) only if firms do not respond, a regulator may respond with a variety of escalating interventions[74]. However this “tit for tat” strategy can only be successful when authorities dispose of concrete means to detect non-compliance and when severe sanctions are available as a backup. In particular, if market surveillance authorities are perceived as unwilling or unable to enforce product legislation because they do not have the means to detect and block non-compliant products then deterrence will be low. Incentives to comply are therefore linked on the one hand to trust and cooperation with the regulators/enforcers, dialogue with interested parties, stakeholder pressure; on the other hand cooperative compliance is generally contingent upon persuading those of goodwill that their responsible conduct will not be exploited by free riders who will get away with the benefits of non-compliance without being held to account for it. Thus deterrent and punitive sanctions must still be available in the background.

The evaluation of Regulation (EC) No 765/2008 attempted to assess the deterrence or rigorousness of the system of controls in the Single Market and concluded, despite the limitations in the analysis due tothe serious lack of data and inhomogeneity of national reports, that market surveillance is not sufficiently rigorous. Lack of relevant information on control activities may be also in some cases an indication of actual enforcement gaps. This

71 Annex 12 and chapter 6.1.2.1 of the evaluation Regulation (EC) No 765/2008.
72 OECD, ibidem. See chapters 6.1 and 7.2 of the evaluation.
73 See Annex 13 section 3.
74 Therefore, enforcement can best be defined as a dialogue between regulators and firms addressing the various forces and motives for compliance within a firm. Third parties, such as public interest groups, and community organizations, can often exert pressure on firms to behave in a socially responsible way, and so be involved in this dialogue. Furthermore, if regulatees trust regulators as fair umpires who administer and enforce laws or regulations that have important substantive objectives, then the evidence is that compliance will be higher, and resistance and challenges to regulatory action will be low. However, it should also be noted that most accounts that find people to be compliant in response to dialogue, goodwill and trust also find that deterrence is necessary as a back-up for the minority of organisations that do not voluntarily comply. They also find that co-operative compliance is generally contingent upon persuading those of goodwill that their compliance will not be exploited by free riders who will get away with the benefits of noncompliance without being held to account for it. Thus deterrent and punitive sanctions must still be available in the background. See Levi, 1988; Scholz, 1997, p. 262.

finding is further supported by stakeholders' perception about the incapacity of the Regulation to deter rogue traders,[75] and the discrepancies in the penalty framework.

When looking at the current system of market surveillance in their respective sectors only 9% of all respondents to the public consultation consider it deterrent to a significant extent, while 33% considers it as deterrent to a moderate extent and 46% as not deterrent.

This is likely linked to **existing gaps and inefficiencies in the enforcement** that **lead to a low probability of detection of non-compliance**. The threat of enforcement will not act as a deterrent if people do not believe non-compliance is likely to be discovered or punished. As regards the causes for these inefficiencies the previous sections already referred to the fragmentation of controls and the limitation in resources available. Further challenges for market surveillance identified during the evaluation of Regulation (EC) No 765/2008 are the difficulties of enforcing products requirements with respect to imports from third countries and e-commerce (see below).

To face these developments the authorities would need to rely on a more suitable toolbox, however the authorities' powers contained in the Regulation (EC) No 765/2008 do not explicitly take into account the developments of online trade. Moreover, many market surveillance authorities still lack some important enforcement tools[76]. Furthermore, border controls of imported products remain fairly limited in relation to the number of imports[77].

Box 4: Enforcement tools of market surveillance authorities

- *Destroy products:* based on information available, the majority of MSAs can destroy products, most frequently in the personal protective equipment and toys sectors, in 17 and 18 Member States respectively;
- *Impose administrative economic sanctions* (without resorting to national courts): this power is granted in all sectors by five Member States;
- *Impose compensation for consumers/users of non-compliant products*: this power is not particularly wide spread;
- *Impose provisional measures pending investigations:* this power is available in more than 30 sectors in five Member States;
- *Publish decisions on restrictive measures:* based on information available, 14 Member States use this power in more than 14 sectors and it is granted in more than 12 Member States in 15 sectors;
- *Recover from economic operators costs borne to test products found to be non-compliant:*[78] a large number of MSAs for which information could be gathered can make use of this power in the majority of sectors. In 13 Member States this power is granted in more than half of total sectors;
- *Sanction economic operators that do not cooperate:* this is the **most common power of sanction** among MSAs, in view of the fact that 15 Member States grant it to MSAs in more than 14 sectors. Six Member States apply it in more than 30 sectors;
- *Shut down websites:* this is **the least adopted power of sanction**, both across sectors and among Member States. As a matter of fact, based on the available information, only one Member States has this power in more than 14 sectors;

75 As widely confirmed by economic operator/civil society representatives - for checks of Market surveillance authorities and checks of Customs respectively – and Market surveillance authorities and Customs. See also section 6.1.2 of the evaluation and section 6.1.1 of its Annex 4.

76 See section 6.1.2.2 of the evaluation.

77 See section 6.1.3 of the evaluation;

78 For instance in the United Kingdom the legislation allows MSAs to recover from economic operators costs borne to test products found to be non-compliant. The ways MSAs use this power differ among them: for example, HSE (Health and Safety Executive, the workplace safety enforcement authority) routinely charge for its enforcement activity, while the Trading Standards Institute (a consumer product safety authority) would generally not charge them, unless there was a prosecution. In Germany, local MSAs impose costs for testing (calculated by the laboratory) and fees for administrative expenses (calculated by personnel costs per hour) on a case-by-case basis.

- *Take off or require taking off illegal content from a website:* only eight Member States confer MSAs with the power of taking off illegal content from websites in more than 14 sectors.

The table below presents an overview of the enforcement tools.

Table 3: Enforcement tools

Powers	Number of MS conferring this power to MSAs in 14 or more sectors	Number of sectors where this power is granted in a significant number of Member States
Destroy products	14	15 sectors (in more than 12 MS)
Impose administrative economic sanctions (without resorting to national courts)	13	14 sectors (in more than 12 MS)
Impose compensation for consumers/ users of non-compliant products	2	9 sectors (in more than 2 MS)
Impose provisional measures pending investigations	13	13 sectors (in more than 11 MS)
Publish decisions on restrictive measures	14	15 sectors (in more than 12 MS)
Recover from economic operators costs borne to test products found to be non-compliant	13	16 sectors (in more than 12 MS)
Sanction economic operators that do not cooperate	15	15 sectors (in more than 13 MS)
Shut down websites	1	7 sectors (in more than 1 MS)
Take off or require to take off illegal content from a websites	8	11 sectors (in more than 7 MS)

Details by Member States: Annex 13. Source: evaluation of market surveillance provisions of Regulation (EC) No 765/2008

1.4.3.1 The development of e-commerce sales and digital supply chains

Firstly, the e-**commerce market is growing very rapidly** within the overall retail sector. The Digital Single Market Strategy considers e-commerce as a main driver for growth. The Commission estimates the value of retail e-commerce at €231 billion (around 1.8% of EU GDP)[79]. Trade in goods is estimated at €212 billion and represents by far the biggest share of the online market. The Digital Single Market is a very important factor to boost jobs, growth, competition, investment and innovation. It will expand markets and foster better services at better prices, offer more choice and create new sources of employment. It will create opportunities for new start-ups and allow existing companies to grow and profit within a market of over 500 million people.

Box 5: E-commerce and the practical questions it raises in the supply chain

E-commerce brings about profound changes in the traditional supply chain, which is being replaced by a more complex model with more and different actors. Specific features of the new model are dematerialisation of transactions, multiplication of online intermediaries, ease for online traders to relocate or hide their identity, rapidity of the spread of marketing practices, and constant innovation. These features have a profound impact on

79 SWD(2015)274.

market surveillance[80]. Many distribution centres ('fulfilment centres') have evolved from mere transport and storing to direct-to-user order fulfilment.[81]. It is not always clear when products are placed on the market and by whom, particularly when they are imported from third countries into the EU. Indeed, it is argued that there appears to be ambiguity as to whether making available for purchase on a retail website constitutes placement of the product on the market. Some stakeholders also suggested that there might also be a lack of clarity over the relative responsibilities of different parties; for example, to what extent should end-users be considered as importers of products? To what extent are e-commerce platform providers responsible for products sold via their platforms? According to the limited liability provisions of the Electronic Commerce Directive, intermediary service providers acting as mere conduits, caches, or hosts of information are not liable for online content, unless they were notified of the presence of illegal content and did not act. The increased complexity of the chain of responsibility therefore raises the question of the role of additional economic players such as fullfilment houses, online platforms or social media allowing offer and demand to meet, along with the boundaries between roles (user, consumer, producer, agent, tenderer, seller) and/or the role they can play in making possible corrective action. As explained in the evaluation, the definitions and powers contained in Regulation (EC) No 765/2008 do not address the reality of e-commerce and do not specify the role expected by these new actors. This create uncertainty for both enforcers and businesses and hampers market surveillance action. 58% of the authorities participating in the public consultation considered that when products are traded online the fact that the business (normally located abroad) contacted does not consider itself as manufacturing, importing or distributing a product limits their ability to obtain information or to take corrective action.

There are very significant practical challenges for market surveillance on products sold on-line. Market surveillance authorities report considerable difficulties in the identification and interception of products that are delivered to the end-user in single consignments via the conventional postal system. The import of individual parcels renders case-by-case controls at the border inefficient. Moreover, even where market surveillance authorities identify websites selling non-compliant products, they may simply be unable to identify the supplier using the website. On-line sales for which often suppliers and buyers are located in different countries exacerbate the difficulties higlighted in previous sections as regards the limitation of authorities' jurisdicition vis-à-vis business based in other Member States or in a third country[82].

As a result of innovations in the digital economy authorities' powers and tools are increasingly challenged and some of the traditional authorities' working tools ineffective. A case in point is mystery shopping which in case of online sales requires authorities to dispose of ad hoc payment tools that do not mention the authority's identity. Therefore they need tools adapted to the specific enforcement challenges of the digital economy (e.g. possibility to request information from Internet registers, powers to take off illegal content from webites).

1.4.3.2 The increase in imports from third countries

Imports of harmonised goods from third countries represent a sizable and increasing share of products supplied on the EU market, as it went up from 24% in 2008 to over 30% in 2015. In 2015 they were estimated to value almost 750 € billions[83].

Many respondents to the public consultation found it difficult to indicate the proportion of products imported from third countries in their sector[84]; however the general perception

80 See chapters 6.1 and 6.4 of the evaluation and sections 6.1 and 6.4 of Annex 4 of the evaluation.

81 http://www.supplychainquarterly.com/topics/E-Commerce/20120827-direct-to-consumer-challenges-for-distribution/

82 More than in cross-border situations within the EU, authorities reported in the public consultation that they experience difficulties to identify and contact 3rd country businesses (45 of 69, 65 % agree viz. 15 of 69, 22% disagree and 13% no opinion). Authorities experience even more difficulties to obtain responses from economic operators in 3rd countries or their cooperation in corrective actions or indeed have no experience on the matter (40 of 67, 60% agree that foreign businesses do not reply, 23 of 67, 34% had no opinion; 40 of 69, 58% agree businesses contacted do not reply to requests for corrective action, 27 of 69, 39% had no opinion).

83 See Annex 5

among stakeholders is that imports are affected by non-compliance[85]. The analysis of RAPEX notifications supports the findings that the non-compliance of imports from extra EU is a relevant issue: from 2010 to 2016 notifications concerning imported products were around 75% of yearly published notifications and the percentage remained overall stable over the period. On average, 59% of total yearly notifications concern products from China.

However, the evaluation of Regulation (EC) No 765/2008 concludes that, in light of the increasing importance of EU trade with third countries, checks of imported products are insufficient[86]. It is often difficult to trace and intercept non-compliant products imported from outside the EU and entering through numerous entry points. In addition EU surveillance authorities have difficulties to effectively contact and sanction businesses established outside the EU who sell non-compliant products directly to buyers in the EU. 65% of authorities participating in the public consultation confirm authorities do not know how to identify and contact businesses located in third countries and 59% confirm that businesses contacted do not reply to requests for information/documentation and for corrective action[87]. Despite some existing informal international cooperation arrangements, the number of non-compliant products that can effectively be traced back to the economic operator and sanctioned at the source in 3rd countries remains limited[88].

More structured cooperation and information exchanges at international level would help having more efficient and effective market surveillance also on the EU market. However, "access" to the Information and Communication System for Market Surveillance (ICSMS)[89] and the RAPEX Rapid Alert System for dangerous non-food products can only be allowed to third countries by way of an international agreement based on strict requirements ensuring reciprocity and confidentiality corresponding to those applicable in the Union.[90] To date, due to these restrictive requirements, only the non-EU members of the European Economic Area have such full access to these systems, based on the EEA agreement.

Furthermore, the procedure for checking products when they enter the EU is fairly outdated. It was conceived in 1993 and slightly updated in 2008 but without any fundamental changes. In 2013 the new EU Customs Code significantly upgraded the use of risk management to target customs controls and established the principle of coordinated 'one-stop shop' controls of customs jointly with other authorities[91]. Furthermore the Customs code consolidated the scheme for Authorised Economic Operators[92] that have a good track-record with customs based on thorough audits and can therefore benefit from certain facilitation of their procedures with customs. The provisions in Regulation (EC) No 765/2008 have not evolved with these changes[93]. As a consequence there is a suboptimal exchange of information and enforcement cooperation between customs and market surveillance authorities on non-compliant

84 49% consider they were unable to provide estimates or did not reply to the question; however 17%of respondents consider the proportion of imported products to be up to 20%, **15% of them** between 21 and 50% and 18% of them **beyond 50%**.

85 15% of respondents believe non-compliance affects **most of imported products**, **43% some of them**, 16% few of them. Only 2% consider imports not affected by non-compliance. 23% did not know or did not reply.

86 See section 6.1.3 of the evaluation.

87 Market surveillance authorities also find that it is often impossible to obtain documentation, including from importers who cannot get access to the required information from manufacturers (VVA study impact of digital compliance, 2017, Annex B 14).

88 E.g. Around a third of notified cases through the RAPEX-China system in 2015 was found to be traceable and could be investigated by the Chinese authorities.

89 Article 23 regulation (EC) N° 765/2008.

90 Article 12 (4) of Directive 2001/95/EC on general product safety.

91 Union Customs Code Art. 46, 47.

92 Union Customs code Art. 38.

93 See chapters 6.1, 6.2 and 6.4 of the evaluation and sections 6.1, 6.2 and 6.4 of Annex 4 of the evaluation.

products[94], risks assessment[95] and economic operators[96]. The provisions on recovery of costs (e.g. for tests or destruction of products) in case of non-compliant products are also not aligned.

1.4.4 Knowledge and information gaps concerning product compliance

Information gaps that have an impact on non-compliance and on the impact of corrective action requested by authorities should also be mentioned.

First of all, market surveillance authorities frequently point out that **lack of knowledge of product rules on the part of businesses** is an important problem to address.[97] Clearly *ignorantia juris non excusat*, nevertheless unawareness or misunderstanding of requirements seems to explain part of the non-compliances that can be found in the market, as an essential condition for regulatory compliance is that businesses have to be aware and understand their obligations under applicable legislation[98]. The public consultation indicated that 80% of respondents consider lack of knowledge of rules among the three top explanations for non-compliance and 27% consider it as the first reason. Furthermore, 63% of the respondents believe it would be effective to reduce the level of non-compliance if authorities, besides enforcement, would also provide information on applicable requirements. On the other hand, most respondents excluded that non-compliance could be mainly due to ambiguity/excessive complexity of the rules, as only 10% of them considered this the primary explanation for non-compliance.

The Commission evaluation of Union harmonisation legislation in 2014[99] recommended the expansion of the role of the Product Contact Points to harmonised products so as to provide a first point of contact for and basic information about Union harmonisation legislation to firms.

Second, **consumers and other stakeholders often lack information about the compliance of products** they purchase, use, distribute or compete with. The general public and individual consumers are normally not aware of issues relating to product compliance, which are often not visible to non-experts, unless the product would be clearly dangerous[100]. For instance compliance does not appear to be a main criterion when choosing a product to purchase. This is supported by the fact that the compliance or non-compliance of the product does not play a visible role in the contractual terms between the seller and the purchaser of a good. Furthermore, information on risks posed by products does not always reach consumers and

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94 There is not a clear and effective communication channel between customs and market surveillance authorities of different countries for customs decision not to release a dangerous or non-compliant product. Cross-border actions are needed to avoid re-entry of goods blocked by one country via another Member State or another entry point (Customs cooperation in the area of product safety and compliance controls of imported goods; Workshop report Vishegrad Group countries, October 2016)

95 E.g. RAPEX listed products are an import source for customs to develop risks profiles; however the wider information available in ICSMS on non-compliant products, restricted measures and economic operators count only among "other" incidental information sources (DGTAXUD, 2015)

96 Art. 38 of the Union Customs Code provides for consultation with other competent authorities if necessary in the process of granting AEO status, which is also subject to monitoring. However only 2 Member States indicated consultation takes place of market surveillance authorities prior to AEO status being granted. Moreover even if AEO status does not affect the operator or products as regards product compliance controls further to Regulation (EC) n° 765/2008, in practice most Member states report that they are generally subject to fewer controls than other non-AEO operators (DGTAXUD report "Mapping of differences in dealing with safety and compliance controls for products entering the Union", June 2016).

97 See chapters 6.1 and 6.3 of the evaluation and sections 6.1 and 6.3 of Annex 4 of the evaluation. See for instance Annex 9 section 3.4 and minutes of expert groups meeting http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=23085&no=1 (section 8).

98 OECD, 'Reducing the Risk of Policy Failure: Challenges for Regulatory Compliance', 2000, http://www.oecd.org/regreform/regulatory-policy/1910833.pdf

99 SWD(2014)23, section 7.2

100 See figure 7 in Annex 9 to the Evaluation SWD.

other end-users at the same time and in a timely, structured way all across the Single Market. It is also noted that authorities' decisions on non-compliant products often contain business secrets and are hardly made available to the public. This lack of transparency contributes to the low incentives to compliance because it reduces the potential for pressure from other interested parties, such as consumers, trade-unions, industry associations and competitors that can also influence compliance through the mechanisms of reputation and legitimacy. Distributors, according to most directives and regulations, must act with due care in relation to the requirements applicable when they make a product available on the market. Thus they potentially play an important role in preventing the marketing of non-compliant products[101]. In practice however, provided that distributors, who are to a large extent SMEs, are aware of the relevance of compliance, they rely mostly on documentation made available (or not) from the product manufacturer or the importer, and only a minority of them uses information on non-compliant products such as the Rapex notifications or newsletters by association or consumer organisations[102].

The above mentioned 2014 evaluation recommended a faster transition towards "e-market surveillance" in which economic operators will be expected to make as much compliance information (e.g. declarations of conformity) available online as possible while more sensitive technical documentation and supporting test data requested by MSAs could be transferred electronically via secure data transmission.

1.5 Who is affected, in what ways and to what extent?

Potentially all people resident in the EU, i.e. about 500 million people, can be affected by non-compliance which exposes them to potentially dangerous products or puts the environment at risk. Similarly, employees of EU businesses purchasing harmonised products (such as electrical and electronic equipment or machinery), i.e. potentially the whole EU workforce regardless of the business sector of the employer, are exposed to the risk of harm from non-compliant products.

Furthermore, non-compliance means that undertakings selling compliant products face distorted competition from those undertakings which cut corners or deliberately flout the rules to gain a competitive edge. The number of manufacturing and retail enterprises active in the harmonised sectors and potentially affected by the unfair competition of businesses trading non-compliant products is mentioned in section 1.2.2 above. 99% of manufacturing enterprises are SMEs (78% micro-enterprises, 16.4% SMEs employing up to 49 persons and 4.4% SMEs employing between 50 and 249 persons). Almost 100% of retail enterprises are SMEs (93.6% microenterprises, 5.4%, employing up to 49 persons and 0.7% SMEs employing between 50 and 249 persons). [103] Furthermore over the period from 2008 and 2014, around 1.2 million manufacturing enterprises were operating within harmonised

101 The general rule is that, before making a product available on the market, distributors have to verify that the product bears the required conformity marking or markings, that it is accompanied by the required documents and by instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the product is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in the applicable Union harmonisation legislation.

102 Study on the promotion on the use of RAPEX information by importers, distributors and retailers in the field of consumer product safety, with a particular focus on SMEs, CIVIC Consulting, August 2015, p. 42.

103 See Annex 5 section 2.1 and section 3.

sectors, representing more than 65% of the total number of active enterprises in the manufacturing sector (around 1.8 million)[104].

The findings of the public consultation confirm that product non-compliance affect negatively citizens and responsible businesses. More specifically non-compliance is considered to have a negative impact on buyers by 76% of respondents (51% consider the impact "significant", 25% "moderate"), while only 8% consider this is not the case and the others reply "I do not know". In practice the type and the seriousness of harm (e.g. injury, property loss, unfair transactions, pollution, security problems) suffered as a consequence of non-compliance depend on the specific product at stake and the degree of the non-compliance presented by the product. For example: toys for children below 3 years old that contain small detachable parts present the risk of choking and may provoke fatal accidents; professional machineries with unprotected cutting parts may provoke cuts or other serious injuries or even death to workers; mobile phones exploding can provoke injury or death to one or more people and damages of different degrees to properties (cars, houses, planes); a faulty meter at petrol pumps may imply economic losses for either the pump manager or the purchasers; energy-using products (e.g. washing machines) consuming more energy than declared on the mandatory label bring about economic harm to the owners; batteries or electronic equipment containing heavy metal will pollute the environment when disposed of; cars producing emissions well beyond the legal limits will exacerbate air pollution. The ecodesign and energy labelling measures in place until 2015 were estimated to save 175 million tons of oil equivalent (mtoe) primary energy per year in the EU[105], yet non-compliance reduces the energy savings by 10%.

Furthermore, the great majority of businesses (80%) participating in the consultation confirm non-compliance has a negative effect on sales and/or market shares of businesses complying with legal obligations. Roughly half of them consider the effect as respectively "significant" or "moderate" (see Figure 8).

The competitive advantage enjoyed by rogue traders can be significant since ensuring products made available are compliant implies necessary costs. For example, the total estimated annual costs of compliance of EU legislation on industrial products across eight harmonised product cases (electric motors, laptops, domestic refrigerators/freezers, lifts, gardening equipment, petrol pumps, air conditioners and integrated circuits) have been estimated[106] at €342 million. At a per company level total compliance costs have been estimated to amount to 0,48% of turnover[107]. Operators who manufacture or distribute non-compliant products do not incur all these costs and thus enjoy significant savings that will be reflected in the final price of their products, hence distorting competition and causing possible loss of market-share by compliant companies. The price differential at stake, putting compliant firms at a disadvantage, cannot be calculated for product sectors or the market as a whole. While nearly 80% of businesses' respondents in the public consultation indicated that sales or market-shares of compliant companies are affected, an accurate quantification of the negative effects of non-compliance on the sales of responsible businesses is difficult to provide: only 24% of business respondents to the public consultation were able to provide an estimate of the loss in sales experiences due to the competition from non-compliant products.

104 For the period 2012-2014 more precise statistics on sector level have become available in EUROSTAT (digit 3 NACE code). These would indicate that about 900,000 businesses are involved in the manufacturing of industrial products (53% of all businesses active in the EU manufacturing sector) employing more than 20 million people (68% of all persons employed in the manufacturing sector.

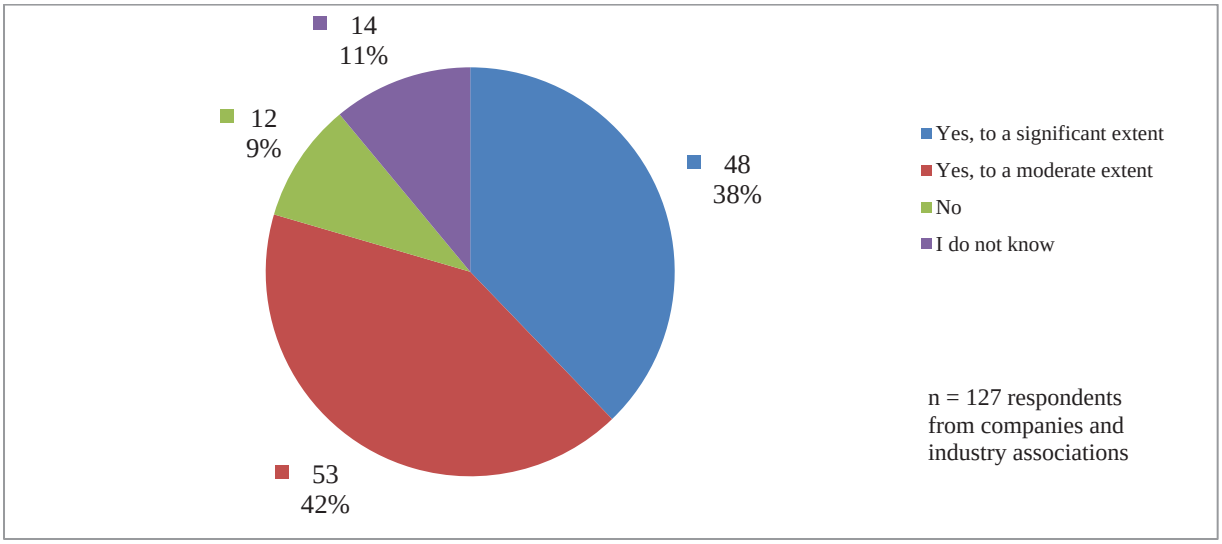
105 SWD(2015) 139 final, p. 15-16 available at: http://ec.europa.eu/transparency/regdoc/rep/10102/2015/EN/SWD-2015-139-F1-EN-MAIN-PART-1.PDF

106 Commission Staff Working Document SWD(2014)23.

107 http://ec.europa.eu/smart-regulation/evaluation/search/download.do?documentId=9966151.

The large majority of the estimates provided fall into the three following ranges: most indicate an approximate loss in their companies' sales due to competition from non-compliant product of 0-10%, and some 11-20%, 21-30%.

Figure 8: Do businesses complying with legal obligations experience negative effects on sales and/or market shares due to the presence of non-compliant products?



Source: public consultation

1.6 How would the problem evolve, all things being equal?

The problem of non-compliant products is not expected to go away in the foreseeable future if no action is taken.

a) Non-compliance: The previous paragraphs provide a number of indications of non-compliance. Due to the underlying variation in sectors and the multiple interlinked factors that lead to non-compliance, an extrapolation from these data or robust conclusions on trends in non-compliance rates are more difficult to project. However, the analysis of the RAPEX notifications on dangerous products between 2006 and 2015 and information reported by national authorities for the 2010-2013 period[108] conducted during the evaluation of Regulation (EC) No 765/2008 suggest that non-compliance has increased in 2010-2015 with respect to the previous period[109]. Although it cannot be excluded that more findings of non-compliance are the results of authorities' increasing efforts, one can reasonably assume[110] that non-compliance will persist and probably continue to increase, especially in areas where product testing is expensive or where in-house laboratories are not available:

Table 4: Annual average of RAPEX notifications by product category over the periods 2006-2009 and 2010-2015

Product category	2006-2009	2010-2015	Average Δ%
Chemical products	24.5	49.83	103%
Communication and media equipment	7.25	13.50	86%
Construction products	0.75	9.33	1,144%

108 The data were included in national reports published according to Article 18(6) of Regulation (EC) No 765/2008.
109 See section 4.3.1 of Annex 4 of the evaluation.
110 See section 5.3 of Annex 4 of the evaluation.

Cosmetics	66.75	75.83	14%
Electrical appliances and equipment	158.5	181.33	14%
Gas appliances and components	9.5	8.33	-12%
Hand tools	3.5	0.83	-76%
Lighting equipment	77	56.50	-27%
Machinery	22.5	20.17	-10%
Motor vehicles	154.75	183.17	18%
Personal protective equipment	13.25	32.17	143%
Pyrotechnic articles	0.5	14.83	2,866%
Recreational crafts	6.5	4.33	-33%
Toys	393.75	458	16%
Total	**1209.25**	**1927.5**	**59%**

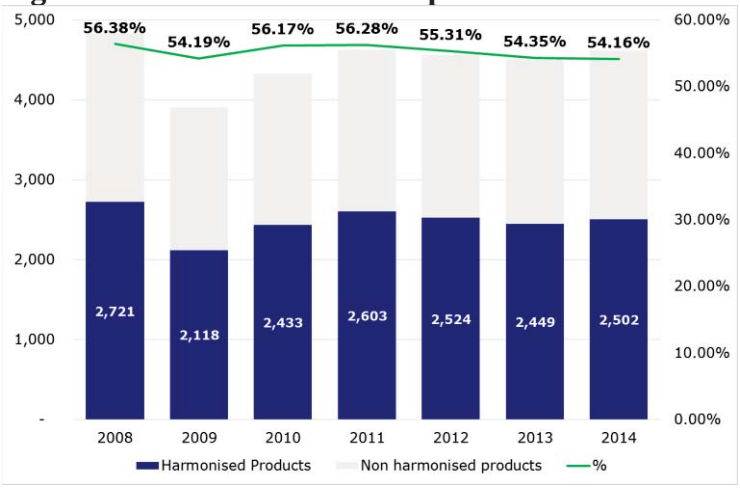
The trend of increasing figures of non-compliance was also confirmed by the national reports, in particular with respect to eco-design and energy labelling and in the pyrotechnics sector:

Table 5: MSAs' Findings of non-compliance[111]

Sector	2010	2011	2012	2013	Average Δ%
Eco-design and energy labelling	247	770	1,008	1,390	116%
Electrical appliances under LVD	4,322	4,928	3,772	4,685	2%
Machinery	1,597	1,450	1,569	1,735	2%
PPE	1,379	1,846	1,496	1,003	-7%
Pyrotechnics	824	1,135	7,479	5,811	151%
R&T under R&TTE	3,576	3,544	3,400	3,692	1%
Total	**11,945**	**13,673**	**18,724**	**18,316**	**13%**

b) Trade in products: One can also reasonably assume that the **value of harmonised products** on the EU internal market, which has been on average **€2,478 billion during the period 2008 – 2014, will remain at the same level.** Since the outbreak of the financial crisis in 2008 the figures show some development which could mean that values of trade could increase in the future.

Figure 9: Value of harmonised products within the EU28 (2008-2014), €b



Source: Evaluation of Regulation (EC) No 7652/2008; elaboration on PRODCOM – statistics by product, EUROSTAT (2016)

111 Data for 21 Member States: AT, BE, BG, CY, CZ, DK, EE, EL, FI, FR, HU, IE, IT, LU, LV, PL, PT, RO, SE SI, SK.

One can also assume that the **imports of products from third countries** will represent an increasing share of products supplied on the EU market, as it went up from 24% in 2008 to over 30% in 2015. In 2015 they were estimated to value almost 750 € billions[112].

c) Fragmentation of market surveillance, wihtin EU and at external borders: The fragmentation of market surveillance competences along national boundaries is not expected to evolve. Informal cooperation among authorities has been exploited to a large extent, however it has reached its limits and has proven insufficient to address the problem of surveillance of the Single Market.

d) Resources constraints limiting market surveillance and controls: There are no indications that the situation of resource allocation will improve. Resources for market surveillance have decreased since 2010 and are unlikely to substantially increase in most Member States.

e) Lacking deterrence and insuffient enforcement tools to respond to evolving markets, business models: The further expansion of cross-border online shopping in the EU and the well-established globalisation of manufacturing processes are expected to further reinforce the problem of fragmentation of jurisdiction defined along national borders and difficulties with the control of imports from third countries. In addition, technological change, increasing complexity of product and innovation in both product design and service delivery are changing the relationship between products and services that are part of the same value chain, and constitute new challenges for all actors in the supply chain and market surveillance authorities.

f) Knowledge and information gaps: The problem of lack of awareness about product rules is expected to persist and even worsen overtime since the possibility of on line trade substantially facilitates the marketing of products by newcomers and non-professional actors. The ongoing Digital Single Gateway intitiative will contribute to facilitate access to information on applicable EU rules already provided on Commission webpages, as it will be found more easily by businesses browsing on national websites. However the initiative will not address the need to set up additional support infrastructure in this domain.

These factors will have an increasingly negative impact on the effectiveness of market surveillance activities carried out by national authorities and the probability of detection of non-compliant products. Consequently businesses' incentives to comply are expected to decrease further overtime and non-complaince increase.

1.7 Conclusions of the evaluations

This impact assessment builds on **two separate evaluations**. The general conclusions are reported here. Where relevant more detailed conclusions and findings are referred to in the different sections of this impact assessment report:

The first is the evaluation of Union harmonisation legislation of 2014[113]. One of its main outcomes was that market surveillance is considered to be the weakest part of the implementation system, partly due to the inherently difficult nature of the task and in part due to varying levels of resources and technical expertise available in different countries[114]. As

112 See Annex 5.
113 COM(2014)25 and SWD(2014)23.
114 SWD(2014)23, section 4.8.

regards market surveillance, it pointed to the importance of coordination mechanisms, the lack of uniformity in approach to market surveillance across EU28 and differing levels of resources and technical capacity[115]. This evaluation recommended to expand information and advice to businesses, and to ensure a faster transition to e-market surveillance with more use of digital means to demonstrate compliance and communicate with market surveillance authorities.

The second is the evaluation of the market surveillance provisions of Regulation (EC) No 765/2008 which examined their effectiveness, relevance, coherence and efficiency and added value of action at EU level[116]. Its mains conclusions are as follows:

Effectiveness: Coordination and cooperation mechanisms have significantly developed, and are recognised as useful, but they have not reached a level that can be considered satisfactory, especially to trigger more effective cross-border enforcement among Member States and achieve more uniform and rigorous market surveillance throughout the Single Market. The evaluation concluded that the Regulation is not fully effective in this regard. The general character of the Regulation's requirements leave too wide scope for different heterogeneous implementations that do not take cross-border and Single Market perspectives sufficiently into account.

Efficiency: The efficiency of the Regulation has been assessed in terms of costs incurred by different stakeholders, benefits produced, and the extent to which desired effects (results and impacts) have been achieved at a reasonable cost. Important gaps and poor quality of data in the national reports hampered the assessment, which would need to be addressed in improvements of the reporting and monitoring mechanisms.

Relevance: The Regulation broadly meets stakeholders' needs, but the evaluation pointed out that it responds less well to needs related to new/emerging dynamics, especially with reference to increasing online trade and budgetary constraints at national level.

Coherence: Differences in definitions and terminology in some sectoral product legislation were noted and sometimes unclear boundaries with the General Product Safety Directive (external coherence). While these issues may cause some uncertainties in the Regulation's application, they do not significantly hinder its implementation.

EU added value: While the potential is not fully reached, the evaluation confirms the added-value per se of a horizontal framework for market surveillance of harmonised products manufactured within the EU and imported from 3rd countries, in addition to sector specific legislation.

Moreover the evaluation identified certain areas where regulatory burdens could be minimised and rules could be simplified, often as part of a wider problem or weakness of the current Regulation[117]. Specific administrative simplifications are highlighted in the impact assessment section of this report.

115 SWD(2014)23, section 7.1
116 REFIT evaluation accompanying this initiative and impact assessment
117 Evaluation, section 7.6.

Box 6: Evaluation findings REFIT potential

Evaluation	Impact assessment
• The **scope** of the market surveillance provisions could become much clearer; a few discrepancies in the definitions and terminology provided in the different sector specific legislations.	• The discrepancies and definitions in product legislation could be addressed when the sector legislation in question is reviewed. This impact assessment covers the particular issue of the **scope of investigative and enforcement powers** of market surveillance authorities to cover new players in global and e-commerce supply chains (see section 1.3.3; option 2 (d) common powers for market surveillance authorities)
• The relation between RAPEX, ICSMS and the safeguard procedures should be improved in order to reduce inconsistencies and confusion, to avoid duplication of work and useless administrative burden.	• This issue does not require a change of the Regulation and is already being addressed: In February 2017 the Commission released the first version of an interconnection between RAPEX and ICSMS. In 2016 safeguard notifications were implemented in ICSMS, with a second release due by end 2017;
• **Inconsistencies** in the approach followed by Member States authorities while carrying out market surveillance (e.g. interpretation of the concept of appropriate scale of controls, penalties, degree of cross-border **cooperation**) could be reduced. Coordination mechanisms within Member States should be improved and simplified;	• The problem driver of **fragmentation of market surveillance** and lack of uniformity of control, resulting need for more **coordination** is set out in section 1.3.1 of this impact assessment. The problem of insufficiencies in the control system and lacking deterrent tools is set out in 1.3.4. Option 3(b) EU **Product compliance network** would improve cross-border coordination; Options 2(a) effective **mutual assistance requests** and 3(a) transferability of enforcement evidence and decisions provide for improvement in **cooperation tools**.
• The 'market **surveillance programmes' and reports** on activities carried out could also benefit from simplification and more strategic use;	• The sub-optimal use of administrative tools is set out in section 1.3.1. Option 2 (b) member state enforcement strategies aims to improve the programming and reporting of the current Regulation.
• Checks of **imported products** are still considered insufficient in light of the increasing import from third countries and online sales, especially due to the limited available resources and fragmentation between authorities in different Member States; exchange of information and coordination among the authorities involved could be improved.	• The problems with controls on imported products are set out in section 1.3.3.2.

2. WHY SHOULD THE EU ACT?

The single market for products is a key achievement of the European Union. Yet, the elimination of national barriers for industrial products offered plenty of opportunities to less scrupulous traders who do not apply the Union harmonisation legislation. The EU has therefore the right to act on the basis of Article 114 TFEU, in order to ensure the proper functioning of the single market for industrial products and to increase the efficiency of cross-border market surveillance. Article 168 (1) and Article 169 (1) of TFEU complement this right to act. The first stipulates that a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities, the latter provides that in order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall, amongst others, contribute to protecting the health, safety and economic interests of consumers.

Despite the existence of the single EU market, the enforcement of Union harmonisation legislation is the Member States' competence. The proper implementation of the principle of subsidiarity therefore requires that the procedures and actions against concrete products posing risks are carried out by Member States.

However, as a matter of fact, the enforcement of Union harmonisation legislation within the single market creates major challenges for public authorities whose action is constrained by their jurisdictional boundaries, while many undertakings implement their business models in several Member States or at the EU level. To increase the level of compliance on the market, every Member State depends on the market surveillance of its neighbours. Consequently, weaknesses in the organisation of market surveillance in one single Member State can seriously undermine the efforts taken by other Member States to keep non-compliant products from the market; this creates a weak link in the chain. This interdependence is reinforced by the fact that the competence of market surveillance authorities is limited to the national territory. Where action is needed in other jurisdictions, authorities must rely on their colleagues in other Member States.

Therefore to ensure consistent enforcement of Union harmonisation legislation across the EU and to tackle efficiently non-compliance spanning over several Member States, it is necessary to coordinate public enforcement activities. The issue being addressed has therefore cross-border aspects which cannot be sufficiently achieved by the Member States' individual actions because they cannot ensure cooperation and coordination by acting alone. This needs to be achieved at the Union level. Furthermore, action at the EU level would produce clear benefits (compared to Member States' action) in terms of effectiveness and efficiency, in order to ensure smarter enforcement of Union harmonisation legislation across the EU.

3. WHAT SHOULD BE ACHIEVED

3.1 General policy objectives

The general objective of this initiative is to improve the functioning of the Single Market by increasing compliance with EU product harmonisation legislation and, conversely, reducing the number of non-compliant products on the EU market. In a single market where products move freely, compliance with EU legislation serves the protection of public interests (consumers and workers' health, environment protection, etc.) and fair competition equally.

Stepping up compliance with EU product harmonisation legislation requires a holistic approach that aims at improving at the same time incentives to comply and effectiveness of market surveillance.

3.2 Specific policy objectives

Against this background, the specific objectives of this initiative are:

1. **Reinforcing market surveillance cooperation procedures**, reducing fragmentation and inefficiencies;

2. **Increasing operational enforcement capacity**, improving efficiency of market surveillance action, targeting of controls, and availability of resources;

3. **Strengthening the enforcement toolbox**, allowing market surveillance authorities to use more deterrent, effective and future proof tools;

4. **Promoting compliance** with EU legislation on non-food products, improving accessibility of compliance information.

The objectives cover market surveillance within the EU and at the external borders and encompass digital and traditional supply chains. Similarly, each objective pursues simplification and possibilities to reduce administrative burden where relevant.

3.3 Consistency with other EU policies and with the Charter for fundamental rights

The Commission recognised the essential role of enforcement networks and set out to encourage and help Member States to improve their capacity to enforce EU law and make sure that administrative authorities and inspectorates are sufficiently and adequately equipped to perform their tasks[118].

The policy options take into account similar work recently undertaken regarding enforcement in other areas, for example in the area of food and feed where Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products[119] will increase Member States' ability to prevent, eliminate or reduce health risks to humans, animals and plants. Furthermore, the Commission put forward a proposal for the reform of the Consumer Protection Cooperation (CPC) Regulation[120], which governs the powers of enforcement authorities and the manner in which they can cooperate. In addition, the Commission proposed new rules to enable Member States' competition authorities to be more effective enforcers of EU antitrust rules[121]. The proposal seeks to make sure they have all the tools they require to achieve this. It is intended to further empower the Member States' competition authorities. Stronger enforcement powers are also a key issue in other recent legislative initiatives[122] and data protection laws[123] and recent legislative developments in the field of fertilisers[124].

With increasing product imports yet declining resources for customs, the Customs Union's governance would need to be better geared to current and future challenges. The policy options take into account the advocated coordination and inter-agency cooperation mechanisms, enhanced risk assessments including at the level of the Customs Union to make controls more efficient and effective[125]. Regarding global trade, the Commission reaffirmed its policy based on openness and cooperation. However to combat situations where rules exist

118 Commission Communication "EU Law: Better Results through Better Application", 13.12.2016, Pages 5-6.

119 Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation), OJ L 95, 7.4.2017, p. 1–142.

120 COM(2016)283 - Proposal for a Regulation of the European Parliament and of the Council on cooperation between national authorities responsible for the enforcement of consumer protection laws.

121 COM(2017)142 - Proposal for a Directive of the European Parliament and of the Council to empower the competition authorities of the Member States to be more effective enforcers and to ensure the proper functioning of the internal market.

122 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU; Regulation (EU) 2017/1369 of the European Parliament and of the Council of 4 July 2017 setting a framework for energy labelling and repealing Directive 2010/30/EU; COM(2016)31 - Proposal for a Regulation of the European Parliament and of the Council on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles]

123 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/ EC (General data Protection Regulation).

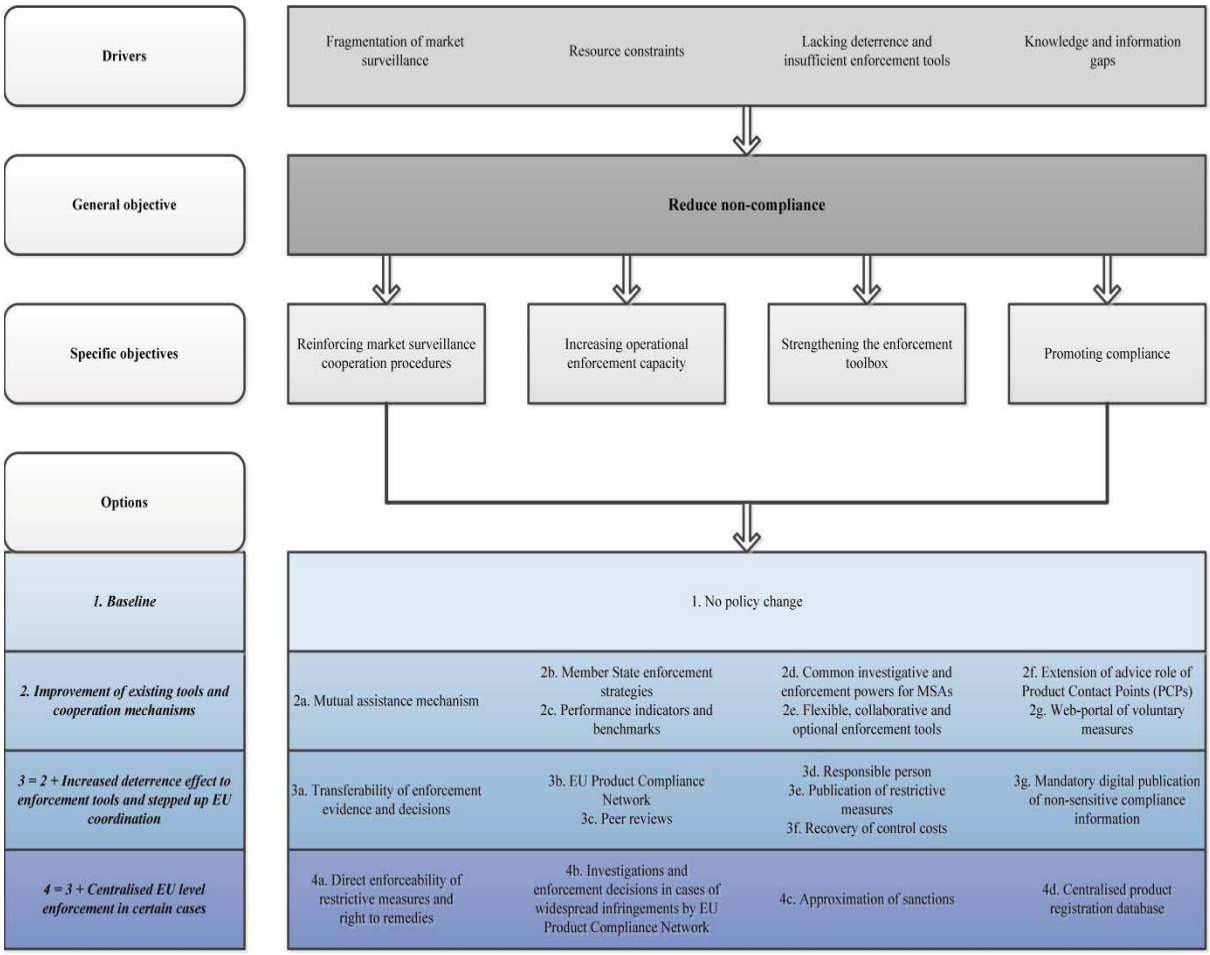
124 COM(2016)157, SWD(2016)64 and 65.

125 Developing the EU Customs Union and its governance, COM(2016)813 final, 21.12.2016.

but are not respected, the EU would need to have the instruments at its disposal to restore a level playing field and act decisively against countries or companies that engage in unfair practices. Strong enforcement of EU rules would also ensure that all companies present or active in the EU which break the rules are effectively sanctioned, in cooperation with Member State authorities and strengthened EU customs risk management in order to facilitate and accelerate legitimate EU trade, while ensuring the safety and security of citizens by stopping fake or dangerous goods permeating EU borders[126].

The consistency with the Charter for fundamental rights is considered in the assessment of the options.

Figure 10: Policy objectives and options to achieve them



4. WHAT ARE THE VARIOUS OPTIONS TO ACHIEVE THE OBJECTIVES?

In order to address the problems identified in section 3 and its underlying drivers, a number of policy options have been identified. These options include a baseline scenario and a series of measures that are presented from the lightest to more far-reaching means to tackle the drivers of the problem and reduce the number of non-compliant products in the single market. A detailed description of the measures in each option is provided in sections 4.3-4.7 below.

126 Point 3.3, Commission Reflection paper on harnessing globalisation, 10 May 2017, https://ec.europa.eu/commission/publications/reflection-paper-harnessing-globalisation_en

Box 7: Discarded options

While the options are grouped by increasing ambition and EU coordination, no transfer of powers to the EU away from Member States are considered. Options that would profoundly change the balance of competence on national versus EU level have been discarded as follows:

- A set of **requirements on national enforcement systems and structures** to **harmonise** the current fragmented market surveillance landscape (e.g. obliging Member States to set up a single surveillance authority): as shown by the evaluation of Regulation (EC) No 765/2008 the multitude of organisational systems and number of different market surveillance authorities with varying delimitation of competence is a factor that complicates swift cooperation within the EU. However the evidence gathered did not find clearly that one organisational set-up (e.g. centralised vs decentralised, cross-sectoral vs sector specific authorities) would perform better than others in all circumstances. Furthermore, certain differences in the distribution of competences at national level are closely linked to national administrative and legal systems of a given Member State. Measures to harmonise national enforcement systems would be disproportionate and the profound changes to national administrative and legal systems would be hard to justify from a subsidiarity point of view.
- A **general centralisation of market surveillance powers at the EU level** (e.g. EU inspectorate), to perform market surveillance and take enforcement decisions instead of national authorities (for all or certain product categories): The high number of economic operators and products would require the capacity to conduct inspections and a presence on the terrain throughout the EU and at entry points for goods into the EU. Relying on a centralised system and/or authority alone for all infringements would be unrealistic from an operational perspective. The investigation of certain wide-spread cases will be considered in option 4.

4.1 Option 1 – Baseline

The **baseline scenario** is the "no policy change" option. This implies that market surveillance provisions in Chapter III of Regulation (EC) No 765/2008 in its current version remain as the applicable legal framework.

4.2 Option 2 – Improvement of existing tools and cooperation mechanisms

*This option would involve a **modest revision** of the market surveillance framework, building on existing legal provisions and formalising current ad-hoc cooperation mechanisms. These additions would address some of the shortcomings identified by the evaluation of the implementation of the current market surveillance rules.*

The measures in this option are

Reinforcing cooperation procedures
2(a) **Effective mutual assistance requests between market surveillance authorities of different member states**[127]: Market surveillance authorities could request assistance to provide information to complete an investigation (e.g. help in tracing traders and legal identity, previous control reports on the same operator) and/or also enforcement action (e.g. verification that corrective actions have been carried out, ensuing restrictive measures if needed). The cooperation procedures would be particularly relevant to target enforcement action upstream in the supply chain, at importers or manufacturers. The measure would also address procedural issues to ensure an efficient flow of the mutual assistance requests between authorities (e.g. minimum contents of requests, the

127 Building on existing informal guidance on cross-border cooperation between market surveillance authorities and practical working arrangements http://ec.europa.eu/DocsRoom/documents/17108/attachments/1/translations

language, time-lines for replies). This would facilitate the actual use of the principle of cooperation that, as shown by the evaluation, is currently underexploited.[128]

Increasing operational enforcement capacity

2(b) **Member State enforcement strategies to improve data and knowledge sharing and to help targeting enforcement and capacity building actions**. This measure would entail a modification and streamlining of the existing requirements on Member States to report control programmes and evaluations of their market surveillance activities[129] and a clearer specification of principles of risks assessment that could be used to select and target controls. The enforcement strategies would in particular contain an assessment of compliance and capacity gaps, priority areas and actions to address these gaps and monitoring. To support the implementation of the strategies and capacity building in Member States, the financing provisions would cover the strategies (within the limits of current multi-annual financial framework, up to 2021; a future expansion of funding could build on the strategies as a tool to access EU co-funding, but is as such not part of this impact assessment[130]). This would contribute to address the problem of lack of resources for controls identified by the evaluation[131].

2(c) **Performance indicators and benchmarks**. Based on the national strategies, indicators and benchmarks would be built to compare information across Member States and to facilitate monitoring[132]. These measures would address the difficulties highlighted in the evaluation as regards the implementation of the current provisions on market surveillance programmes and reports on activities carried out.[133]

Strengthening the enforcement toolbox

2(d) **Adapting the investigative and enforcement powers of market surveillance authorities to new market developments, the global supply chains and e-commerce**[134]. The powers would span the full supply chain, including traders or intermediaries that could be relevant to the investigation[135]. The powers should provide a stronger basis to require cooperation from traders in investigations and/or enforcement and sanction absence of such cooperation or responses, which would be particularly relevant for controls on imports from 3rd countries. With developing e-commerce, the toolbox of authorities should also more explicitly include powers relevant to digital supply chains, such as investigative powers in relation to internet traders, performance

128 See previous section 1.3.1.
129 Regulation (EC) No 765/2008 Article 18 (5) (6)
130 The possibility and in particular the definitive size of a fund or an enforcement component in a new, larger EU fund (including possible continuations of current funds e.g. COSME, Consumer programmes) is not examined as such in this impact assessment. Such an option would depend on the new multi-annual financial framework for the EU budget from 2021 onwards for which the outlines will only become available in the next year(s).
131 See previous section 1.3.2.
132 Besides resources and number of controls, which form the core of the current indicators, this would involve more systematic information collection on compliance gaps and parameters that underlie Member States profiles in terms of market structures, enforcement policies and organisation (see Annex 12).
133 See chapter 7.6 of the evaluation.
134 Member States are required to provide their market surveillance authorities with adequate powers; Article 18(3), 19 (1) of Regulation (EC) No 765/2008.
135 See Annex 13 section 1.2 for investigative and enforcement powers and their current availability in Member States

of on-line test-purchases or, ultimately, enforcement powers to require removal of on-line content related to non-compliant products[136].

2(e) **Additional enforcement tools.** Besides investigative and enforcement powers that authorities must have as a minimum, market surveillance authorities would also have more **flexible, collaborative and optional enforcement tools** to gather market intelligence and prevent non-compliance (e.g. compliance programmes or partnerships with businesses, systems audits, cooperation agreements or memoranda of understanding with stakeholders). A clearer and explicit common toolbox would help market surveillance authorities to cooperate more efficiently which each other and participate in joint actions on similar grounds (e.g. e-commerce controls).

Promoting compliance

2(f) **An extension of the advice role of the Product Contact Points (PCP).** The PCPs currently inform and advise businesses in the area of mutual recognition of non-harmonised products, based on Regulation 764/2008[137] [138]. These PCPs could be tasked to also respond to information requests from businesses on harmonised EU product rules. Typical needs for **tailor-made information or advice** would be which EU product legislation applies to the businesses' product(s) and how several requirements could interact if more legislative acts apply to one product (e.g. in the case of complex products)[139]. A better understanding of whether and how legal requirements would apply to their products would allow businesses to factor these in into their operations, prevent non-compliance and alleviate the need for possible corrective measures by market surveillance authorities.

2(g) **A complement to the web-portal hosted by the Commission[140] on voluntary measures taken by businesses on dangerous products**. This new portal would allow businesses to communicate to the EU-wide public any **voluntary measures they undertake to withdraw or recall unsafe, non-compliant products**. Such a web-portal would help businesses to inform consumers and could assist also in reaching traders in complex decentralised distribution chains, local shops or e-commerce intermediaries. The use of the portal would be optional and would not alter the economic operators' existing underlying obligations to take corrective measures and to inform Member States authorities about such measures[141].

136 Even if internet content and websites can be easily moved and re-opened, stronger digital powers in the toolbox would allow market surveillance authorities to intervene when relevant and at least disrupt certain supply routes, avoiding too easy proliferation of illegal product offers compared to if they were not to have digitally fit powers.

137 Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008R0764

138 The Construction Product Regulation 305/2011/EU also provides for advice to businesses by the Product Contact Points.

139 The provision of relevant product legislation as such will be improved with the implementation of the Single Digital Gateway as part of the baseline (http://ec.europa.eu/DocsRoom/documents/22761).

140 https://webgate.ec.europa.eu/gpsd-ba/index.do; https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.search

141 Market surveillance provision integrated in Union harmonisation legislation (see reference provisions of Decision 768/2008/EC, e.g. R2(4) for manufactures, R4 (7) for importers, R5 (4) for distributors) and Articles 20, 22, 23 of Regulation (EC) No 765/2008 on notifications for products presenting a serious risks, implemented in the ICSMS and RAPEX applications.

Variants of the measures considered but discarded at early stage and not further assessed in detail[142]:

– *Provision of assistance to businesses by a centralised help-desk service at EU level building on the Your Europe Advice service and as a complement to the Digital Single Gateway.*
– *Introducing mandatory frequencies and control intensity covering all product categories and controls within EU Member States and products entering the EU from 3rd countries (complementing or instead of risk based approach to market surveillance controls).*

4.3 Option 3 – in addition to Option 2 Increased deterrence effect to enforcement tools and stepped up EU coordination

*This option would involve **important additions** to the market surveillance framework, expanding existing provisions and adding coordination structures for enforcement cooperation, building on option 2. These additions would address most of the shortcomings identified by the evaluation of the current market surveillance rules.*

The additional measures in this option are:

Reinforcing cooperation procedures
3(a) **Cross-jurisdictional transferability of enforcement evidence and decisions**. This measure would add provisions in the market surveillance framework to facilitate re-use of evidence, test-reports and decisions of one market surveillance authority for use in and by authorities in other Member States. This measure would add legal principles in the market surveillance framework to ensure the **portability of test results**, a **presumption** that products found to be non-compliant in Member State A are also non-compliant in Member State B, and similarly in the area of control of imports, that confirmed non-compliances by market surveillance controls leading to customs' refusal to the release a product for free circulation are communicated and also refused in other Member States[143]. The legal principles would clarify in particular that market surveillance authorities can issue **restrictive measures[144]** directly to economic operators in other Member State(s) – e.g. a non-compliant product is found in distribution in the authorities' member state while the responsible manufacturer is established in another Member State. This would facilitate the follow-up of national restrictive measures that have been found justified after the safeguard clause mechanisms[145] foreseen in the EU product legislation[146],

142 For details see Annex 14 (point 2.6) and Annex 12 (point 2).
143 A general cooperation and information exchange requirement and communication of decisions from market surveillance authorities to customs are covered by Article 27(5) and 29 (5) of Regulation (EC) N° 765/2008.
144 For requests to undertake voluntary measures, Article 19 of Regulation (EC) No 765/2008 already provides for direct issuance to economic operators in other member states by market surveillance authorities.
145 Where a market surveillance authority finds that a non-compliance is not limited to its national territory, the safeguard clause mechanisms requires it to notify any restrictive measure to other member states and the Commission, who can react and/or submit objections within a given period set in the legislative act (normally 3 months). If no objection is raised within the deadline, the notified measure is deemed justified and other member states are required to take restrictive measures against the product concerned. When an objection is raised, the Commission must evaluate the measure, and after consultation with the member states and the economic operator, decides whether or not the notified restrictive measure is justified. In case the measure is justified, all member states are required to take restrictive measures against the product concerned.
146 See reference provisions R31(4) to R32, Decision (EC) No 768/2008, integrated since 2008 into around 20 EU product harmonisation legislative acts; the 2013 proposal on market surveillance generalised this safeguard mechanism for all products and sectors covered by the horizontal regulation.

without requiring the Member State where a concerned economic operator is established and/or where the same product and non-compliance is found to open an infringement case and issue a restrictive measure.

These measures would help reducing the inefficiency in controls and ambiguity on the jurisdiction of authorities due to the current fragmentation of market surveillance competences in the Single Market identified by the evaluation[147].

Increasing operational enforcement capacity

3(b) **<u>An EU Product Compliance Network</u>**, as an administrative support structure to coordinate and help implementing joint enforcement activities of Member States, including in e-commerce and imports.

In this option the Network would pool resources, intelligence and expertise and coordinate Member States' investigative and enforcement activities, based on decisions by the Member States in the network on common priority topics to take forward. The Network would not undertake investigations of its own or take any enforcement decisions. The Network would not modify, replace or in any way supersede the responsibilities for market surveillance that remain the competence of Member States.

This measure would provide a formalised governance structure and step up the operational support capacity, encompassing and expanding existing Commission support (e.g. indicators collection, studies, common IT-tools), ad-hoc co-funding support to market surveillance authorities' control campaigns or projects, organisation of around 50 meetings of sector and market surveillance experts[148].

The Network would be composed of:

- an EU Product Compliance Board, composed of Member States' representatives and the Commission. It would define the priorities for common market surveillance actions and monitor the implementation of the Network's work programme, coordinate and steer the administrative coordination group's activity[149].
- Administrative Cooperation Groups (ADCO's)[150], thematic and sectoral groups of market surveillance competent authorities' representatives. These groups would set-up and coordinate common market surveillance control campaigns, ensure coordinated application of product legislation, develop common practices, methodologies, identify issues of shared interest and suggest common approaches on these.
- Secretariat: it would prepare and organise the meetings of the Board and ADCOs, carry out all the technical, legal analysis and research, IT systems analysis and development necessary to the Network's action. Secretariat staff would also take care of the administrative/financial handling related to joint

147 See previous section 1.3.1.

148 Moreover the 2013 proposed included a European Market Surveillance Forum, to exchange information but with limited operational capacity, and established reference laboratories.

149 In the baseline the Commission supports an expert group Internal Market for Products, sub-group on Market surveillance, meeting once or twice per year; http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2798.

150 In the baseline 25 ADCOs are supported by the Commission (logistic support to meetings, via a service contract). https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups_en

actions.

For this measure the impact assessment considers different variants of **size** (Secretariat's human and financial resources) to modulate the resources input and relate these to the anticipated increased operational actions that the network could achieve. Resources range from 30 to 90 staff and € 6 – 14 million/year[151]. The Network could be hosted by the Commission or in an existing EU agency[152], the EU Intellectual Property Office (EU-IPO[153]) in particular.

The set-up of the Network would allow structured dialogue and cooperation among authorities in different countries favouring the building of a common approach on a number of common issues. This will address the shortcomings identified in the evaluation of Regulation (EC) No 765/2008 as regards heterogeneity in the organisation and the approach to market surveillance and the limited resources for cross-border cooperation.[154]

3(c) **Peer reviews of market surveillance authorities**. The tasks of the network would include peer reviews of market surveillance authorities, to monitor market surveillance efforts and effects across the Single Market (based on the Member State information and indicators further to measures (f) and (g) in option 2).

Strengthening the enforcement toolbox

3(d) **Person responsible for compliance information in the EU**[155]. To improve the **enforceability of decisions** by market surveillance authorities, especially vis-à-vis 3rd country businesses that place products on the EU market. Such businesses (i.e. non-EU manufacturers) would have to appoint a person responsible for compliance information in the EU when they do not work through an importer or an authorised representative. This will address the problem of lack of jurisdiction of market surveillance authorities vis-à-vis manufacturers located in third countries, as identified in the evaluation[156].

3(e) **Publication of restrictive measures taken by market surveillance authorities**. To reinforce the **deterrent effect** of enforcement decisions, market surveillance authorities would be required, firstly, to **publish more systematically restrictive measures** they take against non-compliant products. This measure would add onto the existing

151 Details of the different size variants, core tasks of the Network and corresponding budget breakdown are given in Annex 12.

152 See Annex 12. Of the different governance models and possible hosts of the Network, the Commission and a decentralised agency were examined in more detail. These variants were found to provide in principle the formal, accountable and transparent structure to handle the enforcement coordination tasks as well as technical and legal capacity. The variant of hosting in an executive agency was found to be limited as regards the staffing profiles it could provide (administrative tasks and financial handling of a repetitive nature, linked to programmes in particular). Early discarded variants were: an informal network, outsourcing to an ngo/association structure (lack of authority, limited accountability with strong grant contribution dependence) as well as a new, dedicated market surveillance/product safety decentralised agency (contrary to current policy restrictions on new agencies).

153 https://euipo.europa.eu/ohimportal/en. Among the decentralised agencies of the Union examined in the context of this impact assessment, the EU-IPO was found to provide significant potential for synergies in terms of Single Market objectives pursued, nature and scope of tasks. EU-IPO tasks portfolio includes for instance: promotion of best-practices and common cooperation tools, stakeholder engagement, knowledge gathering and sharing ("Observatory"), enforcement information exchanges, including with customs and international partners (law enforcement databases), and training ("EU-IPO academy"). Counterfeit/IP infringements and non-compliance are often interlinked (cheap, imitation products; imports are an important source). EU-IPO moreover avails of important human and financial resources which could be a facilitating factor to integrate new tasks. See Annex 12 point 2.

154 See chapter 6.1.2 of the evaluation.

155 See also Annex 13 section 2

156 See previous section 1.3.3.2.

obligations of market surveillance authorities to share information on restrictive measures with authorities in other member states and with the Commission[157], to communicate measures concerning products presenting a serious risk through the Rapid Alert system (RAPEX) also published on the Commission's website[158] and to alert users in their territories[159].

3(f) **Recovery of control costs in the case of non-compliant products**. Common provisions to ensure a more systematic recovery of control costs in the case of non-compliant products, thus generalising the practice of costs recovery. The legal powers for costs recovery as a matter of principle are already available in a majority of Member States[160] but not necessarily applied. A similar tool has been operational for many years in the area of food controls[161] and it would align powers of market surveillance in this respect with cost recovery options available to customs[162]. In cases of **suspected non-compliance**, market surveillance authorities could also order an economic operator to provide evidence (e.g. tests) to demonstrate compliance, with the costs and the burden of the requested conformity proof being placed directly on the concerned trader (instead of via recovery, which may be uncertain for instance in the case of imports).

All these measures would contribute to address the problem of insufficient deterrence of current control systems as identified in the evaluation.[163]

Promoting compliance

3(g) **Mandatory digital publication of compliance information.** The publication obligation would be limited to non-sensitive information, in particular the Declaration of Conformity[164]. The economic operators concerned are already required to draw up the declaration and to make it available to other economic operators in their supply chain and to market surveillance authorities on request. This measure would add a pro-active publication via digital means so that easier and widespread accessibility could be ensured.

157 Provisions on procedures to deal with products presenting a risk at national level and union safeguard procedures, reference articles R31 to R33 Decision (EC) No 768/2008; Articles 20, 22, 23 of Regulation (EC) No 765/2008.
158 Article 22 of Regulation (EC) No 765/2008.
159 Article 19(2) of Regulation (EC) No 765/2008.
160 In total 21 of 22 Member States that responded to the evaluation survey, indicated they had such powers. In 14 Member States this power is available in over 14 sectors; in a further 7 Member States the power is available in a more limited number of sectors.
161 The approach of imposing administrative fees to recover inspection costs has been for a long time common practice for controls in the food area (https://ec.europa.eu/food/safety/official_controls/legislation_en). In the non-food area has been advocated by stakeholders to help authorities to effectively take action against non-compliant goods, as controls (e.g. laboratory tests) and corrective actions (e.g. recalls and destruction of products) are very costly.
162 Articles 189, 197 and 198 of the Union Customs Code regulate the sharing or recovery of costs related to the transport of goods to the place of examination, the handling and the taking of samples, as well as costs related to the confiscation or the destruction of goods.
163 See previous section 1.3.3.
164 By drawing up and signing the EU Declaration of Conformity the manufacturer assumes the responsibility for the conformity of the product, declaring that that the fulfilment of the applicable EU product requirements has been demonstrated. Authorised representatives and importers are required to keep copies of the declaration. A model declaration is in Annex III of Decision (EC) No 768/2008. For construction products a Declaration of Performance applies.

Variants of the measures considered but discarded at early stage and not further assessed in detail[165]:

- *Digital compliance systems based on voluntary inputs from economic operators, or including labelling requirements relating to specific or new technologies (e-labelling, bar or quick scan codes);*
- *Introduction of administrative fees for all market surveillance controls (irrespective of whether the product is found compliant or non-compliant);*
- *Outsourcing of the Product Compliance Network to an association or informal network of Member States; the establishment of a formal, new EU decentralised agency to host and manage the Product Compliance Network.*

4.4 Option 4 – in addition to Option 3 Centralised EU level enforcement in certain cases

*This option would involve a **significant modification** of the market surveillance framework, by adding for certain enforcement tools or infringements EU level measures and actions, building on option 3. These modifications would also address additional shortcomings identified by the evaluation of the current market surveillance rules.*

The additional measures in this option are:

Reinforcing cooperation procedures
4(a) **Direct enforceability of restrictive measures and right to remedies**. EU law would allow the direct enforceability of restrictive measures taken by a market surveillance authority in one Member State, to all other Member States wherever the same non-compliant product would occur. This measure would extent a national restrictive measure banning a non-compliant product from its national market, to a ban throughout the EU and for any further imports of the same product[166]. This measure would involve extending the available mechanisms by which authorities and the Commission currently notify each other and scrutinise restrictive measures with a cross-border aspect (see safeguard clause mechanism, option 3(e) above) to cover also restrictive measures of a market surveillance authority for non-compliances that seem limited to the national territory at the moment of investigation. The precise geographical extent of the non-compliance may not always be clear and/or could change in the future (e.g. complex supply chains such as imports via several wholesalers and retailers). The responsible economic operator (manufacturer, importer) would be heard prior to the confirmation of the initial national measure and the restrictive measure as such would be open to administrative and/or judicial reviews in the Member State in accordance with its national rules. Moreover, non-compliance of a product leading to a restrictive measure by market surveillance authorities also entails the right to **remedies** for the consumers and professional end-users who purchased such product. They could return a non-compliant

165 For details see Annex 14 (point 5.8) and Annex 12 (point 2).

166 This would not affect the existing obligations of market surveillance authorities to request first voluntary action by the economic operators (reference article R31 (1) Decision (EC) No 768/2008), nor the general requirements regarding proportionality of the measure imposed on the economic operator (Article 21 Regulation (EC) No 765/2008).

product and request remedies from the economic operator from whom they bought the product. These remedies would apply the principles to situations of non-compliance[167]. Market surveillance authorities in all Member States would also be empowered to order an economic operator to provide remedies on a case-by-case basis to end-users[168].

Increasing operational enforcement capacity

4(b) **EU investigations for widespread infringements**. An additional mandate to the EU Product Compliance Network (option 3(f) above) to perform investigations and take enforcement decisions, in cases of widespread infringements[169]. This measure would introduce the possibility for the EU product compliance network structure to conduct an investigation and take an enforcement decision for widespread infringements with significant impact on a large part of the EU territory. The opening of such an investigation would be subject to the agreement of the Commission and Member States, who would decide on the network's priorities and such EU level investigations and decisions.

Strengthening the enforcement toolbox

4(c) **Approximation of sanctions**, for different types of non-compliance and levels of sanctions, in particular financial penalties. This measure would define in the legal framework **categories of non-compliance** (e.g. formal and/or substantive non-compliance, categories by severity, extent of the non-compliance) and **corresponding nature/level of sanctions**, both administrative and criminal, including minimum levels of penalties. The measure would complement the current legislative framework which sets out a general obligation on Member States to provide for and apply 'effective, proportionate, and dissuasive' sanctions, including criminal sanctions for serious infringements and possible increased penalties for repeat offenses[170]. In some cases the product legislation adds general additional principles to take into account (e.g. the extent of non-compliance and the number of units of non-complying products placed on the EU market[171]).

This measure would address the problem of low deterrence of the current system of penalties identified in the evaluation as a consequence of divergences in national sanctioning rules.[172]

Promoting compliance

4(d) **A centralised product registration database**, in which economic operators would be required to upload compliance information. The information would concern both

167 In addition to Directive 85/374/EEC on liability for defective products.

168 In the baseline, market surveillance authorities must be able to order product recalls (see Art. 20, 21 Regulation (EC) N° 765/2008). When an economic operator recalls a product this would normally entail for the consumer a replacement, refund or other compensation as appropriate. Moreover, in 2 Member States (PL, SI) in most sectors the power is available to order compensation to consumers; 12 Member States have such a power in place for a more limited number of sectors. In total such an additional power related to consumer compensation was found to be available in 14 (of 22 Member States that responded to the survey) for a majority or more limited number of sectors (For a detailed breakdown of powers and availability in Member States see Annex 13; based on the evaluation study of Regulation (EC) N° 765/2008).

169 The proposed market surveillance regulation (2013) included the possibility for the Commission to adopt implementing acts to take appropriate measures against certain products, group or category of products that would present a serious risk.

170 Article 41 of Regulation (EC) No 765/2008; provisions on sanctions and/or penalties in the EU product legislation.

171 Eco-design directive 2009/125/EC, Article 20, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009L0125-20121204

172 See chapter 6.1.2.2 of the evaluation.

sensitive (technical documentation) as well as non-sensitive information. This measure would involve a centrally managed database, by the Commission, and require economic operators to upload and keep up to date all the relevant technical compliance documentation. Access to the information would be separated into **a public part** (declaration of conformity, measure (a) option 3 above) and **a non-public part** for commercially sensitive technical documentation which would be easily but securely accessible for market surveillance authorities and the Commission[173].

Variants of the measures considered but discarded at early stage and not further assessed in detail[174]:
- Carrying out of investigations and ultimately sanctioning of economic operators by the Commission separate from and instead of Member States.

5. WHAT ARE THE IMPACTS OF THE DIFFERENT POLICY OPTIONS AND WHO WILL BE AFFECTED?

5.1 Option 1 - baseline

The **baseline scenario** is the "no policy change" option. This implies that market surveillance provisions of Regulation (EC) No 765/2008 in its current version remain as the applicable legal framework. The impacts are described in section 1.3 , 1.4 and 1.5.

5.2 Option 2 – Improvement of existing tools and cooperation mechanisms

Effectiveness in achieving the objectives
Reinforcing cooperation procedures
2(a) Mutual assistance would allow for efficient work sharing since market surveillance authorities carry out complementary tasks within the remit of their respective jurisdictions. Thanks to the formalised mutual assistance mechanism in this option, the exchange of cases between Member States would become smoother, with faster responses, as there will be clearer common principles for the assistance requests and deadlines[175]. Overall, it should allow reducing the rate of authorities that would never or rarely be able to follow-up on restrictive measures of other Member States, and lead to more regular effective help to the requesting authority[176]. When market surveillance authorities work on the basis of a common toolbox, exchanging cases and responding to assistance requests from other countries will become easier (measure

173 The database could be construed as an extension of the future energy labelling product database, considering that many products in the scope of this energy labelling regulation would also be subject to EU product harmonisation legislation (e.g. the low voltage, electromagnetic compatibility, radio equipment directives); Proposal for a Regulation of the European Parliament and of the Council setting a framework for energy efficiency labelling and repealing Directive 2010/30/EU, COM(2015) 341 final - 2015/0149 (COD), 15.07.2015).

174 For details see Annex 13 (point 11).

175 The passing of cases between authorities in the IT-tool shows that 15% of "baton passing" are rejected, 23% remain pending with sometimes lengthy delays. 62% are accepted.

176 The pattern of follow-up to restrictive measures taken as baseline 30% never/rarely – 35% sometimes – 35% very often/always. Indicatively one could project in this option that the pattern would improve to: 15% never/rarely – 50% sometimes – 35% very often/always follow-up. This pattern relates only to whether follow-up is given, but does not address the nature or depth of follow-up, or its effect (e.g. helping in addressing a detected non-compliance fully or partially). (Estimated pattern, based on public consultation, feed-back to Commission by market surveillance experts).

(d) in this option). The challenge for the receiving authorities will be to mobilise resources quickly to respond to the incoming requests. Possible difficulties, for instance linked to acceptance of findings or test carried out in another Member State, are not addressed in this option. These barriers remain.

The combination of the mutual assistance and the implementation of certain enforcement powers and tools (system audits, compliance programmes with large manufacturers and importers) would allow over time important efficiency gains[177] (see measures e and f in this option).

Increasing operational enforcement capacity

2(b) The use of **enforcement strategies** and performance indicators could in the short term help to promote a strategic and evidence-based approach to enforcement in Member States. The compliance and enforcement gaps assessment would help Member States to identify opportunities for increased cooperation between market surveillance authorities and with customs (e.g. in main entry points to EU market for imports) and improve the targeting of possible concrete control actions.

2(c) The **performance indicators and benchmarks** would also increase visibility of enforcement actions by market surveillance authorities and significantly improve the oversight of the state of market surveillance in the EU.

However this option in itself would not make significantly more resources available for market surveillance authorities or help to overcome the resources constraints that currently hamper them to carry out more inspections, perform product testing or participate in more coordinated cross-border control campaigns or invest in IT-tools. By better enforcement intelligence, controls could be better targeted. The existing resources would then be used more efficiently but this option would be unlikely to trigger a noticeable increase in actual control activity.

Strengthening the enforcement toolbox

2(d) Thanks to a clearer defined set of **investigative and enforcement powers**, market surveillance authorities across the EU would be able to work with common effective and deterrent tools, which would facilitate cross-border enforcement[178] and the coherence of enforcement throughout the EU (in similar cases, all authorities would be able to apply equivalent investigation tools and enforcement powers). In the baseline an average 18-19 Member States already have the envisaged powers in a majority or some sectors (in 11-13 Member States market surveillance authorities have the powers in over 14 of 33 product sectors; a further 7-8 Member States in some product sectors)[179]. In the future these powers

177 In France the mandatory systems audits prior to the first placing of the market is operated nationwide with 18 FTE (covering manufacturers, importer and distributors whose turnover exceeds 2 M€ - see Annex 14). If this practice were to be generalised to the EU, important efficiency gains on resources could be achieved: Assuming more staff as a basis 54 (3*18 in the French example) would be needed to cover subsequent audits, random monitoring and follow-up, extrapolated to the EU this could be covered by 350-675 staff in total (based on average turnover/value added France/EU – number of enterprises France/EU in harmonised sectors). Compared to the total number of market surveillance inspectors for the harmonised sectors reported by Member States (4506 inspectors for 16 member states), the scope for optimisation and efficiency gains would be significant.

178 E.g. Handling of mutual assistance request (request for information that should be obtained from an intermediary in the supply chain), participation in joint control campaigns (e-commerce projects would require all participants to perform mystery shopping)

179 See overview of available powers, annex 13 The information is based on information from 22.Member States. While investigative and enforcement powers are generally available to market surveillance authorities in Member States, there are variations in terms of

will be commonly available to all market surveillance authorities across Member States and sectors, thus guaranteeing an equivalent enforcement toolbox and the possibility for authorities to intervene with the same powers in similar cases regardless of the location of the infringement.

Moreover, the powers to require information and cooperation from any trader, intermediaries and relevant natural or legal persons in the supply chain, and where necessary sanction absence of response[180] would equip market surveillance authorities better for the frequent situations where the economic operator is located in a 3rd country jurisdiction or difficult to trace or elusive (e-commerce)[181].

The availability of powers which are particularly relevant for e-commerce would also significantly improve (mystery-shopping, requiring illegal content to be removed from websites, suspension of websites[182]). Availability of such powers directly to market surveillance authorities would allow them to react swiftly which is needed to be effective in the highly versatile e-commerce context. As a result, more non-compliant or unsafe products offers could be removed from the internet faster.

Ultimately the deterrent effect of a better toolbox would depend on the actual use. For instance, over time, a coherent and regular use across Member States of the power to sanction absence of responses or documentation could incentivise more businesses to comply.

2(e) Besides traditional enforcement powers, optional, **collaborative enforcement tools** and **compliance assistance schemes** with businesses would best be integral components of a comprehensive market surveillance regime[183]. This option would incentivise Member States to develop more compliance schemes as part of their enforcement policy mix[184] (together with measures 2(b) and 2(f)). Businesses and market surveillance authorities could justify the cost they deploy for such tools through reduced inspection scope or frequency, and that compliance problems could be addressed efficiently, in a preventative manner instead of by costly corrective action[185]. Compliance programmes could help businesses to have more efficient

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the coverage of sectors and some Member States reported far fewer availability of powers (notably: AT, BE, ES, IE, IT; DK and RO).

180 The power to sanction economic operators that do not cooperate is available in the 22 member states that reported information on powers (for 15 MS in more than 14 sectors, for 7 in fewer than 14 sectors). Requiring information or cooperation from any natural or legal person can only be done in 14 member states in over 14 sectors; in 8 member states in fewer than 14 product sectors. (Overview of available powers, Annex 13)

181 Market surveillance authorities find it often impossible to obtain compliance documents, especially from importers who cannot access documentation from manufacturers (e.g. intellectual property right protection) (Impact study digital compliance, VVA, 2017, Annex 14).

182 The average availability of these specific powers is lower, around 13 member states and only 7 for website shut downs. The power to order closure of websites is only available in 1 Member State in a majority of product sectors, in 6 member states in fewer sectors; in 14 Member States, market surveillance authorities do not yet have this specific power. It should be noted e-commerce enforcement is fairly recent for most authorities and that such a strong sanctioning power would be used as a last-resort where alternatives are not available or failed to address the infringement. With the developing e-commerce, the toolbox of market surveillance authorities should cover the full range of relevant powers, including strong ones, so that when needed, effective enforcement action can be taken regardless of the Member State thus contributing to an equivalent level of protection.

183 BSI, Study on Good-practices in the area of Compliance assistance and compliance schemes (2017, included in Annex 14); OECD (2014) Regulatory enforcement and inspections, http://www.oecd.org/gov/regulatory-policy/enforcement-inspections.htm.

184 The overview of current practices shows that of the 23 member states that reported practices, all engage in at least one type of activity to promote compliance (awareness raising, compliance assistance, formalised compliance programmes or partnerships; 8 of 23 (35%) engaged in one type of activity, 6(26%) in 2 types, 9 (39%) in all 3, with sometimes overlaps between the different practices types). (BSI study, annex 14). The inclusion of compliance promotion in the market surveillance framework would support the development of different types of compliance promotion and ensure that they become available more widely across the Member States. Formalised compliance programmes or partnerships could develop only over time however, as resources to set-up and maintain such schemes would be an important barrier (25% of identified practices in the study).

185 E.g. (Mandatory) systems audits in France before the first placing on the market; voluntary covenants or protocols in Netherlands (Annex 14)

'one-stop-shop' contacts with inspections and regulatory bodies, and have access to consistent, coordinated advice[186]. This would be especially relevant in Member States where market surveillance is carried out at several levels (national, regional and local).

Market surveillance authorities may however be cautious to engage in structural pro-active co-operation with sector organisations or fees-based assistance to businesses as it may blur the line with their role as independent inspectors (e.g. who decides what should be controlled). While interesting as a source of intelligence, evidence of non-compliance brought forward by businesses, even based on recognised testing-standards, would in many Member States not be admissible as formal evidence in proceedings[187].

Promoting compliance

2(f) Thanks to the extension of the **Product Contact Points** to harmonised product legislation, businesses would have easy access to dependable information and advice[188].

The Product Contact Points are available in all Member States, thus familiar with local chamber of commerce and associations and closer to **smaller businesses** that may have difficulties in easily accessing information or advice from EU centralised sources. By contrast **larger businesses** would be more likely to use the "formal" partnership or compliance programmes[189].

2(g) The **common EU web-portal for voluntary measures** would allow faster and better information for consumers enabling them to timely act and thus protect their health and safety. Distributors would similarly be better informed. Given the overall positive reactions from stakeholders, it can be anticipated that the number of voluntary measures in the portal would increase rapidly, to around at least 800 notifications/year[190].

Stakeholders' views on the option[191]

2(a) Tools such as the mechanism for **mutual assistance requests** would help to work efficiently across jurisdictional boundaries, as clearly advocated by authorities and businesses on different occasions.[192] The majority of respondents to the public consultation (80% of authorities, 73% of businesses and 73% of consumers and other respondents) agree that stricter obligations for authorities to respond to requests for mutual assistance by other authorities would help enforcement vis-à-vis businesses located in another Member State[193].

2(b) and 2(c) The use of **performance indicators and monitoring by the Commission** in this option aims first of all to improve the information basis and transparency on the state of

186 E.g. Primary authority scheme, UK (Annex 14).
187 Market surveillance expert group, IMP-MSG, meeting 31 March 2017.
188 ' Lack of knowledge' by businesses was flagged by 80 % of respondents (190 of 239) in the public consultation among the top 3 reasons underlying non-compliance, and 27% ranked it the top 1 reason.
189 This was confirmed in the review of the 'Primary Authority' scheme in the UK in 2013; the scheme offers businesses the opportunity to establish a partnership with one authority who then coordinates advice and guidance to the business across a range of regulatory matters (one-stop-shop principle) https://primaryauthorityregister.info/par/images/documents/acl-pa-evaluation.pdf
190 Estimate based on the number of notifications of voluntary measures via the RAPEX system. Over the past 5 years these averaged 800, increasing from 609 (2012) to 922 (2016)
191 Results of the public consultation are provided in Annex 2 and on: http://ec.europa.eu/DocsRoom/documents/21181/attachments/1/translations/en/renditions/native .
192 See the results of informal consultation of Member States and minutes of the June 2016 public event (see Annex 2 sections 1.2.2 and 4).
193 See of the brief factual summary of the initiative, p. 21 (http://ec.europa.eu/DocsRoom/documents/21181/attachments/1/translations/en/renditions/native).

market surveillance in the EU, and compare Member State performance. In the public consultation 69% (131 of 190) of respondents strongly agreed/agreed[194] that better verification by the Commission of the functioning of market surveillance in Member States would make market surveillance in the Single Market more effective (55% of authorities, 78% businesses).

2(d) In the public consultation stakeholders expressed mixed[195] views on the general impact that "more" **powers** for market surveillance authorities could have on deterrence and/or resources. Specific powers were rated with varying degrees of approval: 65% of respondents believe authorities should have power to carry out an inspection on behalf of another EU Member State's authority upon request; 59% of respondents believe authorities should have the power to notify acts on behalf of another EU Member State's authority upon request; 45% of respondents believe authorities should have the power to enforce fines on behalf of another EU Member State's authority upon request. The effectiveness and the necessity of powers to act against non-compliant products even if the economic operator is not based in the EU are supported by business stakeholders[196] and authorities.[197]

Member States market surveillance experts recognised that a common set of powers would help to facilitate cross-border cooperation and provide for an enforcement level-playing field across the EU. While some specific powers would need to be used only as last resort (e.g. requiring a take-down of a website, not merely specific illegal content it may feature), the experts expressed broad support for the possible range of powers that could be included in the market surveillance framework[198].

2(e) The public consultation results indicate that there is potential to close knowledge and information gaps by using **collaborative enforcement tools**[199].

2(f) The views expressed in the public consultation show broad consensus that **promotion of compliance** via information provision and guidance would be an effective approach to reduce non-compliance (information provision was rated very effective/effective by 78% (151 of 194) respondents and similarly guidance by 68% (131 of 192) respondents, with fairly equal patterns of responses between authorities and businesses. Business rated 'guidance' as slightly more effective (75%). A narrow focus on corrective enforcement action was rated 'not effective' by 60% of respondents.

2(g) A majority of Member States supported[200] the creation of a **common European portal on voluntary measures** as long as this entailed a voluntary reporting by the economic

194 17% (33 of 190) disagreed/strongly disagreed.

195 Although there are more strong agreement/agreement answers, the pattern in the responses show a comparable spread over agreement and disagreement answers, relatively high 'no opinion' answers. No significant differences between authorities and business respondent categories.

196 http://www.orgalime.org/position/efficient-market-surveillance-online-trade-suggestions-better-handling-fulfilment-centres

197 http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=28611&no=1 (section 3.6)

198 Market surveillance expert group, IMP-MSG, meeting 31 March 2017.

199 Authorities' and business' responses concur that if the market surveillance authorities would have more knowledge about the relevant sector, they could use available resources more efficiently (81% of authorities agree/strongly agree; 86% of business respondents). Examples could be memoranda of understanding with business organisations to exchange information and common actions; agreements with certain intermediary traders (e.g. express carriers or internet intermediaries).

200 RAPEX Contact Points meeting of 14 October 2016 (see a summary of national RAPEX Contact Points' positions in Annex 14 (point 6).

operators without any investigation or approval by the national competent authority. Also other stakeholders generally agreed[201] on the usefulness of comprehensive and up-to-date information on a single website.

Administrative simplifications

As explained in the evaluation most of the enforcement costs stemming from current market surveillance rules are borne by public authorities, while costs on businesses only relate to information obligations (responding to requests from authorities, information on non-compliances detected) and are therefore regarded as insignificant by them[202]. For this reason this section focuses on measures in this option that would result in specific benefits in terms of administrative simplifications for authorities.

The ability to apply **investigative and enforcement powers** across all relevant parties in the product supply chain, streamlining the applicable definitions, implies an important simplification for market surveillance authorities. They will be able to investigate, require cooperation and act where needed and where their action can be most effective. The flexibility to work across the supply chain would be a major improvement in legal empowerment and certainty for market surveillance authorities who in the current system are confronted with varying definitions and texts, in particular for e-commerce[203]. While online sales and market surveillance will increase, it is difficult to project the number of enforcement cases authorities would take on in future years and more in particular the specific proportion of infringement cases linked to new, additional economic players in the supply chain[204]. In the longer term Member States would also benefit from the opportunity to organise their market surveillance more flexibly, as the powers will be common, independent of specific sectors or legislation.

Effective mutual assistance requests would allow targeting controls at manufacturers/importers in the Member State of establishment. A market surveillance authority may choose to focus less on certain products/operators in the (local) distribution phase and rely instead on systems controls upstream for the concerned manufacturer/importers in another Member State. The market surveillance authority would avoid costs associated with the case-handling as well as economise on the reporting or on communicating information to others authorities and the Commission on individual cases. The realisation of these simplification benefits would however develop over time, depending on the uptake of the mutual assistance requests scheme, the use of powers including systems audits of large economic operators, and the implementation of enforcement strategies by Member States.

The **reporting requirements** on Member States and communication of control programmes would be streamlined. The common IT-tool (ICSMS) would be used for simpler and quicker notification of competent authorities and exchange information on planned controls. This could result in the short term in some reduction of administrative burden linked to the communication to the Commission of control programmes[205]. Most costs are linked to the

201 Stakeholders (businesses, consumer representatives, test laboratories, etc.) were consulted during two workshops held in April and November 2016 on how to "boost the use" of RAPEX.

202 See chapter 6.2 of the evaluation.

203 See section 1.3.3.1. Development of e-commerce and digital supply chains.

204 The number of cases depends on a number of variable factors, such as the availability of information to the authority to detect infringements, the nature and complexity of (new) cases, and the evolving handling capacity of authorities.

205 A rough estimate could be a reduction in the order of 2 days (0,01 FTE/year) by Member State, thanks to direct uploading of information into ICSMS by market surveillance authorities instead of requiring collection, handling and transferring of data in spreadsheet format via a national coordination point. This reduction would only be a small part of the total effort linked to planning and programming of inspections. Based on a tentative estimate in one Member State the total programming effort by authorities and

planning and programming of controls. This part would remain, as it constitutes a necessary basis of enforcement strategies. For Member States, the strategy would become a strategic and information sharing tool, adding benefits over a mere reporting obligation. The direct uploading by Member States of this information in the common database (instead of dispatching on paper/electronic documents) would reduce handling requirements by the Commission (-0,5 FTE).

Compliance and implementation costs

Costs for businesses

2(a), (b), (c) The measures in this option would not entail additional costs for businesses or create additional administrative burden. **The common powers for market surveillance authorities,** procedures for **mutual assistance** between authorities, and **enforcement strategies** and performance indicators would be measures directed at and implemented by Member States authorities and would not entail new obligation or costs for businesses.

Costs for Member States

2(a) Mutual assistance requests: The authority receiving a request for mutual assistance would incur the operational costs related to the necessary investigative or enforcement steps. The size of the costs would depend on the specific case and number of requests[206]. In most cases, the authorities receiving a mutual assistance request would only carry out ad hoc steps (e.g. request of information) while the requesting authorities would maintain the responsibility. The additional costs per request would amount only to a relatively small portion of the average costs of inspections (which are estimated roughly to average 703€, ranging from 50€ - 5 000€[207]). In the baseline scenario, Member States are already required to follow up on other authorities' notifications; the mutual assistance request mechanism may lead to more requests being circulated among Member States. Depending on the nature of the request, this may imply more effort for market surveillance authorities, i.e. more systematic researches of non-compliant products found abroad and, if needed, adoption of a higher number of decisions. On balance the effort would however be off-set by efficiency gains that market surveillance authorities could obtain by receiving assistance for their own cases, and the reliance on systems audits on manufacturers and importers in the Member States where these are operators are established.

2(b) Enforcement strategies: Under the current Regulation (EC) N° 765/2008 Member States are obliged to set up control programmes and assess and report on the effectiveness of such programmes (Article 18 (5) and (6)). The use of 'enforcement strategies' would imply a shift in the contents of such programmes, rather than adding a new layer or reporting obligation[208].

national coordinating body would amount to just under 1 FTE/year, covering annual control programmes (180 days, 0,8 FTE/year), 4-yearly evaluation programmes (42 days, 0,2 FTE every 4 years) and a national plan (4-6 days, <0,05 FTE/year). For comparison, the drawing up of yearly updates of control programmes in the food area was estimated at around 42 person days (€10.430) per Member State. Only a part of this effort is related to collecting, uploading and transferring data (Annex XXII, impact assessment proposal for a regulation on official controls to ensure the application of food and feed law, SWD(2013) 167 final, May 2013).

206 Costs would be lower for requests for information and higher for enforcement measures. Requests are only expected for cases handled by foreign authorities that may concern economic operators based in a given countries but only in those cases where the businesses initially contacted by the requesting authority is not willing to cooperate.

207 See Annex 11, table 11-7, section 3.1.

208 Based on a tentative estimate in one Member State, the total programming effort by authorities and national coordinating body would amount to just under 1 FTE/year, covering annual control programmes (180 days, 0,8 FTE/year), 4-yearly evaluation programmes (42 days, 0,2 FTE every 4 years) and a national plan (4-6 days, <0,05 FTE/year). For comparison, the drawing up of yearly updates of control programmes in the food area was estimated at around 42 person days (€10.430) per Member State (Annex

Besides initial alignment costs to adapt to the new form of programmes (estimated on average 15.000€ per MS[209] in the first year), no significant additional administrative burden would be anticipated for Member States[210].

2(d) One-off training costs to familiarise market surveillance authorities with the **new common powers** can be estimated at 2 000€ per authority (~500 000€ for all Member States)[211]. The most affected Member States would be those who currently lack certain investigative and/or enforcement powers: overall 18-19 of Member States provide for the powers either in a majority or in some product sectors. Member States who currently have the least number of powers and who would thus face more adaptation are AT, BE, ES, IE, IT, and to a lesser extent DK and RO[212]. The costs of optional, **collaborative enforcement tools** would depend on the actual uptake by businesses and associations. The main challenge for authorities would seem to be resources, both human and financial. When businesses would pay a fee for the services rendered, authorities would not incur additional costs.

2(f) Product Contact Points[213] are already available in all Member States and run by experts in product legislation. Due to the expansion of the remit of PCPs to harmonised goods, it would be likely that the number of information requests would increase quite sharply requiring an estimated 1 to 3 supplementary FTE per PCP (running costs for all 28 Member States could total 3,5 M€/year[214]). Set-up costs would be negligible as the strengthening of the Product Contact Points is already planned to deal with their mutual recognition tasks[215].

2(g) The **new common portal** for voluntary measures would not create any administrative burdens or costs for Member States.

Costs for the Commission/EU budget

2(a) IT set-up costs to include a **mutual assistance mechanism** would be limited (50.000 – 75.000€), given that a basic functionality to pass on cases to other authorities already exists in ICSMS. Additional effort would be required at EU level to monitor the implementation of the stricter rules on mutual assistance and existing 'follow-up' obligations, liaise with authorities and address questions (1 FTE).

XXII, impact assessment proposal for a regulation on official controls to ensure the application of food and feed law, SWD(2013) 167 final, May 2013). The transmission of control programmes via the IT tool ICSMS would imply an administrative simplification estimated at 2 days (0,01 FTE/year) by Member State.

209 One-off efforts to adapt to new format and contents, around 0.2 to 0.3 FTE in the first year, i.e. 12,400 – 18,600 € (average staff costs 61.971€/year based on EUROSTAT 2006, updated 2010, for category ICSO1 legislators and senior officials; including salary, non-wage labour costs, 25% overhead costs)

210 In the longer term, post 2020, the strategies could be the basis for applications for funding, while at the same time constitute an instrument for strategic planning and coordination.

211 Estimate aligned with the impact assessment for the Consumer Protection Cooperation. The powers in this initiative are largely aligned with the CPC proposal. Most affected are 32-35% of Member States who would have more new powers to foresee for market surveillance authorities and/or to extend significantly the coverage of powers to more product sectors: 35%*500 authorities*2000€ = 350,000 €, plus general training and familiarisation for others. The estimates of number of Member States concerned are based on a survey carried out as part of the evaluation of Regulation (EC) n° 765/2008, in which 22 Member States responded. The % used is rounded upward to 35% and applied to the full number of 500 authorities in order to include more rather than too few possible adaptation efforts. 15 (68%) of the 22 reporting MS had 10 or more of the 16 powers in over 14 sectors; 7 (32%) Member States had fewer than 10 of the 16 powers in over 14 sectors.

212 See availability of powers in Member States, Annex 13.

213 Annex 11 (2).

214 1 FTE on average 61,971€/year per Member State; 3 FTE would be 185,913 €/year (staff costs based on EUROSTAT 2006, updated 2010, for category ICSO1 legislators and senior officials; including salary, non-wage labour costs, 25% overhead costs)

215 Product Contact Point are operational in all Member States, dealing with mutual recognition requests. Reference is made to the impact assessment with respect to the initiative on mutual recognition indicating that most Product Contact Points are integrated in an already existing department dealing with internal market issues. PCPs, at the moment, are served by one person on average. The Product Contact Points would be strengthened to improve the functioning of the mutual recognition principle.

2(b) and 2(c) Enforcement strategies and **performance indicators**: Based on the existing funding provisions of Regulation 765/2008, and within the existing spending ceilings, grant co-funding could be directed to some first national strategies as pilot cases in the short term (1-3M€/year). A possible new fund or part of a new fund post 2020 to support Member State enforcement strategies would require a considerable co-funding from the EU budget to ensure adequate coverage of all Member States and sectors[216].

Initial set-up costs for the Commission would be 1 FTE to define the performance and benchmark system, building on the existing indicators and national reporting (including market studies and/or survey to establish methodology and reference levels (1M€). Running costs to manage the possible co-funding for pilot strategies, accompany the implementation of the strategies and performance indicator system by Member States, collect data, analyse and share the performance information, monitoring and reporting are estimated at 3 FTE.

2(g) Common EU portal: Set-up costs of the IT platform and connection to the RAPEX webpage would be in the order of 45 000€. Moreover, the management of this portal would require 0.7 FTE for IT maintenance and to screen the information received from the economic operators and ensure that the requirements are met. Yearly maintenance costs would be 15 000€.

Other economic impacts (SMEs, functioning of internal market, competition, consumers)

The more equal available enforcement powers in all Member States, improved mutual assistance mechanisms, better shared enforcement information and benchmarked performance would improve the level playing field and thus the functioning of the internal market for responsible businesses affected by the unfair competition of non-compliant products.

The impact of this option on the competitiveness of business would overall be positive since it would help businesses to comply without any further costs. SMEs would benefit from more assistance and information. Consumers would benefit from easily accessible and more comprehensive information on dangerous non-compliant products in the Common Portal. They could also contact the Product Contact Points about compliance issues and could be guided to possible solutions.

Social Impacts

Improved market surveillance would increase consumer protection and safety levels. Regarding governance, the use of enforcement strategies and performance indicators would enhance the transparency of market surveillance and have a positive effect in the area of good administration.

Environmental impacts

No significant environmental impacts were identified.

216 The possibility of a future fund, upscaling financial support for market surveillance, is not part of this impact assessment as such. Based on other EU support programmes (e.g. food controls), indicatively the size could range from 35 to 45 M€/year and 10-15 FTE to manage the funds, taking into account that additional, dedicated resources for coordinated cross-border are covered in option 3 (b) EU Product Compliance network. See Annex 12.

Impacts on fundamental rights (EU Charter of fundamental rights)
The implementation of the **investigative and enforcement powers** in this option may impact on certain fundamental rights (right to due process/effective remedy, rights of defence, freedom to conduct business, data-protection and right to privacy). In accordance with Article 52 of the Charter a careful balancing of limitation to these rights has to be made with the objective of general interest of protection consumers, users and the environment from unsafe and non-compliant products. Market surveillance authorities would use powers on the basis of proportionality and necessity (e.g. possibly more intrusive investigative powers would only be used if needed for the investigation and no less-intrusive alternative would be available to obtain the evidence; certain enforcement powers such as requiring the closure of a website could only be used as last-resort). Moreover the use of the powers would be subject to national procedural safeguards.

Summary assessment of the option (2)	
Effectiveness in achieving the policy objectives	
Reinforcing cooperation procedures	++
Increasing operational enforcement capacity	+
Strengthening the enforcement toolbox	++
Promoting compliance	++
Costs	
For economic operators	neutral
For Member States	-
For the Commission/Impacts on the EU budget	-
Administrative simplification	**++**
Magnitude of impact as compared with the baseline scenario (the baseline is indicated as 0): +++ strongly positive; ++moderately positive, + positive; neutral; - - - strongly negative; - - moderately negative, - negative;? uncertain; n.a. not applicable. When talking about costs: + means 'savings', while – means 'cost'	

5.3 Option 3 – in addition to Option 2 Increased deterrence effect to enforcement tools and stepped up EU coordination

Effectiveness in achieving the objectives
Reinforcing cooperation procedures
3(a) <u>Cross-jurisdictional transferability of enforcement evidence and decisions</u>. The recognition of test results among Member States as a default principle, would allow much faster exchange and re-use of enforcement evidence for a majority of cross-border cases. Thanks to the 'presumption of non-compliance' once an authority in the EU would have taken a decision against a particular product, authorities elsewhere in the EU would be able to base

their own decisions more systematically on the findings of the initial authority and then consult the concerned businesses, instead of investigating a case from scratch[217].

Overall, these measures would allow the majority of authorities to follow-up at least regularly on restrictive measures of other Member States[218]. They would significantly reduce duplication of work and the inefficiencies linked to the need to carry out new tests or proceedings in different Member States as regards the non-compliance of the same products (either manufactured in the EU or imported from third countries)[219].

The support from the EU Product Compliance network and more use of ICSMS (b) (e.g. more control reports) and improved exchanges of information with customs would further reinforce these effects.

Increasing operational enforcement capacity

3(b) The **EU Product Compliance Network** would allow bringing together a critical mass of resources and implement activities that would lead to better prioritised joint actions based on improved intelligence, more joint and coordinated actions (including e-commerce) and improved information flow through ICSMS. More risks profiles shared with customs would lead to more and better controls on imports.

Thanks to the sharing of market information, intelligence and stepped-up coordination in the Network, market surveillance authorities would be able to better integrate into their national controls the **EU single market dimension** (e.g. significant supply chains distributed over several countries but originating in one country, where controls would be most effective and efficient (sea/airport for imports, large manufacturers for intra EU trade)).

Overall**, consistency of enforcement** in the EU would see a strong improvement, due to the coordination on a much wider scale that the Network would support. In turn this will benefit businesses that trade cross-border (level-playing field, legal certainty and predictability).

The increased operational activity that the EU Product Compliance Network could trigger, would have a positive effect on the visibility of the enforcement activity, and hence on deterrence. Member State authorities would take restrictive actions against specific non-compliant products that are found in the more frequent joint actions. Moreover the publication of restrictive measures, guidance and compliance assistance promotion by the EU Product Compliance Network would have a preventative, dissuasive effect and help to improve compliance rates. Economic operators would see **more EU-wide action** rather than a patchwork of control campaigns or uncoordinated actions in individual Member States, which would discourage possible jurisdiction hopping of economic operators that could search for

217 Limitations nonetheless remain to the potential for re-use of evidence from one jurisdiction in another. Each case still has to be assessed on its own, and particulars may slightly vary. Procedural law will require authorities sometimes to perform the full investigation themselves, including securing evidence, according to specific criteria (e.g. investigations under criminal law).

218 See option 2, measure (a) mutual assistance: The pattern of follow-up to restrictive measures taken as baseline 30% never/rarely – 35% sometimes – 35% very often/always. The mutual assistance mechanism was indicatively project to improve this pattern to: 15% never/rarely – 50% sometimes – 35% very often/always follow-up. In option 3 (a) the additional measures would allow to further improve to 10% never/rarely – 40% sometimes – 50% very often/always follow-up.

219 The total efficiency gains or savings are difficult to project, given the gaps and variability of information on cost as well as on restrictive measures that could be concerned. Considering the varying use of ICSMS an average of 2000 non-compliant cases involving a medium, high or serious risk are nonetheless already recorded per year (see table 11 SWD evaluation, average 2014/2015/2016) and few safeguard notifications (e.g. 350 on average/year for the low voltage directive, from a limited number of countries). Even assuming a modest cost of a few hundred or few thousand € for testing and/or proceeding that could be saved per case, the potential for cost saving and efficiency gains would be very high.

areas where controls would be weaker in the Single Market.

By the **different size variants** of the Network, moderately (low variant) to significantly more (medium to high variant) activity could be undertaken and corresponding results achieved[220]. The most significant tasks and resources of the Network would be concentrated on the management of coordinated actions, market studies and common priority setting for these actions, as well as the management of communication and IT systems that would need to link up market surveillance authorities and customs to exchange relevant enforcement information. The depth and impact of the tasks carried out critically depend on the staffing level and operational budget allocated to the Network. The biggest difference would be:

- The low estimated size of the Network: The number of yearly coordinated control campaigns could double, to around 1 campaign every 2 years in the 25 product sectors where ADCO groups currently exist[221].
- The medium and higher estimated size would allow increasing control campaigns more significantly, by a factor 5 to 10, covering more sectors and products, involving more member states and addressing cross-cutting issues (e.g. online sales, complex products)[222]. This would allow stepping up joint actions to 35-40/year (~at least 1 campaign/year per sector, medium size) or 75-80/year (~ at least 2 campaigns/year per sector, upper estimated size).
- The yearly number of new product controls records in the IT tool ICSMS could at least double, as all Member States would be linked up to ICSMS and its usage would be stimulated by the joint control campaigns that the EU Product Compliance Network would support[223]. In the lower estimate progress may require a longer period of time and only a more step-wise upscaling of ICSMS would be feasible with fewer resources. The impact of the Network will range from addressing merely the basic needs of the existing systems (lower estimate) to significantly expanding their functionalities to support more extensive monitoring of enforcement actions, interfacing with Member State systems and efficient information relay to a public website (medium estimate), up to ensuring efficient interoperability with Member States and customs systems (upper estimate).

Overall the lower estimated scenario of staffing and budget would allow a moderate level of cross-border coordination: compared to the baseline, it would imply a significant improvement in coordination effort. However impacts on product compliance or the visibility of the joint enforcement action would be less noticeable due to the limited number of actual control campaigns. The medium estimated scenario would constitute a more concrete step forward with more regular controls across product sectors, underpinned by stepped-up enforcement intelligence and information exchange. The upper level scenario would represent very significant progress in concrete and more wide-spread joint enforcement action, resulting in stronger deterrent effect against non-compliant products.

The **different hosting options** of the Network (Commission, decentralised agency EU-IPO) would not lead to significant differences in the outputs and impacts that could be realised by the Network. However the political and resourcing feasibility would differ:

- The main strength of the Commission hosting variant would be the strong synergies that

220 For details of the resources for each variant and the related outputs by key tasks of the Network: see Annex 12.

221 From a baseline estimate of 5-7 campaigns or projects maximum to some 15/year (~ 1 campaign every 2 years by product sector, for a stable number of around 25 sectoral administrative coordination (ADCO) groups).

222 More ADCO groups could first of all be supported by the Network (at least 30, up from current 25), and at least one to two campaigns envisaged per year, and in addition cross-sector coordinated actions (e.g. novel, complex products) and specific actions such as controls targeting online sales, specific imports flows, etc.

223 From average 7000 new records/year in baseline. The current use of ICSMS varies by sectors and Member State (see Annex 14.1).

could be maintained with the product policy and legislation development. The agency EU-IPO variant would be more geared to deliver operational outputs and allow Member States to take more ownership of enforcement coordination in the EU in which a strong role of the Commission could meet with reservations from Member States.

- Within the Commission the mobilisation of resources would be subject to more constraints compared to the EU-IPO hosting option, which has more flexibility to hire expertise as well as using its own operational budget resources. To establish and maintain the Network's secretariat support structure, the Commission would have to exploit synergies and redeploy staff from different departments in a context of competing policy demands on its resources. The EU-IPO hosting variant would offer better prospects for upscaling of the Network to the medium size variant, which is more performant as regards the impacts it could achieve.
- The legal construct of the Compliance and Enforcement initiative would be more complex in case of hosting of the Network by the EU-IPO, given that its founding regulation would need to be amended to include market surveillance tasks in its mandate[224], as well as some additional financial control and monitoring provisions should the agency require in the future a possible ad-hoc grant or subsidy from the EU budget to complement its existing resources. Given the recent difficult reform of the EU trade mark regulation, this indirect re-opening of the EU-IPO founding regulation may imply a risk regarding the adoptability of the legal proposal.

3(c) In this option the Network's tasks would include "**peer reviews**", building on the performance indicators and benchmarks (option 1). The Network would allow to facilitate more in-depth exchanges of underlying differences in Member States (such as risks assessment policies, frequencies of controls, sanctioning practices), leading to more coherent and uniform enforcement across Member States. The resources allocated to the Network condition the number of in-depth reviews and the time span over which Member States market surveillance systems could be reviewed:

- In the lower estimated size for the Network, a limited number of 3 reviews per year would be feasible, a cycle covering all Member States requiring 10 years to be completed;
- In the medium estimate size, 5 in-depth review per year could be undertaken, completing a review cycle of all Member States in 6 years;
- In the high estimated variant, the Network could undertake 7 in-depth reviews per year and complete a review cycle of all Member States in 4 years.

The medium and higher size variants of the Network could thus ensure a robust peer review cycle, underpinned by more and more regular reviews, in-depth exchanges on the results of the reviews and ultimate impacts towards more coherent enforcement across Member States. The impacts in the case of the lower estimated Network size would be much more diffuse given the long time period over which a review cycle could be completed.

Strengthening the enforcement toolbox

3(d) Detection and corrective action by authorities would be enhanced with the obligation to appoint a **person responsible for compliance information** in EU who would represent the 3rd country operator. Authorities would find it easier to contact and enforce requests for action,

224 Article 151 of Regulation (EU) 2017/1001 of the European Parliament and the Council, codified version of the EU trademark regulation (http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R1001).

information such as the technical file, product samples etc. via such a person responsible for compliance information in the EU[225].

Respectively 85% and 69% of respondents in the public consultation agreed that the inclusion of an obligation to have an authorised representative and the possibility to broaden the responsibility of main contractors of the manufacturer (lacking other responsible persons) would increase effectiveness of enforcement. This would also be consistent with other policy areas such as data protection[226], and obligations in certain product sectors[227].

3(e) The **publication of information on restrictive** measures would increase the transparency of information concerning compliance of products. Besides a blame message, publishing information on enforcement decisions also sends a message about correct behaviour therefore providing guidance to firms as to the correct implementation of product requirements[228]. Availability of information on specific examples of non-compliances, especially when further disseminated by chambers of commerce and industry associations, also contributes to the goal of helping economic operators to comply. This measure will increase public opinion's awareness about the relevance of compliance and allow for increasing pressure from civil society and businesses peers[229]. Disclosing information on non-compliant products identified by authorities and the companies involved in their supply triggers and empowers third parties (competitors, industry and consumers associations, etc.) to act as watchdogs pressuring companies to comply[230]. They also allow responsible buyers to make more informed choice when purchasing products.

3(f) The more systematic **recovery of control costs** in the case of non-compliant products would have an important deterrent effect as it would increase the costs of infringement both in terms of money (recovery of costs borne by authorities for the controls and corrective measures)[231] and with the **publication of restrictive measures** also in terms of reputation[232]. The wider and more consistent application of cost recovery in all Member States would also level out possible perceived cost advantages or areas with weaker controls that could be exploited by unscrupulous traders.

Promoting compliance

3(g) Thanks to the wider **digital availability of the basic product compliance information** and manufacturer's details (on the Declaration of Conformity), authorities would be able to contact the economic operators more quickly and all parties in the supply chain and consumers will find it easier to access this information (e.g. to address questions, complaints)[233].

225 See Annex 13, chapter 2.
226 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG&toc=OJ:L:2016:119:TOC
227 Cosmetics, medical devices, chemicals (REACH).
228 Judith van Erp, *Naming without shaming*, Regulation and Governance (2011) 5, 287-308
229 See http://www.howtoregulate.org/wp-content/uploads/2015/04/Handbook-INT-V1-3.pdf (section 7.11.2)
230 Gunningham N. et al. (2004) *Social License and Environmental protection: why businesses go beyond compliance*. Law and Social Inquiry 29, 307-341.
231 Although these are not fines, in practice they would be perceived as such by business. Therefore, as regards to their impact it is noted that 65% of respondents to the public consultation consider that deterrence of market surveillance would increase by imposing higher fines for serious non-compliance.
232 74% respondents to the public consultation believe deterrence could be increased by giving more publicity to restrictive measures adopted against non-compliance would increase (reputation effect). Similar measures are used for instance by UK authorities to strengthen the enforcement of minimum wages rules: http://www.bbc.com/news/uk-27751722.
233 The benefits of such mandatory publication of basic compliance information were rated high compared to voluntary options. Positive impacts were noted regarding access to information, transparency, and ultimately positive impacts on compliance levels, product safety and environment (table 10, Impact digital compliance options, VVA, 2017; annex 14)

Publication in decentralised manner, on the companies' websites, would come at minimal cost and offer flexibility for manufacturers and importers who would be responsible for publishing the declarations of conformity. The drawback is that it would be less easy for all interested parties, including traders, consumers and market surveillance authorities to find the information when it is dispersed over many websites. Additional tools (such as adding automatic object and data identification[234]) would however overcome this disadvantage.

Stakeholders' views on the option[235]

3(a) 73% of the respondents (81% of public authorities, 69% of businesses and 69% of consumers) to the consultation agree that **legal principles to ensure easy replication of measures** taken by authorities in other EU Member States (e.g. portability of test results, presumption that products found to be noncompliant in Member State A are also non-compliant in Member State B) increase the effectiveness of surveillance. The possibility of using information on measures taken by another authority in the EU creates a spill-over effect ensuring they can be effective on a larger part of the Single Market (84% of respondents - 90% of public authorities, 80% of businesses and 84% of consumers).

66% of the respondents (58% of public authorities, 69% of businesses and 77% of consumers) to the consultation agreed that the principle of recognition of national decisions in other EU Member States increases the effectiveness of surveillance (contrasting with 33% that would support an even further step to simply apply any national decision across the EU).

3(a)/(b) Authorities rank an increase in their resources as the best way to improve deterrence (87%, vs. 72% of overall responses). The efficiency gains in cooperation procedures and the increase in available resources that the **EU Product Compliance Network** could trigger, would be instrumental to overcome the current resources constraints.

In March 2017, the Commission consulted Member State market surveillance experts on the possible Network, its key tasks[236] and options to host the Network in the Commission or in an existing EU Agency. While the remit of the Network would be coordination and cross-border enforcement issues, it was made clear in this consultation that the Network would not modify, replace or supersede responsibilities for market surveillance that remain the competence of Member States[237]. The experts expressed broad support for an EU Product Compliance network[238], as an administrative support structure that would coordinate and assist implementation of market surveillance actions.

234 52% of businesses consulted in the study on digital compliance already add automatic identification tags and information to at least one item in their product portfolio. Automatic identification technologies were found to be often used to optimise logistics and supply chain management, however with varying degrees by sector (Impact digital compliance options, VVA, 2017; annex B 14).

235 Results of the public consultation are provided in Annex 2 and on: http://ec.europa.eu/DocsRoom/documents/21181/attachments/1/translations/en/renditions/native .

236 Moreover, the tasks of the Network are based on the measures that were rated most favourably in the public consultation, scoring ~80% of agree/strongly agree answers (How could resources for market surveillance be increased; be used more efficiently? Questions 11 and 13, see details of responses Annex 12 point 3.2). The additional consultation in the Expert group confirmed the selected key tasks.

237 The acceptability of stronger coordination and/or coordinated decisions at EU level was tested in the public consultation: respondents were more favourable to enforcement decisions taken in close coordination via a product compliance forum (63% strongly agree/agree) than enforcement decisions taken by the Commission (42%stronlgy agree/agree). The basic remit proposed for the Network (option 3(b) would be limited to coordination of enforcement, without a mandate to take enforcement decisions (Public consultation question 8 section cross-border market surveillance in the EU). The expert group consultation confirmed this basic remit as appropriate. (Option 4 (b) would add to the basic remit, coordinated enforcement decisions in case of widespread infringements.)

238 Broad support was noted on the concept and tasks of the Network. Further information was asked on issues such as size, available funding and how the Network would function in practice, including how existing IT systems could be re-used without adding new

3(d) 86% of the respondents (89% of public authorities, 85% of businesses and 80% of consumers) considered an obligation useful on businesses to appoint a **person responsible for compliance information** or designate an importer located in the EU. 67% support a broader definition of EU importer to explicitly include possible EU based main contractors of the manufacturer in the absence of another person responsible for compliance information in the EU.

3(e) Respondents in the public consultation rated **publication of restrictive measures** as the top 1 measure to increase deterrence of market surveillance (75% (179 of 239) respondents agreed/strongly agreed). Authorities perceived the effectiveness of this tool higher (83%) than business respondents (67%).

Administrative simplifications

As explained in the evaluation most of the enforcement costs stemming from current market surveillance rules are borne by public authorities, while regulatory costs on businesses only relate to information obligations (responding to requests from authorities, information on non-compliances detected) and are therefore regarded as insignificant by them. The enhanced enforcement coordination and priority setting supported by the EU Product Compliance Network and peer reviewed enforcement strategies would results in a better level-playing field, reducing some of the negative impacts of across-the-board enforcement inconsistencies that businesses face[239]. The main potential for simplification and burden reduction lie nonetheless with authorities. This section focuses therefore on the measures in this option that would result in specific benefits in terms of administrative simplifications for authorities.

Concrete improvements for authorities would results in the short term from the common principles on **test-reports portability, presumption of non-compliance**, and issuance of **restrictive measures** in cross-border cases. These measures would provide more legal certainty to market surveillance authorities, who would find it easier to rely on evidence and enforcement decisions already produced by other authorities elsewhere in the EU. These measures would reduce and/or simplify the handling of infringement cases compared to the current situation where authorities often have to duplicate work also performed by other authorities on the same product[240]. With clearer possibilities to issue restrictive measures directly to operators in other Member States, following the notification via a safeguard procedure, the authority in the country where the operator is established would not need to intervene in this phase – its role and thus handling costs could be reduced and limited only to cases where no satisfactory enforcement results could be obtained (e.g. residual mutual assistance requests to enforce sanctions).

The easier enforceability of market surveillance measures through the availability of a **person responsible for compliance information** and the **possibility to order testing and compliance demonstration**, directly from and at the cost of the economic operator, would reduce the burden on market surveillance authorities. They would spend less time and costs

ones. Apart from one expert expressing concern about the risk of the Network loosing operational focus if it were hosted in the Commission, the hosting variants either by the Commission or in an existing Agency did not give rise to comments from the experts (IMP-MSG meeting, 31 March 2017).

239 See chapter 6.2 of the evaluation.

240 Potential efficiency gains or costs saving could be considerable: considering the varying use of ICSMS, already some 2000 cases per year are reported of non-compliant products involving a medium, high or serious risk. A rough estimate of inspection costs indicate costs range from 100€ to 5000€. If 10% of the recorded cases and test report evidence could be re-used by other member states, this would imply avoided costs 20 000€ to 1 M€ per year.

associated with tracing traders (in particular for imports) and other evidence gathering in the case of suspected non-compliance, as the person responsible for compliance information could be ordered to take care of this[241].

Compliance and implementation costs

Costs for businesses

3(a) The authorities' reliance on **existing evidence and enforcement decisions** issued by a national authority would not entail significant additional costs with respect to the baseline. Administrative burden for businesses would be lower as the measures would avoid additional sampling and duplication of requests for information from different authorities concerning the same product. The burden for businesses consulted by an authority prior to the adoption of enforcement measure (e.g. to provide additional information/explanations and counter-arguments to the authority's assessment) is not expected to be higher with respect to the baseline.

3(d) Some businesses located outside the EU that place products directly in the EU (i.e. without an importer such as in the case of on-line sales) and who would not already have a contact in the EU, would incur cost to **appoint a person responsible for compliance information**. The overall cost of businesses regularly supplying the EU market would not increase because most of these businesses, as part of their normal supply chain, already have a business partner in the EU who would answer questions from market surveillance authorities and take steps to remove non-compliant products from the market. For the operators that supply directly to EU consumers from outside the EU, costs would relate to the selection of a party able to fulfil the function of e.g. authorised representative or importer and the set-up of the relative contract. Annual fees would range between about €360 and €1500 per year per business depending on the complexity of products. These costs concern only a portion of third-country businesses and do not imply an unequal treatment vis-à-vis other business, as they actually remedy the current unbalanced situation where EU and third countries businesses with a presence in the EU can be reached and possibly sanctioned by authorities while others cannot[242].

The bulk of additional "costs" linked to this option are strictly for businesses (both those based in the EU and in third countries) selling **non-compliant products**. They would be asked to face their responsibilities and bear the costs linked to non-compliance. They would also pay the cost incurred by authorities for **controls and corrective actio**n concerning their products **3(f)**. All these costs would be linked to the non-compliance found and its seriousness. Cost recovery would be proportionate to the expense effectively incurred by authorities to test the products. The measures would incentive more businesses to internalise compliance cost, instead of marketing non-compliant products creating unfair competition and placing cost on businesses that abide by the EU product legislation. Overall additional costs on compliant businesses will be more than compensated by the benefits in terms of level playing field as

241 See annex 13 section 2. The potential for cost reduction would be considerable for authorities, given that in the baseline around 60% of authorities indicate to experience difficulties in contacting foreign businesses and/or not to obtain responses to requests (public consultation). In relation to imports, the volumes of small consignments and parcels total 185 million and the inflow of such shipments is increasing rapidly. Controls by customs and/or market surveillance authorities would be done on the basis of risks management, with parameters and criteria defined in each Member State and point of entry. Therefore it is difficult to establish, first of all, a reliable estimate of the number of future controls, the nature/depth of such controls and then an associated potential for costs reduction that would specifically be linked to infringement found as a results of the controls and that could be handled faster/more easily.

242 For more details, see Annex 13, chapter 2.

more deterrence will reduce the risk of 'free-trading' by unscrupulous operators.

3(b) The **EU Product Compliance Network** would not lead to additional requirements or need for extra compliance efforts by businesses, nor does it entail new reporting obligations. If anything the improved consistency and predictability of enforcement could reduce regulatory costs for cross-border trading businesses.

3(g) Digital publication of compliance information could cause, for some companies, a one-off setup cost to create an in-house database with electronic versions of the documents to be uploaded. Costs would be limited (only non-sensitive documents are concerned; the declaration of conformity as such is a fairly simple document). Recurrent additional cost would be negligible at company level (estimated at an average of €48/year, according to company size from actual savings to €14/year to €102/year); totalling for all concerned companies in the EU around 22 M€/year[243].

Costs for Member States

3(a) The principles ensuring the possible **re-use of evidence (portability of test-reports)** across all Member States would allow important cost savings for the authorities re-using the evidence, partly or fully. The authorities would not duplicate the investigative phase but would nevertheless incur the costs of adopting own decisions. The total saving would depend on the number of cases in which a market surveillance authority could rely on evidence or decisions produced by others and the sector or type of investigation concerned (e.g. standard, relatively low cost physical testing for some consumer products or more complex tests involving chemical analysis[244]). Costs of testing equipment and (outsourced) laboratory test represented 30 to 50% of recent market surveillance co-funded projects[245] [246]. No additional costs are anticipated linked to the communication of the initial evidence, since information concerning investigations (test reports, etc.) would be available through the existing cooperation tools (ICSMS).

3(b)/(c) Member States may have adjustment costs to ensure liaison to the **EU product Compliance Network**, including participation in the peer review mechanism[247]. However on balance the Network would be able to take on project management and coordination tasks that now fall on market surveillance authorities' staff including ADCO chairs. Product testing costs that are part of joint actions could be financed directly by the Network. Pooling of resources (e.g. joint market studies, procurement of tests) would also allow costs savings to Member States[248].

243 Small companies would save costs, micro enterprises incur higher costs. See Table 14 and 15, study on the impacts of digital compliance options, VVA, 2017, Annex B 14.

244 A rough estimate of inspection costs indicate costs range from 100€ to 5000€. While the number of re-use cases in the future is difficult to project, the potential for efficiency gains or costs saving could be considerable: considering the varying use of ICSMS already some 2000 cases per year are reported of non-compliant products involving a medium, high or serious risk. If 10% of the recorded cases and test report evidence could be re-used by other member states, this would imply avoided costs 20 000€ to 1 M€ per year.

245 Joint actions on heat and electricity measuring instruments; LED floodlights; vehicle service lifts, chain saws resulting from the 2013and 2014 call for proposals, DGGGROW.

246 For instance, in the case of the "Market Surveillance Joint Action for Measuring Instruments-MarketSurv MID" the tests of the 40 measuring instruments checked, which were sub-contracted to external laboratories, cost about € 190 000 (€ 4 750/product).

247 84 000€ in total. By member state 3000€/year = 28*0,05FTE*average salary 61 971€ (based on EUROSTAT 2006/2010, category ICS01 legislators and senior officials).

248 E.g. Joint procurement of tests by the Network would allow participating authorities to benefit from procurement/framework contracts with less administrative burden than if they had to do the procurement process fully themselves and each on their own. Joint procurement could also lead to better prices and conditions compared to purchases by individual authorities with lower volumes. It is difficult to project what reductions could be obtained, for which sectors/tests and how many tests could be performed

Besides savings in administrative handling costs, Member States would benefit from efficiency gains due to joint preparations and legal analysis which they would have to perform each on their own if they were to do the controls purely on their own. In the baseline only a few coordinated campaigns take place, on an ad-hoc basis. Therefore compared to the baseline, precise efficiency gains are difficult to project, but examples from other areas and projects suggest that they could be significant[249] [250].

3(e) The **publication of restrictive measures** is expected to imply some (modest) additional procedural costs (notably to ensure businesses views are correctly represented and confidential information excluded).

3(f) The authorities are expected to incur lower operational costs for investigations and corrective action thanks to the possibility to **recover costs** of checking products found to be non-compliant. The percentage of saving is directly linked to the share of non-compliant products found. For instance in the case of the "Market Surveillance Joint Action for Measuring Instruments-MarketSurv MID" on active electrical energy meters and heat meters, the costs of which amount approximately to 350 000 €, authorities could have been able to recover about 175 000€.

For both **3(f) and 3(g)** some limited initial set-up costs compared to option 2 would occur for authorities to familiarise themselves with access and use of digital compliance information and new powers, including possible adjustment of existing provisions at national level[251].

Costs for the Commission/EU budget

3(a) No additional costs would derive from the measures to ensure **portability of evidence and enforcement decisions**. The existing cooperation tool ICSMS includes in the baseline the functionalities to review enforcement decisions of other member states, to exchange test results and would be adapted for better mutual assistance exchanges in option 2.

3(b) / 3(c) The costs to support the **EU Product Compliance Network** could range from 10 to 26M€ per year in total for the Network's Secretariat[252], covering human resources (30 to 90 FTE), building/infrastructure costs and an operational budget (e.g. procurement of market studies, meeting support costs, product testing costs in joint control campaigns):

- low estimated size of the Network (32 staff, 5.7 M€ operational budget – 10 M€ in total)
- medium estimated size (59 staff, 9.95 M€ operational budget - 18 M€ in total)

at lower costs. However the potential for cost savings could be important reaching several million euros for all Member States (a 7,5 M€ saving would be realised if a 5% cost reduction were obtained over the average costs of 7 000 € for tests and 770 laboratory tests/year by Member State (average calculated costs and number of tests see table 14, SWD evaluation). The % cost reduction is a hypothesis, and merely serves to illustrate the potential benefits applied to market surveillance testing costs. The 2016 Commission study on the Feasibility of cross-border joint public procurement confirms that such joint procurement actions would require extra coordination effort, however realise significant benefits in terms of economies of scale and better prices (procurement savings), saving on process costs, learning effects and improved use/attraction of external co-funding (http://ec.europa.eu/DocsRoom/documents/22102/).

249 The collaborative market surveillance by the Nordic countries to implement the eco-design and energy labelling directive led, is assessed to achieved a €28 million saving for the MSAs for a cost of €2,1 million in the joint project i.e. an ROI of 13 http://www.energy-efficiency-watch.org/fileadmin/eew_documents/EEW3/Case_Studies_EEW3/Case_Study_Nordic_Market_Surveillance_Final.pdf

250 Improved cooperation was assessed to potentially achieve a 50% efficiency in online investigation campaigns ('sweeps') of the Consumer Protection Cooperation network ; Annex VI impact assessment http://ec.europa.eu/consumers/consumer_rights/unfair-trade/docs/cpc-revision-proposal-impact-assessment_en.pdf

251 The possibility to publish restrictive measures and recover costs are already available in around 21 Member States as a basis (for 14 in majority of sectors, 7 in more limited number of sectors), the power to order consumer remedies is available in 14 Member States, in a limited number of sectors.

252 See Annex 12 for breakdown of costs by tasks and assumption underlying the costs estimates.

- higher estimated size (90 staff, 13.9 M€ operational budget - 26 M€ in total).

The main part of the resources would be dedicated to support for cross-border and coordinated enforcement activities and IT tools. Set-up costs to allow interfacing of MSA and customs systems (including Single Window development) amount to 3,2 M€ over 5 years (~640K€/year). The costs to conduct peer reviews would be covered by these estimated network costs, including the performance indicators and benchmark costs that form the basis for peer reviews (option 1).

The ultimate budget needs would depend firstly on the size variant and its corresponding lower, medium or upper ranges of staff and operational costs. Secondly, the hosting of the Network in the Commission or in EU-IPO would lead to differences in charges to the EU budget:

- In case of Commission hosting of the Network, the costs would be charged in full to the EU budget (staff costs to as administrative costs to heading 5, and the operational budget, in principle Internal Market budget lines, heading 1A in the current Multi-annual Financial Framework).
- In case of EU-IPO hosting, while the costs would be incurred by the agency[253], the charge to the EU-budget would be limited to an ad-hoc grant or balancing subsidy in future years in case the EU-IPO own resources would not suffice (from an Internal market budget line/heading 1A of current Multi-annual Financial Framework)[254]. One-off start-up costs would be limited and relate to adaption of internal procedures and transfer of IT systems from the Commission[255].

In particular in the lower estimated size of the Network (30 staff, 6 M€ operational budget), the cost would be comparatively modest considering the number of sectors to cover by this initiative[256]. The medium size Network (59 staff, 10 M€ operational budget) would be more performant in achieving more concrete results with more and more regular actual controls and enforcement information exchanges that the input resources would support. While costs would be incurred for the Network at EU level, the joint activities would allow important efficiency gains for Member States and trigger cross-border controls and coordinated enforcement that is currently hampered by a lack of resources. In the baseline only few coordinated control campaigns are conducted and/or co-funded, so that a quantification of impacts over the baseline are difficult to project; however in principle the Network's cost-benefit ratio would be positive. Overall, put into perspective of the 500 market surveillance authorities that the EU Product Compliance Network would coordinate, the staff and costs levels are relatively

253 Staff costs would be corrected for the location of the agency in Spain (correction coefficient 88,1, per staff AD/AST 121 578€/year, CA 61 670€/year) and thus be slightly lower than the standard costings applicable for Brussel/Luxembourg (coefficient 100, AD/AST 138 000€/year, CA 70 000€/year).

254 Subject to integration of market surveillance among the tasks set out in Article 151 of in the EU-IPO founding Regulation (EU) 2017/1001, its resources can be used to cover new tasks associated with the Product Compliance Network. The EU-IPO counted at the end of 2016 with considerable resources which would facilitate the integration for the foreseeable future of additional tasks within its own existing resources structure (854 statutory staff, 62 national experts; yearly budget volume around 400M€ (average 2014/2015/2016), and an accumulated surplus of 182 M€) https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/contentPdfs/about_euipo/annual_report/ar_2016_annex_01_en.pdf

255 Overall less than €70.000. Estimated adaptation costs 0,15 FTE * €138,000; IT systems migration 1*0,15FTE*€138,000 + 2*0,15FTE*€70,000. In addition some travel and meeting costs in case the hosting agency is located outside Brussels. The changes to formal regulations or decisions would be part of a possible legal proposal resulting from this impact assessment and not included in these operational start-up costs.

256 As part of the Commission's proposal to strengthen enforcement of type approvals in the single sector of cars, the Commission's supported Technical Committee on Motor Vehicles was estimated at around 10 FTE, including 20 coordination meeting with member states/enforcement bodies, and requiring in addition 7.5 M€/year for technical assistance and testing primarily through the Joint Research Centre (COM(2016)31). In the baseline for this impact assessment, the Administrative Cooperation Groups (ADCOs) already cover around 20 sectors and over 50 meetings/year, and around 5 horizontal expert group meeting/year are supported.

moderate. If only 5 staff in each of the 500 market surveillance authorities would be related to activity with a cross-border dimension, the additional coordination staff projected for the Network would represent 1-4%[257].

The EU Product Compliance Network would support the relay of publication of restrictive measures issued by Member States and the sharing of information on restrictive measures information between market surveillance authorities and customs. The measures related to the enforcement toolbox ((e) publication of restrictive measures / (f) recovery control costs) are implemented by national market surveillance authorities and would not entail costs for the Commission or EU budget.

3(g) The mandatory digital publication of compliance information by businesses would not entail additional costs for the Commission.

Other economic impacts (SMEs, functioning of internal market, competition, consumers)

Due to the increased enforcement activity, easier cross-border enforcement cooperation and the added deterrent effect of enforcement tools, this option would have positive impacts on the functioning of Single Market as more non-compliant products could be detected and removed and unfair competition from rogue traders more effectively addressed. The stronger enforcement tools would incentivise operators to comply, including those supplying or sourcing from 3rd countries.

The improved consistency of enforcement across the EU would provide more predictability and legal certainty to cross-border trading businesses, in particular SMEs.

Consumers and other professional users, including SMEs, would directly benefit from easier access to relevant information (publication restrictive measures, digital compliance information, identity/address of responsible economic operators (e.g. manufacturer) and a person responsible for compliance information in the EU where applicable). With more information and to the extent that actual improvement of compliance levels would be achieved, consumers would benefit in terms of lower search and transaction costs.

Social Impacts

Some positive impacts on employment could be expected due to reduced unfair competition and an improvement of competitiveness of EU manufacturers.

The increased enforcement and stronger deterrent tools in this option will have a positive preventative impact on consumer protection and product safety.

The EU Product Compliance Network would allow improving the public information and transparency of enforcement across the EU, similar to option 2 but with increased impacts. The peer reviews would contribute to promoting best-practices in good administration.

Environmental impacts

257 Compared to partial data on total staff the projected staff for coordination would represent 0,4 to 1,2%. Detailed human resources data were reported by 19 Member States for the period 2010-2013 and amounted to 7,741 staff available for market surveillance in total. (Annex 13 point 3).

Improving enforcement of legislation aimed at the protection of the environment (e.g. legislation chemicals substances, detergents, pollutant emissions, etc.) is expected to have a positive environmental impact.

Impacts on fundamental rights (EU Charter of fundamental rights)

Certain measures in this option may impact on fundamental rights. In accordance with Article 52 of the Charter a careful balancing of limitation to these rights has to be made with the objective of general interest of protecting consumers, users and the environment from unsafe and non-compliant products.

In the implementation of the principle of **presumption of non-compliance** and the **issuance of restrictive measure** in cross-border cases (a), the right of defence and effective remedy would have to be ensured for the businesses concerned. The measures would only take place in the case of confirmed non-compliant product(s), after investigation by market surveillance authorities. Non-compliant products infringe EU product law and thus compromise the public interests these rules set out to protect (e.g. health and safety of users, consumer and environment protection). The existing principles of proportionality of restrictive measures by market surveillance authorities and consultation of the economic operator prior to a restrictive measure remain fully applicable. The restrictive measures themselves would be subject to national procedural safeguards and remedies.

The implementation of the **publication of restrictive measures** ('naming', (e)) in this option may impact on certain fundamental rights (presumption innocence, right to due process/effective remedy, rights of defence, data-protection and right to privacy). The publication of restrictive measures contributes to risks prevention, increased information and awareness by users about the specific products involved and product safety and compliance in general. The publication of restrictive measures would concern primarily confirmed measures (rather than interim findings, yet to be investigated cases). This is without prejudice to the rapid publication of dangerous products, where due to the seriousness of the non-compliance and risk for the users, an early publication in the Rapid alert system is warranted as soon as possible. The restrictive measures themselves and their publication would be subject to national procedural safeguards and remedies.

The **digital publication of the Declaration of Conformity** by businesses would have an impact on protection of personal data, as the names of the persons signing the declaration would become more easily traceable when made available online. This impact could be moderated by allowing electronic seals or full company references, yet without personal names.

Summary assessment of the option (3)

Effectiveness in achieving the policy objectives	
Reinforcing cooperation procedures	+++
Increasing operational enforcement capacity	++ /+++
Strengthening the enforcement toolbox	+++
Promoting compliance	+
Costs	
For economic operators	- / neutral

For Member States	++/ +++
For the Commission/Impacts on the EU budget	- - / - - -
Administrative simplification	+++
Magnitude of impact as compared with the baseline scenario (the baseline is indicated as 0): +++ strongly positive; ++moderately positive, + positive; neutral; - - - strongly negative; - - moderately negative, - negative;? uncertain; n.a. not applicable. When talking about costs: + means 'savings', while – means 'cost'	

5.4 Option 4 - in addition to Option 3 Centralised EU level enforcement in certain cases

Effectiveness in achieving the objectives

Reinforcing cooperation procedures

4(a) Direct enforceability of national restrictive measures and the right to remedies extended to the whole EU would further reduce duplication of work and different proceedings. The deterrent effect would potentially be very high and improve the response of traders to requests for voluntary measures in the initial phases of the proceedings, preceding the issuance of restrictive measures. Early resolution of non-compliance, avoiding coercive enforcement would add to the efficiency gains for market surveillance authorities[258].

The intensified consultation on all national restrictive measures as part of the extended safeguard procedures in this measure would contribute to the consistency of enforcement in the EU. The number of restrictive measures could however be significant[259], with possible difficulties for the authorities to effectively screen them in an extended safeguard mechanism. The feasibility of the measure may also be lower given that only a minority of stakeholders rated direct applicability of national measures favourably.

Overall, the extended direct application of national measures, coupled with approximation of sanctions **4(c)**, would allow focussing mutual assistance request on demands for complements to an investigation or systems audits, or cases that remain unresolved due to non-responsive traders and/or litigation. The rate of authorities that would never or rarely be able to follow-up on restrictive measures of other member states would be reduced[260].

Increasing operational enforcement capacity

4(b) The additional **mandate to the Network to investigate and take decisions in case of widespread infringements** (e.g. serious non-compliance found with well-known smartphones or toys brands) would improve the effectiveness of enforcement for the cases concerned and significantly raise the visibility of EU action (viz. EU traders and third country operators).

The possibility for the Network to conduct investigations and take enforcement decisions, would allow to further streamline work and reduce duplication of investigations and decisions

258 In the area of consumer protection based on enforcement experiences in the UK at local level, costs for the settlement of non-complex cases was reported to be 30% of costs of cases involving issuance of (simple) court orders (Consumer protection cooperation, SWD(2016)164)).

259 19 member states in 3 sectors reported in total an average of 2,300 measures per year (overview of market surveillance activities, based on national reports 2010-2013; Evaluation Regulation 765/2008).

260 See options 2(a) and 3(a): the pattern of follow-up to restrictive measures taken as baseline 30% never/rarely – 35% sometimes – 35% very often/always. Indicatively one could project in this option that the pattern to further improve to: ~0% never/rarely – 20% sometimes – 80% very often/always follow-up.

(in the extreme 28 decisions would be reduced to one in this measure). One could see a potentially faster elimination of the infringement in the EU, compared to reliance on mutual assistance or gradual elimination as/when the concerned product is found and action taken in each Member State. The consistency of enforcement would be maximised in this measure.

The overall number of individual cases that could be tackled in this way might however be limited[261]. Beyond cases related to widespread non-compliant products, this measure could however also be suitable and effective for certain supply streams or business models (e.g. specific imports supply routes, e-commerce business models involving several traders).

Strengthening the enforcement toolbox

4(c) Approximation of sanctions, including penalties would help to increase the deterrent effect of the authorities' toolbox. The approximation of the types of infringements and non-criminal sanctions would create a more level field for companies in terms of the sanctions to which they are exposed. Businesses trading non-compliant products would be subject to more uniform penalties (possibly also more proportionated to the seriousness of non-compliance) regardless of their location.

However the likelihood of detection and the certainty of sanctions play a more important role than severity of sanctions in deterring crime[262]. Furthermore, even if all Member States would introduce the same notional minimum penalty into their national criminal codes, this would by no means result in a common penalty level available to the sentencing judge. The lower penalty level available to the sentencing judge is influenced by other legal mechanisms that continue to be diverse across national criminal justice systems. For example, rules on mitigation, aggravation and judicial powers to predetermine the proportion of the sentence that must actually be served can all significantly affect notional minima. Therefore, it is important to note that the *in abstracto* minimum sanctions provided for in the national criminal codes, the nominal minimum penalties, by no means correspond to the *in concreto* sanctions imposed in a specific case. Even if the penalty level could influence deterrence, rules on early and conditional release are also relevant to the calculus[263].

The feasibility of approximation of the types of sanction and corresponding level of penalties may be low as it could be perceived to constitute an undue interference in the design of Member State enforcement systems as this is a fundamental aspect of how enforcement systems are set up[264].

261 In the baseline the number of coordinated control campaigns is low (5-7 per year, by ADCO groups and/or EU-co-funded projects). There would be limited experience with exchanges as a basis to step up to much more strongly coordinated single procedures; the uptake would therefore be limited as a start and only gradually increase with more intensified intelligence sharing, coordination and cooperation (option 2). For a similar measure in the area of Consumer Protection Cooperation (COM(2016)164) it was estimated that 4 widespread cases with an EU dimension could be dealt with per year by the Commission in coordination with member states.

262 This literature focuses on the influence of three sanction characteristics, being certainty, severity and celerity. Certainty refers to the likelihood of being sanctioned. Severity refers to the stringency of the sanction. Celerity refers to the swiftness with which the sanction is imposed after committing the crime. Whereas there is substantial evidence that increases in the certainty of sanctioning substantially deter criminal behaviour, it is less clear that increases in the severity of the sanction yield general deterrent effects. It is the possibility that the sanction will actually be incurred if the crime is committed that will deter crime; R. Apel & D. Nagin, 'General Deterrence', in M. Tonry (ed), The Oxford Handbook of Crime and Criminal Justice (Oxford University Press, 2011), 179–206, at 180.

263 Ibidem.

264 In other policy areas it has proven a major stumbling block making the approval of proposed legislation politically unfeasible (see Proposal for a Directive of the European Parliament and Council on the Union legal framework for customs infringements and sanctions (COM(2013)884).

Promoting compliance

4(d) With a **Centralised product database**, with commercially non-sensitive information (declaration of conformity, user instructions) as well as the sensitive technical documentation, market surveillance authorities would benefit from the centralised, immediately available documentation. It could especially improve the availability of information on products from 3rd country manufacturers. A centralised database in itself however would not mean that the underlying information is correct and which would be a concern in relation to imports from China in particular. Moreover, for imports and within the EU, most of the interaction between companies and market surveillance authorities when they investigate a product concern specific questions and issues beyond the documentary information[265].

Distributors and other intermediaries could not have full access to documentation, but most of the detailed technical documentation would not be relevant for them in order to verify the compliance of the product with the legal requirements. They would find it easier to search a centralised database, instead of researching the information on decentralised websites of companies[266].

Stakeholders' views on the option[267]

4(a) While 66% of the respondents (58% of public authorities, 69% of businesses and 77% of consumers) to the public consultation agreed that the recognition of national decisions in other EU Member States would increase the effectiveness of surveillance, only 33% supported the possibility of the **direct applicability of national decisions** in other Member States.

4(b) 63% of the respondents (49% of public authorities, 74% of businesses and 58% of consumers) agreed that the effectiveness of market surveillance would increase by using decisions against non-compliant products established by authorities of different Member States in close coordination (e.g. in a EU product Compliance forum) and being applicable simultaneously in all relevant jurisdictions. Only 43% of the respondents (47% of public authorities, 37% of businesses and 56% of consumers) to the consultation expressed support for the possibility of **centralised decisions against non-compliant products** supplied in various EU Member States by the Commission.

4(c) 63% of respondents (54% of public authorities, 65% of businesses and 72% of consumers) to the public consultation favoured a more detailed common methodology in calculating **fines** and 65% (65% of public authorities, 65% of businesses and 63% of consumers) considered the deterrence of market surveillance would increase by imposing higher fines for serious non-compliance.

4(d) In the public consultation 68% of authorities rated a **centralised digital compliance system** favourably. The majority (56%) of business respondents disapproved of this option (only 29% agreement).

265 Annex 14, study on Impacts of digital compliance, VVA, 2017.

266 The benefits of mandatory publication of full compliance documentation in a central database were rated higher comparatively to voluntary options. Positive impacts were noted regarding access to information, transparency, and ultimately positive impacts on compliance levels, product safety and environment. See Annex 14, Study Impact of digital compliance, VVA, 2017.

267 Results of the public consultation are provided in Annex 2 and on: http://ec.europa.eu/DocsRoom/documents/21181/attachments/1/translations/en/renditions/native .

Administrative simplifications
The direct applicability of national restrictive measures, centralising for widespread cases the investigation and decision into one single process and decision by the EU Product Compliance Network would simplify and reduce the handling of separate national proceedings in the Member States. Approximated sanctions, including penalties, would further reduce the burden on Member States when they need to follow-up those cases where the trader does not comply with the restrictive measures. A more common framework on the types and levels of sanctions would facilitate the handling of the enforcement phase of cases that originated in other Member States (especially in administrative proceedings).
Compliance and implementation costs
Costs for businesses
4(a) / 4(b) Costs of extended **enforceability of national restrictive measures** and the single investigations and decisions by the EU Product Compliance network would concern businesses trading non-compliant products. They would face single proceedings, instead of multiple ones. The right to **remedies to consumers** would imply additional costs for businesses selling non-compliant products. Should remedies be contractual this would imply a direct cost for the distributor who made available the product to the consumer, amounting to the selling price of the product, and a cost to the manufacturer against which the distributor has a right to redress, according to procedures under national jurisdictions. Should remedies be non-contractual, damages would largely depend on the type of product and the personal detriment to the consumer. **4(c) Approximation of sanctions** as such would not entail costs for businesses. Sanctions when applied would only concern businesses trading non-compliant products. **4(d)** Comparatively to the total compliance costs, the additional cost for the companies concerned (manufacturers, importers) to upload and update the documentation in a **central database** is relatively modest: around 122,37 €/year (for different company sizes ranging from 105,52 €/year to 144,54 €/year)[268]. For larger companies and/or those manufacturing complex products with many compliance documents there may be one-off set-up costs to allow automatic updating or transferring of documents to the central database. These one-off costs could be considerable but are difficult to estimate as they depend on the number of products/compliance documents and the extent of each company's systems[269]. The main costs are linked to the risks of undue disclosure or access to commercially highly sensitive information in the technical documentation, and potential loss of confidential information to competitors. Even individual incidents would entail very high costs for the companies concerned and would outweigh possible benefits.

268 Annex 14, Study impacts of digital compliance, VVA, 2017.

269 It is assumed that manual feeding and updating of documentation in a central database would be onerous for larger companies with many compliance documents, so that they are likely to seek forms of automatic transferring to the central database involving one-off set up costs (Annex 14, Study impacts of digital compliance, VVA, 2017).

Costs for Member States
4(a) The extension of **enforceability of national restrictive measures** would not entail costs related to the initial investigation. The more extensive consultation with other Member States may sometimes involve a need for discussion and resolution of objections[270]. Market surveillance authorities relying on the initial investigation and decision when they encounter the same non-compliant product later, would save an important part of costs (testing, more limited procedural costs). The introduction of the measure would entail alignment of procedures and legislation in the Member States. The higher number of safeguard notifications to submit and review would require additional effort (1-3 FTE/Member State, 3,5 M€/year). In most Member States a procedure for **remedies for consumers** and other end-users would need to be adapted or created and this implies additional costs, which however are difficult to quantify due to several different organisational structures. **4(b)** The extended **mandate of the EU Product Compliance Network** to perform **investigations and adopt enforcement decisions** would require the coordination and participation of market surveillance authorities for the widespread infringements concerned. On balance market surveillance authorities would save costs, as the joint, single process would be managed by the Network, and allow sharing out efficiently the investigation and legal analysis tasks, according to need. Based on estimates of the average cost of product investigations potentially available everywhere in the Single market rough estimates of cost savings for a single investigation could total at least some 20 000 €[271]. **4(c)** The **approximation of sanctions** would entail significant costs for Member States to adapt their national systems for administrative and criminal sanctions including penalties[272]. The alignment cost of national systems would vary according to the national structures.
Costs for the Commission/EU budget
4(a) The **extended enforceability of national restrictive measures** could entail some additional costs for the Commission, but these are not expected to be very significant[273] (mainly monitoring of the notifications, which could however be facilitated by the EU Product Compliance network (3 b)). The **right to remedies** for consumers would not entail any cost for the Commission. **4(b)** The added mandate to the **EU Product Compliance Network to conduct investigations and take decisions** would imply a one-off setting up of internal procedures (0,2 FTE). It would require resources to manage the single investigation and decisions for the widespread infringements and coordinate the consultation and input into the investigations by member states, consultation of economic operator(s) (for each case 0,5-1 FTE, 69,000€-138,000€ and

270 The experiences with the implementation of the safeguard clause mechanism for non-compliances with a cross-border aspect show however that reactions or objection are very limited.

271 See Annex 11. Average inspection cost 703€ * 28 = 19 684 €. Further savings could be made on testing costs (average test cost 6837 €).

272 In a study on the legal framework for the protection of EU financial interests by criminal law (RS 2011/07) for a limited number of infringements legislative adaption costs alone were estimated to total € 3,583,572 for all Member States.

273 ICSMS already includes notification and reactions functionalities. In the current experience with objections in the safeguard procedures requiring action by the Commission, are limited.

possible testing costs, depending on the products/test a few hundred to thousands € per product[274]). The number of cases would not be very high in the first years, but would develop with increased coordinated market surveillance (e.g. one or two cases in a majority of sector by year, would total for around 15-20 sectors the need for 10-20 FTE). This tasks would not seem feasible in the lower variant of the Network (30 FTE, 6 M€ operational budget), but could be more easily phased in the medium (60 FTE) and higher (60 FTE) estimated sizes.

4(d) The Commission would incur the cost of the set-up of the **centralised product database** and the maintenance (set-up 4.5 M€, maintenance costs 450.000€/year[275]).

Other economic impacts (SMEs, functioning of internal market, competition, consumers)

This option would further improve the functioning of the Single Market with wider-ranging, faster decisions against non-compliant products (manufactured in the EU and/or imported) and with more deterrence effect. Competitiveness of law-abiding companies would be improved due to the further reduced unfair competition from non-compliant products.

This option would maximise the consistency of enforcement, providing more predictability and legal certainty to cross-border trading businesses, in particular SMEs.

Consumers and other professional users, including SMEs, would have easier access to product compliance information (centralised digital compliance information, more visibility of restrictive measures, including widespread infringements). Improved information and better compliance levels that would be achieved in this option would also benefit consumers in terms of lower search and transaction costs, as product would be more truly comparable in the purchasing process.

Social Impacts

Some further positive impacts on employment could be expected due to reduced unfair competition and an improvement of competitiveness.

The increased enforcement, including the efficient tackling of widespread infringements and stronger deterrent tools in this option will have a positive preventative impact on consumer protection and product safety.

Environmental impacts

Improving enforcement of legislation aimed at the protection of the environment (e.g. legislation chemicals substances, detergents, pollutant emissions, etc.) is expected to have a positive environmental impact.

Impacts on fundamental rights (EU Charter of fundamental rights)

Certain measures in this option may impact on fundamental rights. In accordance with Article 52 of the Charter a careful balancing of limitation to these rights has to be made with the

274 Average testing costs calculated on the basis of data available for the 2010-2013 period were roughly 7 000€ per inspection. See annex 11.

275 Estimate based on costs energy labelling product database: 1.5 M€ * 3 taking into account that the sectors and type of documents to be covered are more extensive, and non-standardised unlike energy labelling and interface/integration to be made with the labelling database. Similarly maintenance costs 150.000/€ * 3.

objective of general interest of protecting consumers, users and the environment from unsafe and non-compliant products.

4(a) / (b) The **national restrictive measures** would only take place in the case of confirmed non-compliant product(s), after investigation by market surveillance authorities. For the **joint, single investigations** by the Network the decision to launch an investigation would need to be duly motivated and recorded. Non-compliant products infringe EU product law and thus compromise the public interests these rules set out to protect (e.g. health and safety of users, consumer and environment protection). The existing principles of proportionality of restrictive measures by market surveillance authorities and consultation of the economic operator prior to a restrictive measure remain fully applicable. The same principles would apply to the joint, single procedure. The national restrictive measures themselves would be subject to national procedural safeguards and remedies; or to the European Court of Justice for decisions taken in widespread infringement cases by the EU Product Compliance Network/Commission.

A **right to remedies** for the consumers stemming from the purchase of non-compliant goods would strengthen the current set of consumers rights and thus empower consumers and their confidence when buying goods.

4(c) For the implementation of an **approximation of sanction** it would be essential to ensure the rights to effective remedy, fair trial, right of defence and the principles of legality and proportionality.

4(d) In addition to the digital publication of the Declaration of Conformity (option 3 g), the **centralised product database** should ensure appropriate security of its contents (protection of commercial property).

Summary assessment of the option (4)	
Effectiveness in achieving the policy objectives	
Reinforcing cooperation procedures	+++
Increasing operational enforcement capacity	++
Strengthening the enforcement toolbox	+++
Promoting compliance	++
Costs	
For economic operators	-- / ---
For Member States	-
For the Commission/Impacts on the EU budget	--/---
Administrative simplification	+++

Magnitude of impact as compared with the baseline scenario (the baseline is indicated as 0): +++ strongly positive; ++moderately positive, + positive; neutral; - - - strongly negative; - - moderately negative, - negative;? uncertain; n.a. not applicable. When talking about costs: + means 'savings', while – means 'cost'

6. HOW DO THE OPTIONS COMPARE?

- **Option 2 - Improvement of existing tools and cooperation mechanisms**

Formalised procedures for mutual assistance requests and a common toolbox of investigative and enforcement powers would allow market surveillance authorities to work more efficiently and effectively in cross-border cases and tackle infringements in digital and international supply chains. Better available information and assistance for businesses would help them to comply with product legislation upfront, avoiding costly corrective action. Increased monitoring and comparison of performances would give better oversight of the state of market surveillance across the EU and strategic member state enforcement strategies would allow targeting controls better. However this option improves first and foremost the legal framework and procedures. This option would be less instrumental to overcome resources constraints, and as such it would be unlikely to trigger a noticeably increase in actual control activity or coordinated enforcement. Modest costs would be incurred by the Commission and the Member States.

This option builds on existing legal provisions and tools that are already available and used in many Member States. The feasibility of this option from technical and legal perspectives is considered to be high and a few concrete simplification measures would be feasible in the short term. There is broad stakeholders support for the measures in this option, but it would not meet stakeholder expectations in achieving more robust market surveillance activity and deterrence.

- **Option 3 - in addition to Option 2 Increased deterrence effect to enforcement tools and stepped up EU coordination**

Adding-on to option 2, the easier transferability of evidence and enforcement decisions would make cross-jurisdictional cooperation much more efficient and allow Member States to benefit from cost-savings. The potential effect of individual restrictive measures in the Single Market and on imports would be enhanced. The EU Product Compliance Network would practically assist coordination and facilitate joint control campaigns. The pooling of resources and additional joint capacity would alleviate resources constraints in Member States that prevent them to engage in more coordinated, cross-border controls and to take the wider Single Market perspective better into account.

Depending on its size and resources, the Network could achieve moderate to significant increases in coordinated controls, support prioritisation and targeting of action based on improved market intelligence at the level of the Single Market, as well as the Customs Union for imports, and conduct peer reviews of market surveillance performance in Member States. While the lower size variant of the Network (32 FTE, 6M€ operational budget) would imply a significant improvement over the baseline in enforcement coordination, the medium estimate size variant (59 FTE, 10 M€ operational budget) and *a fortiori* the higher size variant (90 FTE, 14 € operational budget) would be more effective in achieving concrete results based on noticeable stepped up joint control campaigns in all product sectors and robust underlying exchange of intelligence and enforcement information.

The added deterrent effect to enforcement tools would discourage the trading of non-compliant product (more systematic publication of restrictive measures, control costs' recovery in case of non-compliant products). Market surveillance authorities could more easily trace and contact a person responsible for compliance information whenever there are doubts or findings about non-compliance. The mandatory publication of basic compliance information would facilitate users and authorities' access to such information.

This option would meet with broad stakeholder support, regarding the measures' content and the focus on increasing controls and deterrence throughout the EU. It would extend the deterrent effect of certain enforcement tools, however within the scope of market surveillance practice and applicable enforcement tools in relevant other policy areas. The increased operational support would build on and expand existing joint projects and networking activities that meet with strong Member State support. The feasibility of this option from technical and legal perspectives is therefore considered to be high. The hosting of the EU Product Compliance Network in the Commission would however be subject to greater uncertainty over the effective resources that could be allocated and maintained to the Network's Secretariat. The EU-IPO hosting of the Network would lead to a more complex legal proposal, amending the EU-IPO founding regulation to add market surveillance to its mandate, with the associated political risks for the adoptability of the proposal.

- **Option 4 – Centralised EU level enforcement in certain cases**

The direct enforceability of national restrictive measures in the whole of the EU and against non-compliant imported products, after a safeguard consultation procedure, would significantly increase the effect of restrictive measures against non-compliant products and would add to the deterrence of market surveillance. For certain widespread infringements the single process coordinated by the EU Product Compliance network could achieve potentially faster elimination of infringements in the whole EU territory and would increase the visibility of EU enforcement action. Approximated sanctions would in principle set a better level playing field, in particular for penalties, and would facilitate cooperation procedures up to actual imposition of penalties. A centralised database with full compliance information provided by businesses would enhance transparency for all users in the product supply chain and facilitate market surveillance authorities' work. This option would therefore maximise the coordination and consistency of enforcement in the Single Market.

Costs for Member States would on the one hand be very significant linked to the profound adaptations of their legal systems to include the approximated sanctions; on the other hand they would benefit from efficiency gains and cost savings due to the single process for widespread infringements and by relying even more than in option 3 on other Member States' decisions and evidence. The EU budget would incur moderate additional costs to cover the added tasks of the EU Product Compliance Network (in case of the Commission hosting the Network) to deal with widespread infringements and the centralised digital compliance database.

Some measures would have limited support from Member States in particular as they would seem to impact too heavily on national legal systems and enforcement prerogatives (direct enforceability of restrictive measures from other Member States, approximation of sanctions, adoption of EU level enforcement decisions). Businesses would not favour a centralised scheme for digital compliance. The feasibility of this option from political and stakeholder acceptance perspectives is therefore considered to be low.

	Option 1 Base line	**Option 2 Improvement of existing tools and cooperation mechanisms**	**Option 3 In addition: Increased deterrence to enforcement tools and stepped up EU coordination**	**Option 4 In addition: Centralised EU level enforcement in certain cases**
Effectiveness	**0**	**Medium** Moderate improvements of information provision,	**High** Significant improvement in coordination of	**High** Significant improvement in enforcement (extended

		cooperation tools, and some coordination of market surveillance. However limited improvement of actual market surveillance activity and controls.	enforcement, and EU/Single Market dimension of market surveillance. Moderate (low size EU Product Compliance Network) to more significant effective and actual increased enforcement activity and capacity (medium, higher size Network variants). Significant improvement of deterrence of market surveillance tools, incentivising business to comply.	and direct applicability of national restrictive measures) and stronger coordinated enforcement effect in certain cases (wide spread infringements). Improved access to full compliance information for market surveillance authorities.
Costs	**0**	**Low** Member States would incur costs to align to new powers and procedures. Commission/EU budget would incur modest cost (improved performance monitoring)	**Medium/high** Member States would benefit from significant efficiency gains and costs saving (better cooperation procedures, coordination and Network support) Instead the EU budget would incur moderate to significant cost for the EU Product Compliance Network in case of the Commission hosting the Network; zero to reduced cost to the EU-budget would result from the EU-IPO hosting variant of the Network. "Cost" on businesses are linked to correction of infringements, internalisation of these costs by companies whose products are found to be non-compliant.	**High** Member states would incur more significant costs (more profound revision of their national systems administrative and criminal sanctions). Significant costs for business to provide and update full compliance information in central database,
Subsidiarity - Proportionality	**0**	**High** High feasibility from technical and legal perspectives. Moderate improvement of the legal framework, yet limited progress in actual enforcement and controls would risk not meeting stakeholder expectations.	**High** High feasibility and stakeholder support. The Commission hosting variant for EU Product Compliance Network would entail uncertainty over effective resource allocation; the EU-IPO hosting variant would entail more political risks in the adoption phase of the proposal. Proportionate measures to increase market surveillance and deterrence, based on coordination and cooperation without significant impact on Member States' systems.	**Low/medium** Low stakeholder acceptance. Extended direct applicability of other Member States enforcement decisions, EU level enforcement decisions and approximation of sanctions would significantly impact in Member states systems and be highly intrusive. Businesses: Concerns over confidentially, high risk of undue access to sensitive commercial information (centralised digital compliance system)
Coherence with other policies and	**0**	**Low** The strengthening of enforcement would remain lower than in other	**High** Positive coherence the strengthening of	**High** Strong coherence with the strengthening of

EU Charter on Fundamental rights		policy areas, where stronger tools and stronger EU level coordination would apply.	enforcement in other policy areas (competition, food and feed controls, data/privacy and consumer protection).	enforcement in other policy areas (competition, food and feed controls, data/privacy and consumer protection, or customs sanctions). The measures in this option would more strongly impact on fundamental rights, thus requiring safeguards or mitigating measures to be explicitly addressed.

Effectiveness

Overall as regards the effectiveness of the different options to achieve the policy objectives identified, option 2 is expected to lead to moderate improvements of information provision and cooperation tools, and a slight improvement of the coordination of market surveillance. This option would also lead to a limited improvement of actual market surveillance activity and controls. Adding on option 3, however, would be much more effective for improving the coordination of enforcement, and for achieving cross-border market surveillance. It would also constitute a considerable improvement of the deterrent effect of market surveillance tools and incentivise businesses to comply. The effectiveness of option 4 would also be high as a consequence of the extended and direct applicability of national restrictive measures, the stronger coordinated enforcement effect in certain cases (wide spread infringements) and the direct access to full compliance information for market surveillance authorities.

Costs - Efficiency

The costs of option 2 would be quite modest. Member States would incur some costs to align to new powers and procedures. The Commission/EU would incur modest cost for the improved performance monitoring. Adding on option 3 would be much more efficient for the Member States who would benefit from significant efficiency gains and costs saving (better cooperation procedures, coordination and Network support). However, the EU budget would incur significant cost for the establishment and running of the EU Product Compliance Network in case the Commission would host the Network; far reduced costs for the EU budget would results from the EU-IPO hosting variant. Businesses that sell non-compliant products would incur more costs as a result of a stronger improvement of market surveillance but would be expected to internalise these costs. The addition of option 4 would be quite costly, particularly for Member States as a result of the profound revision of their national systems and their administrative and criminal sanctions. In parallel, businesses would also incur costs for providing and updating full compliance information in the central database and expose their commercially sensitive information to high risks of undue access.

Coherence

Option 2 would be much less ambitious compared to enforcement in other policy areas, where stronger tools and stronger EU level coordination would apply. Option 3, however, would align the enforcement of Union harmonisation legislation for non-food products to the enforcement in other policy areas (competition, food and feed controls, data/privacy and consumer protection). Option 4 would also be very coherent with enforcement in other policy areas. However, option 4 would also have quite considerable impacts on fundamental rights which should be explicitly addressed.

Accordingly, the **preferred option** would be **Option 3** (measures of option 2 and additional measure of option 3). This option will address in the most effective and efficient manner all policy objectives to lead to less non-compliant products and a fairer Single Market.

The EU Product Compliance Network is the measure entailing the most significant costs and would ensure a pivotal role in realising the expected improvement of enforcement in the Single Market.

While the lower size variant of this Network would imply a significant improvement over the baseline in terms of enforcement coordination, more concrete impacts would require stepping up to the **medium size variant** which is consequently preferred as the targeted scale for the Network.

The differences between the **hosting variants of the Network**, either by the Commission or by the EU-IPO, are different in nature and require essentially a political balanced choice, between outsourcing of the Network to the EU-IPO with a more complex legal proposal and possibly more controversy in the inter-institutional phase and the feasibility of Commission hosting, taking into account the appreciation of the future multi-annual financial framework and resources that could be prioritised within the Commission to support the Network. Consequently the impact assessment does not express a preferred option among these hosting variants.

7. PREFERRED OPTION

7.1 Preferred option contents and costs

Preferred option – 3 **Option (2) Improvement of existing tools & Option (3) increased deterrence to enforcement tools and stepped up EU coordination**	
Objectives	***Measures***
Reinforcing market surveillance cooperation procedures	• A mechanism for **effective mutual assistance** requests between market surveillance authorities of different member states (2(a)) • **Cross-jurisdictional transferability of enforcement evidence and decisions** (3(a))
Increasing operational enforcement capacity	• **Member State enforcement strategies** to improve data and knowledge sharing and to help targeting enforcement and capacity building actions (2(b)) • An **EU Product Compliance Network**, administrative support structure to coordinate and help implementing joint enforcement activities (3(b)) • **Performance indicators** and benchmarks (2(c)); **Peer reviews** of market surveillance authorities (3(c))

Preferred option – 3 Option (2) Improvement of existing tools & Option (3) increased deterrence to enforcement tools and stepped up EU coordination	
Objectives	***Measures***
Strengthening the enforcement toolbox	• Common **investigative and enforcement powers** for market surveillance authorities, adapted to new market developments, the global supply chains and e-commerce (2(d)) • Additional **collaborative enforcement tools**, to work in partnership with businesses and stakeholders (2(e)) • Obligation to **appoint a person responsible for compliance information** in the EU for 3rd country businesses when they do not work through an importer (3(d)) • **Publication of restrictive measures** taken by market surveillance authorities (3(e)) • **Recovery of control costs** in the case of non-compliant products (3(f))
Promoting compliance	• An extension of the **advice role of the Product Contact Points** (PCP) (2(f)) • A **web-portal** hosted by the Commission on **voluntary measures taken by businesses** on dangerous products (2(g)) • **Mandatory digital publication of compliance information** (3(g))

How does the preferred option address the problem drivers (identified in section 1.3)?:

- *Fragmentation of market surveillance hampering effectiveness and uniformity of controls*

  Working across borders would be made easier for Member States with new legal principles on the portability of test-reports, re-use of evidence and enforcement decisions taken in another Member State. Restrictive measures taken against non-compliant products in one member state could be more quickly and frequently replicated in other Member States, against non-compliant products traded within the EU and viz. imports. Thanks to effective mutual assistance requests, authorities in different member states could more easily call on each other to help in cross-border investigations and enforcement cases.

  Moreover, the common toolbox of investigative and enforcement powers for all market surveillance authorities would ensure that similar cases could be treated in the same rigorous way regardless of location. The EU Product Compliance Network would coordinate market surveillance actions, and based on Member State enforcement strategies, conduct peer reviews to ensure equally performant enforcement is available throughout the Single Market.

- *Resources constraints leading to limited actual control activity, within the EU and on products entering the EU*

  The EU Product Compliance Network would pool resources and provide additional joint capacity so that more coordinated, cross-border controls could take place. National enforcement strategies and shared market intelligence with an EU-perspective would help prioritise and target controls better. Upgraded IT tools supported by the Network, including exchanges with customs, would allow market surveillance authorities to cooperate and report efficiently.

  More efficient work-sharing between authorities in the coordinated controls, and re-use of evidence and enforcement decisions would allow them saving time and costs, which in turn would become available to reinvest in additional controls.

- *Lacking deterrence and insufficient enforcement tools to respond to evolving markets, business models*

  The added deterrent effect to enforcement tools would discourage the trading of non-compliant product (more systematic publication of restrictive measures, control costs' recovery in case of non-compliant products). The common powers for market authorities would span the full supply chain and include specific digital investigation and enforcement tools. Market surveillance authorities could more easily trace and contact a person responsible for compliance information when there are doubts or findings about non-compliance, require intermediaries in digital supply chains to cooperate, and sanction absence of responses or lack of cooperation.

- *Knowledge and information gaps concerning product compliance*

  Advice on product legislation by Product Contact Points would help businesses to comply with the EU product legislation. More wide-spread and easy accessible compliance information would be ensured for all users by (1) digital publication of basic compliance information by manufacturers and importers; (2) more systematic publication of restrictive measures taken by authorities, and (3) a web-portal for voluntary measures business may undertake to recall dangerous products. Partnerships and collaborative enforcement tools would allow businesses and market surveillance authorities exchange sector and compliance information efficiently.

Costs:

- The main costs of the preferred option would fall on the **EU budget in the case of Commission hosting** in relation to the EU Product Compliance Network 18 M€/year (staff, overheads and an operational budget for the medium size estimate Network). In the case of the EU-IPO hosting of the Network no immediate costs to the EU budget would occur, apart from modest set-up costs (70 000€). Set-up costs to allow interfacing of the IT tool for market surveillance and customs systems (incl. Single Window development) amount to 3,2M€ over 5 years.

  Other costs relate to pilot funding support to national enforcement strategies of 1 to 3 M€. The other measures (mutual assistance, performance indicator system, web-portal) would amount to set-up costs of 1 FTE and 1.1 M€, and running costs estimated at 4.7 FTE. The systematic use of IT-tools to communicate strategies and enforcement

information may result in a small reduction of handling costs by the Commission (-0,5 FTE).

- **Member States** would face costs to adapt and align (some) of their legislation and procedures (set-up costs 700 000€ all Member States), and as main running costs the advice service by Product Contact Points (3.5 M€/year, all Member States). However they would benefit from significant **efficiency gains** and cost savings thanks to the increased joint actions and coordination, assisted by the EU Product Compliance Network. The stronger and more fit-for-purpose enforcement powers, enhanced enforcement cooperation tools and re-use of other Member States' enforcement decision and evidence would allow market surveillance authorities to realise important costs savings and rationalise the market surveillance framework in the EU.

- The preferred option would have minimal costs implications for **businesses** that trade compliant products. The stepped-up enforcement coordination, better knowledge exchange, prioritisation and peer reviewed enforcement strategies supported by the EU Product Compliance Network, would create a more level playing field and a more transparent and predictable enforcement environment across the Single Market. As a result businesses may see a reduction of some of the negative impacts of the across-the-board inconsistencies they currently face. Businesses' regulatory costs stemming from the market surveillance rules relate to their information obligations towards public authorities (e.g. responding to requests from authorities, information on non-compliances detected). These costs only occur occasionally and are considered insignificant especially compared to ensuring product conformity and traceability. The preferred option would only marginally increase costs for some businesses: The mandatory digital publication of some compliance information would imply a cost of 22 M€/year in total for the economic operators concerned (manufactures and importers). Some 3rd country traders might incur some extra costs to ensure a person responsible for compliance information is available in the EU. On the contrary businesses trading non-compliant products would face costs to incentivise them to better internalise the full compliance cost (e.g. via recovery of control costs, reputation costs).

The effects of the preferred option on the various stakeholders, including SMEs, are set out in Annex 3.

7.2 Subsidiarity and proportionality of the preferred option

The preferred option would ensure consistent enforcement of Union harmonisation legislation across the EU and allow tackling efficiently non-compliance spanning over several Member States. The measures contained in the preferred option would provide a proportionate response to the challenges national market surveillance authorities currently face as their action is constrained by jurisdictional boundaries, while products circulate freely in the Internal Market and many undertakings implement their business models in several Member States or at the EU level. With the high levels of intra-EU trade in harmonised products and increasing imports, through the main entry sea- and airports, the enforcement action – or weak spots in controls - in individual Member States impact directly on others and the Single Market as a whole. Over 500 authorities are engaged in market surveillance throughout the EU territory. Some 5 million businesses in the EU produce or distribute products covered by this initiative, for a value of 2 400 billion € or 69% of all manufacturing products. The unfair competition by the persistent and widespread presence of non-compliant products would gradually erode this economic basis. Achieving performant, coherent and consistent

enforcement of EU harmonised product legislation would require a commensurate coordination effort at the EU level, coupled with effective tools for market surveillance authorities.

A very large majority of stakeholders endorse the need for more coordination of enforcement among Member States, better sharing of intelligence and knowledge[276]. Pooling efforts in these areas, as envisaged in the EU Product Compliance Network, would allow overall resources for market surveillance to be used more efficiently and increase coordinated, joint control activities in priority areas related to intra-EU trade as well as imports. More exchange of information and discussion among EU authorities would contribute to more consistent enforcement and the easier replication and re-use of evidence and enforcement decisions across jurisdictional boundaries would help to save costs[277]. The stronger deterrent effect of enforcement tools in the preferred option would be directed at businesses trading non-compliant products.

The preferred option would thus allow to step-up coordination of public enforcement activities while respecting subsidiarity principles:

The measures would neither affect the Member States' competences in market surveillance, nor would it interfere with national enforcement or judicial systems. The deterrent effect of certain tools would be improved and the reach of measures extended, yet building on existing tools and aligning with comparable tools in other EU policy areas. The preferred options would not affect internal division of competences among authorities at national level, as Member States would remain responsible for their institutional set up and designation of competent authorities for market surveillance.

While the existing Regulation (EC) No 765/2008 already requires Member States to grant necessary powers to market surveillance authorities, the further specification of some common, future-proof powers is foreseen to ensure market surveillance authorities could act more uniformly and cooperate on a more equivalent basis in cross-border enforcement. These powers may have to be reflected in national procedural laws according to the current availability of such powers in the Member States. They are in essence a refinement of the existing requirements and would not unduly impact or interfere with the institutional choices of Member States or the set-up of their enforcement and legal systems.

The preferred option only establishes general principles, procedures and operational support mechanisms to the extent necessary for smooth, coordination between Member States. In line with the principle of subsidiarity, the implementation of the measures, in particular the enforcement decisions and actions against concrete products posing risks, are carried out by Member States.

276 Annex 2, public consultation results. Question 13, rates of agreement by various stakeholder groups: More enforcement coordination between member states: 80% authorities, 87% businesses, 84% consumers; More intelligence sharing between Member States: 84% authorities, 88% businesses, 88% consumers.

277 In the public consultation, Section 3, in Question 8 76% of respondents agree that more exchanges and discussion would prevent divergent conclusions among EU authorities; Question 5, 82% of respondents agreed to stronger procedures for mutual assistance, 86% agree re-use of evidence and enforcement decisions would be more efficient as inspections could focus better on other/specific issues, 81% would expect time and costs savings.

8. HOW WOULD ACTUAL IMPACTS BE MONITORED AND EVALUATED?

8.1 Practical arrangements of the evaluation: when, by whom

The evaluation of Regulation (EC) No 765/2008 and the preparation of this impact assessment revealed important gaps in available information and the quality of data reported by Member States. It will be essential to establish a robust system to verify whether and to what extent the proposal has been effective in reaching its objectives, and whether the objectives have been met efficiently (i.e. at least cost), as well as the reasons for its success or shortcomings. Meanwhile, a number of the current reporting requirements for market surveillance authorities need to be simplified in order to alleviate the administrative burden for authorities.

The most efficient scheme for a future evaluation is to use ICSMS as a main source of information and, on the basis of the indicators, to assess whether the proposal was effective and efficient, relevant given the needs and its objectives, coherent both internally and with other EU policy interventions and achieved EU added-value. The monitoring through ICSMS would be completed by the work of the EU Product Compliance Network and the provision by Member States of more reliable and more comprehensive information on compliance rates and enforcement activity as part of their national enforcement strategies.

By using ICSMS the monitoring of operational activity could take place on an ongoing basis at least yearly (e.g. number of mutual assistance requests, restrictive measures taken). The review of Member States enforcement strategies, market studies, user surveys and the identification and implementation of common priorities by the EU Product Compliance Network would allow on a yearly to bi-annual basis an analysis of progress towards higher level indicators (e.g. control levels in Member States, compliance gaps, usage of compliance assistance schemes). In this regard, an important task for the EU Product Compliance Network would be to set up and monitor overall performance indicators and perform peer reviews.

To provide an adequate basis for the monitoring and evaluation of the initiative, reference levels will be established to form a consolidated baseline. The methodology to monitor trends in (non)compliance will be examined, to complete the information from market surveillance controls where possible with surveys based on sampling , across sectors or in a selection and for special supply channels (e-commerce, imports). An evaluation by the Commission of the functioning of the new legislative framework could be foreseen in the mid-term (e.g. after 5 years of implementation).

8.2 Operational objectives and indicators to monitor compliance for the preferred option

OBJECTIVES	INDICATORS
1) Reinforcing cooperation procedures	• Usage of mutual assistance mechanisms by market surveillance authorities (number, types, timelines, outcomes) • Number of measures taken by other authorities 'replicated' in each Member State

OBJECTIVES	INDICATORS
2) Increasing operational capacity	• Number and scope of Member States enforcement strategies (performance indicators) • Compliance rates by Member State/sectors and for e-commerce (improvements in availability and quality of information, progress in reduction of compliance gaps) • Number of coordination controls campaigns: scope (number of MS/sectors/ products) finding (detection infringements) and results (corrective measures) • Awareness of EU network and user satisfaction with its services (by economic operators, consumers and other end-users; market surveillance authorities)
3) Strengthening the enforcement toolbox	• % of costs recovered by authorities • Availability and accessibility of information on (non)compliance and on restrictive measures • Application of sanctions (infringements detected leading to penalties, types and levels of penalties effectively applied)
4) Promoting compliance	• Number, type of requests for information handled by Product Contact Points • Number, type of partnerships/compliance assistance schemes in MS; (usage of schemes, by type of business) • Awareness/understanding of product rules by businesses • Availability and accessibility of relevant compliance information (on economic operators' websites) - by MS, sector, type of operator • Usage of information by market surveillance authorities, consumers and professional end-users • Number of voluntary measures registered in the common web-portal

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PART 2/4

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council

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{SWD(2017) 469 final} - {SWD(2017) 470 final}

Contents

Glossary

Non-food or industrial product	A substance, preparation or good produced through a manufacturing process other than food, feed, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction.
Union harmonisation legislation	Any Union legislation harmonising the conditions for the marketing of products
Manufacturer	Any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark
Authorised representative	Any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under the relevant Union legislation.
Importer	Any natural or legal person established within the Union who places a product from a third country on the Union market.
Distributor	Any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.
Economic operators	The manufacturer, the authorised representative, the importer and the distributor
Market surveillance	The activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection.
Market surveillance authority	An authority of a Member State responsible for carrying out market surveillance on its territory.
Recall	Any measure aimed at achieving the return of a product that has already been made available to the end user
Withdrawal	Any measure aimed at preventing a product in the supply chain from being made available on the market
Making available on the market	Any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.
Placing on the market	The first making available of a product on the Union market.
Sanction	Action by one or more market surveillance authority toward an undertaking in order to force it to comply with legal obligations. It includes all measures to prohibit or restrict the product's being made available on the national market, to withdraw the product from that market or to recall it, and administrative penalties.
Penalty	A punishment for breaking the law of either administrative or criminal nature.
RAPEX	Rapid alert system for the transmission among all competent market surveillance authorities in the EU of information on measures taken against products presenting a serious risk – ec.*europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm*
ICSMS	Internet-supported information and communication system for market surveillance authorities in the EU - *https://webgate.ec.europa.eu/icsms/*

ANNEX 1: PROCEDURAL INFORMATION

1. IDENTIFICATION

- Lead DG: DG Internal Market, Industry, Entrepreneurship and SMEs (GROWTH)
- Agenda planning/Work programme references: 2017/GROW/007

2. ORGANISATION AND TIMING

Work started in January 2016. An Inter-Service Steering Group (ISSG) chaired by DG Internal Market, Industry, Entrepreneurship and SMEs (GROWTH) was established to this purpose. Its members included representatives of:

- Secretariat-General
- DG Climate Action (CLIMA)
- DG Economic and Financial Affairs (ECFIN)
- DG Employment, Social Affairs and Inclusion (EMPL)
- DG Energy (ENER)
- DG Environment (ENV)
- DG Justice and Consumers (JUST)
- DG For Mobility and Transport (MOVE)
- DG Health and Food Safety (SANTE)
- DG Taxation and Customs Union (TAXUD)
- DG Trade (TRADE)

The ISSG met in total nine times (29/01/2016, 07/03/2016, 21/04/2016, 29/09/2016, 28/11/2016, 27/01/2017, 10/02/2017, 27/02/2017 and 06/03/2017).

3. CONSULTATION OF THE REGULATORY SCRUTINY BOARD

The Regulatory Scrutiny Board (RSB) of the European Commission assessed a draft version of the present impact assessment and issued a negative opinion on 07/04/2017. The Board made several recommendations. Those were addressed in the revised IA report as follows:

RSB opinion	Follow-up
(B) Overall assessment and main issues The Board acknowledges the effort to collect evidence on product non-compliance with EU harmonised rules. However, the Board gives a negative opinion, because the report contains important shortcomings that need to	

be addressed with respect to the following key aspects:	
1) The report does not relate this proposal to other legislative initiatives under negotiation. It does not explain why an EU-level response is necessary and proportional to observed problems of product non-compliance.	A new section 'Regulatory context' has been added (1.2.1). It explains the existing framework, how it relates to legislative initiative under negotiation. The problem description (1.3) and proposed options (4) have been expanded to show clearly what/how EU level action is considered to address the problems.
2) The policy options are vague about what actual measures would be taken. As currently organised in the report, they do not provide policy-makers with a transparent choice. Moreover the options do not fully address the issues that the evaluation identifies (e.g. e-Commerce and third countries imports).	The objectives and options have been reorganised and a detailed description of the measures in the options is given (section 4). Reference to how these measures address e-commerce and imports have been added.
3)The report does not do enough to exploit the evidence to quantify costs, and does not identify the potential for simplification or burden reduction as required by REFIT.	The assessment of the options (5) has been expanded adding where possible quantification of costs. In each option assessment (5.2, 5.3, 5.4) a dedicated part is included on simplification potential. Costs of the preferred option are finally also provided (section 7).
(C) Adjustment requirements and other recommendations for improvement	
(1) Context and scope:	
The report explains the existing legislative framework. It should also explain the link with the 2013 Market Surveillance and Product Package. Against this background, it should further clarify the envisaged (broad) scope of this initiative.	The description of the regulatory context is expanded (1.2.1). References to the 2013 package and the rationale for the new initiate have been included. The broad scope of the existing framework and the new initiative is highlighted in this context.
(2) Problem definition and use of the evaluation:	
The report should better highlight the reasons for a more prominent EU dimension to deal with non-compliance. Doing so would usefully underpin the EU solutions that the report presents, e.g. option 5. In addition, the report should establish a stronger link	The problem description and the options have been revisited taking the conclusions of the evaluation into account. The relevant conclusions of the evaluations have been also included in the report (1.7). Besides the evaluation on the market surveillance

between the results of the related evaluation and its identification of problem drivers.

provisions of Regulation (EC) N° 765/2008, the evaluation of the Union harmonisation legislation (2014) is also included in the text.

(3) Baseline and options

The baseline needs to take into account the implications of the pending 2013 Market Surveillance and Product Package. The report needs to properly explain and justify the various (sub-) options, including all related measures (reliance on PCP, introduction of the representative). It needs to explain the measures to deal with the non-compliance of imported goods from third countries. To do this it will need to consider both the market surveillance and the customs dimensions. The report needs to be clear on how the initiative will address the challenges related to the increasing role of e-commerce. It needs to elaborate on the EU dimension and commitments in terms of resources and enforcement competences of option 5. The report should reorganise the options to provide policy-makers with more transparent choices across the various policy dimensions.

The objectives and options (4) have been completely reorganised to respond to the comments of the Board. The options are presented by increasing ambition and EU dimension/coordination. The report also clearly spells out that none of the options fundamentally changes the balance of enforcement competences, which remain at MS level. The measures in each option are described in more detail. Where relevant specific references have been included to how these measures build on the existing framework or 2013 proposal, or how they address e-commerce or imports and customs controls. The resources implications of each option have been elaborated in the assessments (5.2, 5.3, 5.4).

(4) Impacts

More detail on measures contained in the options would improve the analysis of the impacts. The report should draw more from the rich (anecdotal) empirical evidence in the annexes. This would help to improve its quantification dimension and provide information on the potential for simplification and burden reduction. The report should also show the cost of the preferred option, including for instance implications in terms of funding and resources at the EU level.

More reference to examples have been incorporated and where possible estimations or indicative impacts and costs added.

The costs of the preferred option are set out also in section 7, separating out costs for the EU, member states and businesses.

(5) Presentation

The report needs to be a self-standing document. It should improve the presentation of a number of sections: scope, the existing legislative framework, the baseline, the policy options and the comparison of the policy options. In this regard, the report should draw policy relevant information from the very

The regulatory context, baseline/problem description sections have been reviewed and significantly expanded to explain the existing framework. The sections 3 to 6 on the objectives, options and comparison of the options have been entirely reworked, adding more information into the report and adding

extensive annexes.	further references and elements to make the report as self-standing as possible.

On 08/06/2017 the RSB issued a 2nd positive opinion on the revised impact assessment report. The Board made several recommendations, which were addressed as follows:

RSB Opinion	**Follow-up**
(B) Main considerations The Board notes that the report addresses several concerns that the Board raised in its first opinion. However, the report still contains important shortcomings that need to be addressed. As a result, the Board expresses reservations and gives a positive opinion only on the understanding that the report shall be adjusted to integrate the Board's recommendations with respect to the following key aspects:	
• The links with the results of the related evaluation are not sufficiently spelled out.	• More explicit links to the evaluation findings have been integrated in the report (in the problem definition as well as in the options and measures).
• The report does not substantiate the feasibility of an externalised EU Product Compliance Network under option 3b and leaves many issues unanswered (resources, governance, and expected impacts). While making the case for the network, the report does not provide an adequate basis for deciding on its implementation modalities.	• The description in the report is expanded to include more information on the intended governance structure of the Network, details on resources, including inputs and results which can be expected in the different scenarios. The report also analyses more in detail the implications of hosting of the Network in an regulatory agency (EU-IPO) versus hosting in the Commission. Full detailed information on the EU Product Compliance Network is added in Annex 12.
• The report does not provide sufficient evidence that the obligation to appoint a responsible person in the EU for third country business is effective and proportionate.	• Details on the responsible person measure are added in Annex 13 (2).
• The REFIT dimension of the report is not clear enough**.**	More explicit links to the evaluation and the REFIT dimension are inserted in the report. The sections on administrative simplifications

	and the costs of the preferred option have been expanded.
(C) Further considerations and adjustment requirements	
(1) Problem definition	
The problem definition should draw more strongly on the REFIT evaluation of the application of the market surveillance provisions of regulation (EC) no 765 (2008). The report should better reflect the evaluation's conclusions and should address the problems that the evaluation identified.	More explicit links to the evaluation findings have been integrated in the report (in the problem definition as well as in the options and measures). In section 1.6 (Conclusions of the evaluation), the findings on the refit-potential have been added with cross-references to the problem definition and measures that address the findings.
(2) Options	
An important measure of the preferred option is the establishment of a **Product Compliance Network.** For this option to be rigorously assessed, an informed analysis of the pros and cons of the different alternative governance forms of the Network (e.g. network within the Commission, integration in existing agency, new agency, regulatory versus executive agency…) is required. As it presently stands, the report does not substantiate the feasibility or the adequacy of the current sub-option of hosting the network in the Agency EU-IPO. This proposal does not appear to have been tested in the consultation and Member States have voiced opposition to an intergovernmental body. In the absence of further analysis and consultations, the evidence-base for considering this option is insufficient.	The description of the measure 3(b) has been expanded, summarising the various governance and hosting variants. The impacts and feasibility of the main hosting options Commission or EU-IPO are compared. Full details on the outputs and costs in different scenarios and the pro's and con's of various hosting option have been included in Annex 12. While the impact assessment is completed with all the elements requested, the report does not express a preferred option for the hosting variant Commission or EU-IPO, as this is essentially a political choice. The Network, including hosting sub-options in the Commission or an existing EU agency, was tested with Member States in March 2017, and received broad support. On the occasion it was clarified that the Network would not entail a transfer of competencies from MS to EU level over which concerns were voiced in initial stages of the impact assessment and scoping of options (written submissions of Member States in response to the public consultation, member state expert group meeting 21 October 2016). The corresponding text in the report ("stakeholder views" on option 3(b)) has been elaborated.
The **sub-option 3(d) requiring a "person responsible"** for goods which are not imported through an importer needs further	Details on the responsible person measure are added in Annex 13 (2).

explanation and substantiation:

• To whom will the obligation apply? Specifically, will it cover passive sales? Fulfilment centres? Online markets?	Sections 2.1 and 2.2.1 of Annex 13(2)
• What is the added value of this measure, as compared to the mandatory digital publication of compliance information (sub-option 3g), also included in the preferred option?	Section 2.4.3 of Annex 13(2)
• How reliable is the EUR 200 estimated cost of having a responsible person?	Section 2.4.3 of Annex 13(2)
• How will market surveillance authorities enforce such an obligation? What are the related enforcement costs?	Section 2.4.3 of Annex 13(2)
• Would the measure discourage third country online compliant retailers to sell in the EU, and therefore run against the Digital Single Market Strategy objective of promoting eCommerce?	Sections 2.1 and 2.4.3 of Annex 13(2)
• What are the liabilities which the responsible person will be submitted to? Are they the same as the liabilities in other existing frameworks? How does this liability affect the estimated costs?	Section 2.4.3 of Annex 13(2)
• Has the concept of responsible person in the legal framework for cosmetics and medical devices demonstrated its effectiveness to address the market surveillance issue of imports of small consignments from third countries?	Section 2.4.3 of Annex 13(2)
• How big is the market segment affected by the obligation? Calculations point to a small proportion (5.6%) of eCommerce and very small segments of the EU harmonised market (EUR 465 million against EUR 2500 billion).	Section 2.2 of Annex 13(2)

(**3) Impact and REFIT**

The report should present more quantitative data on the REF**I**T dimension. It could draw on the related evaluation for this. Besides information on what the preferred option	Additional quantitative estimates have been added in the report, including on possible administrative simplifications (e.g. costs of reporting). In section 7.1 in addition to costs

would cost, the report should comprehensively present the potential for simplification and burden reduction. Finally, it should try to present some estimates of the costs of strengthening the enforcement tools in Member States, since they might vary heavily between Member States which currently have investigative powers and Member States which do not.

of the preferred option, simplifications and cost reduction potential has been included. The report has been adapted to indicate more clearly which Member States currently have the least investigative and enforcement powers and could as a consequence face more adaptation costs than others (option 2(d), and 3 (e)/(f)). A detailed breakdown by power and by Member State has been put into annex 13, based on the information obtained in the REFIT evaluation.

4. EVIDENCE USED FOR THE IMPACT ASSESSMENT

Besides the evidence that results from the consultations of stakeholders and from the REFIT evaluation, section 5 below and annexes 7, 8 and 9 contain the main elements on which the problem description is based. Annexes 11 to 15 contain the remaining evidence used for assessing the options

5. SOURCES USED FOR THE IMPACT ASSESSMENT

5.1 Other reports, Commission documents and impact assessments

- COM(2016) 1958 final, Commission Notice. The "Blue Guide" on the implementation of EU product rules.

- Centre for Strategy and Evaluation Services (2010), "Interim Evaluation of the Measuring Instruments Directive", Final report.

- Department for Business, Innovation & Skills, Better Regulation Delivery Office (2013), Interim Evaluation of Primary Authority.

- European Commission (2007), Commission Staff Working Document *Accompanying the document Proposal for a* Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and a decision of the European Parliament and of the Council on a common framework for the marketing of products – Impact Assessment – SEC(2007) 173.

- European Commission (2007) Commission Staff Working Document *Accompanying the document Proposal for a* Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and a decision of the European Parliament and of the Council on a common framework for the marketing of products - Executive summary of the impact assessment – SEC(2007) 174.

- European Commission (2008) Commission Staff Working Document *Accompanying document* to the Proposal for a Directive of the European Parliament and of the Council amending Directive 88/378/EEC on the safety of toys – Impact Assessment. SEC(2008) 38.

- European Commission (2011) Commission Staff Working paper. Impact Assessment *Accompanying the document* Directive of the European Parliament and of the Council amending Directive 94/25/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft, as amended by Directive 2003/44/EC.

- European Commission (2011) Commission Staff Working Paper. Impact Assessment *Accompanying document* to the 10 Proposals to align product harmonisation directives to Decision No 768/2008/EC.

- European Commission (2011) Commission Staff Working Document. Bringing e-commerce benefits to consumers. SEC(2011) 1640 final.

- European Commission (2012) Commission Staff Working Document Impact Assessment (Disclaimer: This report commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission) *Accompanying the document* Proposal for a Directive of the European Parliament and of the Council on the harmonisation of laws of the Member States to the making available on the market of radio equipment – SWD(2012) 329 final.

- European Commission (2012) Commission Staff Working Document Executive Summary Of The Impact Assessment *Accompanying the document* revision of Council Directive 96/98/EC of 20 December 1996 on marine equipment - SWD(2012) 437 final.

- European Commission (2013) Commission Staff Working Document – Impact Assessment *Accompanying the document* "Product Safety and Market Surveillance Package: A proposal for a Regulation of the European Parliament and the Council on consumer product safety and a proposal for a Regulation of the European Parliament and of the Council on market surveillance for products" and Annexes – SWD(2013) 33 final.

- European Commission (2013) Commission Staff Working Document – Executive Summary of the Impact Assessment *Accompanying the document* "Product Safety and Market Surveillance Package: A proposal for a Regulation of the European Parliament and the Council on consumer product safety and a proposal for a Regulation of the European Parliament and of the Council on market surveillance for products" – SWD(2013) 34 final.

- European Commission (2014) Commission Staff Working Document Part 1: : Evaluation of the Internal Market Legislation for Industrial Product *Accompanying the document* the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee A vision for the internal market for products – SWD (2014) 23 final.

- European Commission (2014) Commission Staff Working Document Part 2: Results of the case studies *Accompanying the document* the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee A vision for the internal market for products – SWD (2014) 23 final.

- European Commission (2014) Commission Staff Working Document Impact Assessment *Accompanying the document* Commission legislative proposal for a

revision of Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to cableway installations designed to carry persons – SWD(2014) 116 final.

- European Commission (2014) Commission Staff Working Document Impact Assessment *Accompanying the document* Proposal for a Regulation Of The European Parliament And Of The Council on personal protective equipment – SWD(2014) 118 final.

- European Commission (2014) Commission Staff Working Document Impact Assessment *Accompanying the document* Proposal For A Regulation Of The European Parliament And Of The Council on appliances burning gaseous fuels.

- European Commission (2015) Commission Staff Working Document. A Single Market Strategy for Europe – Analysis and Evidence. Accompanying the document Upgrading the Single Market: more opportunities for people and business. SWD(2015) 202 final.

- European Commission (2015) Commission Staff Working Document Executive Summary of the Impact Assessment *Accompanying the document* Proposal for a Regulation of the European Parliament and of the Council setting a framework for energy efficiency labelling and repealing Directive 2010/30/EU – SWD(2015) 140 final.

- European Commission (2016) Commission Staff Working Document Impact Assessment *Accompanying the Proposal* for a Regulation of the European Parliament and the Council on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles – SWD(2016) 9 final.

- European Commission (2016) Commission Staff Working Document SWD(2016)172 on Online Platforms and accompanying the Commission Communication on Online Platforms and the Digital Single Market.

- European Commission (2017) Commission Staff Working Document Impact Assessment *Accompanying the Proposal* for a Directive of the European Parliament and the Council to empower the competition authorities of the Member States to be more effective enforcers of the rules on competition laid down in Articles 101 and 102 TFEU and to remove obstacles to the proper functioning of the internal market – SWD(2017)…

- European Commission (2017) Commission Staff Working Document Impact Assessment *Accompanying the Proposal* for a [Single Digital Gateway] – SWD(2017)…

- European Commission, GROW B1 (2016), Summary of Member States' assessment and review of the functioning of market surveillance activities according to Article 18(6) of Regulation (EC) No 765/2008. Available at: http://ec.europa.eu/DocsRoom/documents/15241/attachments/1/translations/en/renditions/native

- European Commission. Proposal for a Directive of the European Parliament and of the Council on the placing on the market of pyrotechnic articles – Impact Assessment.

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- European Commission (2013) Report From The Commission To The European Parliament, The Council And The European Economic And Social Committee on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/9 – COM(2013) 77 final.

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ANNEX 2: STAKEHOLDER CONSULTATION

1. OBJECTIVES OF THE CONSULTATION

The Commission wanted to make an evidence-based assessment of the extent to which the provisions on market surveillance of Regulation (EC) No 765/2008 have been effective, efficient, relevant, coherent and achieved EU added-value. The results of the evaluation will support taking actions to enhance efforts to fight non-compliant products made available in the Single Market.

1.1 Consultation methods and tools

The **market surveillance authorities** have been consulted during the meetings of the Expert Group on the Internal Market for Products in 2016 .

A **stakeholder conference** - open to all interested participants - **was** organised by the Commission on **17 June 2016**.

A **public consultation in all EU official languages**, published on a website hosted on *Europa*, run from 1 July to 31 October 2016. Participation of SMEs in the consultation was promoted and supported through the European Enterprise Network.

2. RESULTS OF THE CONSULTATION ACTIVITIES

2.1 Meetings of the Expert Group on the Internal Market for Products – Market Surveillance Group

The Expert Group on the Internal Market for Products – Market Surveillance Group held its last meetings on 1st February 2016, 21st October 2016 and 31st March 2017.

During the first meeting, the Commission recalled the challenges reported by market surveillance authorities in the national reviews and assessment of activities carried out between 2010 and 2013. The detailed IMP document is annexed to the Impact Assessment (Annex 2).

During the meeting held on 21 October 2016, the Commission informed the participants of the state of play of the enforcement and compliance initiative and explained that the purpose was to receive feedback on the suitability of the ideas under examination. The detailed minutes can be found at: http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=28611.

The meeting held on 31 March 2017 focused on the legislative proposal and especially on how to enhance cooperation between the member states, create a uniform and sufficient level of market surveillance and have stronger border controls of imported products to the European market.

2.2 Meetings of the Customs Expert Group

The Customs Expert Group that met on 22 April was informed about the launch of the Enforcement and Compliance initiative. Customs authorities were invited to participate in the consultations and provide their views on possible challenges and actions needed.

The Expert Group PARCS met to discuss product safety and compliance controls on 1 December 2016. At the meeting the Commission presented the state of play on the revision of Regulation (EC) No 765/2008.

2.3 Stakeholder conference of 17 June 2016

A stakeholders' event was organised on 17 June 2016, to identify the main issues related to the compliance and better enforcement in the Single Market and to identify possible ways forward. 144 participants attended the event, representing businesses (62), national authorities (60) and others (22). The detailed minutes of this conference can be found at: http://ec.europa.eu/DocsRoom/documents/17963.

2.4 Public Consultation

239 replies were received via the online form foreseen during the public consultation. The numbers and percentages used to describe the distribution of the responses to the public consultation derive from the answers under the EU-Survey tool. Other submissions of stakeholders to the public consultation have been taken into account, but without being considered for the statistical representation.

The consultation was divided into five parts. Since only part B1 was obligatory, the other sections were partly answered. Therefore, the average ratio of replies was **80%** for section B2, **66%** for section B3, **80%** for section B4 and **84%** for section B5.

All statistics included in this summary are based on the data gathered from the replies for each section. Detailed statistics for each category can be found in Annex 2 of the Impact Assessment.

Businesses were strongly represented (**127**), followed by public authorities (**80**), and citizens (**32**). More specifically for businesses, **49%** of them represent product manufacturers, **21%** product importer / distributors, **8%** product users, **5%** conformity assessment bodies, **1%** online intermediaries and **16%** other.

Concerning the geographical distribution of responses, all countries were represented except for Latvia, Luxembourg, Malta, and Liechtenstein. The majority of respondents (**116**) exert their activities only in their country of establishment.

2.4.1 Product compliance in the Single Market and deterrence of existing enforcement mechanisms

The majority of respondents (**89%**) consider that their products are affected by non-compliance with product requirements laid down in EU harmonisation legislation.

However, **45%** of the respondents are unable to estimate the approximate proportion of non-compliant products for their sector. This percentage is approximately equal for all type of respondents.

80% of businesses participating in the consultation confirm non-compliance has a negative effect on sales and/or market shares of businesses complying with legal obligations. Many businesses (**42%**), however, are unable to estimate their approximate loss in sales due to non-compliance.

As to the most important reason for product compliance in the Single Market, **33.47%** of the respondents consider that it is about a deliberate choice to exploit market opportunities at the lowest cost, followed by a lack of knowledge (**26.78%**), a technical or other type of inability to comply with the rules (**10.88%**), ambiguity in the rules (**10.46%)** and carelessness (**9.62%**).

All types of respondents have experience / knowledge of instances where market surveillance authorities lacked sufficient financial and human resources as well as the technical means to carry out specific tasks. Nevertheless, **67.36%** of the respondents could not estimate the approximate financial resource gap of the national authority.

Regarding the increase of resources for market surveillance activities, although two of the three solutions receive a unanimous acceptance by the respondents, for the third one, namely that market surveillance authorities should levy administrative fees on operators in their sector to finance controls, the results are contradictory. **55.91%** of the businesses and **40.63%** of the consumers and others strongly disagree with this option, while **50.00%** of the public authorities agree with it (15% strongly agree and 35% agree).

Stakeholders have similar views as regards the effective use of resources for market surveillance activities.

Many respondents (**46%**) agree that market surveillance does not provide sufficient deterrence in their sector or that it provides deterrence to a moderate extent (**34%**) and that the options proposed by the Commission would improve the deterrence of market surveillance action.

2.4.2 Compliance assistance in Member States and at EU level

This section of the questionnaire was optional, so the average ratio of replies came up to **80%** (approximately **190** replies per question).

There is a consensus on the fact that **sometimes** it is difficult to find but also understand the correct information on the technical rules that products need to meet before they can be placed on the domestic and on other EU markets.

The approach taken by respondents to look for support and information on technical rules that products need to meet **slightly** differs according to the type of respondent. The majority of respondents prefer to refer to the information available on Commission websites. Regarding the approaches that should be followed by national authorities to reduce the level of non-compliant products on the market, the respondents consider that the best approach is the **combination of information, support and enforcement by the public authorities**.

2.4.3 Business' demonstration of product compliance

This section of the questionnaire was optional, so the average ratio of replies came up to **66%** (approximately **158** replies per question).

Businesses were asked to provide answers on how they supply information about product compliance. Approximately **30%** of the respondents consider that the proposed options **are not applicable to them**.

A large majority of respondents strongly agrees or agrees that a broader use of electronic means to demonstrate compliance would help to reduce the administrative burden for businesses (**70.62%)**, reduce administrative costs of enforcement for authorities (**65.14%**), provide/allow information to be obtained faster (**82.29%**), and provide more and up-to-date information to consumers/end users (**68.00%**)**.**

2.4.4 Cross-border market surveillance within the EU

This section of the questionnaire was optional, so the average ratio of replies came up to **80%** (approximately **190** replies per question).

Most of the respondents (**91**) were unable to estimate the approximate proportion of products placed on the market by manufacturers or EU importers located in another EU Member State.

Public authorities believe that businesses contacted do not reply to requests for information/documentation or for corrective actions, while for **businesses** the main difficulty is that authorities find it more costly to contact businesses located in another EU Member State.

Concerning, the exchange of communication between national authorities in the EU Member States, the majority of respondents stated lack of opinion / experience (**33%**) while **25%** of the respondents consider that national authorities rarely restrict the marketing of a product following exchange of information about measures adopted by another authority in the EU against the same product.

Additionally, as to the adequate mechanisms to increase the effectiveness of the market surveillance in the Single Market, the results showed an extremely large support **for more exchange of information and discussion among authorities**, but also for **close coordination between Member States and simultaneous applicability of decisions against non-compliant products.**

2.4.5 Market surveillance of products imported from non-EU countries

This section of the questionnaire was optional, so the average ratio of replies came up to **84%** (approximately **201** replies per question).

Many respondents (**39%**) were unable to estimate the approximate proportion of products imported from non-EU countries in their sector. However, **21%** of them indicated that the proportion of products imported from non-EU countries is **more than 50%.** At the same time, **88%** of the respondents believe that the products in their sector imported from non-EU countries are affected by non-compliance.

As to the country of origin of often non-compliant imported products, China lead with **137** replies, followed by India (**30**), Turkey and United States (**18**) and Hong Kong (**17**). Finally, the most preferred options in taking actions against non-compliant products traded by businesses located in a non-EU country were the need for more coordination of controls of products entering the EU between customs and market surveillance authorities (**88.27%).**

2.5 Targeted Consultation conducted by the Contractor

In general, **all stakeholders consulted** through the targeted surveys and interviews **uniformly recognise the effectiveness of the Regulation needs to be improved**.[1] Around half respondents declare that the **dimension of product non-compliance** has not changed after the entry into force of the Regulation. While this is true for public authorities, respondents from the private sector perceive that product non-compliance has increased. Most economic operators, industry associations and civil society representatives state to experience discrepancies across Member States in terms of market surveillance. Such discrepancies have more negative impacts in terms of hindering the **free circulation of goods**, influencing **market behaviour, reducing the safety of products** and **raising costs** for public authorities and economic operators to comply with the Regulation. Among all respondents, only customs have a positive opinion on the **adequacy of current border controls**. In general, **industry representatives want to be more involved** in market surveillance activities. According to respondents, the **efficiency** of the Regulation could be improved by solving the existing discrepancies in its implementation.

The majority of respondents **confirm the Regulation's relevance**, this being confirmed by all economic operators and a large part of customs and coordinating authorities. However, the Regulation's relevance can be challenged by its low capacity to **address emerging issues.** All stakeholders agree that the Regulation is not able to tackle issues deriving from **online sales**. **No stakeholder category reported major issues in term of coherence** of the Regulation, both within its provisions and with other legislations relevant for market surveillance.

All stakeholders recognise the EU added value of the Regulation, which enhanced the **free movement** of goods and **legislative transparency**. The **harmonisation of rules** and **cooperation between Member States** are also reported as benefits by all. Different categories also argued that the Regulation can establish **a level playing field across businesses in the EU**.

2.6 Informal consultation of SMEs at the Small Business Act follow-up meeting with stakeholders in December 2016

The Commission presented the reflections on the possible options to address the problem of non-compliance and asked for feedback. Businesses representatives confirmed that SMEs are also hit by non-compliance like bigger companies.

3. FEEDBACK TO STAKEHOLDERS

The consultation processes provided a wide range of views regarding the functioning of market surveillance in terms of what has worked well and what has not worked so well, seen through the eyes of these stakeholders. The meetings with the stakeholders provided an early opportunity to promote the engagement of the national authorities, thus enhancing the chances of a good response rate.

The general objective of this initiative is to reduce the number of non-compliant products in the Single Market by improving at the same time incentives to comply and effectiveness of market surveillance..

[1] All questions of the Public Consultation were basically related to evaluating the effectiveness of the Regulation.

The considered options covered in order of increasing ambition and EU coordination and action: (1) Baseline, (2) Improvement of existing tools and cooperation mechanisms; (3) in addition increased deterrence effect to enforcement tools and stepped up EU coordination and (4) further added-on centralised EU level enforcement in certain cases.

The preferred option (3) includes:

- the extension of Product Contact Points advice role to businesses and ad-hoc public-private partnerships;
- digital systems through which manufacturers or importers would make compliance information available to both consumers and market surveillance authorities and common European portal for voluntary measures;
- regime of publicity for decisions to restrict the marketing of products, fine-tuning authorities powers notably in relation to on-line sales imports from third countries, recovery of costs of controls for products found to be non-compliant;
- stricter obligations for mutual assistance and legal presumption that products found to be noncompliant in Member State A are also non-compliant in Member State B;
- Member States' enforcement strategies setting out national control activities and capacity building needs and an EU Product Compliance Network providing an administrative support structure to peer review Member States' performance coordinate and help implementing joint enforcement activities of Member States.

The measures underlying the preferred option were rated highly favourable across the different categories of respondents in the public consultation. Stakeholders concur on the need for much stronger coordination, more resources and efficient use of resources for market surveillance and more effective tools to improve the enforcement framework for controls within the Single Market and on imports into the EU. A more pro-active approach to prevent non-compliance by providing information and assistance to economic operators is also supported by stakeholders. On a more detailed level some variations occur between the views of authorities and businesses on the most appropriate form of the digital compliance system or the specific powers and sanctions; these concerns have been integrated in the assessment.

More information on the different options, on those retained and on the views of the stakeholders can be found in Sections 6 and 7 of the Impact Assessment.

4. FEEDBACK FROM THE EXPERT GROUP ON THE INTERNAL MARKET FOR PRODUCTS – MARKET SURVEILLANCE AND CONFORMITY ASSESSMENT POLICY (IMP-MSG) – 1 FEBRUARY 2016

4.1 Difficulties and challenges for market surveillance for non-food products in the Single Market

4.1.1 Contributions sent to the Commission in accordance with Article 18(6) of Regulation (EC) No 765/2008

Article 18(6) of Regulation (EC) No 765/2008 requires Member States to periodically review and assess the functioning of their market surveillance activities. Such reviews are to be carried out at least every four years and the results are to be communicated to the other Member States and the Commission and made available to the public.

Many of the national reports reviewing market surveillance activities carried out between 2010 and 2013 comment on major difficulties identified. Common challenges mentioned appear to be the following:

1. Lack of sufficient resources for market surveillance.

2. Current control procedures are not suitable for handling products sold online. Moreover, for effective market surveillance of products sold on the internet and that are offered from outside the EU, collaboration with customs authorities is of crucial importance.

3. There is a need to reinforce customs controls. Furthermore, to make it harder for non-European manufacturers, whose non-compliant products have been rejected by a customs authority, to switch to other customs clearance locations, improved cooperation between the customs authorities of the EU Member States also seems necessary. For some Member States there exists a mismatch between the customs product classification and the nomenclature used by market surveillance authorities, which hamper cooperation in some areas (e.g. electrical low voltage equipment, personal protective equipment, pressure equipment, equipment for use in potentially explosive atmospheres, lifts and machinery).

4. There is insufficient cross-border cooperation in some sectors (i.e. equipment for use in potentially explosive atmospheres, pyrotechnic articles, civil explosives and gas appliances), which is difficult to tackle when relevant economic operators are located abroad. Complications due to the lack of ADCOs for marine equipment and motor vehicles are also mentioned.

5. There is a lack of traceability of information especially when products are imported into the EU by intermediaries located in other Member States

6. There is the difficulty of dealing with products from third countries sold via informal channels (marketplaces), and the ineffectiveness of market surveillance techniques in this case.

7. Penalties laid down in national law might not be a sufficient deterrent, in particular in the case of larger companies trying to market non-compliant products;

8. The non-existence of test laboratories makes conformity assessment difficult and costly.

9. There is a lack of knowledge amongst economic operators about applicable product rules. In some sectors formal requirements such as technical documentation and CE marking are disregarded by businesses, possibly due to lack of knowledge or misunderstanding of those requirements.

10. There is a lack of cooperation by certain economic operators and some abuses by businesses of the legal principles concerning the notification of restrictive measures contained in Article 21 (1) and (2) of Regulation (EC) 765/2008.

11. There is the need to reduce the administrative burden for market surveillance authorities (i.e. simplify current safeguard clause procedures for serious risk products by using the Rapex system). Furthermore, there is a demand for a single integrated system since reporting in different information exchange systems is deemed cumbersome and not always suitable.

4.1.2 Future new actions to improve market surveillance – initial suggestions by Member States

At the joint IMP-MSG and CSN meeting on 30 January 2015 the Commission asked Member States representatives to come up with informal suggestions about possible future new actions to improve market surveillance. A Member State suggested that a possible way to increase the availability of resources for market surveillance would be to ensure EU-wide agreements (financed by EU funds), with laboratories having recognised competence in a given domain to which national authorities could send on a pro-rata basis products to be tested.

The question about possible new actions to improve market surveillance was also asked at the meeting of ADCO Chairs that took place on 12 March 2015. Some of the suggested new actions informally proposed during that meeting were the following:

1. Workshops with other ADCO Groups

2. Cooperation between inspectors checking products during use and market surveillance

3. Cooperation with producer countries, especially China

4. Supervision of notified bodies and collaboration with market surveillance authorities

5. More documents to be shared through CIRCA BC

6. Joint actions between directives

7. Feedback on safeguard notifications from the Commission

8. Shorter dates between publication of legislation and guidance

9. Exchange between inspectors across Member States

10. Easier contacts with economic operators abroad

11. Team building, networking, exchange of experience

12. More information on what is happening in other fields

13. Review of notified bodies' certificates

14. Exchange of ADCO members

15. Convergence of ICSMS and RAPEX platforms

16. E-commerce: administrative requirements for information to be displayed on websites, legal powers for authorities to carry out test purchases, campaign aimed at consumers

17. More responsibilities for importers

18. More resources

19. Applicability across the EU of sale bans issued by national authorities.

4.2 Questions to the Members of the IMP-MSG Group and overview of replies

On 2 December 2015, the members of the IMP-MSG group were invited to provide input on the following questions:

(1) Do you share the analysis of the problem of non-compliant products in the internal market made by the Commission in the Single Market Strategy? Is there any other relevant problem to take into account?

(2) What action do you consider necessary to tackle those problems?

(3) What action is necessary to address the difficulties faced by national authorities that have emerged in the context of the national reviews according to Article 18(6) of Regulation (EC) 765/2008?

(4) What should be the main priorities when it comes to improving market surveillance and to generally reducing non-compliance in the internal market?

Thirteen Member States provided answers to the above questions.

As to question (1) most of these Member States share the analysis carried by the Commission. The following additional qualifications are noted:

A Member State also stresses the problems of (i) several pieces of legislation applicable to the same product which makes it more complex and difficult for both economic operators and authorities to maintain the overall picture, (ii) uneven quality and quantity of market surveillance activities in different Member States, which could be addressed by establishing common standards, (iii) limited availability of resources.

Another one notes that the problem of non-compliance is to be addressed to ensure a level playing field among economic operators, although accidents due to non-compliance are limited in number overall.

Furthermore, there is no solid proof that the number of non-compliant products is increasing, as statistics on market surveillance differ from statistics on non-compliance that could result from market research.

Similarly, two other Member States note that since market surveillance inspectors focus on areas where non-compliance is expected to be high, results of inspections are not representative of the level of non-compliance in general. Denmark stresses that it is not possible to measure the percentage of non-compliant products in the market.

Some questions exclusive focus on the non-compliance of products stating that market surveillance should also play a role to ensure that legitimate products do not face unfair barriers to trade.

Finally, another Member State would have appreciated a deeper analysis of if, when and in what ways the impact of varying degrees of market surveillance (or the lack of it) harm consumers, compliant competitors, and Member States as a whole (loss of manufacturing, reduced competitiveness, etc.). Such an analysis could indeed give valuable input regarding when and where a lack of enforcement has the least impact on the different interests that a product rule is designed to protect, which in turn could be used in subsequent Refit procedures with a view to reducing the administrative burden.

The suggestions made by the Member States who responded to questions (2) to (4) have been grouped as far as possible by topics as follows:

4.2.1 Information to economic operators

The **lack of knowledge of product rules on the part of economic operators** is one of the main problems that should be addressed.

Informing the national economic operators – who are sometimes not aware of their responsibilities - about specific legislation and their obligations, is a main priority.

Economic operators probably disregard the rules mainly because of a lack of knowledge, or because they lack the resources to follow up the complicated rules on their own (SMEs).

There is a need to intensify efforts to provide early information to economic operators, especially small and medium-sized enterprises, on existing and future product legal requirements but also to raise awareness amongst economic operators via better channels of communication.

It is also suggested **developing rules and best practices** concerning products to be disseminated via internet and improving information on European regulations on the **websites of the Commission** to make it more educational and useful for economic operators (input by product type, not directive).

If the problem which has been identified is referring to economic operators “in general” the solution has to be Commission-led. This might be done, for example, by revisiting the guidance and how it is made available to them, making changes where appropriate. However, if this refers to specific economic operators the approach also has to be specific, and it is more likely to fall to individual Market Surveillance Authorities and Member States to determine the action which should be taken.

In addition, the Commission does not have sufficient manpower to handle a **'first port of call'** to address businesses' questions on all areas of product legislation, which would **require a huge amount of work**. An **eLearning system** is proposed for raising awareness and

educating economic operators through graphic interfaces, and access to applicable standards and conformity assessment procedures, and a "10-20 questions card" for importers to ask when they buy goods overseas.

4.2.2 Simplification of product legislation; alignment between legal requirements and verification procedures by MSAs

Legislation should **set out economic operators' obligations more clearly** and it should be possible to make a clear distinction between basic non-compliance and more serious safety issues. Legislation needs to be simplified and updated.

As regards future legislation, there is a suggestion reflecting on how to **include** the necessary **new rules in existing legal acts** rather than developing new (unknown) specifications but also to better take into account the concerns of market surveillance authorities during the legislative process: the **feasibility of checking specific requirements** and the foreseeable costs of those requirements should be assessed in the development stages of legislation.

The **weakness of verification procedures** in some sectoral legislation is also pointed out. Even when a Member State performs verification tests, the results of these tests may turn out to be inconclusive, because of the unreliability of the results when the tests are replicated, and/or because of ambiguities in dealing with those results. A comprehensive “fitness check” on verification procedures based on established best practice would be useful. For example: a wet-grip-in-tyre labelling regulation where the test method seems to be unsuitable to providing sufficient accuracy (actually the 2sigma-interval of reproducibility uncertainty covers 3 grading classes). Technical requirements for verification of **big products** at the manufacturers site, for instance by means of witness-testing during factory acceptance tests, should also be definitively introduced.

4.2.3 Coordination of market surveillance at EU level

The need for closer cooperation and exchange of information is generally acknowledged. Specific proposals are made with respect to the use of current tools or to the need for additional forms of cooperation.

4.2.3.1 ICSMS and RAPEX

The importance of the development of the **ICSMS and RAPEX** systems for communication between all authorities involved in market surveillance (market surveillance authorities of all Member States, COM and, where appropriate, customs authorities) is stressed. ICSMS should be used consistently by Member States in all areas of legislation while interfaces with national systems should be provided. The creation of single system for exchange of information has also been requested but also the idea of fusion between ICSMS and RAPEX platforms to avoid the double encoding of data; however, this should take into account the fact that the RAPEX system has been used for a long time by all stakeholders.

The focus of the Commission’s wording on the Single Market Strategy is on working better together, with better sharing of information. In this regard Member States could make better and more consistent use of ICSMS; they recognise that this is a medium- to long-term issue, and one which might require funding/support from the Commission in order to make it work – in particular for those Member States who do not use the system.

There is a need for closer cooperation between surveillance authorities in Member States and between surveillance and custom authorities, and between surveillance authorities and notified bodies, and suggests it would be good to converge the ICSMS and RAPEX platforms, so that all information can be in one platform.

4.2.3.2 ADCOS and IMP-MSG groups

The role of **ADCOs** should be revisited and clarified (many discuss policy issues rather than focussing on issues related to technical cooperation, for example), and absences from meetings/participation should be marked. The Commission desk officers for the relevant directives should also take a stronger role in encouraging attendance/participation. Furthermore, the European Market Surveillance Forum, which was proposed in the "Regulation on Market Surveillance", would be a positive way of addressing this issue.

Member States welcome the proposal mentioned in section 3.2 above relating to workshops with other ADCOs. Similarly, a Member State suggests a better use of ADCOs to improve coordination, exploit synergies and avoid duplication. Furthermore, it suggests that the **IMP-group** should develop a shared understanding of the horizontal rules and promote more interaction between the market surveillance authorities of the Member States in the different fields of law by means of visits, joint actions, etc.

There is also a proposal devoting an extra IMP-MSG meeting to the exchange of best practice. ADCOs should contribute to the meeting by reporting on experience accumulated during their earlier joint action projects.

4.2.3.3 Cross-border cooperation

The need for consistent implementation of the **guidelines on cross-border–cooperation** is stressed, complemented if necessary by the set-up of additional legal arrangements. Furthermore, under the **safeguard clause procedure** all European market surveillance authorities must take, where necessary, measures to enforce requirements under European law. Furthermore, a Member State suggests that where a public authority prohibits the making available on the national market, this should **automatically apply in all MS,** with the ECJ possibly acting as appeal. Member States should reflect on the possibility of **specialising in specific fields**. In order to achieve an effective market surveillance system, the adaptation of **national legislation** to the EU legislation will be necessary in a number of areas (cross-border cooperation, mutual recognition of activities of the market surveillance authorities of other Member States - for example, recognition of test reports, etc.). The **organisation** of market surveillance **at national level** should be reconsidered in order to reduce the fragmentation of responsibilities.

There is also a need for **guidance on cross-border cooperation** to improve and optimize the results of authorities' actions. To achieve better results in trans-border cooperation between the Member States, in cases of non–compliant products a **contact points list for each product group** should be prepared which could provide fast and easily accessible communication.

A **mandatory harmonized procedure for MSA cooperation** will facilitate cases of cross-border cooperation and will further harmonize existing market surveillance approaches. The administrative burden for MSAs of this procedure should nevertheless be as minimal as possible.

Prior to setting additional requirements for mutual change of information, the Commission should ensure that all Member States **actively use the present procedures** and notes that for example EMC and LVD notifications are made by only a few States.

It would be useful for Member States to receive **more feedback on safeguard notifications**. In general, more cooperation and exchange of information is needed at EU and **national level**.

'Language borders' are considered as the main obstacle to day-to-day cooperation among authorities.

4.2.4 Harmonisation of market surveillance practice across Member States

There is a suggestion developing **common European standards on the quality and quantity** of their market surveillance activities.

The development and publication of **guidelines and best practices** on market surveillance in general is welcomed as a means to achieve the consolidation of the procedures of the EU market surveillance authorities in many problematic areas.

Publication of guidance documents would considerably help the harmonization of market surveillance in Europe as they would help inspectors and economic operators to interpret and correctly apply the directives and regulations. Shorter dates for the publication of guidance documents are required.

In addition, it is proposed to encourage via EU funding the **participation of** more **Member States in common projects** in which different products can be tested in order to achieve more representative results, and the dissemination of all information, analysis, results and decisions taken for this specific product group after a project is completed.

According to feedback from domestic surveillance authorities having taken part in international cooperation projects, they have provided a good overview of the practices of other countries and have contributed to carrying out uniform surveillance in different Member States.

The problem of limited human resources and **training opportunities** has been pointed out **and** a suggestion was made to promote the **exchange of inspectors** across Member States and closer cooperation among surveillance authorities to improve knowledge and exchange experiences.

Training programmes and exchange of experience between Member States' inspectors are also proposed.

The exchange of experience and best practices between inspectors across the Members States is very important to improve the harmonization of market surveillance in Europe. Regular exchanges of officials could be a solution.

Similarly, exchange of inspectors, teambuilding and networking are endorsed by other Member States.

Moreover, the **Product Safety & Market Surveillance Package** has to be finalized, since it will enable better coherence of the rules regulating consumer products and will improve

coordination of the way authorities check products and enforce product safety rules across the European Union.

The current delay with revision of the Market Surveillance Regulation is considered to be problematical, and stresses the importance of a **horizontal legislative framework on market surveillance**.

The Commission should provide more information on what **instruments are available to the authorities** and how they are used in practice (frequency, criteria for deciding what tools to use in different cases), so that the barriers for putting non-compliant products on the market might be the same for all Member States.

4.2.5 Better control of products imported from third countries

There is a need to strengthen border controls, where the goods are centralised before being dispatched throughout the EU. This could be achieved either by **reinforcing the role of customs** or by ensuring detailed cooperation with market surveillance authorities.

More effective cooperation between market surveillance and customs authorities should also be achieved via a **clearer definition/better alignment of the tasks performed by the customs authorities** in order to ensure compliance with the European product rules. The need for **improved communication** between the customs and market surveillance authorities is also stressed.

Controls would improve if there was **better communication between authorities**. This might potentially be done through an electronic forum which authorities could use to discuss and agree issues which arise on products, and better guidance on the application of the directives concerned and the procedures which need to be followed.

Both the importance of cooperation between customs and market surveillance authorities and the importance of **cooperation among customs** on market surveillance matters are mentioned.

Customs should be enabled to request **manufacturer and type designation as part of the customs declaration**. Furthermore, combined nomenclature (**CN**) **codes** must be amended to be also useful for market surveillance purposes.

There is a need to improve border control of non–compliant products and to ensure **regular exchange of information** on results of controls and lists of products not released for free circulation.

Another problem is that, while many products come from outside the EU, authorities can do little against those manufacturers. Products are often placed on the EU market through "once only importers" that disappear after one or two years, so even there we can do little. **Strong measures against** these **products** are needed **to target the non EU economic operator**. For example, a strong message could be sent when all products need to be recalled if there is no technical file present.

A Member State supports the **strengthening of responsibilities of importers**, especially when the manufacturer is outside the EU. For the supervisory authorities it is especially helpful to have a partner in the EU, which has full responsibility and all the technical

documentation. According to France this could possibly be done by creating a concept of "first placer on the market", which would need to be an economic operator on the EU territory (manufacturer, agent or importer if the manufacturer outside the EU).

Improving the opportunities for the European market surveillance authorities to impose **penalties on operators in third countries** by means of agreements between the EU and third countries was also pointed out. It was also proposed to have a sustainable **education** strategy on the existing European rules in third countries that export mainly to Europe but also some **guidelines** on how to deal with different types of non-conformity (e.g. should a product be rejected at the border if there are shortcomings in labelling?). Measures must be proportionate and consistent across the EU.

4.2.6 Better control of Internet commerce

E-commerce is a great challenge because it's very difficult to trace products which are imported from non-EU countries, and to get the required information from the economic operators who are responsible for the product. A solution would be to improve **market surveillance organisation and strategies** with respect to internet commerce, as well as **broadening the concept of economic operators**.

There is an agreement on the need to incorporate Fulfilment Houses into new legislation (in particular, this might be achieved by including it in a revised Regulation on Market Surveillance), but also the need for **clarity on market surveillance tools** to be used for products bought online, either through guidance documents or legislative action.

The biggest future challenge in e-commerce is the changeover from imports of big consignments (containers with a number of the same products) sent to a distributer vs. a **high number of small consignments** consisting of only one product sent directly to the end user. In such a scenario, market surveillance authorities can only learn of a case when they are involved by customs.

Stronger border controls are also an important factor in terms of control procedures of products sold online. It is also necessary to improve the way authorities **communicate market surveillance work electronically**.

A Member State stresses the need for **authorities' powers to purchase goods** to be tested and to increase the budget for purchase and test of products found **online**. It also notes that MSAs face similar problems to those presented by Internet sales in cases of sales via catalogues (for example for construction products).

As to the products purchased through e-commerce platforms, the need to **develop a method** covering both border control, testing and cross-border communication between market surveillance and customs authorities is noted.

The Commission should capitalise on the opportunity presented by the **revision of the E-commerce Directive** and submit to the competent service the feedback from ADCOs on the needs of market surveillance over the internet.

4.2.7 More and/or better use of resources; tools to support market surveillance authorities

Lack of resources has prevented some authorities from carrying out sufficient market surveillance in some specific sectors. Often, resources are just enough to cover one part of the total market surveillance activities as initially foreseen, so some specific sectors are neglected.

In the current climate it is unrealistic to expect Member States to attribute more funding to market surveillance and that the emphasis should be on how to **use the existing allocation of resource more effectively**, and to consider better and more effective ways to improve market surveillance. The Primary Authority system is considered as a good example of a model which the Commission and other Member States might wish to adopt more broadly.

The problem of limited resources can only be tackled by **streamlining the whole market surveillance process,** from planning to sanction the use of the latest technologies. The following specific suggestions are put forward:

Carry out studies on the inherent risk of the different product categories under the different directives; as an example, see the preliminary study for the next Ecodesign working plan.

Collect information on the number of product categories on the European market: this is one of the crucial factors in determining the "adequate scale of the checks" stipulated in Art. 19 (1) of Reg. 765.

Consider mandatory registration in a product database, as is done partially under the RED, and is envisaged for energy labelling and adaptation of existing registration obligations (WEEE directive) to make them suitable for market surveillance planning.

Facilitate checks at the border by including information on the manufacturer in customs declarations, and amending CN (Combined Nomenclature) to make it useful for market surveillance purposes.

Facilitate documentary checks via a digital compliance system (see below) and by including compulsory photos in the DoC to enable a positive identification of products, EAN (Bar)-Codes and CN-Codes.

Future standardisation mandates, including affordable preliminary testing: only products exceeding the preliminary limits would deserve full testing.

Simplification of reporting duties by providing an integrated IT solution from planning to documentary checks to product identification and reporting.

Market surveillance should be risk-based and should **focus on the minority of non-compliant products that pose a high risk** to persons, livestock and property, while other non-conformities should be addressed by means of education of businesses (see proposals under section4.1 above).

The **lack of notified bodies and testing laboratories** in many technical areas is stressed, which makes testing of products expensive. This lack of laboratories might be a problem **in some sectors**, however **not in all**.

For market surveillance authorities without their own laboratories, budget and administration of external testing costs are a major issue limiting the effectiveness of their surveillance.

Thus, programs **facilitating sufficient laboratory capacity** would be necessary. **EU-wide agreements with laboratories**, to which market surveillance authorities could send products to be tested on a pro-rata basis, would be a perfect solution.

This option of EU-wide agreements with laboratories is also proposed by another Member State, while another one suggests EU **financial support** from the Commission **for laboratory tests** (rather than for 'joint actions', which imply prohibitive administrative costs for MSAs).

On the other hand, the availability of laboratories is not considered as an issue by other Member States, since they believe they have excellent access to a number of test laboratories (test houses) which are also available for other Member States to use. It is not necessary or proportionate to introduce this at a supranational level.

A Member State also stresses the need for: (i) an on-line database where the national market surveillance authorities would be able to download the **harmonised standards**; (ii) **the c**reation of a **rapid advice forum** at EU level; (iii) **legal assistance** from the Commission.

The simplification of the work of national authorities by means of an **easier administration of joint actions** and an integrated reporting system is suggested.

A very serious reshaping by the Commission of the internal approval procedure for joint actions is needed.

Finally, the need for adequate and **reliable 'facts and figures' on products, volumes and economic operators** is stressed as a necessary basis for developing and improving a risk-based approach. This kind of information is also considered useful in showing the importance of market surveillance.

4.2.8 Stronger measures against economic operators; Penalties

There is a need to take **stricter measures against economic operators** and to apply sanctions against economic operators located in third countries.

The **harmonisation of the levels of penalties** has been considered by one Member State, while keeping the possibility to adapt them on a case by case basis.

However, another Member State considers that penalties must remain the **responsibility of Member States** – it is for the Member State to determine what is effective, proportionate and deterrent. It is therefore also for the **Member State to revise its legislation** if it does not provide a sufficient deterrent.

For SMEs especially, limited financial leeway implies **limited ability to react to more deterrence**.

4.2.9 Digital compliance

There should be a **greater emphasis on e-commerce and e-compliance** as there are many more opportunities to take advantage of new and developing technology and make market surveillance more effective (e.g. using e-labelling whereby relevant information is provided online at the point of purchase).

Studying the impact of a possible e-compliance system, which could be useful for strengthening border controls, is supported: the system could be tried for products manufactured outside the EU, for which the technical documentation is more complicated to obtain.

The need for a database where manufacturers upload their declarations of conformity, technical documentation and instructions for **easy reference by market surveillance authorities** is stressed. This database would facilitate data collection of checked products but also provide an excellent basis for information on new and revised products on the market.

By contrast, other Member States **strongly disagree with the suggestion of** developing **a digital compliance system**. Some of the reasons reported are:

- The main problem for market surveillance authorities is not access to documentation but the fact that the documentation received does not always correspond to the actual product. The problem of falsified certificates etc. will not be solved by a digital system.

- The authorities cannot trust the data in the system, because they are supplied by those they are supposed to check.

- While a voluntary system would provide no added value, a mandatory system would create unjustified administrative burdens for economic operators as well as for market surveillance authorities. Compliant economic operators are already put at a competitive disadvantage vis-à-vis rogue traders, who will either report nothing or report false information to the system. Businesses in third countries would more easily escape the application of a mandatory system.

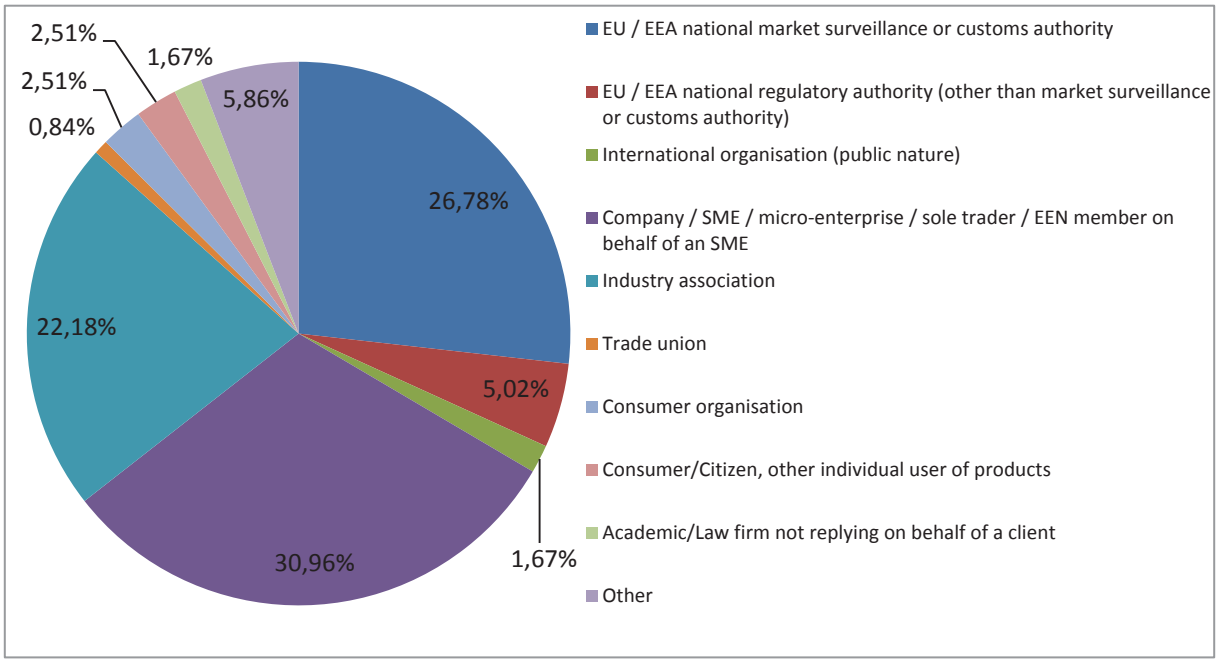
- It could lead to a practice where authorities allow undue time and resources to checking documentation in the database instead of focusing on the actual compliance of products. There is a fear that the emphasis will shift from checking products to checking the data entered in the system, without consideration of the reality of the market.

- There are many questions regarding the confidentiality of data in such a system.

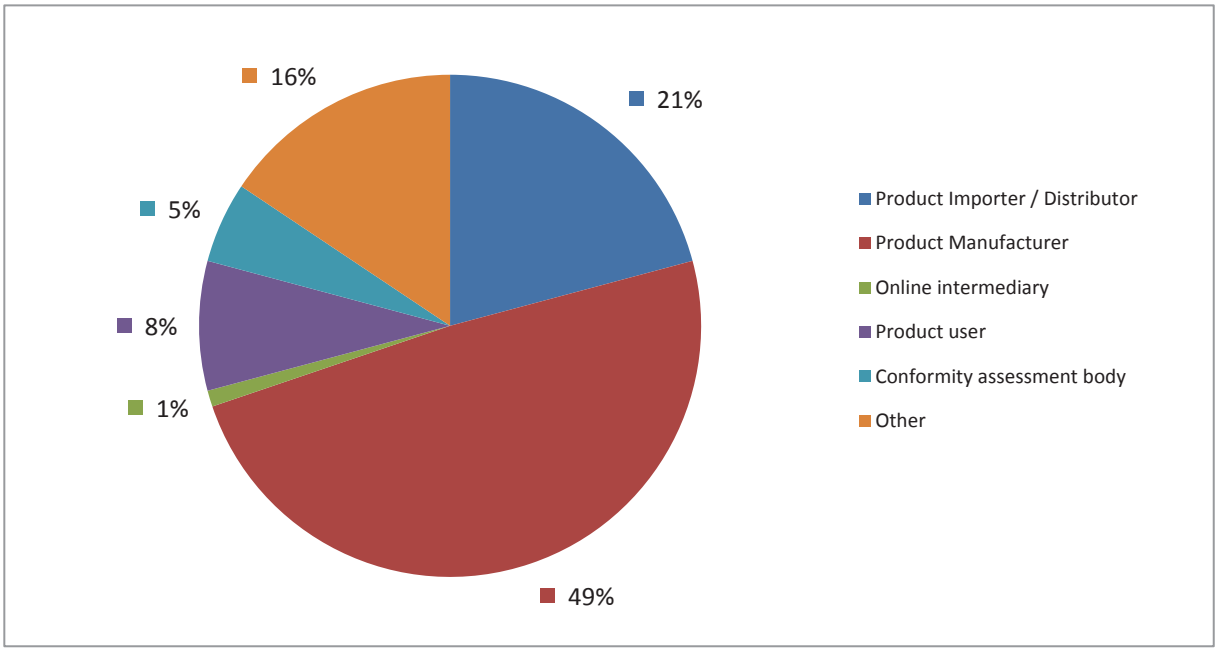
5. DETAILED STATISTICS FROM THE PUBLIC CONSULTATION

A. About you

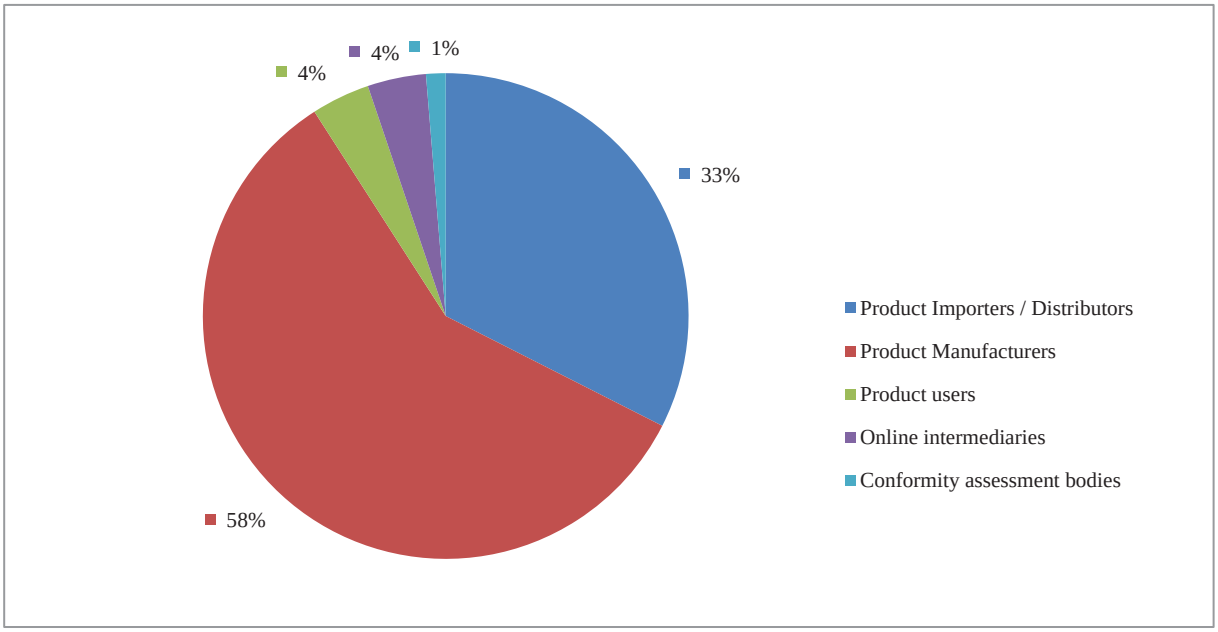
1. Are you replying as:



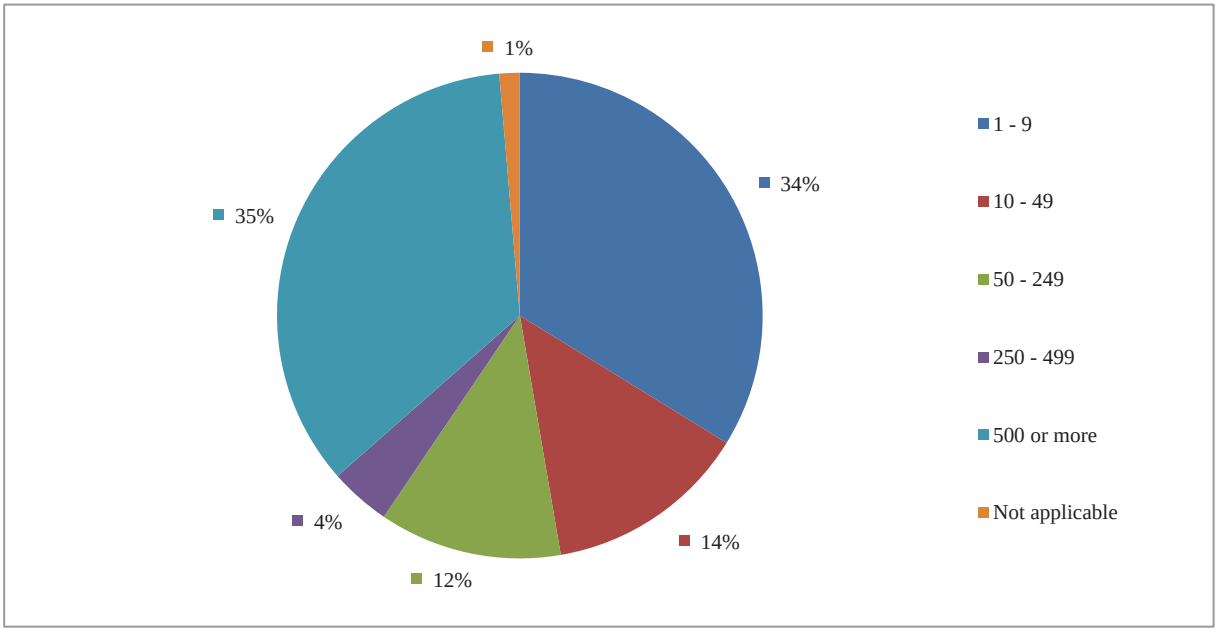
If company/SME/micro-enterprise/sole trader, you are:



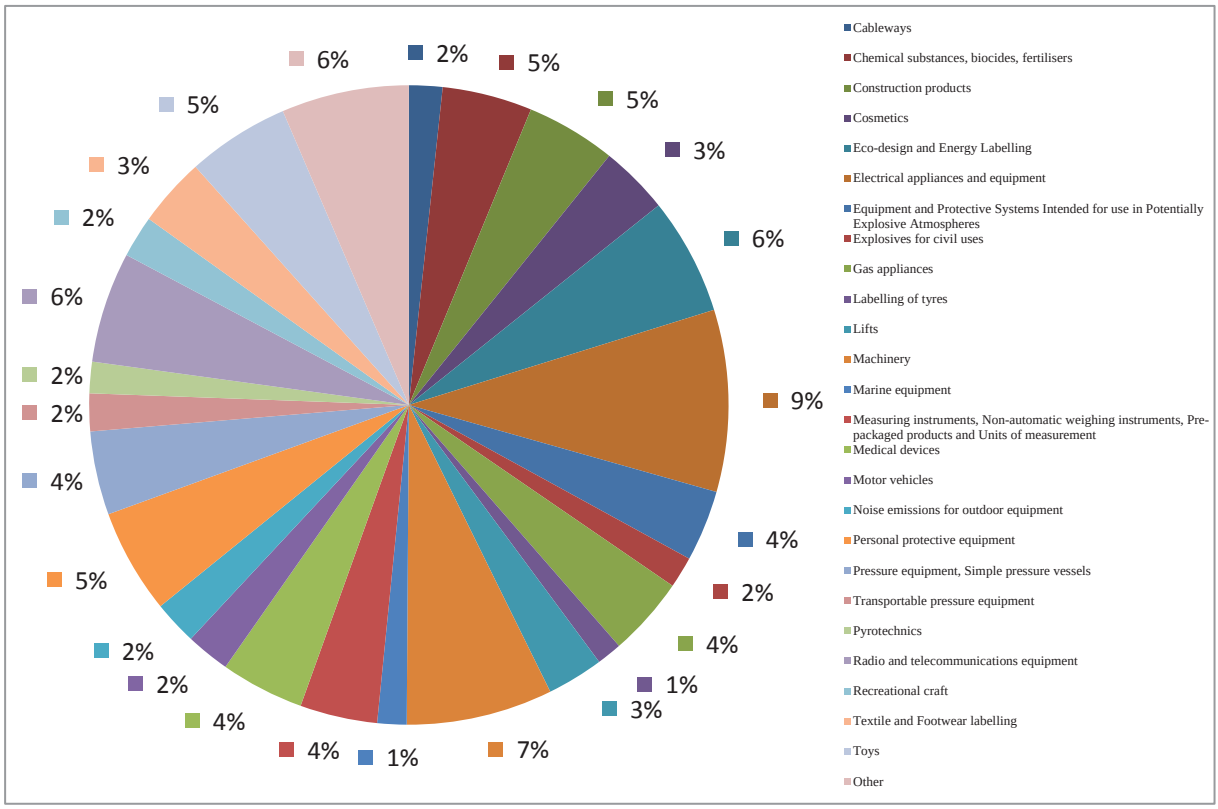
If industry association, you are representing:



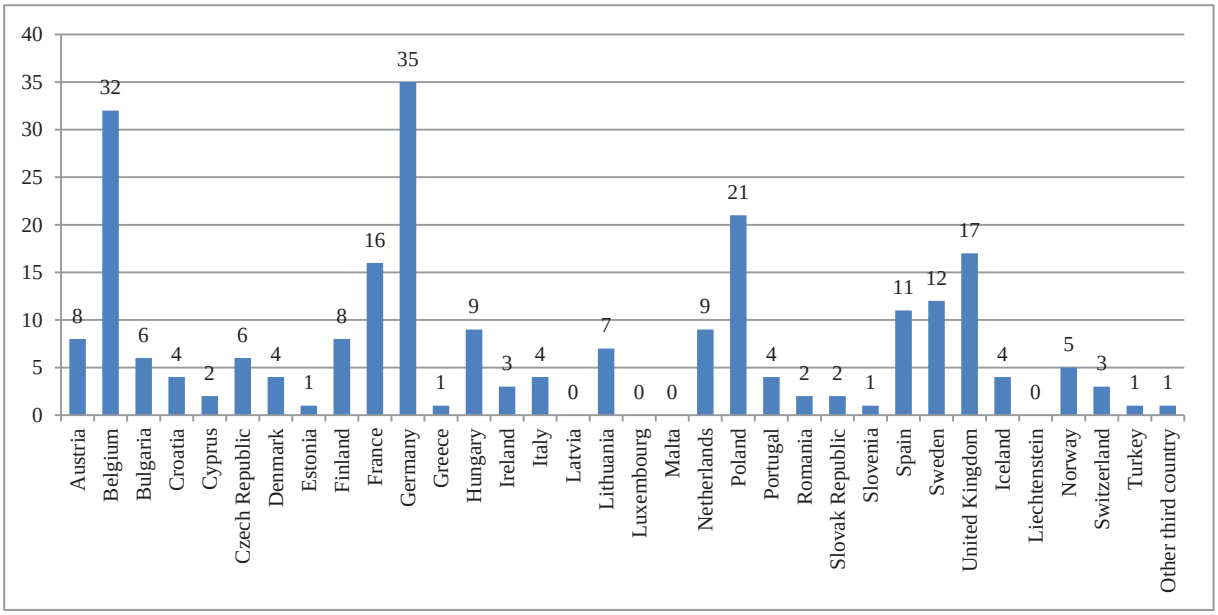
How many employees does your organisation have?



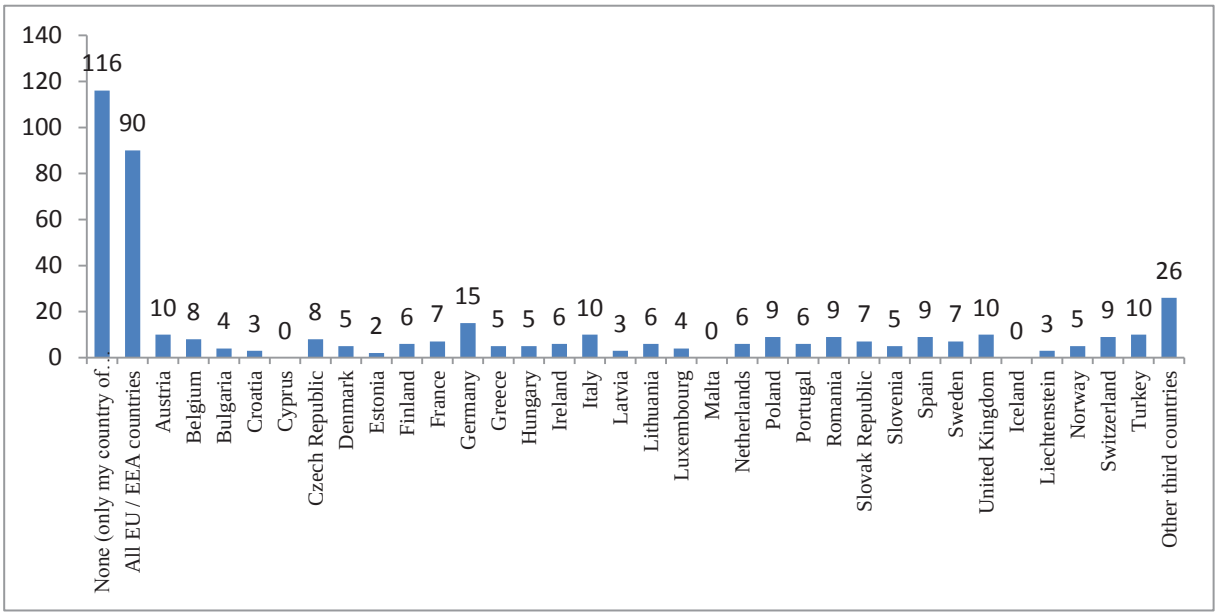
2. Which product sectors do you deal with? (multiple choice possible)



3. Where are you based?

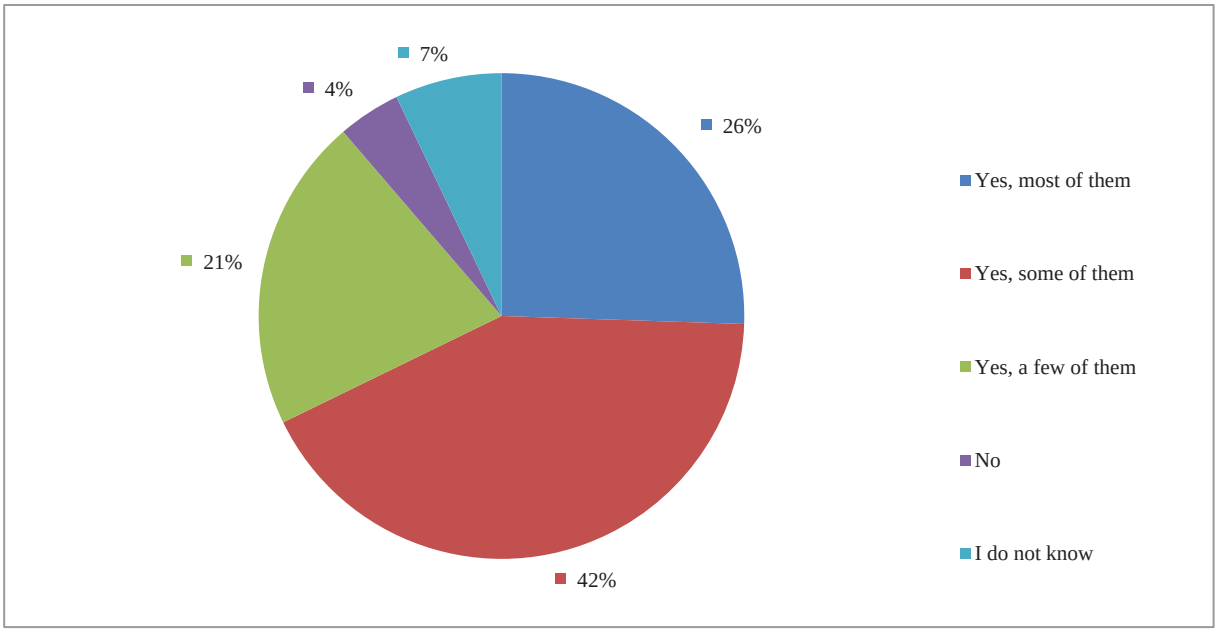


4. In which countries, other than the country of your primary establishment, are you active?

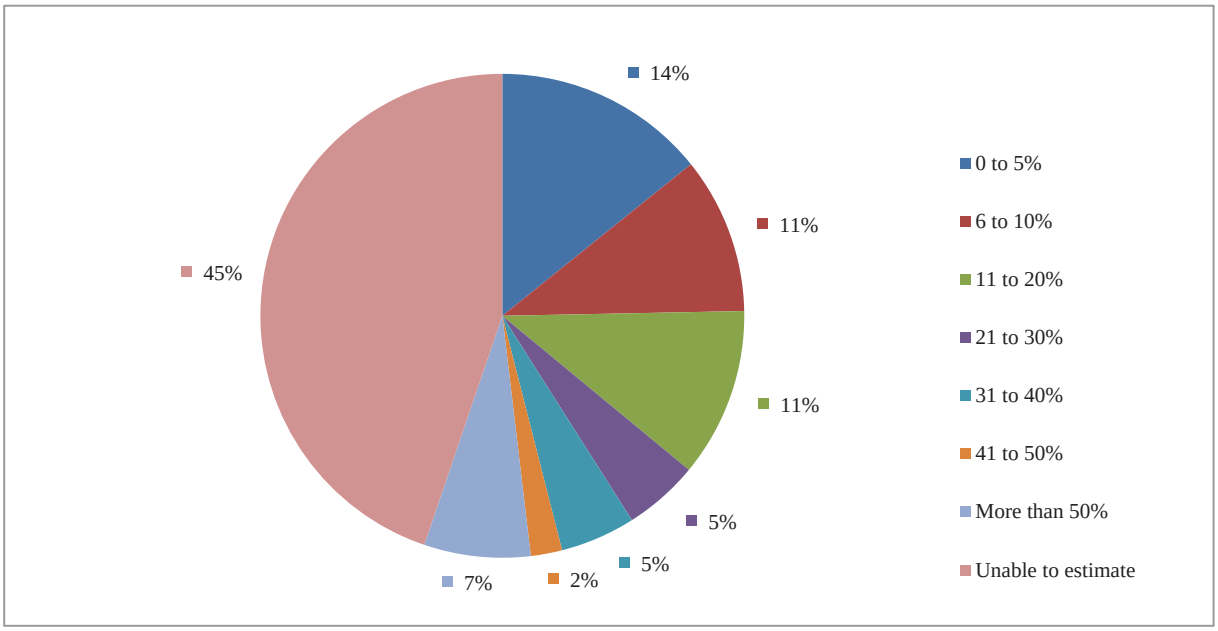


B1. Product compliance in the Single Market and Deterrence of existing enforcement mechanisms

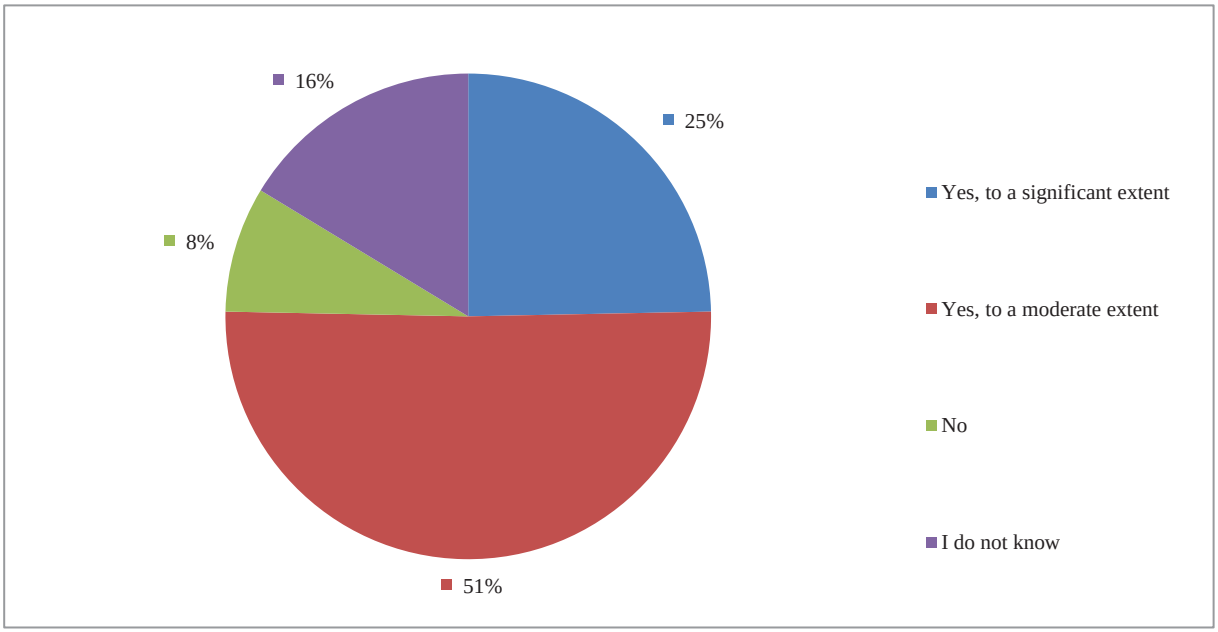
1. Are the products in your sector(s) affected by non-compliance with product requirements laid down in EU harmonisation legislation?



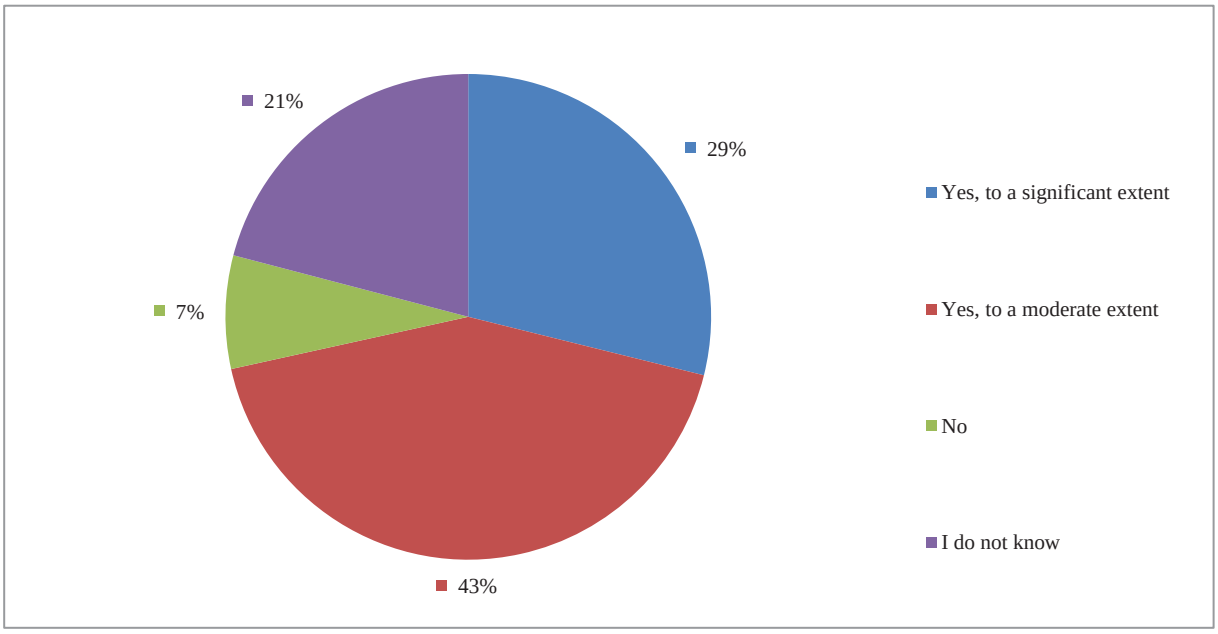
2. What is the approximate proportion of non-compliant products for your sector (product volumes)?



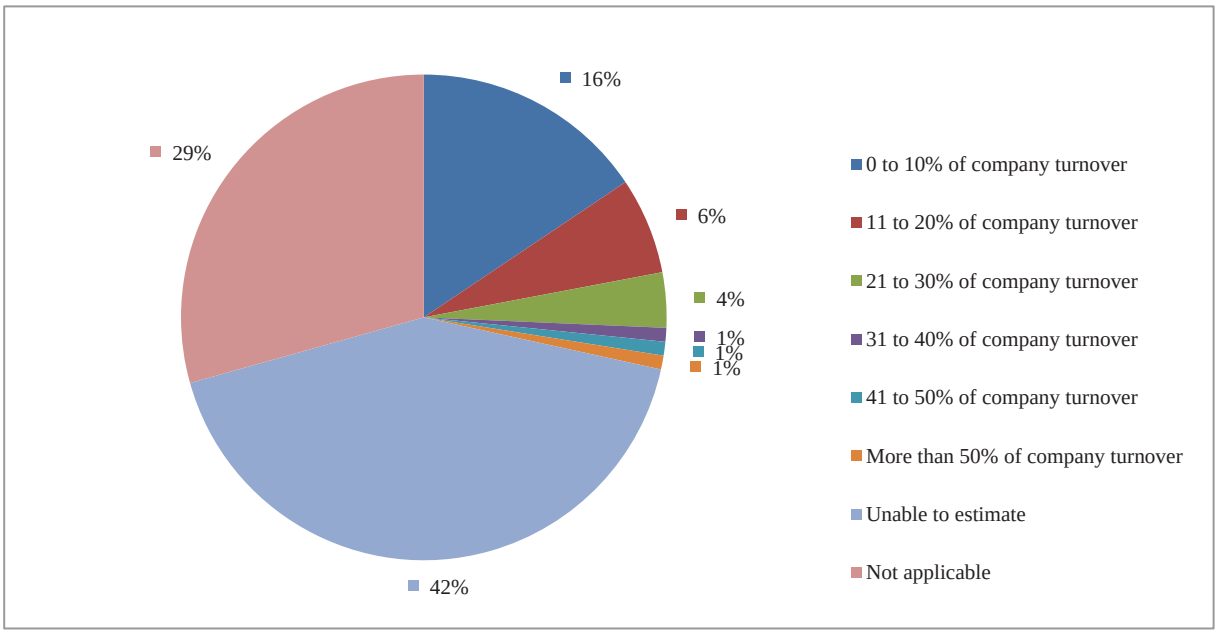
3. Does the problem of non-compliance negatively affect consumers and other end-users in your sector?



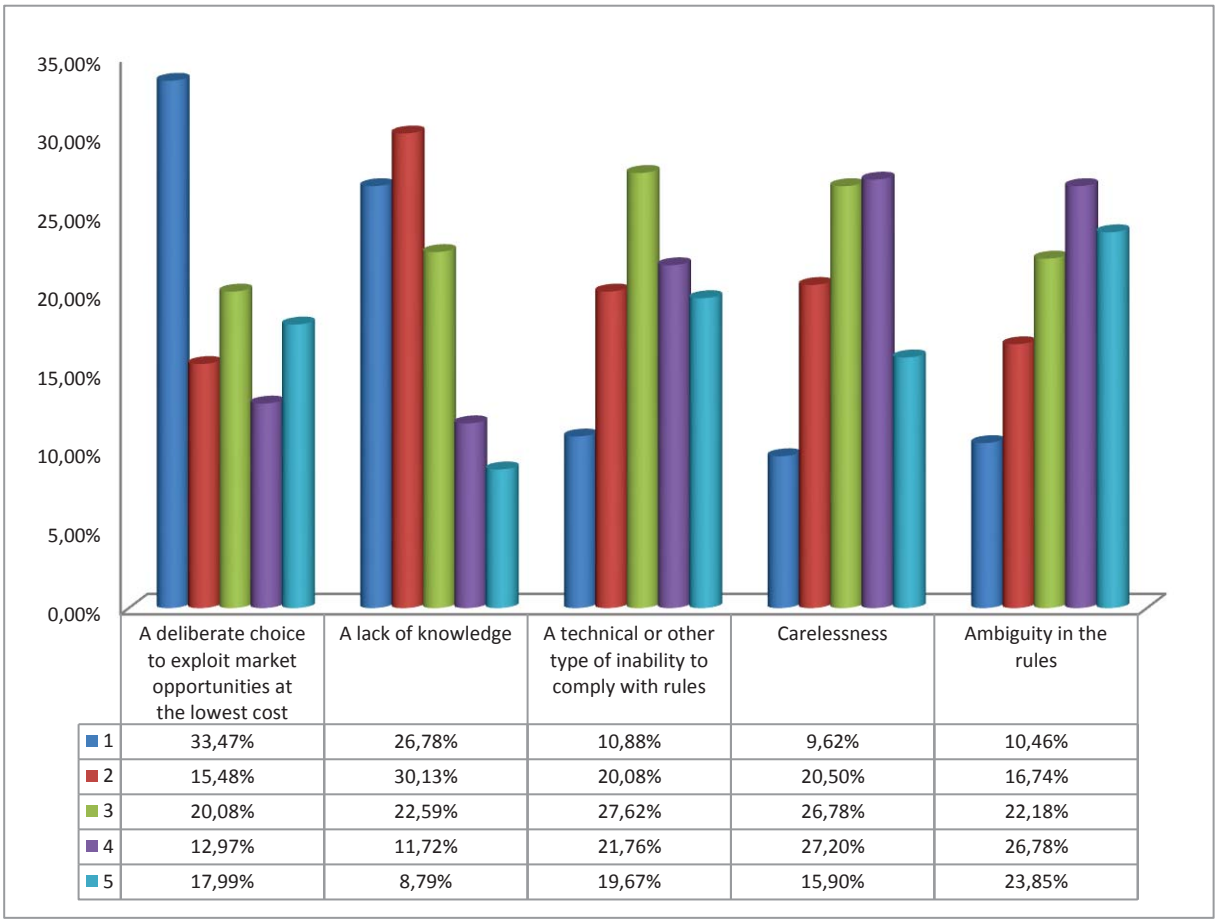
4. Do businesses complying with legal obligations experience negative effects on sales and/or market shares due to the presence of non-compliant products?



5. [Question for businesses only:] What is the approximate loss in sales for your company due to competition from non-compliant products?

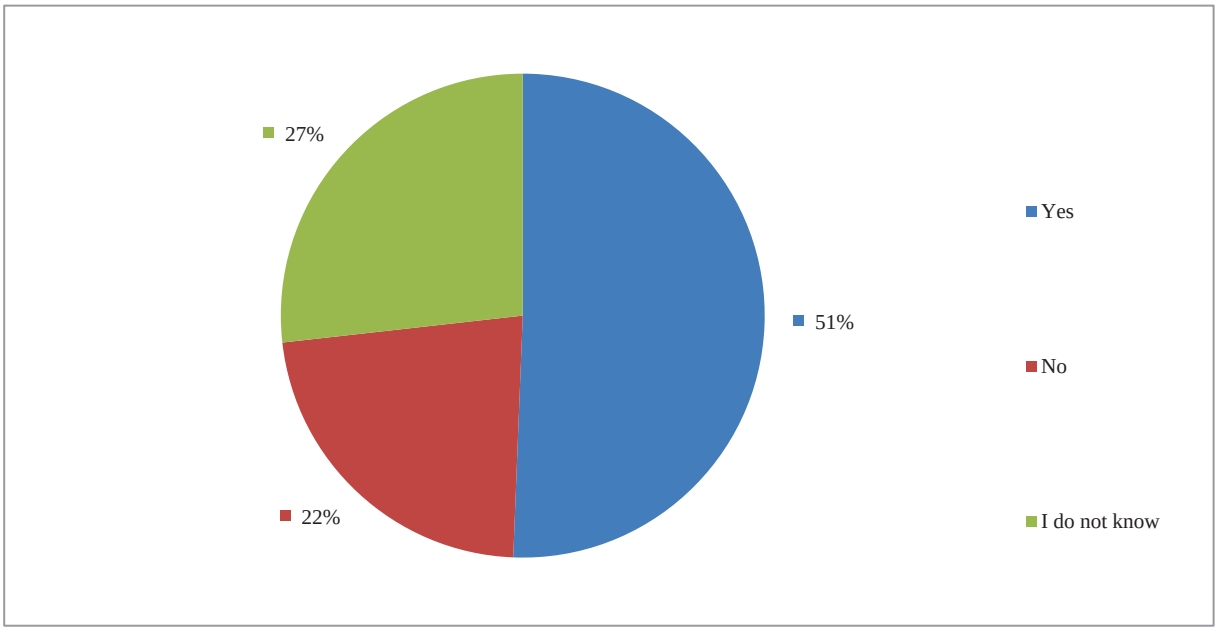


6. What is the main reason for product non-compliance in the Single Market? (Please rank from 1 to 5, 1 being the most important reason):

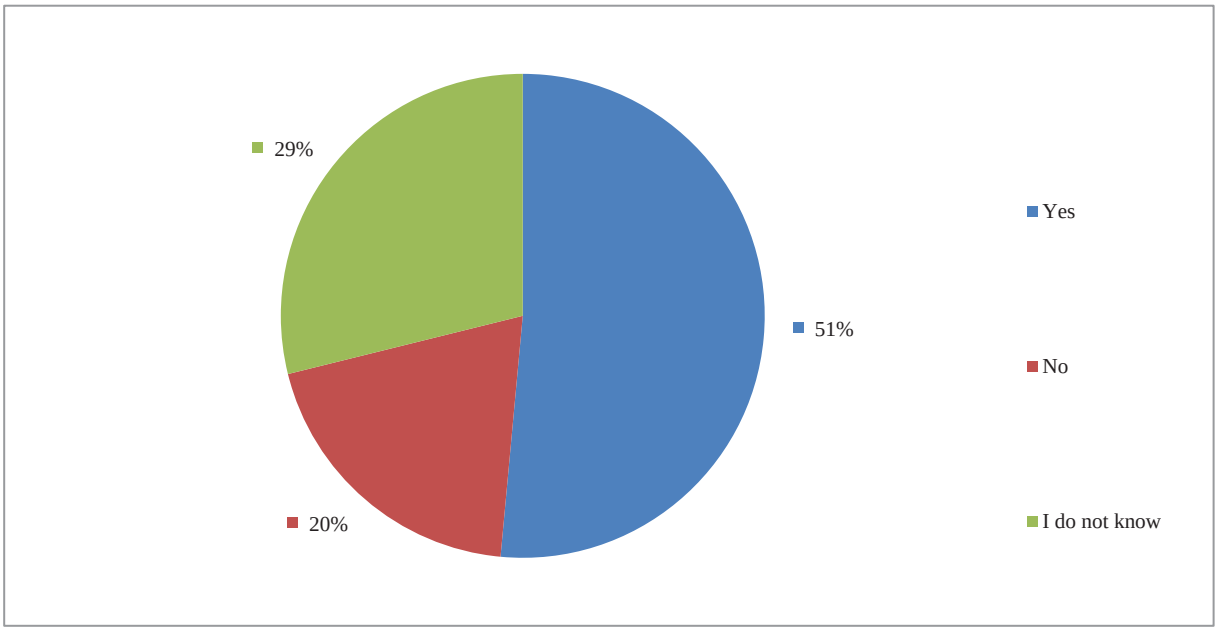


	A deliberate choice to exploit market opportunities at the lowest cost	A lack of knowledge	A technical or other type of inability to comply with rules	Carelessness	Ambiguity in the rules
1	33,47%	26,78%	10,88%	9,62%	10,46%
2	15,48%	30,13%	20,08%	20,50%	16,74%
3	20,08%	22,59%	27,62%	26,78%	22,18%
4	12,97%	11,72%	21,76%	27,20%	26,78%
5	17,99%	8,79%	19,67%	15,90%	23,85%

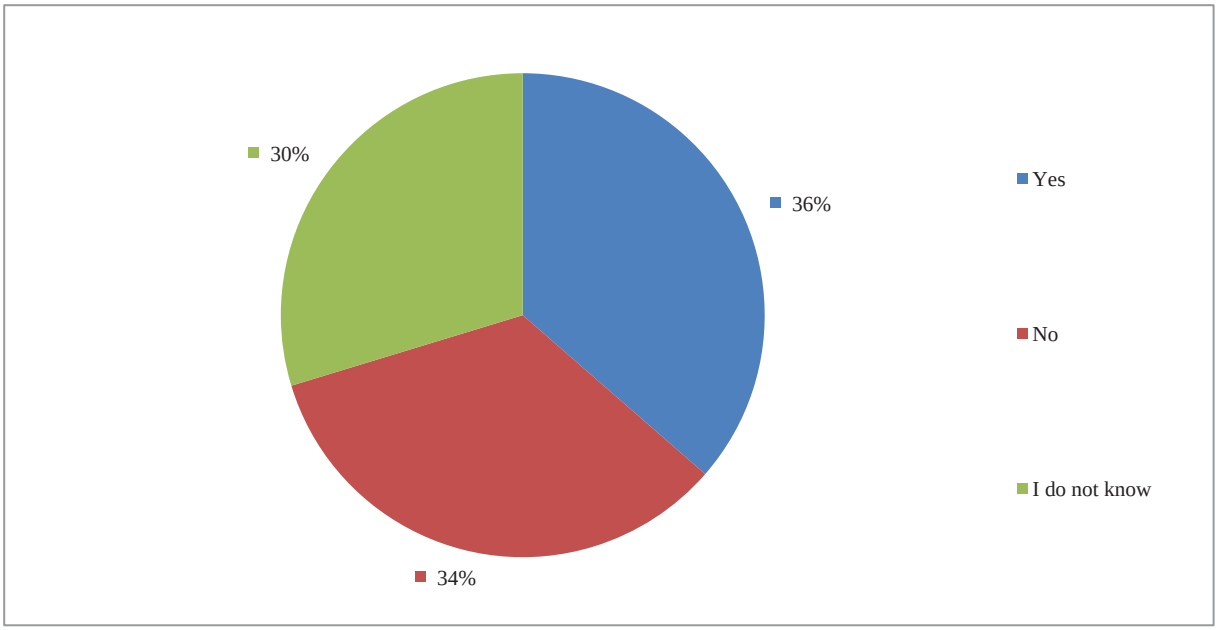
7. Do you have experience/knowledge of instances where a market surveillance authority lacks/lacked sufficient financial resources to carry out specific tasks in your sector?



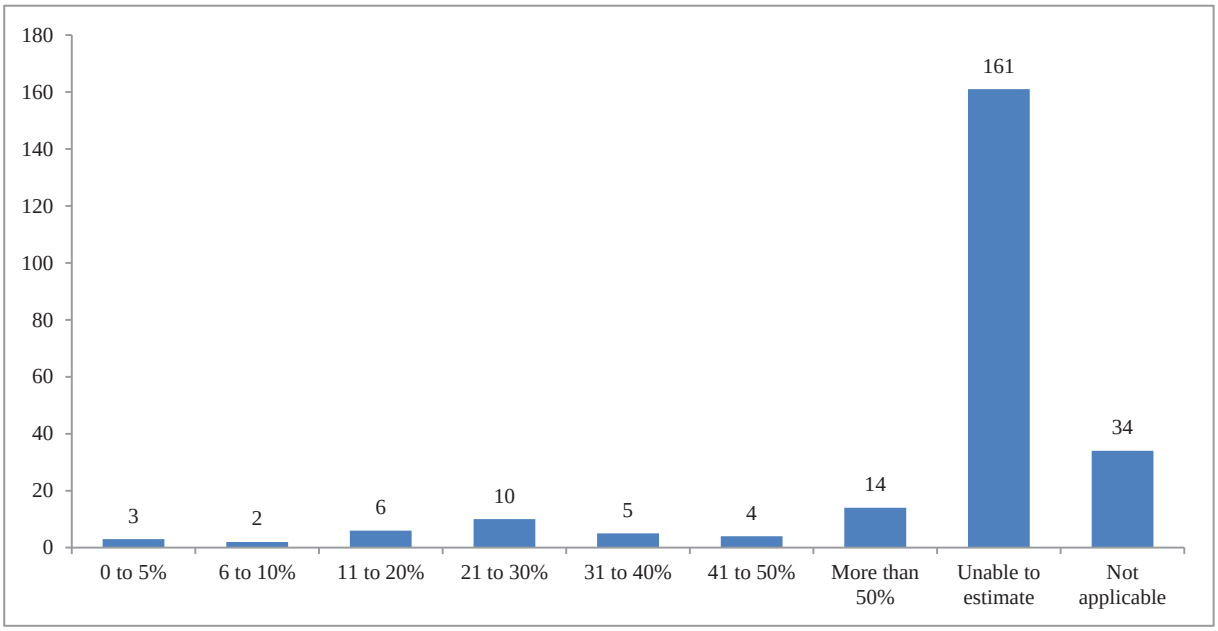
8. Do you have experience/knowledge of instances where a market surveillance authority lacks/lacked sufficient human resources to carry out specific tasks in your sector?



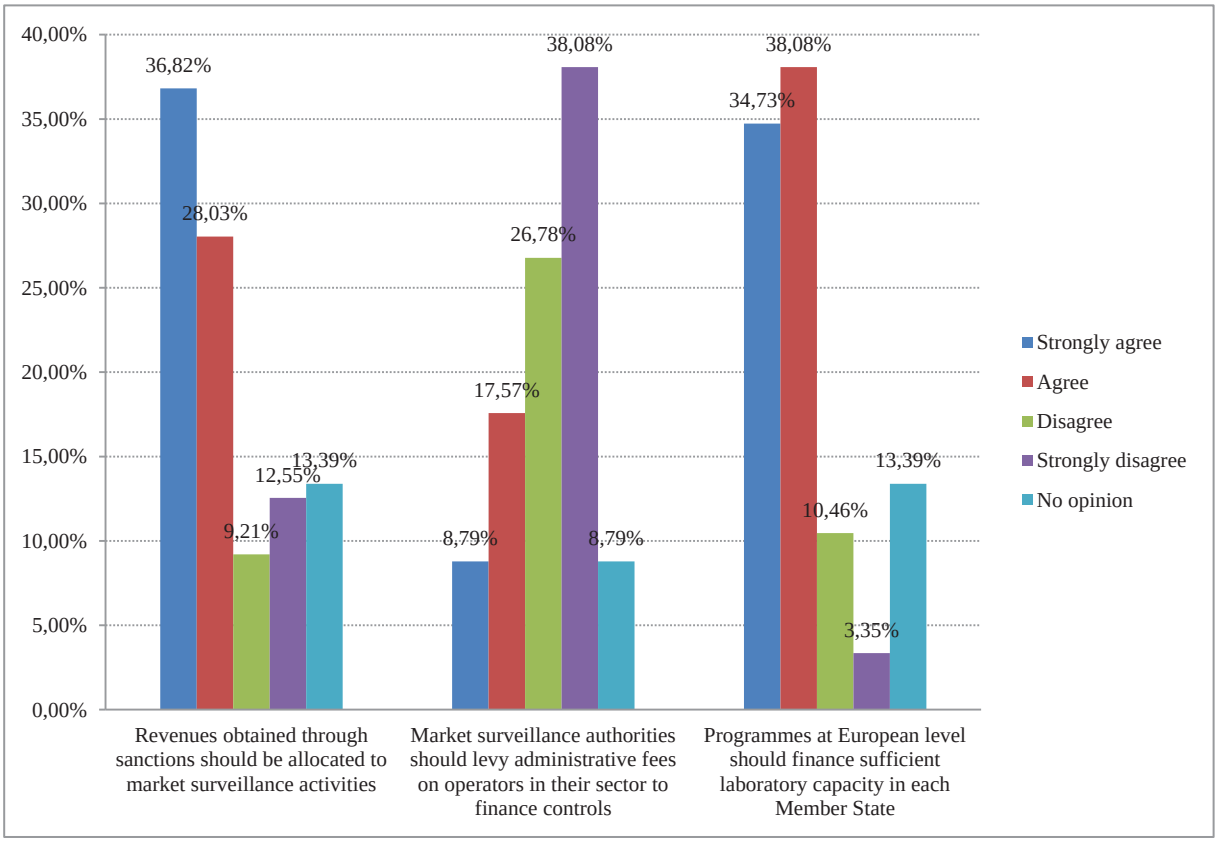
9. Do you have experience/knowledge of instances where a market surveillance authority lacks/lacked the technical means (notably testing facilities) to carry out specific tasks in your sector?



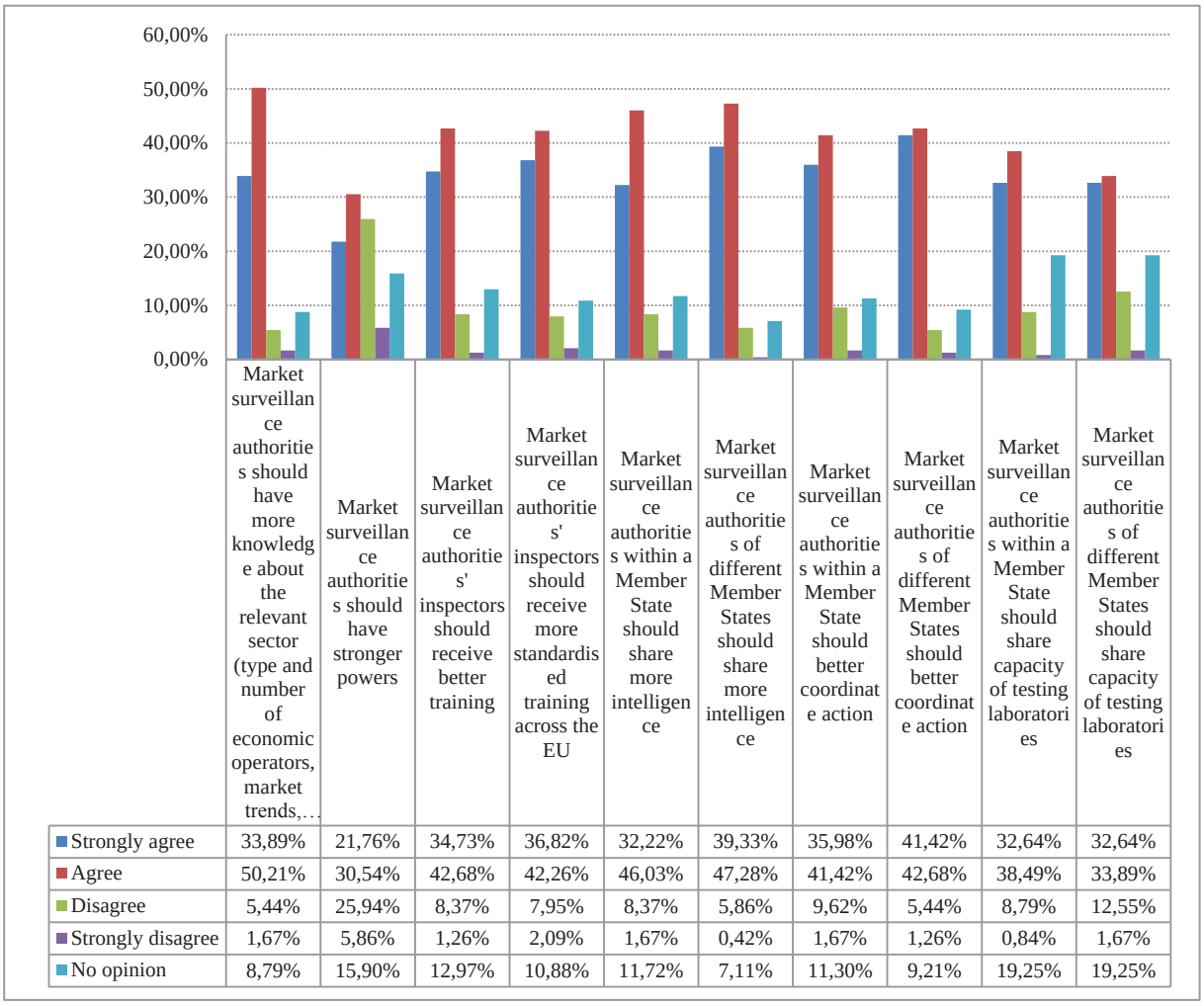
10. What is the approximate financial resource gap of the national authority in your sector?



11. How could the resources for market surveillance activities be increased in your sector?

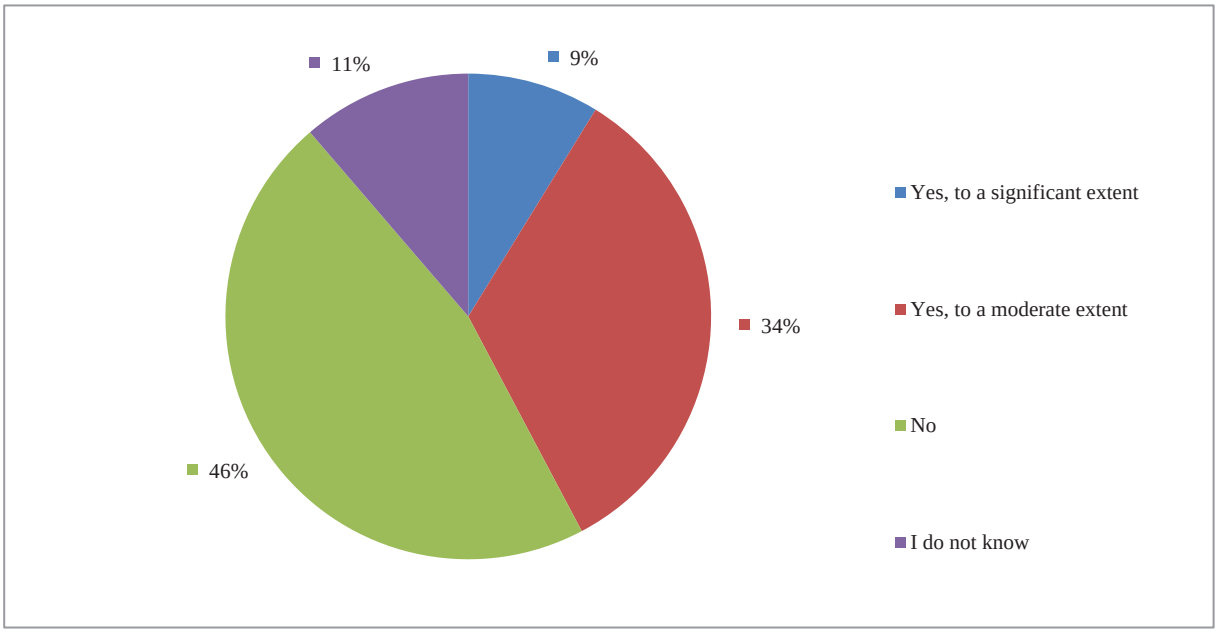


13. How could the resources for market surveillance activities be used more efficiently in your sector?

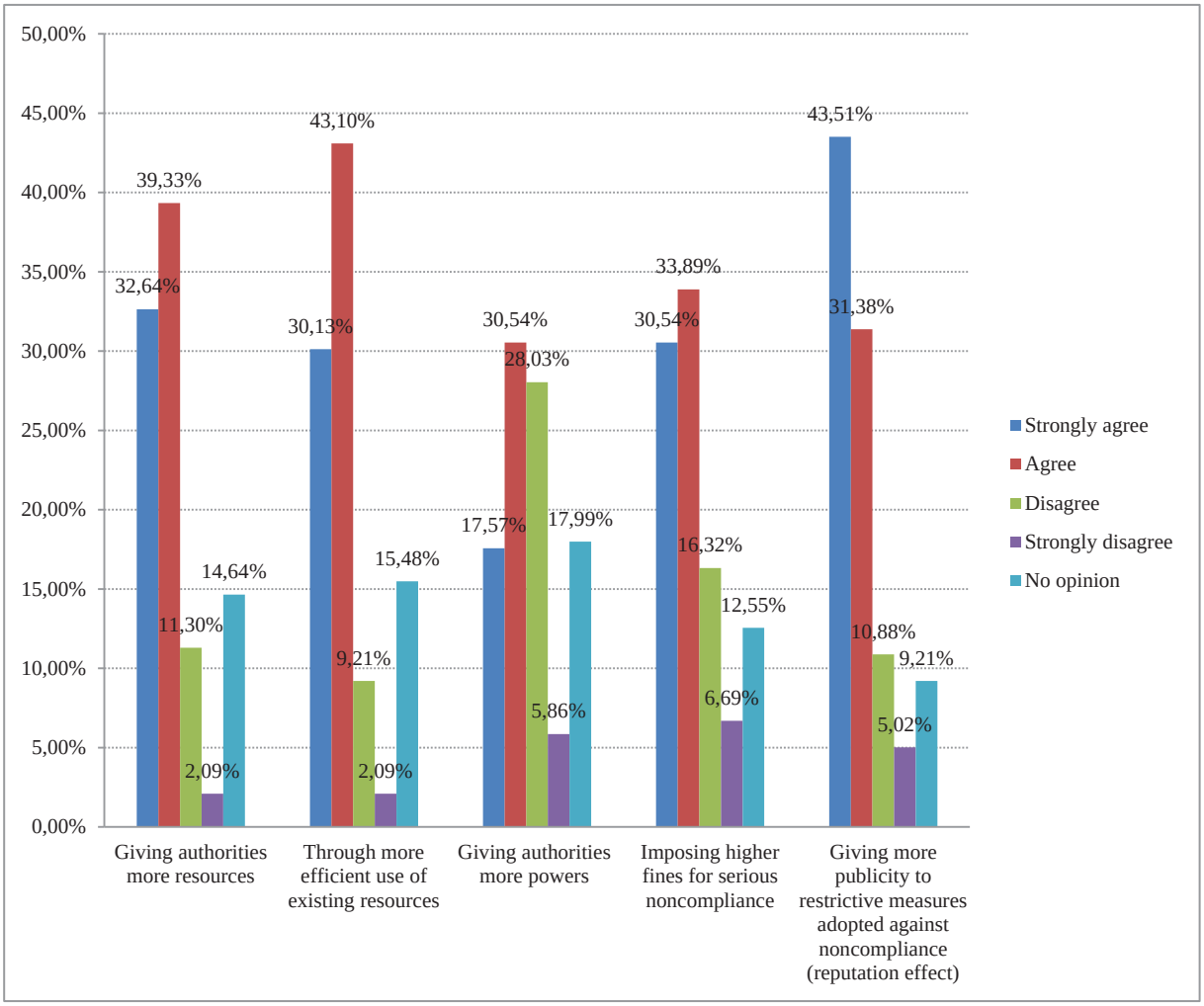


	Market surveillance authorities should have more knowledge about the relevant sector (type and number of economic operators, market trends,…	Market surveillance authorities should have stronger powers	Market surveillance authorities' inspectors should receive better training	Market surveillance authorities' inspectors should receive more standardised training across the EU	Market surveillance authorities within a Member State should share more intelligence	Market surveillance authorities of different Member States should share more intelligence	Market surveillance authorities within a Member State should better coordinate action	Market surveillance authorities of different Member States should better coordinate action	Market surveillance authorities within a Member State should share capacity of testing laboratories	Market surveillance authorities of different Member States should share capacity of testing laboratories
Strongly agree	33,89%	21,76%	34,73%	36,82%	32,22%	39,33%	35,98%	41,42%	32,64%	32,64%
Agree	50,21%	30,54%	42,68%	42,26%	46,03%	47,28%	41,42%	42,68%	38,49%	33,89%
Disagree	5,44%	25,94%	8,37%	7,95%	8,37%	5,86%	9,62%	5,44%	8,79%	12,55%
Strongly disagree	1,67%	5,86%	1,26%	2,09%	1,67%	0,42%	1,67%	1,26%	0,84%	1,67%
No opinion	8,79%	15,90%	12,97%	10,88%	11,72%	7,11%	11,30%	9,21%	19,25%	19,25%

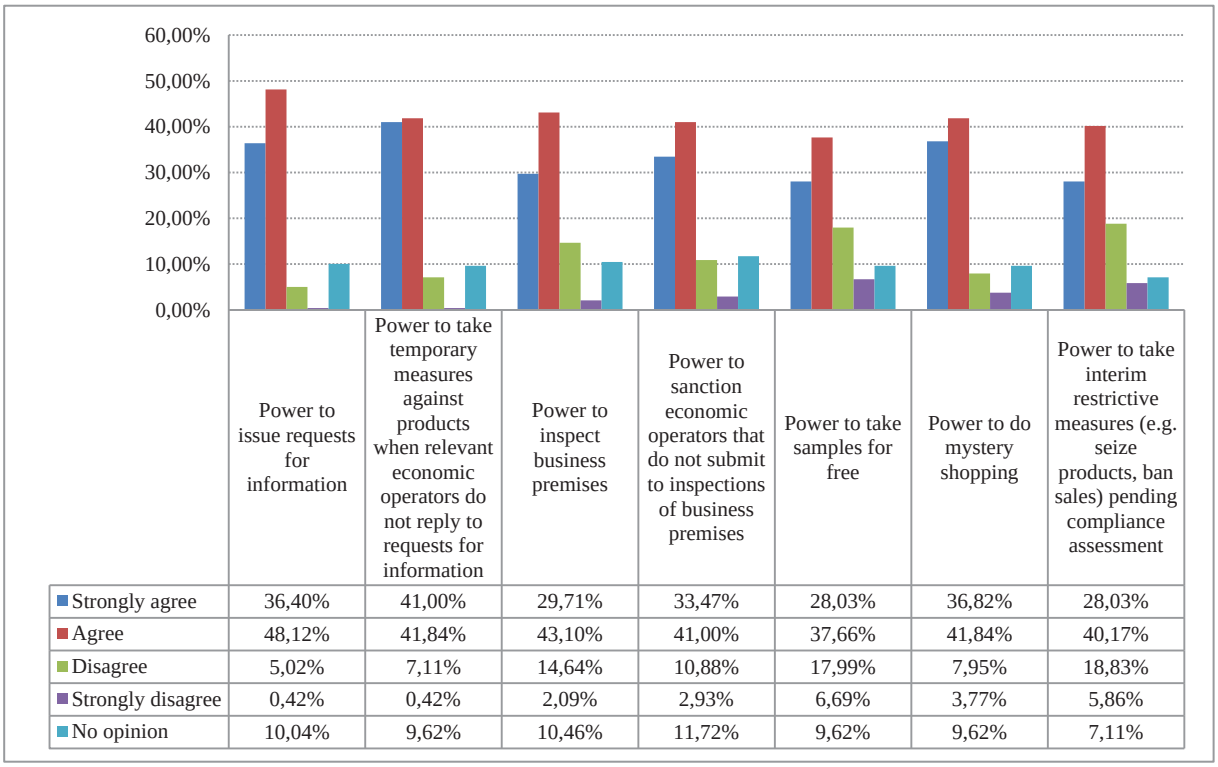
14. Do you think that market surveillance in your sector provides sufficient deterrence?



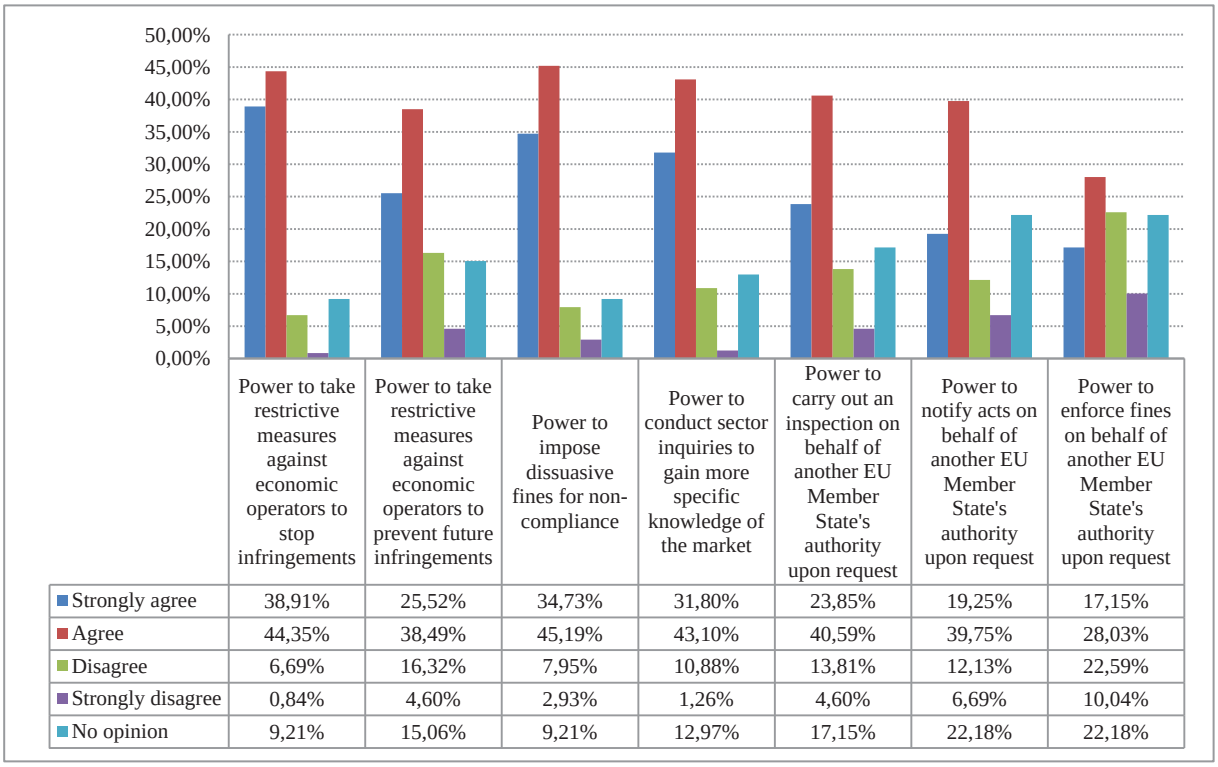
15. How could the deterrence of market surveillance action be improved in your sector?



17. What powers do you think market surveillance authorities need in order to carry out more effective and deterrent action in your sector?

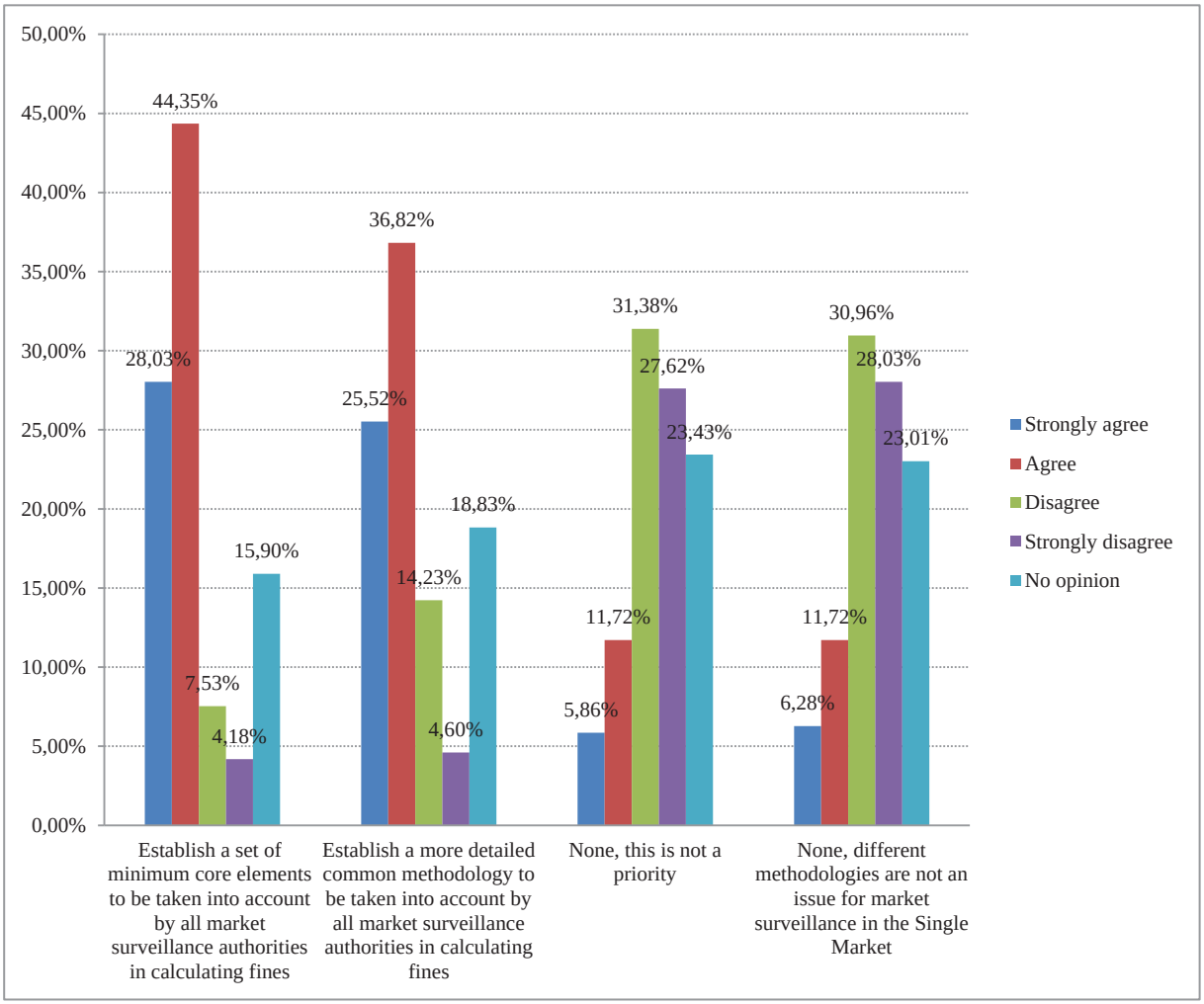


	Power to issue requests for information	Power to take temporary measures against products when relevant economic operators do not reply to requests for information	Power to inspect business premises	Power to sanction economic operators that do not submit to inspections of business premises	Power to take samples for free	Power to do mystery shopping	Power to take interim restrictive measures (e.g. seize products, ban sales) pending compliance assessment
Strongly agree	36,40%	41,00%	29,71%	33,47%	28,03%	36,82%	28,03%
Agree	48,12%	41,84%	43,10%	41,00%	37,66%	41,84%	40,17%
Disagree	5,02%	7,11%	14,64%	10,88%	17,99%	7,95%	18,83%
Strongly disagree	0,42%	0,42%	2,09%	2,93%	6,69%	3,77%	5,86%
No opinion	10,04%	9,62%	10,46%	11,72%	9,62%	9,62%	7,11%



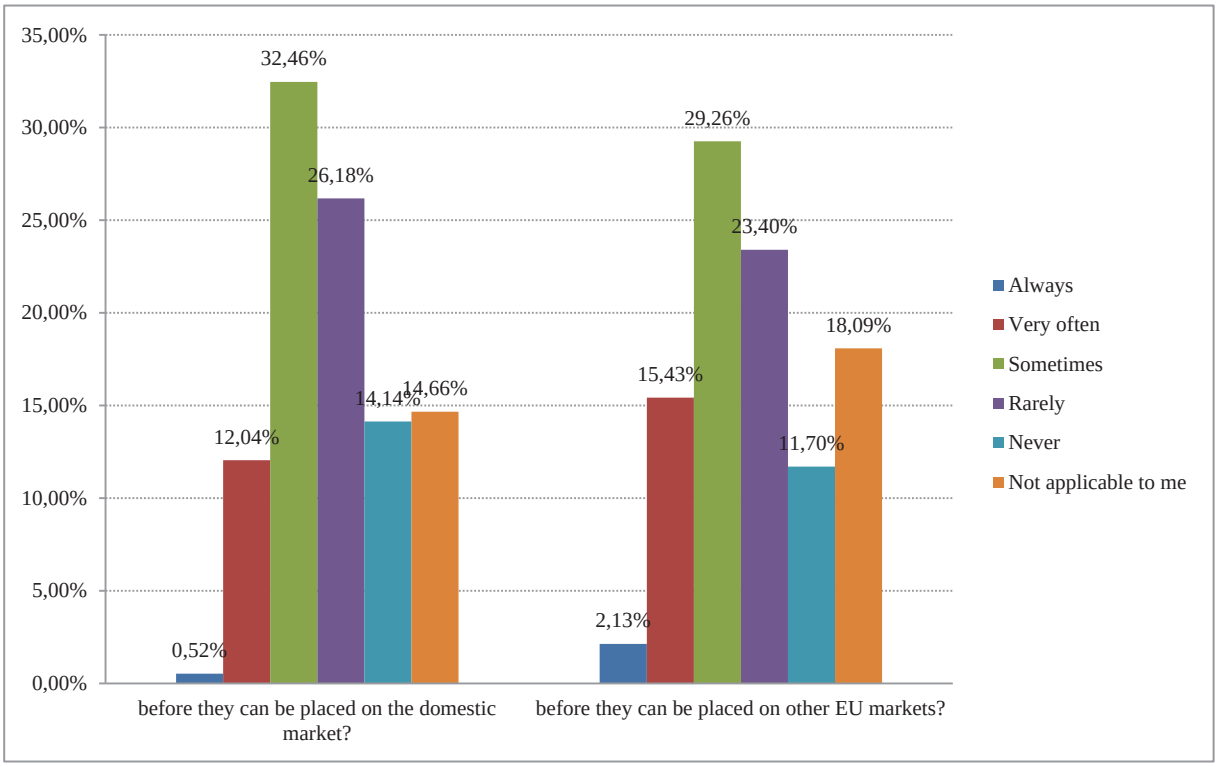
	Power to take restrictive measures against economic operators to stop infringements	Power to take restrictive measures against economic operators to prevent future infringements	Power to impose dissuasive fines for non-compliance	Power to conduct sector inquiries to gain more specific knowledge of the market	Power to carry out an inspection on behalf of another EU Member State's authority upon request	Power to notify acts on behalf of another EU Member State's authority upon request	Power to enforce fines on behalf of another EU Member State's authority upon request
Strongly agree	38,91%	25,52%	34,73%	31,80%	23,85%	19,25%	17,15%
Agree	44,35%	38,49%	45,19%	43,10%	40,59%	39,75%	28,03%
Disagree	6,69%	16,32%	7,95%	10,88%	13,81%	12,13%	22,59%
Strongly disagree	0,84%	4,60%	2,93%	1,26%	4,60%	6,69%	10,04%
No opinion	9,21%	15,06%	9,21%	12,97%	17,15%	22,18%	22,18%

18. Divergences exist in the methodologies applied by market surveillance authorities in different Member States to sanction non-compliant businesses. Which measures do you think should be taken to address this issue?

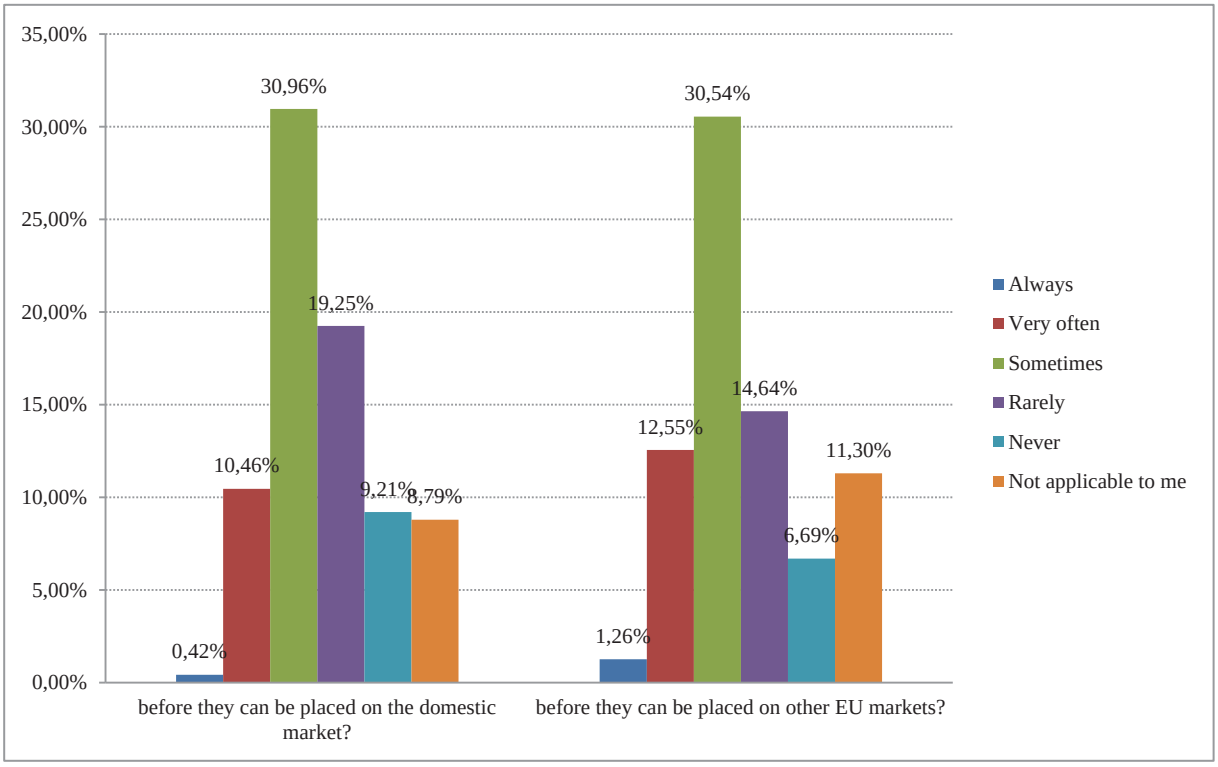


B2. Compliance assistance in Member States and at EU level

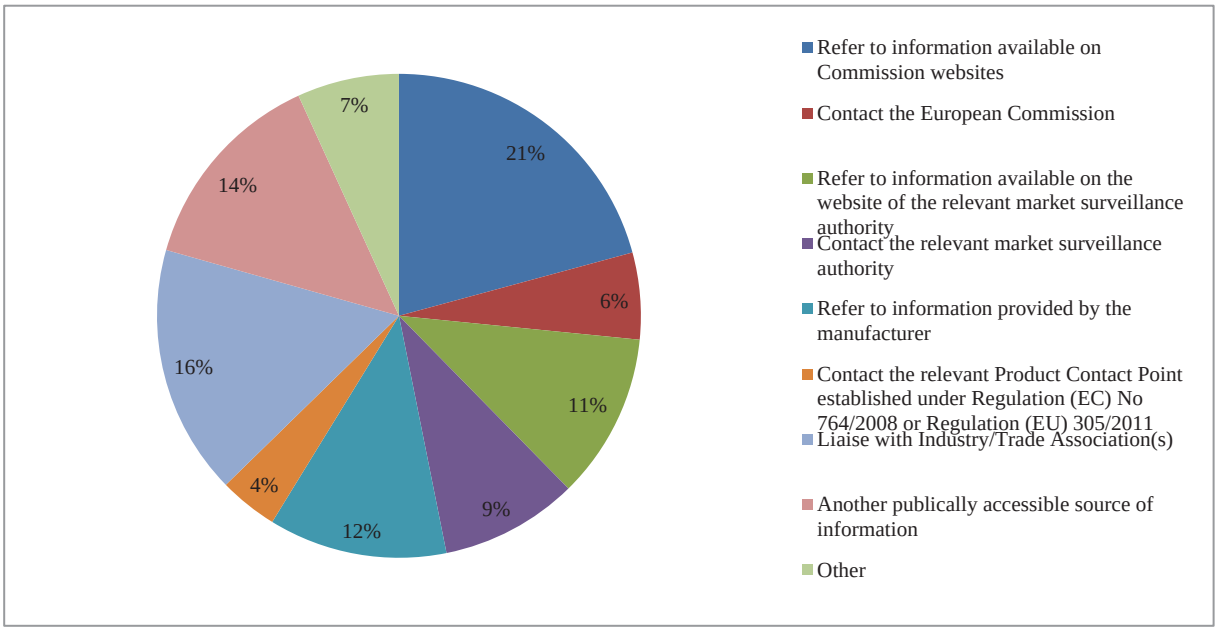
1. Have you had difficulty in finding the correct information on the technical rules that products need to meet?



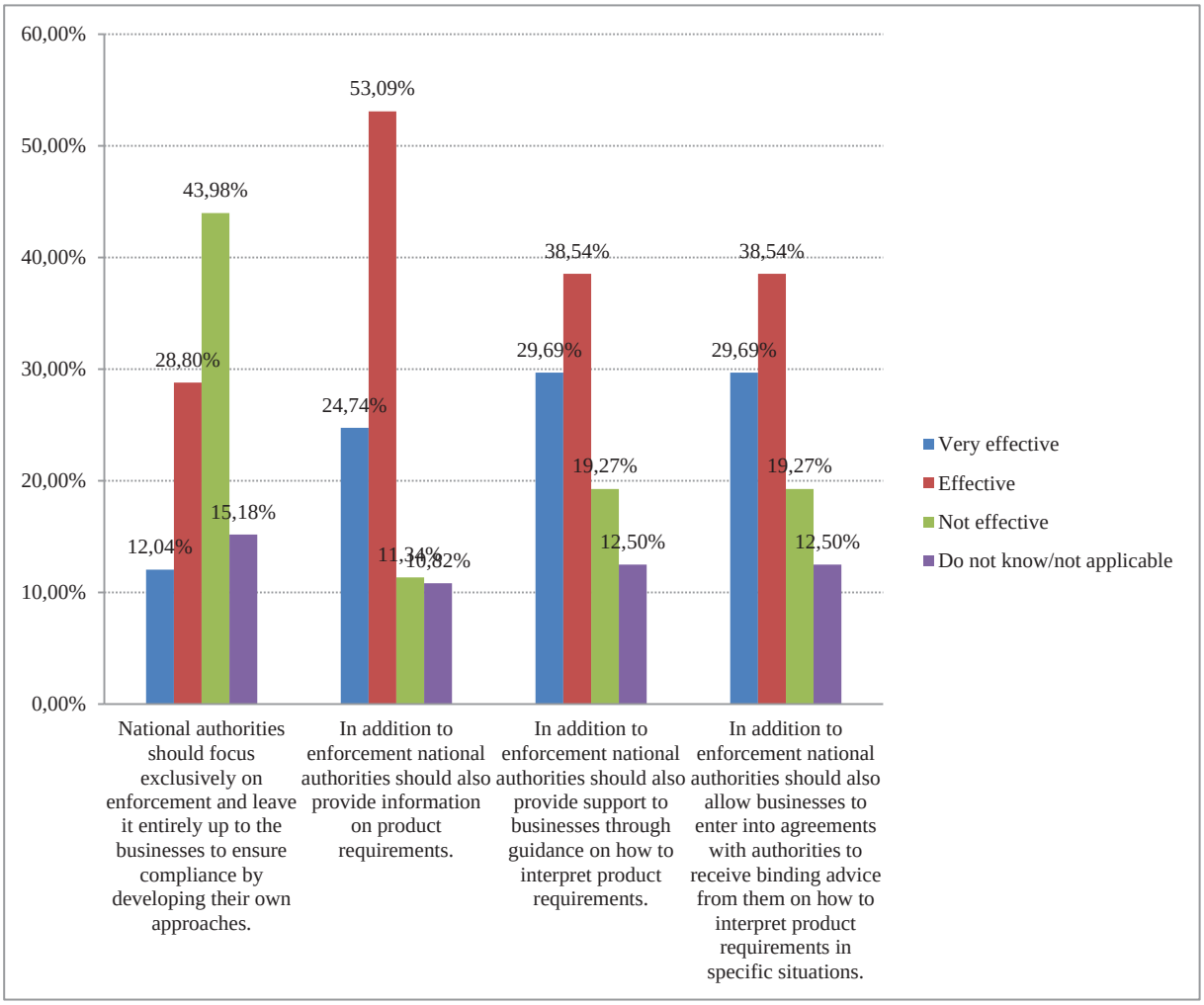
2. Have you had difficulty understanding the correct information on the technical rules that products need to meet



3. What is the approach you most often use to look for support and information on technical rules that products need to meet?

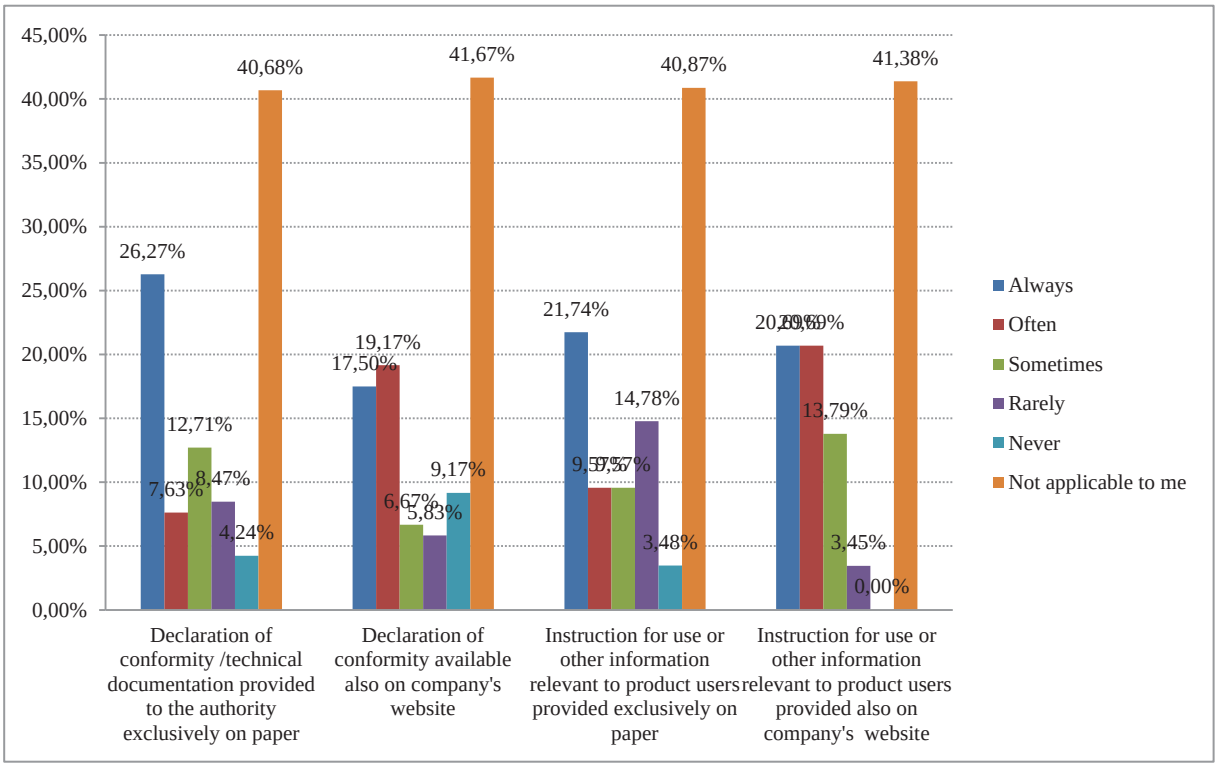


4. What is your opinion on the following approaches by national authorities to reduce the level of non-compliant products on the market?

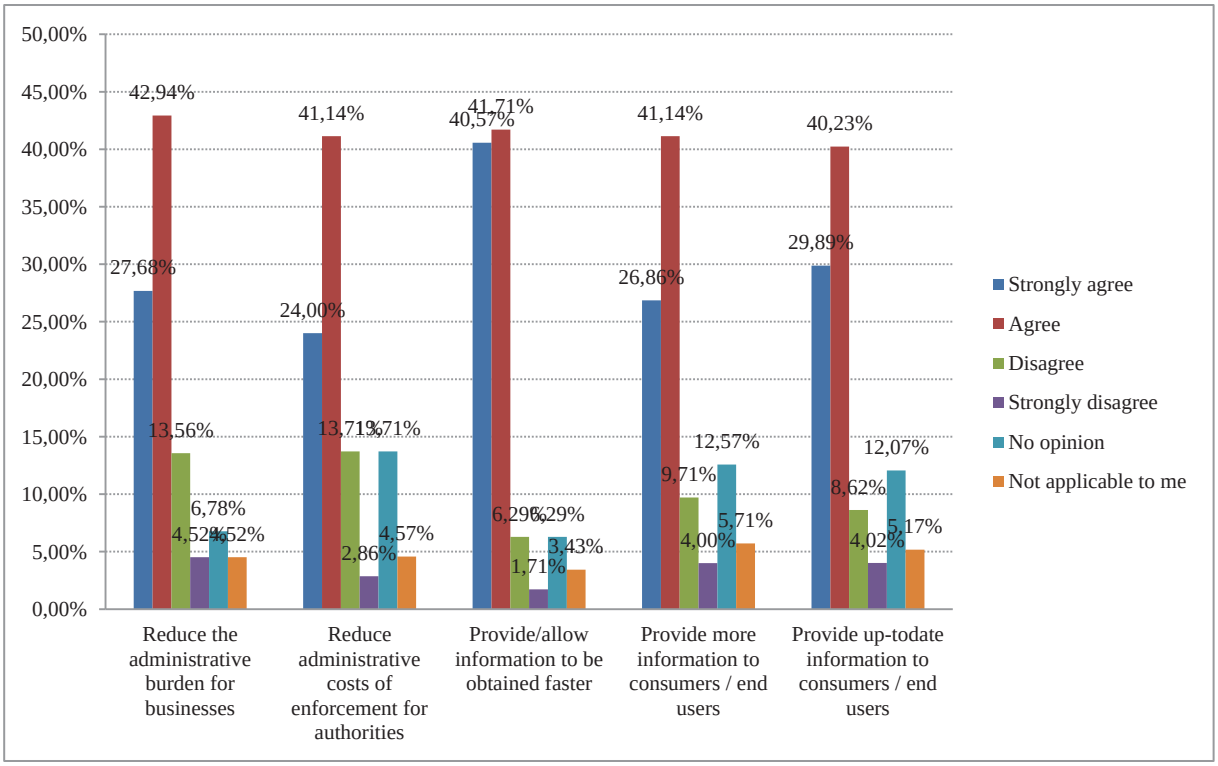


B3. Businesses' demonstration of product compliance

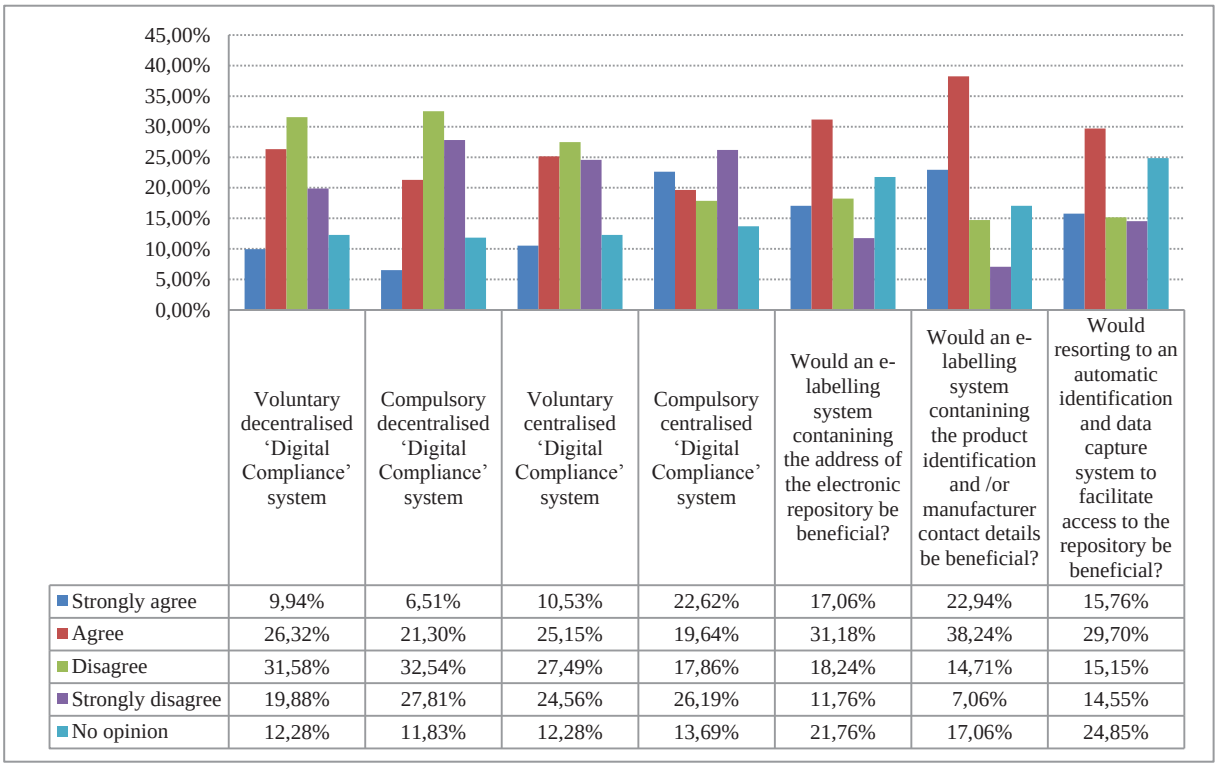
1. [For businesses only] How do you supply information about product compliance?



2. In your experience or understanding would a broader use of electronic means to demonstrate compliance help to:



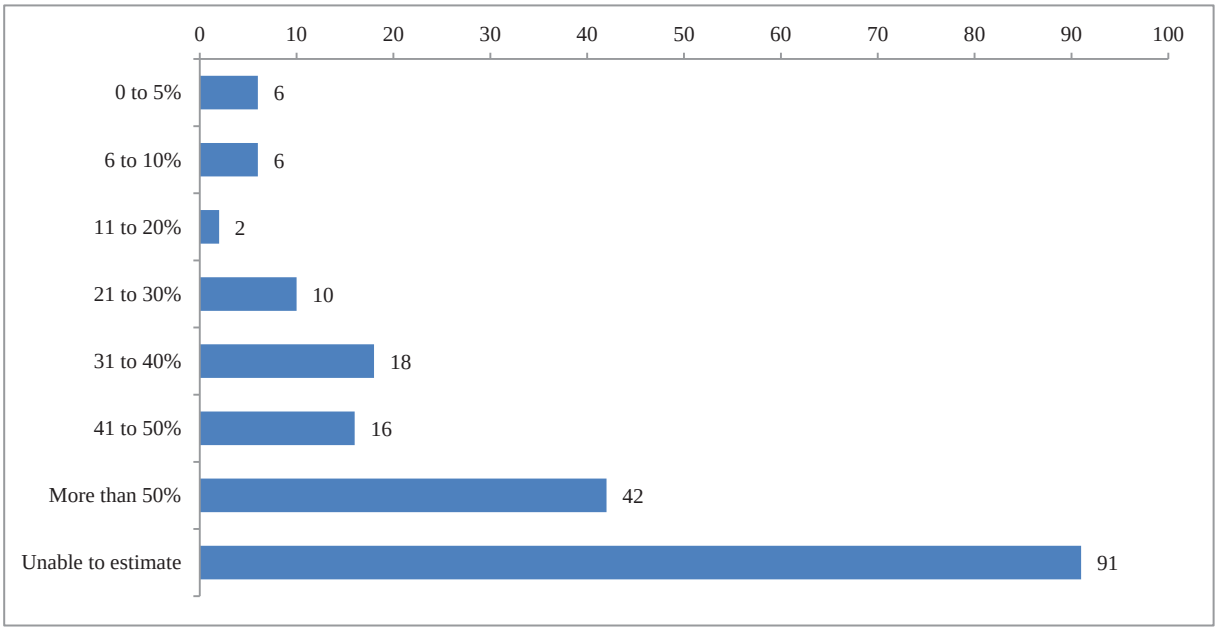
3. What is your view about the following options to better exploit the potential of electronic means for demonstrating compliance?



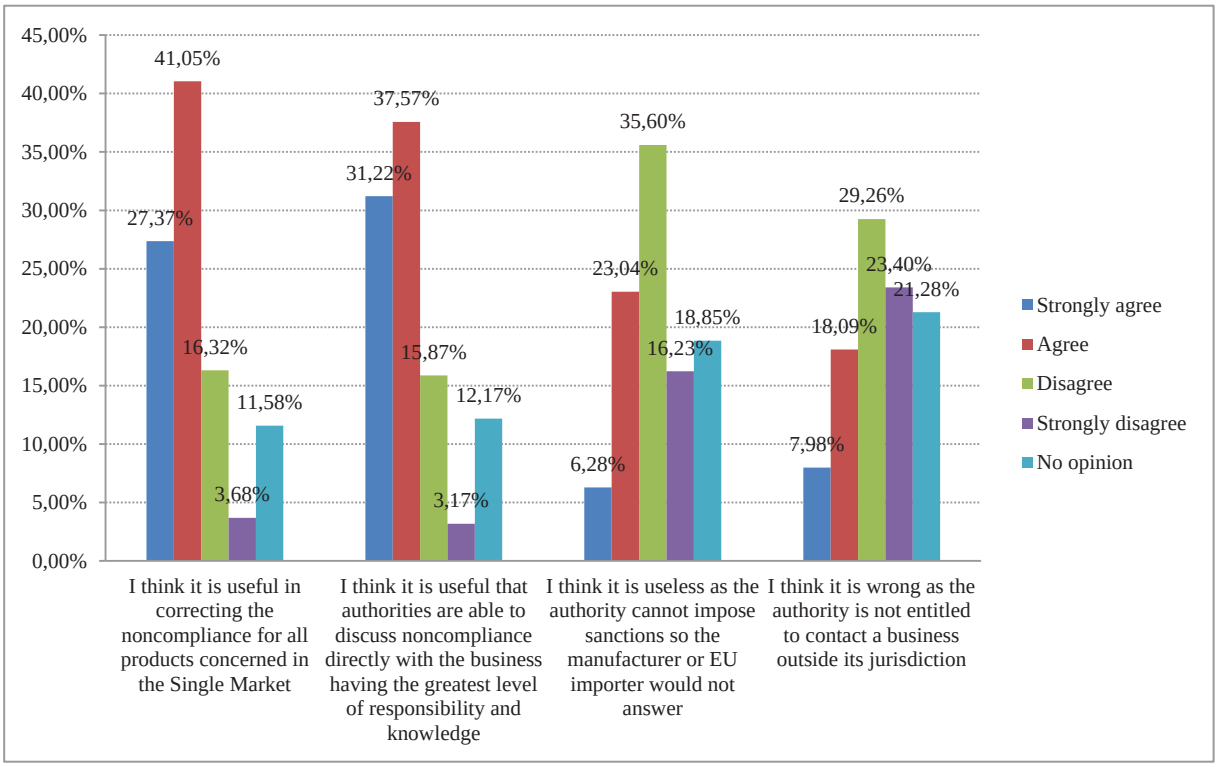
	Voluntary decentralised 'Digital Compliance' system	Compulsory decentralised 'Digital Compliance' system	Voluntary centralised 'Digital Compliance' system	Compulsory centralised 'Digital Compliance' system	Would an e-labelling system containing the address of the electronic repository be beneficial?	Would an e-labelling system containing the product identification and /or manufacturer contact details be beneficial?	Would resorting to an automatic identification and data capture system to facilitate access to the repository be beneficial?
Strongly agree	9,94%	6,51%	10,53%	22,62%	17,06%	22,94%	15,76%
Agree	26,32%	21,30%	25,15%	19,64%	31,18%	38,24%	29,70%
Disagree	31,58%	32,54%	27,49%	17,86%	18,24%	14,71%	15,15%
Strongly disagree	19,88%	27,81%	24,56%	26,19%	11,76%	7,06%	14,55%
No opinion	12,28%	11,83%	12,28%	13,69%	21,76%	17,06%	24,85%

B4. Cross-border market surveillance within the EU

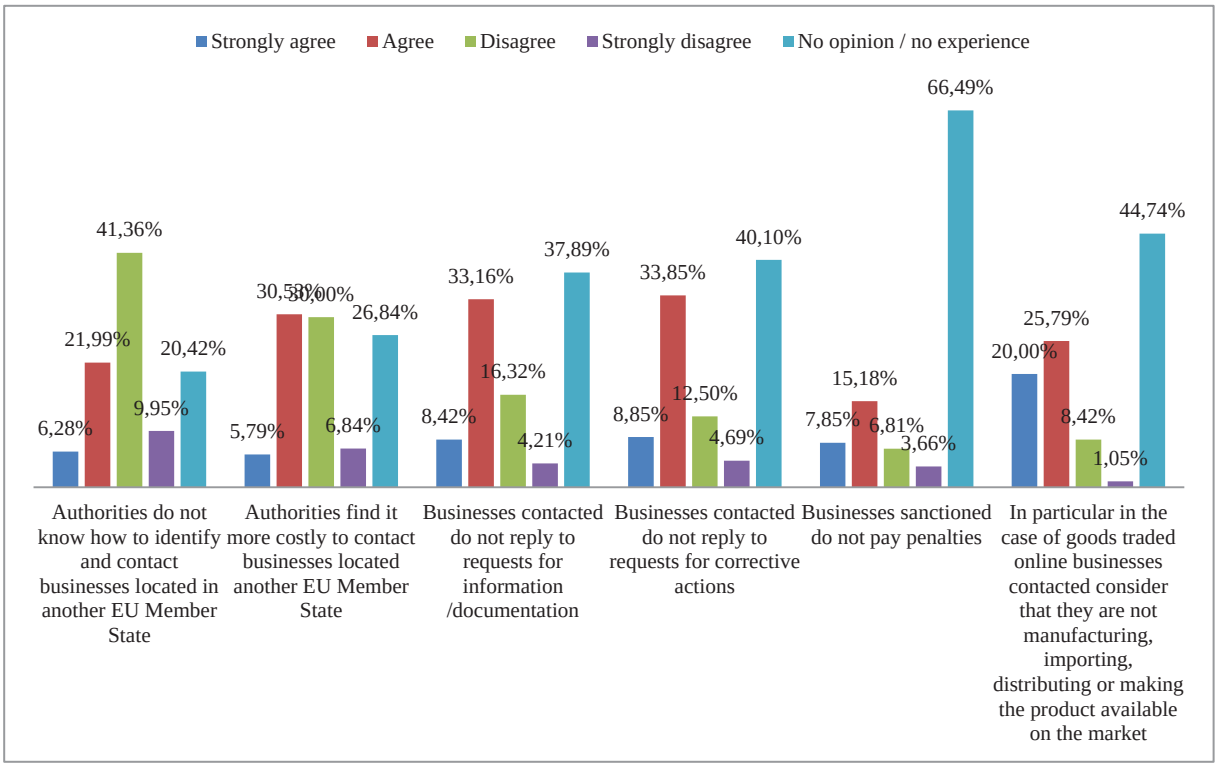
1. What is the approximate proportion of products placed on the market by manufacturers or EU importers located in another EU Member State in your sector (based on product volumes)?



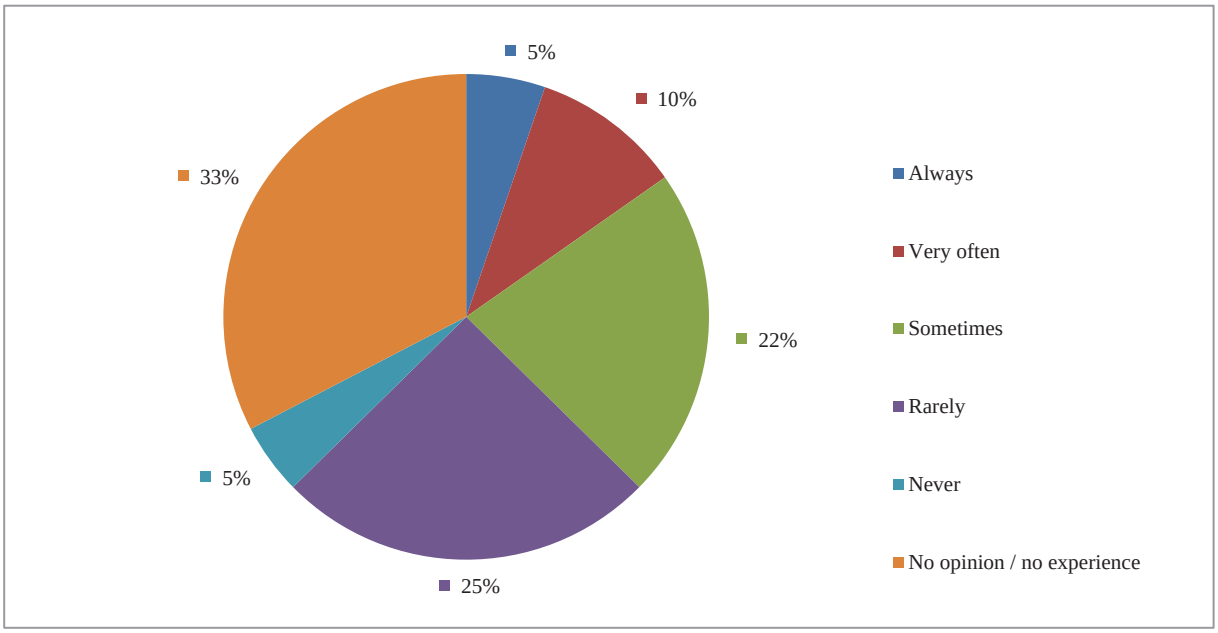
2. Based on your experience what is your view on manufacturers or EU importers being contacted by a market surveillance authority of another EU Member State?



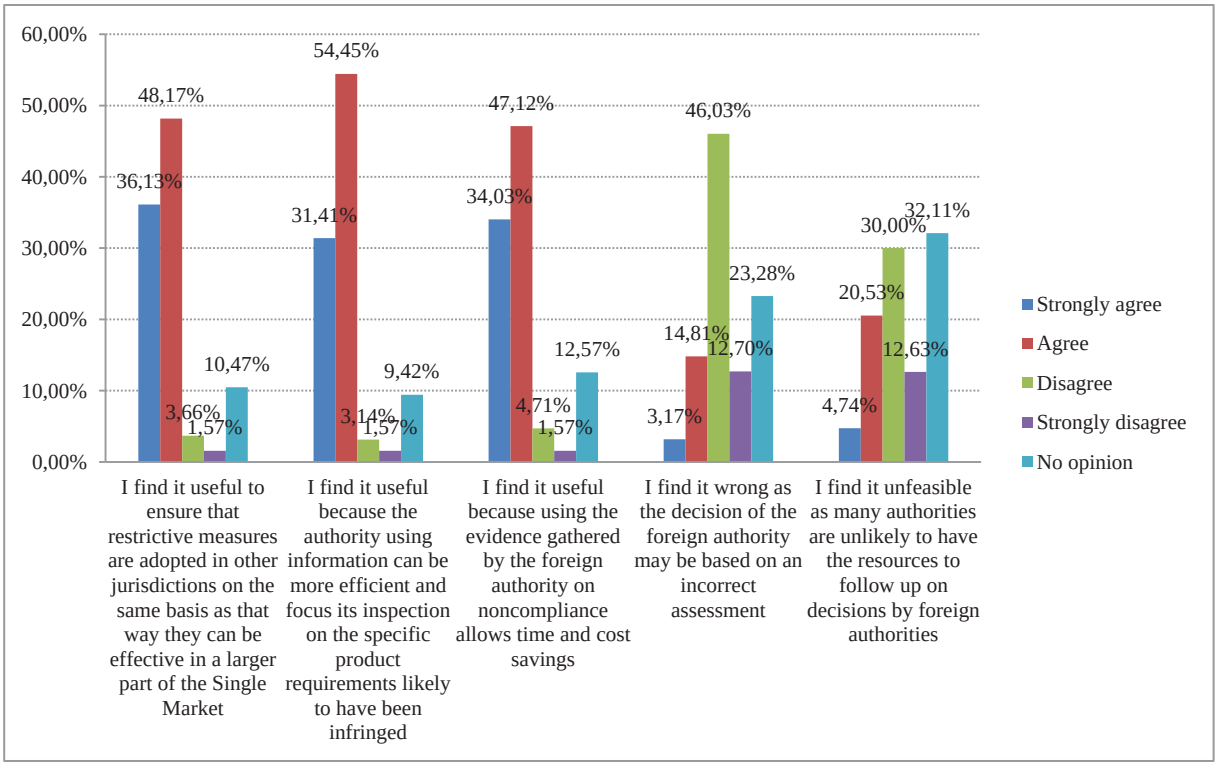
3. In your experience what makes it difficult for a surveillance authority to take action against non-compliant products traded by businesses located in another EU Member State?

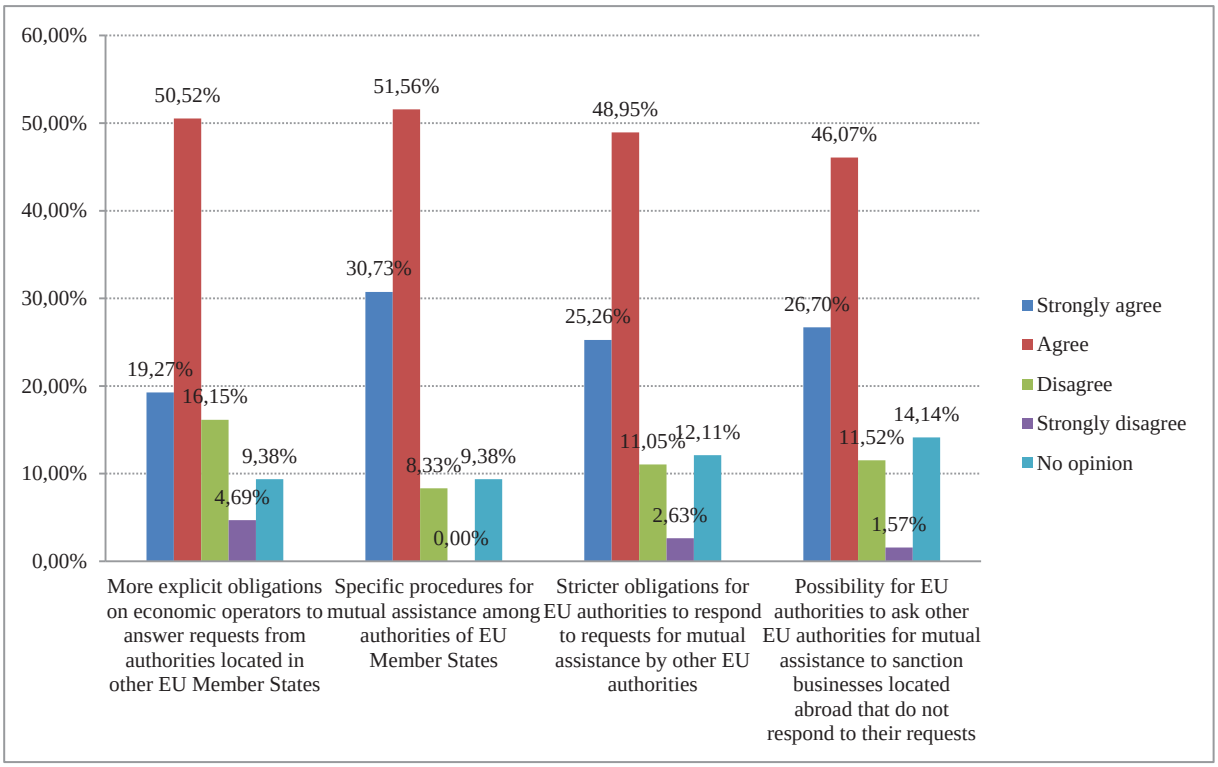


4. National authorities in the EU Member States can currently exchange information on measures adopted to restrict the marketing of non-compliant products via several means (Rapid Alert System, notification procedures, common databases (ICSMS), expert groups, administrative cooperation groups). In your experience or knowledge in the relevant product category(-ies) how often do national authorities restrict the marketing of a product following the exchange of information about measures adopted by another authority in the EU against the same product?

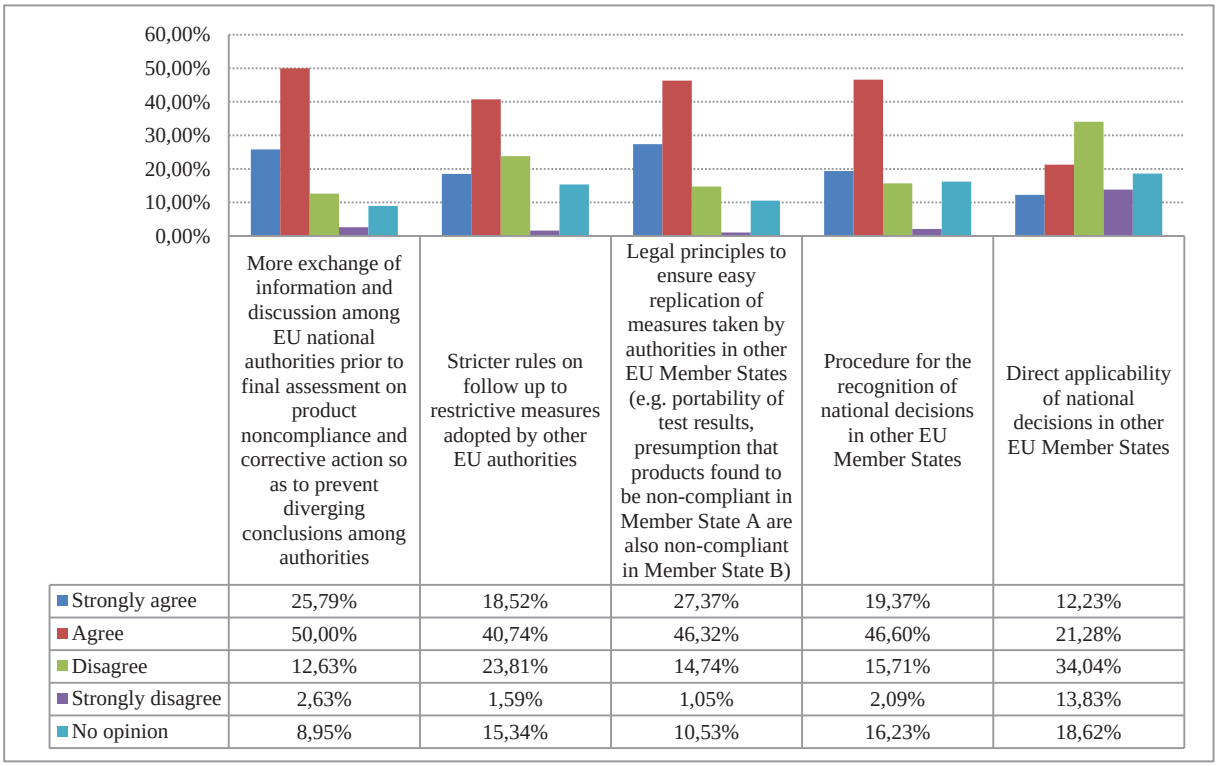


5. What is your view about the possibility that a national authority uses information on measures adopted to restrict the marketing of non-compliant products by another EU authority to adopt restrictive measures against the same products supplied within its own jurisdiction?

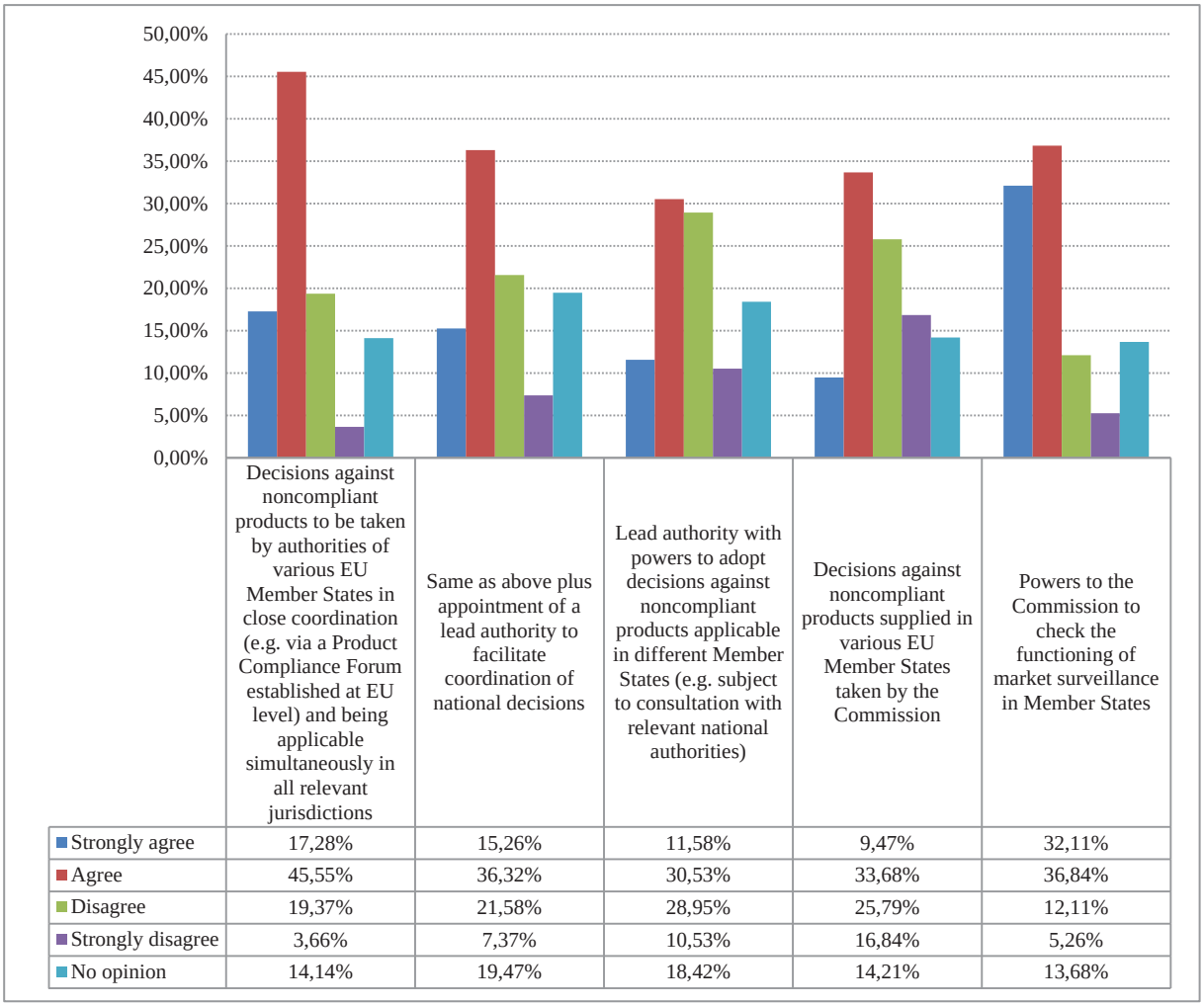




8. Do you agree that the following mechanisms would increase the effectiveness of market surveillance in the Single Market?

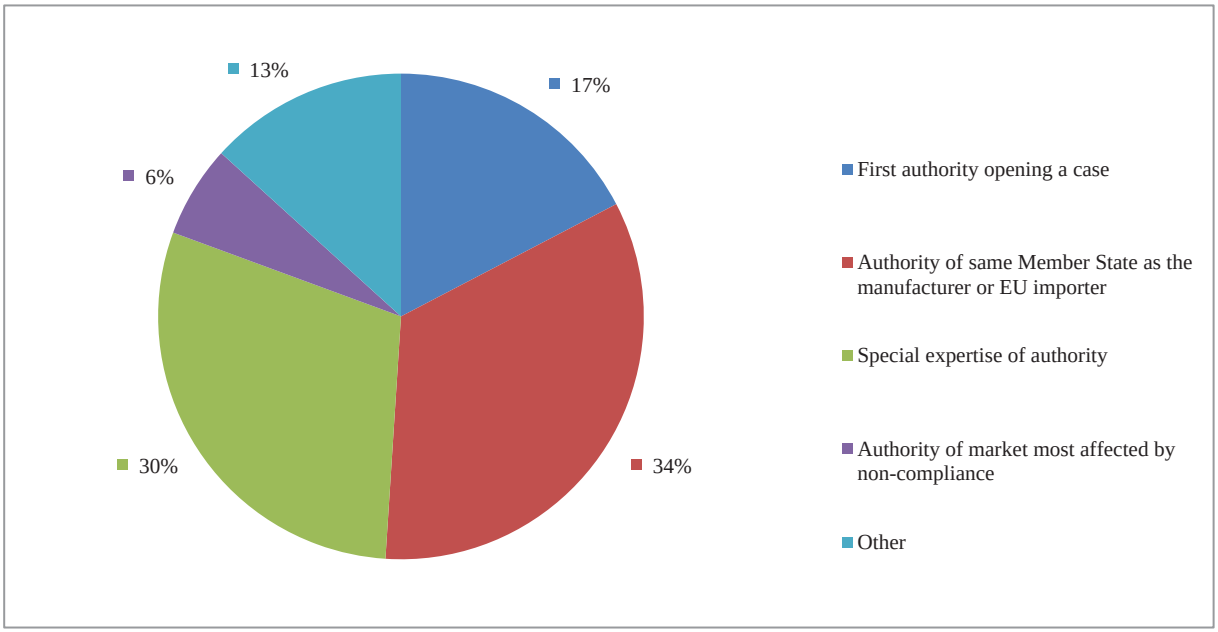


	More exchange of information and discussion among EU national authorities prior to final assessment on product noncompliance and corrective action so as to prevent diverging conclusions among authorities	Stricter rules on follow up to restrictive measures adopted by other EU authorities	Legal principles to ensure easy replication of measures taken by authorities in other EU Member States (e.g. portability of test results, presumption that products found to be non-compliant in Member State A are also non-compliant in Member State B)	Procedure for the recognition of national decisions in other EU Member States	Direct applicability of national decisions in other EU Member States
Strongly agree	25,79%	18,52%	27,37%	19,37%	12,23%
Agree	50,00%	40,74%	46,32%	46,60%	21,28%
Disagree	12,63%	23,81%	14,74%	15,71%	34,04%
Strongly disagree	2,63%	1,59%	1,05%	2,09%	13,83%
No opinion	8,95%	15,34%	10,53%	16,23%	18,62%

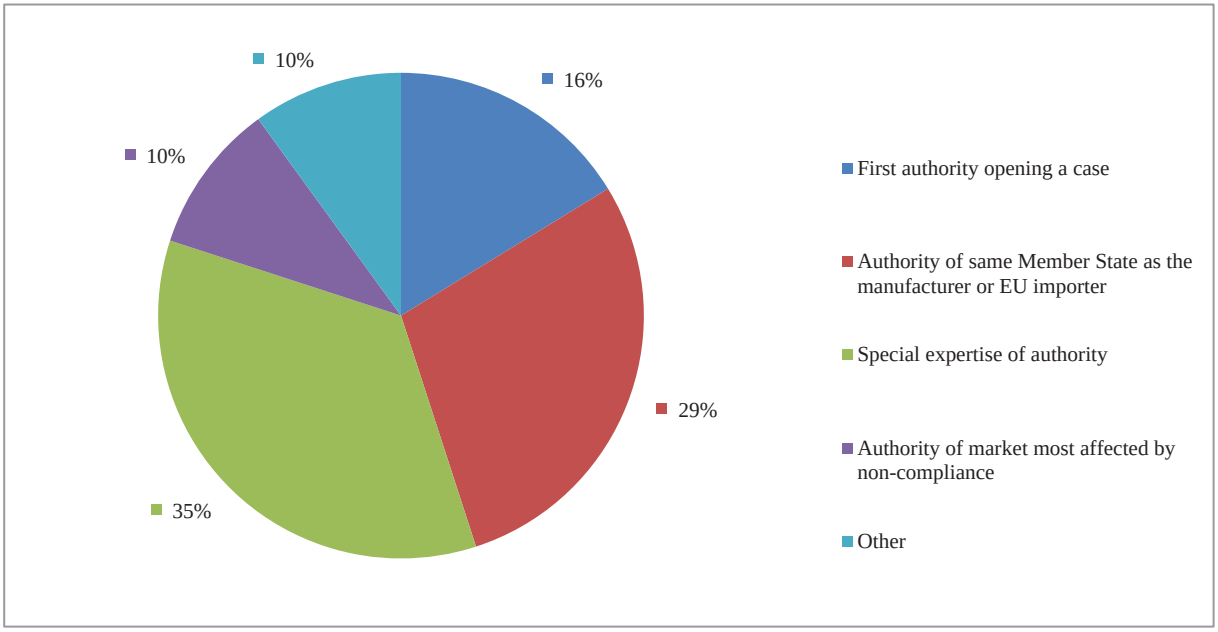


	Decisions against noncompliant products to be taken by authorities of various EU Member States in close coordination (e.g. via a Product Compliance Forum established at EU level) and being applicable simultaneously in all relevant jurisdictions	Same as above plus appointment of a lead authority to facilitate coordination of national decisions	Lead authority with powers to adopt decisions against noncompliant products applicable in different Member States (e.g. subject to consultation with relevant national authorities)	Decisions against noncompliant products supplied in various EU Member States taken by the Commission	Powers to the Commission to check the functioning of market surveillance in Member States
Strongly agree	17,28%	15,26%	11,58%	9,47%	32,11%
Agree	45,55%	36,32%	30,53%	33,68%	36,84%
Disagree	19,37%	21,58%	28,95%	25,79%	12,11%
Strongly disagree	3,66%	7,37%	10,53%	16,84%	5,26%
No opinion	14,14%	19,47%	18,42%	14,21%	13,68%

If you agree with the concept of a lead authority coordinating decisions to be taken simultaneously by authorities in different Member States, which criterion should be used to select the lead authority?

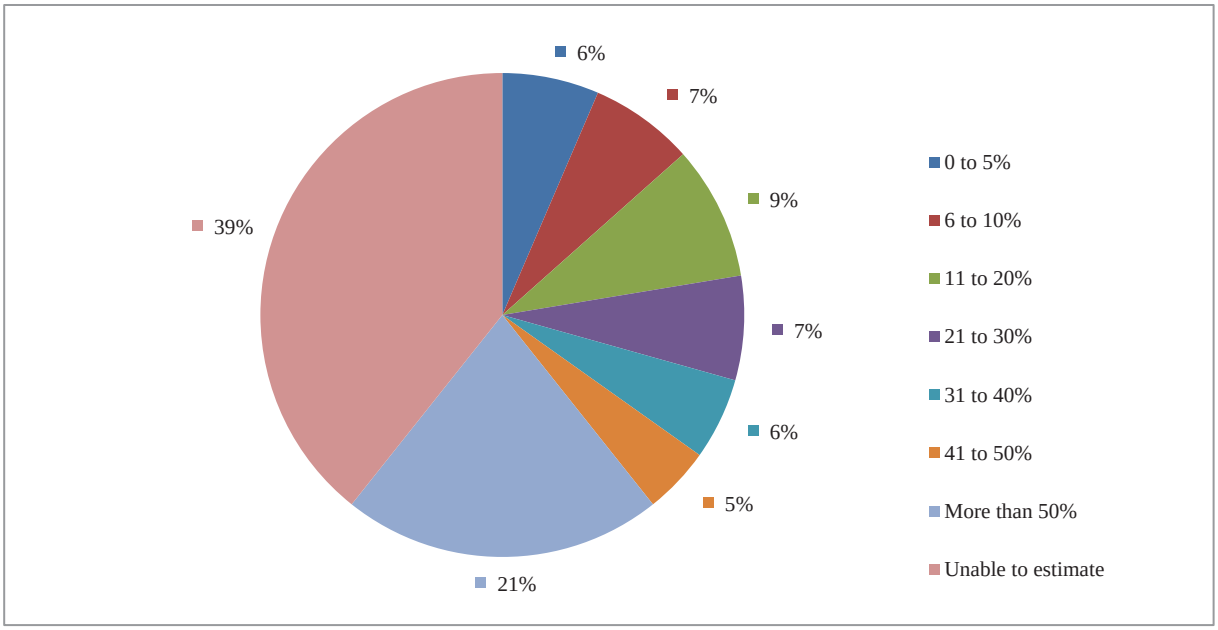


If you agree with the concept of a lead authority with powers to adopt measures applicable in different Member States (e.g. subject to consultation with relevant national authorities), which criterion should be used to select the lead authority?

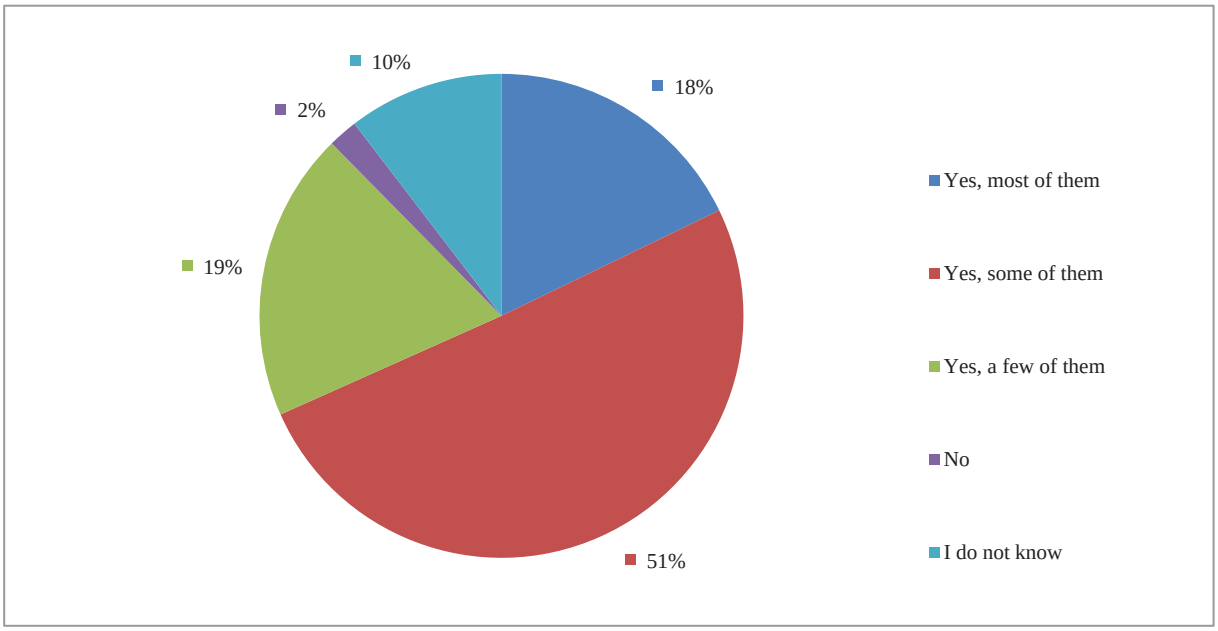


B5. Market surveillance of products imported from non-EU countries

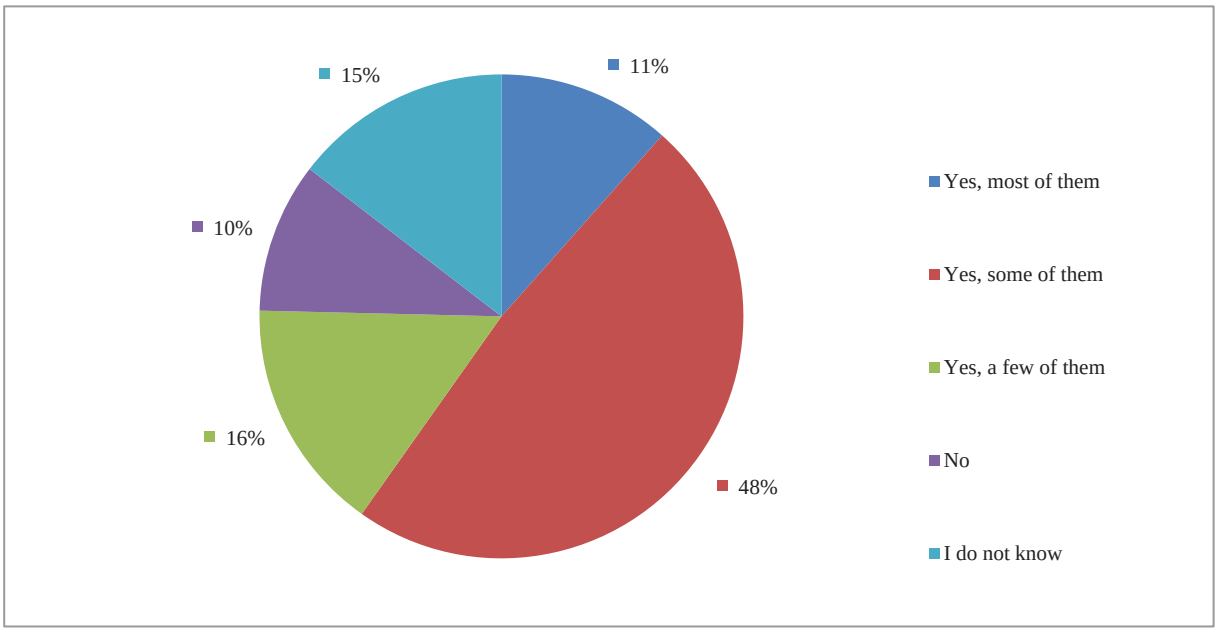
1. What is the approximate proportion of products imported from non-EU countries in your sector (based on product volumes)?



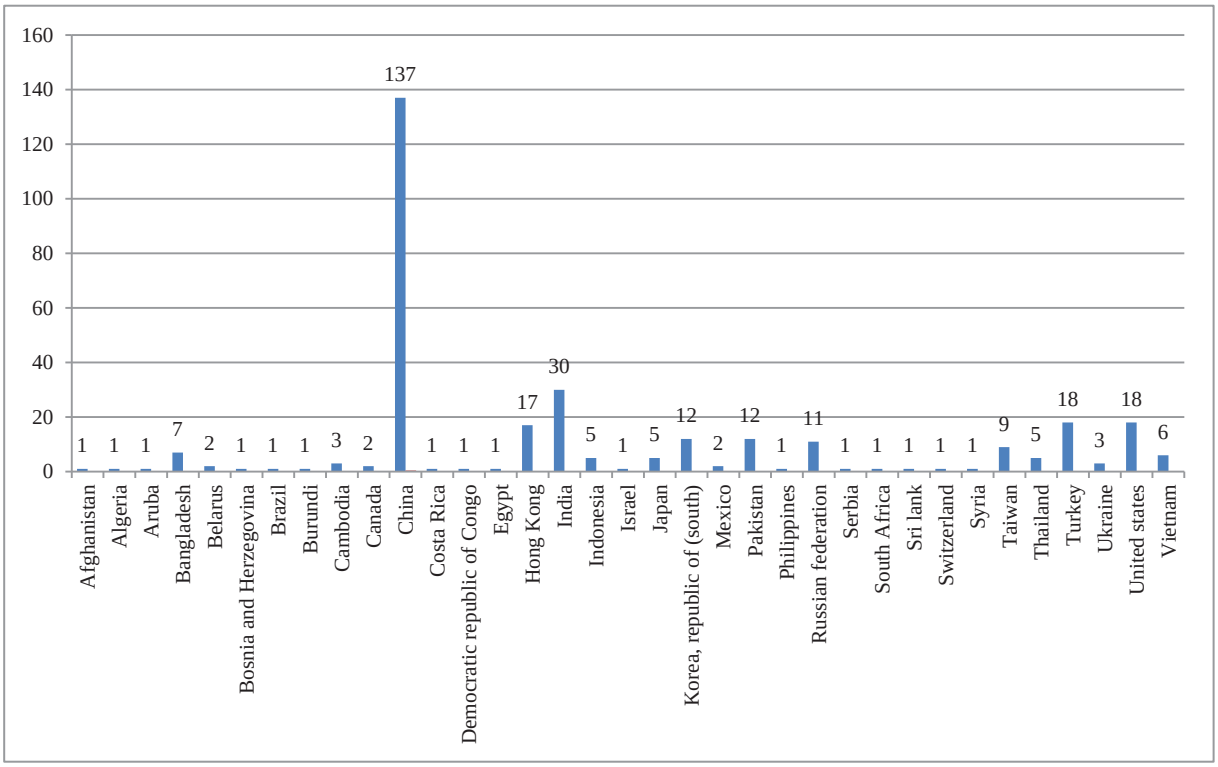
2. Are products in your sector imported from non-EU countries affected by non-compliance?



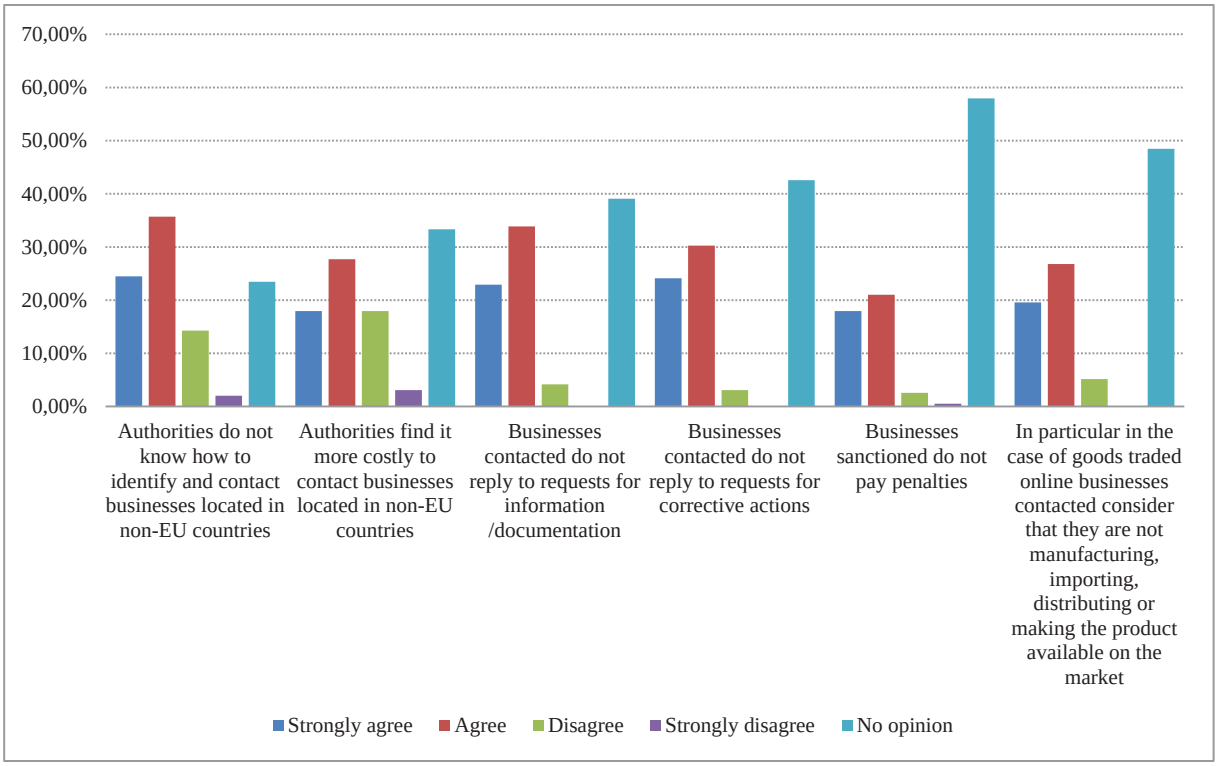
3. Are the non-compliant products in your sector imported from non-EU countries supplied 'online'? (as opposed to through 'brick and mortar' shops)



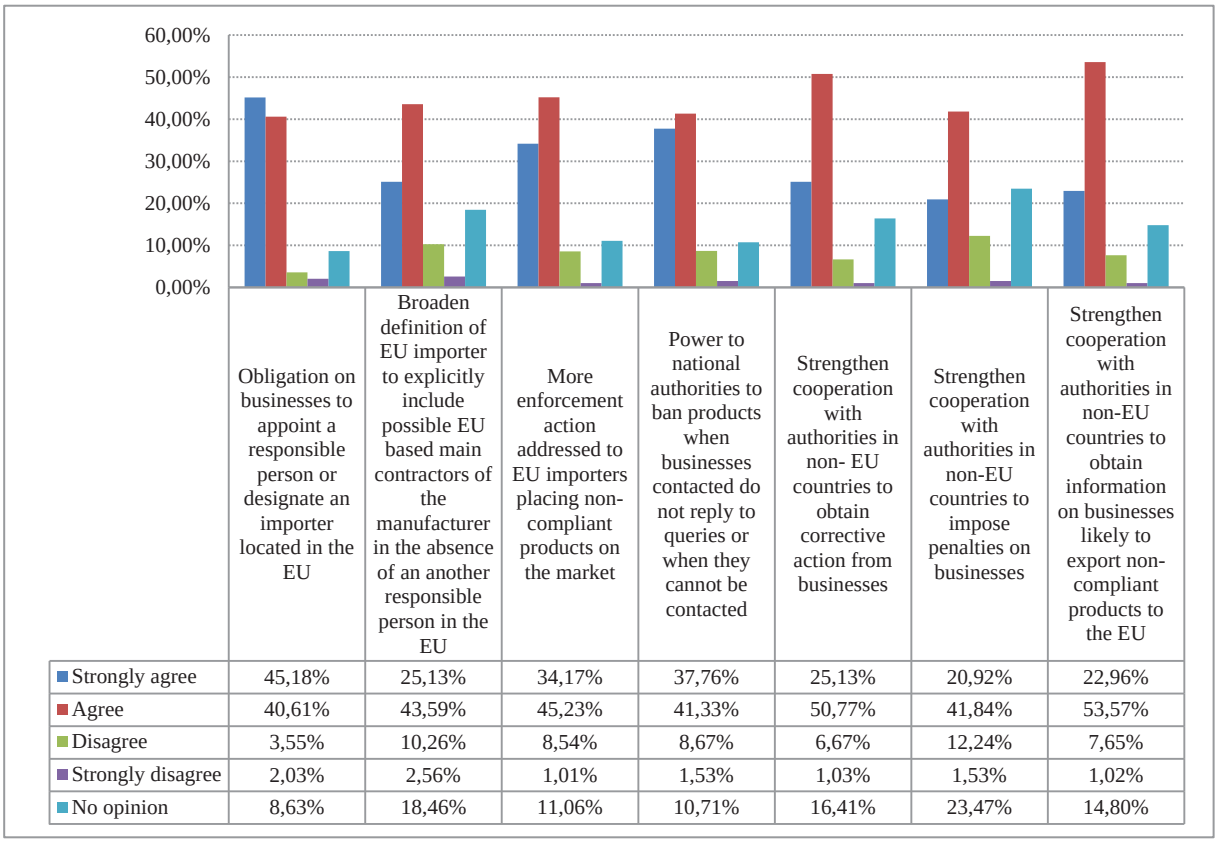
4. What is the country of origin of imported products you often found to be non-compliant (if any)



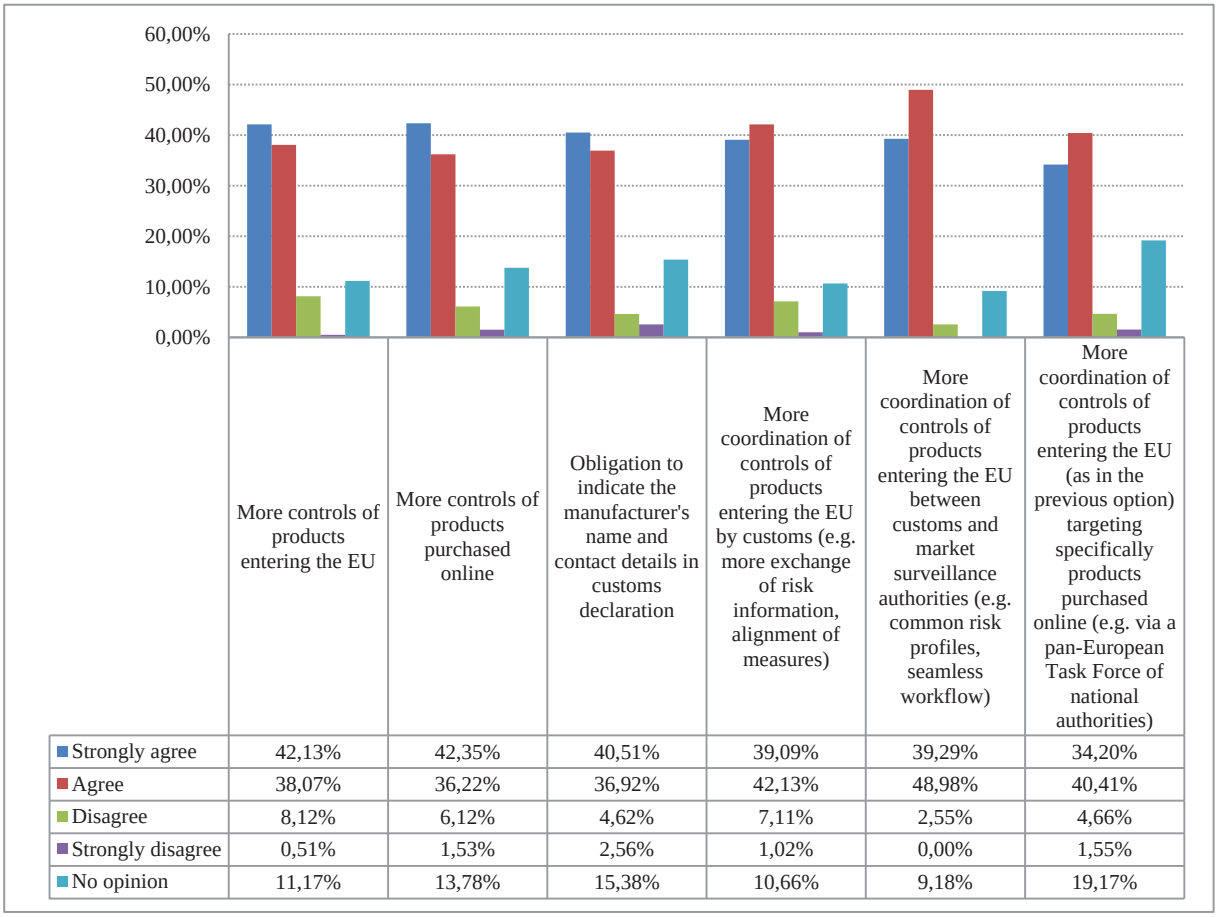
5. In your experience what makes it difficult to take action against non-compliant products traded by businesses located in a non-EU country?



6. In your experience or understanding would the following options help in taking action against non-compliant products traded by businesses located in a non-EU country?



	Obligation on businesses to appoint a responsible person or designate an importer located in the EU	Broaden definition of EU importer to explicitly include possible EU based main contractors of the manufacturer in the absence of an another responsible person in the EU	More enforcement action addressed to EU importers placing non-compliant products on the market	Power to national authorities to ban products when businesses contacted do not reply to queries or when they cannot be contacted	Strengthen cooperation with authorities in non- EU countries to obtain corrective action from businesses	Strengthen cooperation with authorities in non-EU countries to impose penalties on businesses	Strengthen cooperation with authorities in non-EU countries to obtain information on businesses likely to export non-compliant products to the EU
Strongly agree	45,18%	25,13%	34,17%	37,76%	25,13%	20,92%	22,96%
Agree	40,61%	43,59%	45,23%	41,33%	50,77%	41,84%	53,57%
Disagree	3,55%	10,26%	8,54%	8,67%	6,67%	12,24%	7,65%
Strongly disagree	2,03%	2,56%	1,01%	1,53%	1,03%	1,53%	1,02%
No opinion	8,63%	18,46%	11,06%	10,71%	16,41%	23,47%	14,80%



	More controls of products entering the EU	More controls of products purchased online	Obligation to indicate the manufacturer's name and contact details in customs declaration	More coordination of controls of products entering the EU by customs (e.g. more exchange of risk information, alignment of measures)	More coordination of controls of products entering the EU between customs and market surveillance authorities (e.g. common risk profiles, seamless workflow)	More coordination of controls of products entering the EU (as in the previous option) targeting specifically products purchased online (e.g. via a pan-European Task Force of national authorities)
Strongly agree	42,13%	42,35%	40,51%	39,09%	39,29%	34,20%
Agree	38,07%	36,22%	36,92%	42,13%	48,98%	40,41%
Disagree	8,12%	6,12%	4,62%	7,11%	2,55%	4,66%
Strongly disagree	0,51%	1,53%	2,56%	1,02%	0,00%	1,55%
No opinion	11,17%	13,78%	15,38%	10,66%	9,18%	19,17%

ANNEX 3: WHO IS AFFECTED BY THE INITIATIVE AND HOW

1. SME TEST

(1) Consultation with SMEs representatives	Consultation with SMEs took place throughout the following process: • A stakeholder conference held on 17 June 2016, open to all interested participants (industry, consumers, authorities, SMEs etc.) • Public consultation which ended on 31 October 2016. Participation of SMEs in the consultation was promoted and supported through the European Enterprise Network. Regarding the number of employees, 33.78% of the business representatives declare that their organisation has 1 – 9 employees, 13.51% 10 – 49 employees, and 12.16% 50 – 249 employees. • Informal consultation of SMEs at the Small Business Act follow-up meeting with stakeholders in December 2016. **Feedback from SMEs:** The Commission presented the reflections on the possible options to address the problem of non-compliance and asked for feedback. Businesses representatives confirmed that SMEs are also hit by non-compliance like bigger companies. When SMEs are themselves non-compliant this is most likely due to the lack of adequate knowledge about applicable requirements and therefore compliance assistance would be welcome. Deterrence could be improved if authorities could take into account feedback from businesses (notably following peer reviews among businesses).
(2) Preliminary assessment of businesses likely to be affected	The value of EU harmonised products amounted on average to more than 2 400 billion euro per year during the period 2008-2014, and corresponds to about 69% of the overall value of manufacturing products in the EU. About 900,000 businesses are involved in the manufacturing of industrial products (53% of all businesses active in the EU manufacturing sector) employing more than 20 million people (68% of all persons employed in the manufacturing sector. Furthermore, the value added of wholesale and retail traders whose sales are likely to include harmonised products during the 2008-2015 period is estimated around 850 billion euro per year. The number of enterprises active in the distribution of products in these sectors is estimated around 4 million and the number of their employees over 22.5 million people. 99% of manufacturing enterprises are SMEs (78% micro-enterprises, 16.4% SMEs employing up to 49 persons and 4.4% SMEs employing between 50 and 249 persons). Almost 100% of retail enterprises are SMEs (93.6% microenterprises, 5.4%, employing up to 49 persons and 0.7% SMEs employing between 50 and 249 persons).

	The public consultation revealed that finding and understanding the correct information on the technical rules that products need to meet before they can be placed on the domestic and on other EU markets is a problem but probably not a major problem. Yet, considering that few compliance practices are specifically aimed at SMEs, the need for **assistance** is probably more pressing for SMEs in the supply chain. National and multi-national economic operators already have the resources to determine product compliance and current schemes do not benefit SMEs sufficiently. 50% of the SMEs' respondents to the public consultation declared that they had difficulty in finding the correct information on the technical rules that products need to meet before they can be placed on the domestic market and 47.7% before they can be placed on other EU markets. Additionally, 50% of the same respondents agreed that a broader use of electronic means to demonstrate compliance would help to allow information to be obtained faster. Furthermore, an increased level of **transparency** of compliance, via various means such as the publication of compliance related information on company websites and the publication of enforcement decisions addressing non-compliant products should help SMEs to determine product compliance. The reduction of the risk of 'free-trading' by unscrupulous operators and improvement of the level playing field among businesses trading harmonised products in the Single Market will have a positive impact on the competitiveness of responsible businesses which are affected by the unfair competition of non-compliant products. Among others, improving **fairness** on the Single Market will affect SMEs. 61.36% of the SMEs representatives replied to the public consultation that the products in their sectors are affected by non-compliance with product requirements laid down in EU harmonisation legislation. 50% of them agreed that the problem of non-compliance negatively affects consumers and other end-users, while 61.37% stated that businesses complying with legal obligations experience negative effects on sales and/or market shares due to the presence of non-compliant products. SMEs like other businesses will be able to benefit of more information at lower or no costs. SMEs will also be able to return non-compliant products purchased for their use or to have them replaced at no cost]. On the other hand, SMEs found to be trading non-compliant products will be asked, like other business, to pay the costs of controls borne by authorities.
(3) Measurement of the impact on SMEs	The proposals under the selected option would imply benefits for businesses helping them to comply, increasing transparency and reduce the negative effects of unfair competition. Concerning the compliance assistance to businesses via information, the assumption is that mainly information would be

	given, free of charge. Therefore, this option would not entail any costs for businesses. There would be indirect positive impacts on the efficiency and availability of resources for market surveillance. The digital compliance system would create, for many companies, a one-off setup cost to create an in-house database with electronic versions of the documents to be uploaded into the centralised database as well as a new process for demonstrating compliance. In particular, this database would impose potentially significant costs related to security. The significance of these costs would depend to a large extent on the system that would be implemented and how compatible it is with each company's current procedures For the common for voluntary measures, no costs for businesses were identified. The possibility to inform consumers through this portal would not create a new obligation for economic operators, thus it would not constitute an additional administrative burden. It would help them to comply with their obligations to take the necessary measures to inform consumers free of charge, thus not entailing additional expenses for economic operators. In general, no other costs or significant impacts were identified, which would lead to additional requirements or need for extra compliance efforts by businesses. However, there is no specific analysis of the distribution of the potential costs and benefits of the policy options over the businesses' size.
(4) Assess alternative options and mitigating measures	At the end of the impact assessment, the selected option shows that the initiative might have a very positive economic impact on the stakeholders in general, including SMEs. Consequently, there is no element showing the need for SME specific measures in order to ensure compliance with the proportionality principle.

2. STAKEHOLDERS AFFECTED BY THE PREFERRED POLICY OPTION

The following stakeholders would be affected by the initiative as set out in the preferred policy option (section 7 of the impact assessment report):

National market surveillance authorities

National market surveillance authorities will benefit from a **more effective tool box** to trace, intercept and punish trader of non-compliant products. They would **save costs** by making use of evidence and enforcement decisions prepared by other authorities. Also costs recovery of control costs from operators supplying non-compliant products would be extended to more member states. Respondents in the public consultation rated these measures **highly favourably**.

They would benefit from direct support of the EU Product Compliance Network which would allow them to **coordinate and participate in cross-border joint action in a more efficient manner** than is currently the case. On the other hand Member States would have

adjustments costs to more intensive use or new mutual assistance or coordination procedures and the EU Product Compliance Network.

Commission

Cost for the Commission/EU budget would be associated with the establishment of an EU Product Compliance Network. In the baseline scenario, the Commission manages various tasks (support contract, IT tools) in a fragmented, ad-hoc manner. These tasks would pass onto the Network which could upscale and provide a more substantial and coherent support structure. Regardless of a possible hosting of the Network within the Commission or within an existing agency, the Commission would continue to participate in the Networks activities and focus on legislative and regulatory matters. This role of the Commission would be proportionate and carefully balanced viz. subsidiarity concerns. Respondents in the public consultation were more favourable to enforcement decisions taken in close coordination via a product compliance forum (63% strongly agree/agree) than enforcement decisions taken by the Commission (42% strongly agree/agree).

The improved coordination and strengthened enforcement strategies by Member states would allow the Commission to **gain better insight** in the gaps and needs of market surveillance authorities and the overall performance of market surveillance in the Single Market. This will help the Commission to exercise oversight.

Businesses

In the public consultation 71% of respondents indicated that in their sector businesses would be negatively affected by problems of non-compliance (of which nearly 30% even to a significant extent). The impacts specifically on SME are detailed above in section 3,1 of this annex.

The measures in the preferred option should help to reduce the magnitude the problems:

The initiative would have positive effects on the business environment of law-abiding companies at little to no additional costs or new obligations. By reducing the risk of 'free-trading' by unscrupulous operators and improving the l**evel playing field among businesses trading harmonised products in the Single Market** the measures in the preferred option will have a positive impact on the competitiveness of responsible businesses which are affected by the **unfair competition** of non-compliant products. On the contrary, the more and more effective enforcement by market surveillance authorities in domestic markets and viz. imports should lead to **more detection of non-compliant and sanctioning of rogue traders**.

To increase transparency and facilitate compliance throughout the supply chain, manufacturers and importers would be asked to provide in a digital form (e.g. website) relevant compliance information which they are already require to hold and maintain.

To ensure the implementation of this principle, businesses that place products on the EU market (i.e. including directly from 3rd countries without an importer such as in the case of on-line sales) will be asked to ensure a **responsible person for compliance information** acting in their behalf is in located the EU. These businesses will then incur additional one-off costs for the selection of party able to fulfil the function of representative and the set-up of the relative contract. Additional costs concern only a portion of businesses and do not imply a discrimination of third country businesses vis-à-vis other business, as they actually remedy to

the current unbalanced situation where EU and third countries businesses with a presence in the EU can be reached by authorities while others cannot.

Economic operators in the supply chain would **find more easily relevant compliance information** on products they purchase from other operators. Stepped-up compliance information and information by market surveillance authorities would in addition give them more **legal certainty**.

Finally the preferred option contains a Common European Portal though which businesses could provide information to EU consumers on **voluntary measures** regarding their products. This measure would help businesses to comply with their existing obligations to inform consumers free of charge. It would not create new reporting obligations or administrative burden.

Consumers and other end-users

In the public consultation 75% of respondents indicated that consumers and other end-users would be negatively affected by problems of non-compliance (of which 25% even to a significant extent). The measures in the preferred option should help to reduce the magnitude these problems:

Consumer and other, professional end-users of products that are subject to EU harmonisation legislation will benefit from the more and more effective enforcement against non-compliant products and increased level of protection that will result from the initiative. **Fewer non-compliant products** that circulate in or enter the Single Market, implies that consumers would be less likely to purchase such products inadvertently and they would be less exposed to the potential harm that could be caused by such non-compliant products (e.g. adverse health or safety impacts, property losses, higher energy consumption, incorrect measurement of quantities traded).

The increased visibility of enforcement efforts, including by publication of restrictive measures, would create a **higher awareness** among consumers and professional end-users about the risks of non-compliant products.

ANNEX 4: METHODS AND ANALYTICAL MODELS USED IN PREPARING THE IMPACT ASSESSMENT

The absence of detailed, reliable and systematic statistics on enforcement activity and compliance rates across sectors and Member States makes it difficult to provide quantified estimates of the scale of positive impacts on compliance that could results from the policy options[2]. The impact assessment relies on triangulation of the results from the public and other targeted consultations, analysis of data reported by Member States, results from joint enforcement actions, where relevant data or cases from related policy areas, case-studies and literature, and ultimately expert judgement.

Member States have implemented the market surveillance provisions of Regulation (EC) n° 765/2008 many different, specific forms, in terms of organisational structures, level of deployed resources (financial, human and technical), market surveillance strategies and approaches, powers of inspection, and sanction and penalties for product non-compliance[3]. In relation to choices of enforcement regimes, the OECD (2006) concludes that it is highly unlikely that any single model of practices and procedures will provide the most cost-effective means of achieving a high degree of compliance[4]. That being said a 'mix' of best-practice principles for enforcement and inspection can be proposed (OECD 2014)[5] [6] and could serve as a basis to benchmark policy actions[7].

[2] Few authoritative models are available on effectiveness of market surveillance. The UNECE's ongoing work on a Market Surveillance Model Initiative attempts to arrive at a quantitative modelling tool for MSA's to assess the effectiveness of their market surveillance actions. At present however the research does not allow concluding unequivocally what constitutes an effective market surveillance system.https://www.unece.org/fileadmin/DAM/trade/wp6/documents/2009/wp6_09_GMS_012E.pdf; http://www.unece.org/index.php?id=43283#/

[3] Technopolis, Ex-post evaluation of the application of the market surveillance povisions of Regulation (EC) n° 765/2008, 2017.

[4] Best practices for consumer policy: Report on the effectiveness of enforcement regimes, DSTI/CP(2006)/21Final, OECD, 2006.

[5] OECD, 2014 http://www.oecd.org/gov/regulatory-policy/enforcement-inspections.htm

[6] Further refinements could be considered e.g. including elements from ISO standard criteria for bodies performing inspections; see also Annex 12.

[7] Similarly in the area of competition policy, the OECD has developed competition law and policy indicators measure the strength and scope of competition regimes and are the foundation for assessing the impact of competition regimes. OECD, 2013, http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ECO/WKP(2013)96&docLanguage=En

ANNEX 5: GENERAL MARKET STATISTICS

1. MARKET ANALYSIS

The market analysis and the detailed statistics were based on the reference list of sectors included in the annex of "Template for drafting a national market surveillance programme pursuant to article 18(5) of Regulation (EC) No 765/2008"[8]. In order to focus on the variables to be included in the analysis, the appropriate NACE divisions have been identified in an attempt to create a correspondence between the list of harmonised sectors and economic sectors / products included in the market analysis. All results should be considered as an estimate, as some divisions might contain one or more classes for which harmonised product rules do not exist.

The analysis for manufacturing had a two-stage approach:

- An analysis a sectorial level oriented towards the macro dimension, looking at:
  - The number of economic operators that are active within the economic sectors for which EU harmonised product rules exist (harmonised sectors);
  - The current contribution of the harmonised sector to the EU economy;
- An analysis at product level focused on the value of harmonised products that are traded within the EU Single Market.

Around 1,850 harmonised products have been identified that represent around 46% of all products (around 4,000) included in the PRODCOM list. The value of harmonised products traded within the EU Single Market has been on average €2,478 billion during the period 2008 – 2014, this corresponds to around 69% of the overall value of traded manufacturing products. This value has been computed considering the following values for the identified harmonised products: value of sold production – Value of Extra EU Exports + Value of Extra EU Imports. 30% of the value of harmonised products (€756 billion) is related to goods imported from non-EU countries. The intra EU imports of products for which harmonised product rules exist represent also 66% of the value of the overall (intra-EU) imports of manufacturing goods (€1,183 billion).

All data were extracted from three databases:

- Structural business statistics (SBS)[9] provided by EUROSTAT to describe the structure of harmonised sectors and measure their economic performance;
- Prodcom - Statistics by Product[10] provided by EUROSTAT to estimate the value of non-harmonised products;
- EU trade since 1988 by Standard International Trade Classification (SITC)[11] provided by EUROSTAT to estimate the value of intra EU trade of harmonised products.

8 http://ec.europa.eu/DocsRoom/documents/20141
9 http://ec.europa.eu/eurostat/web/structural-business-statistics
10 http://ec.europa.eu/eurostat/web/prodcom/overview
11 http://ec.europa.eu/eurostat/web/international-trade-in-goods/data/database

The statistics for trade looked at the number of economic operators that are active within the economic sectors for which EU harmonised product rules exist and the current contribution of the harmonised sector to the EU economy.

Data was extracted from the SBS database[12] based on NACE Rev. 2 classification. In particular the following were considered:

- Business demographic variables (number of enterprises)
- Input related variables: labour input (number of people employed)
- Output related variables (i.e. value added).

2. DETAILED STATISTICS (MANUFACTURING)

2.1 Analysis at sectorial level

It is important to underline that since data are available at NACE division level (Digit 2 – NACE code), all results should be considered as an upper estimate, as some divisions might contains one or more classes for which harmonised product rules do not exist.

Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2] – EU 28

Last update: 17.02.2017

Extracted on: 20.02.2017

Source of data: Eurostat

INDIC_SB: Number of enterprises

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
C13 - Manufacture of textiles	64,422	61,087	61,940	60,798	59,821	59,285	61,311
C14 - Manufacture of wearing apparel	140,824	130,704	130,292	125,953	125,029	122,901	123,399
C15 - Manufacture of leather and related products	40,770	37,337	36,523	36,692	36,418	36,240	36,624
C20 - Manufacture of chemicals and chemical products	28,932	28,634	28,770	28,206	28,320	28,331	28,560
C21 - Manufacture of basic pharmaceutical products and pharmaceutical preparations	3,827	4,604	3,814	3,903	4,021	4,176	4,124
C22 - Manufacture of rubber and plastic products	67,811	66,006	66,872	65,097	63,360	62,182	62,484
C23 - Manufacture of other non-metallic mineral products	106,758	101,683	103,673	101,687	98,020	95,457	95,314
C24 - Manufacture of basic metals	17,789	17,513	18,017	18,371	17,343	17,068	17,183

12 http://ec.europa.eu/eurostat/web/structural-business-statistics/data/database

C25 - Manufacture of fabricated metal products, except machinery and equipment	380,680	369,561	392,794	391,034	382,816	373,925	382,277
C26 - Manufacture of computer, electronic and optical products	46,449	45,045	44,385	42,627	41,447	41,807	41,681
C27 - Manufacture of electrical equipment	50,812	50,636	52,315	51,242	50,204	48,510	48,320
C28 - Manufacture of machinery and equipment n.e.c.	103,368	97,445	98,230	96,621	92,938	91,981	91,692
C29 - Manufacture of motor vehicles, trailers and semi-trailers	21,174	19,818	20,189	20,178	19,481	19,338	19,678
C30 - Manufacture of other transport equipment	14,442	14,393	14,588	14,423	14,004	13,766	14,209
C32 - Other manufacturing	138,155	136,943	146,585	146,016	147,609	149,306	155,086
Total	**1,226,213**	**1,181,409**	**1,218,987**	**1,202,848**	**1,180,831**	**1,164,273**	**1,181,942**

Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2] – EU 28

Last update: 17.02.2017

Extracted on: 20.02.2017

Source of data: Eurostat

INDIC_SB: Turnover or gross premiums written

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
C13 - Manufacture of textiles	84,512	69,784	75,988	79,997	74,677	74,605	76,525
C14 - Manufacture of wearing apparel	87,910	72,976	72,808	75,678	69,500	67,917	70,754
C15 - Manufacture of leather and related products	47,269	38,525	43,289	47,082	48,698	45,340	53,633
C20 - Manufacture of chemicals and chemical products	480,385	418,208	495,208	541,016	544,910	539,577	537,109
C21 - Manufacture of basic pharmaceutical products and pharmaceutical preparations	188,831	208,889	211,024	214,725	227,031	226,752	237,383
C22 - Manufacture of rubber and plastic products	284,629	237,886	267,637	293,898	287,066	288,755	295,398
C23 - Manufacture of other non-metallic mineral products	253,900	208,533	204,657	220,901	207,513	201,079	204,754

C24 - Manufacture of basic metals	428,242	266,576	335,619	390,939	365,273	339,896	340,584
C25 - Manufacture of fabricated metal products, except machinery and equipment	493,358	403,229	435,087	471,949	468,254	460,153	469,450
C26 - Manufacture of computer, electronic and optical products	327,877	268,583	292,428	273,853	278,275	273,776	289,714
C27 - Manufacture of electrical equipment	296,774	255,789	280,483	303,628	294,145	289,359	289,758
C28 - Manufacture of machinery and equipment n.e.c.	613,887	508,448	545,318	618,338	631,858	622,272	640,140
C29 - Manufacture of motor vehicles, trailers and semi-trailers	801,102	624,875	739,934	839,818	846,599	866,735	924,548
C30 - Manufacture of other transport equipment	163,374	157,901	163,471	161,232	174,014	177,649	194,201
C32 - Other manufacturing	98,301	94,216	104,660	112,103	113,696	111,907	116,735
Total	**4,650,349**	**3,834,416**	**4,267,611**	**4,645,156**	**4,631,508**	**4,585,771**	**4,740,685**

Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2] – EU 28

Last update: 17.02.2017

Extracted on: 20.02.2017

Source of data: Eurostat

INDIC_SB: Value added at factor cost

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
C13 - Manufacture of textiles	23,613	19,654	21,793	22,159	21,126	21,153	21,899
C14 - Manufacture of wearing apparel	23,938	19,393	19,463	20,439	18,717	18,645	19,670
C15 - Manufacture of leather and related products	11,644	9,707	11,713	12,299	12,643	11,455	14,235
C20 - Manufacture of chemicals and chemical products	102,247	91,775	110,988	111,538	106,492	104,991	114,710
C21 - Manufacture of basic pharmaceutical products and pharmaceutical preparations	66,717	71,581	73,512	76,397	83,653	69,035	80,447
C22 - Manufacture of rubber and plastic products	80,103	70,299	77,118	81,576	80,394	81,228	85,064
C23 - Manufacture of other non-metallic mineral products	79,114	63,147	63,076	65,644	60,577	58,843	62,149
C24 - Manufacture of basic metals	80,324	46,718	60,626	63,847	57,498	56,862	61,843

C25 - Manufacture of fabricated metal products, except machinery and equipment	163,659	137,121	149,191	158,766	159,229	158,946	167,101
C26 - Manufacture of computer, electronic and optical products	82,029	64,528	77,613	71,914	73,555	72,591	77,918
C27 - Manufacture of electrical equipment	83,068	74,717	85,277	86,529	85,176	84,388	85,666
C28 - Manufacture of machinery and equipment n.e.c.	182,609	150,111	172,592	191,675	190,700	190,137	199,542
C29 - Manufacture of motor vehicles, trailers and semi-trailers	133,857	99,018	140,797	154,252	150,137	157,813	181,251
C30 - Manufacture of other transport equipment	47,474	42,657	46,306	47,304	51,057	53,608	54,229
C32 - Other manufacturing	35,970	34,872	39,503	42,506	41,559	37,541	43,333
Total	**1,196,366**	**995,298**	**1,149,568**	**1,206,842**	**1,192,512**	**1,177,235**	**1,269,055**

Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2] – EU 28

Last update: 17.02.2017

Extracted on: 20.02.2017

Source of data: Eurostat

INDIC_SB: Number of persons employed

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
C13 - Manufacture of textiles	730,477	635,594	602,122	638,431	611,137	602,942	608,060
C14 - Manufacture of wearing apparel	1,288,220	1,108,524	1,078,032	1,046,414	1,005,144	973,918	969,762
C15 - Manufacture of leather and related products	455,967	393,606	412,550	424,091	421,773	423,887	433,945
C20 - Manufacture of chemicals and chemical products	1,076,079	1,031,277	1,169,929	1,172,142	1,159,566	1,147,688	1,146,472
C21 - Manufacture of basic pharmaceutical products and pharmaceutical preparations	422,206	436,363	491,390	454,206	540,069	497,736	542,522
C22 - Manufacture of rubber and plastic products	1,563,742	1,436,169	1,618,215	1,650,655	1,619,321	1,622,869	1,649,665
C23 - Manufacture of other non-metallic mineral products	1,440,147	1,293,147	1,333,697	1,342,452	1,278,170	1,231,496	1,224,781
C24 - Manufacture of basic metals	1,055,689	943,086	1,006,950	1,015,355	991,598	963,838	962,384

C25 - Manufacture of fabricated metal products, except machinery and equipment	3,557,995	3,343,947	3,599,634	3,655,127	3,598,328	3,569,223	3,604,522
C26 - Manufacture of computer, electronic and optical products	1,127,975	1,002,575	1,136,659	1,095,643	1,126,657	1,108,699	1,089,980
C27 - Manufacture of electrical equipment	1,433,374	1,332,254	1,466,551	1,488,681	1,459,910	1,449,203	1,432,494
C28 - Manufacture of machinery and equipment n.e.c.	2,941,171	2,727,707	2,840,648	2,902,308	2,920,152	2,917,483	2,912,683
C29 - Manufacture of motor vehicles, trailers and semi-trailers	2,162,516	1,984,939	2,167,171	2,236,181	2,289,826	2,297,415	2,365,720
C30 - Manufacture of other transport equipment	631,983	625,854	717,065	707,530	706,256	713,710	735,450
C32 - Other manufacturing	798,121	755,245	871,055	895,623	882,347	866,872	881,221
Total	**20,685,662**	**19,050,287**	**20,511,668**	**20,724,839**	**20,610,254**	**20,386,979**	**20,559,661**

If the size of enterprises is considered, micro and SMEs active in harmonised sectors represent **more than 99% of the manufacturing** in these sectors.

Value added at factor cost – EU 28

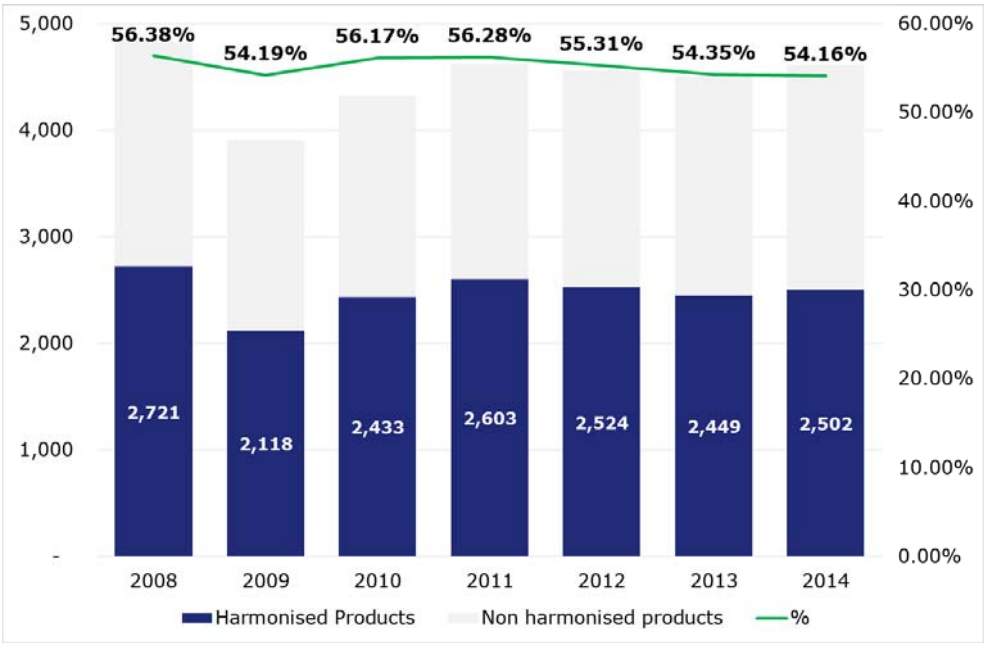
Size of enterprises	**Harmonised Sectors**		**Manufacturing**		**a/b**
	Total (€b) (a)	**%**	**Total (€b)**	**%**	**%**
Micro enterprises (0-9 employees)	**49.02**	6%	84.64	7%	**4%**
SMEs (10 – 249 employees)	**323.54**	38%	451.88	39%	**28%**
Large enterprises (> 249 employees)	488.56	57%	627.25	54%	42%
Total	861	100%	**1,164 (b)**	100%	74%

Turnover or gross premiums written

Size of enterprises	**Harmonised Sectors**		**Manufacturing**		**a/b**
	Total (€b) (a)	**%**	**Total (€b)**	**%**	**%**
Micro enterprises (0-9 employees)	146.15	4%	251.03	5%	3%
SMEs (10 – 249 employees)	1,091.72	33%	530.30	34%	24%
Large enterprises (> 249 employees)	2,067.94	63%	2,782.93	61%	45%
Total	3,306.81	100%	4,564.26	100%	72%

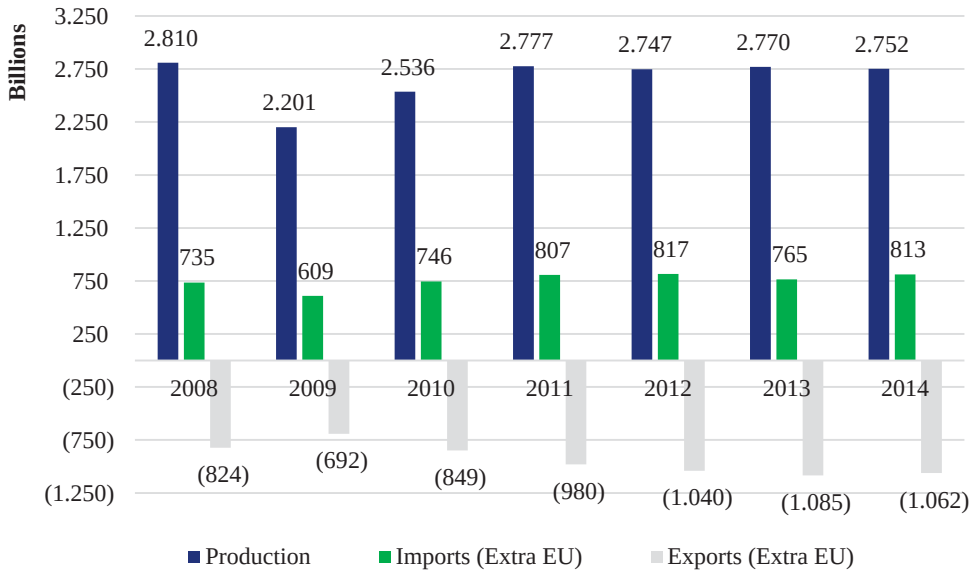
2.2 Analysis at product level

Value of harmonised products circulating within the European Single Market (2008-2015), € billions, EU28



Source: Prodcom – statistics by product, EUROSTAT (2016)

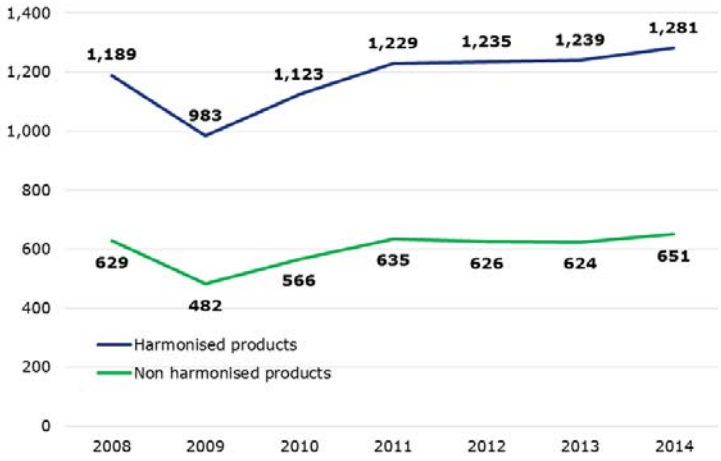
Trade of harmonised products: sold production and trades with non EU countries (2008-2015, EU-28), € billions

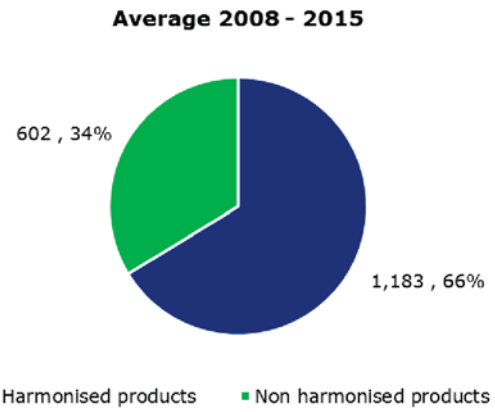


Source: Prodcom – statistics by product, EUROSTAT (2016)

The intra EU imports of products for which harmonised product rules exist represent also 66% of the value of the overall (intra-EU) imports of manufacturing goods (€1,183 billion).

Value of intra EU imports: harmonised products vs non-harmonised products (annual value and annual average 2008-2015, EU-28, EUR billion)





Source: EU trade since 1998 by SITC, EUROSTAT (2016)

3. DETAILED STATISTICS (RETAIL)

Annual detailed enterprise statistics for trade (NACE Rev. 2 G) [sbs_na_dt_r2] – EU 28

Last update	13/01/17
Extracted on	03/02/17
Source of data	Eurostat
INDIC_SB	Number of enterprises

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
Sale of cars and light motor vehicles	178,747	184,435	182,110	189,127	189,835	192,212	198,430
Sale of other motor vehicles	11,335	12,724	12,724	14,000	14,089	14,471	14,781
Sale of motor vehicle parts and accessories	106,823	106,823	110,000	113,509	114,560	115,432	117,558
Wholesale on a fee or contract basis	533,922	533,922	579,659	590,000	588,690	583,523	583,431
Agents involved in the sale of timber and building materials	37,435	38,049	38,956	38,431	37,572	36,506	36,436
Agents involved in the sale of machinery, industrial equipment, ships and aircraft	38,544	41,284	41,692	41,651	41,753	40,197	40,872
Agents involved in the sale of textiles, clothing, fur, footwear and leather goods	49,822	49,762	50,496	50,220	49,179	48,185	44,449
Agents involved in the sale of a variety of goods	142,182	135,424	165,673	170,242	171,493	174,055	178,561
Wholesale of textiles	24,988	23,220	23,497	22,758	22,462	22,225	23,284
Wholesale of clothing and footwear	68,821	62,802	62,940	62,722	63,872	61,021	62,079
Wholesale of electrical household appliances	34,560	32,761	30,907	29,851	29,166	28,772	28,476
Wholesale of china and glassware and cleaning materials	17,235	18,202	18,427	17,744	17,335	16,516	16,455

Wholesale of perfume and cosmetics	18,380	18,472	18,951	18,663	19,829	21,471	21,624
Wholesale of furniture, carpets and lighting equipment	25,681	24,692	24,695	24,742	24,028	24,606	24,579
Wholesale of watches and jewellery	11,935	12,350	13,136	12,976	12,905	13,709	13,904
Wholesale of other household goods	87,579	85,197	89,707	90,205	86,849	87,462	85,658
Wholesale of information and communication equipment	59,241	60,000	60,000	61,081	60,706	61,256	62,322
Wholesale of agricultural machinery, equipment and supplies	22,507	19,782	21,633	21,774	22,499	23,468	22,696
Wholesale of machine tools	13,141	13,726	14,076	14,602	13,982	13,782	14,190
Wholesale of mining, construction and civil engineering machinery	9,779	9,910	10,173	10,152	10,167	11,226	10,247
Wholesale of machinery for the textile industry and of sewing and knitting machines	2,858	2,858	2,858	2,451	2,483	2,400	2,242
Wholesale of other office machinery and equipment	10,965	11,003	11,163	11,761	10,971	10,584	10,733
Wholesale of other machinery and equipment	93,560	99,363	101,202	102,338	103,453	103,095	105,612
Wholesale of wood, construction materials and sanitary equipment	116,192	116,095	115,587	114,767	114,114	113,312	113,775
Wholesale of hardware, plumbing and heating equipment and supplies	41,977	45,723	44,955	46,211	46,407	46,350	46,781
Wholesale of chemical products	26,356	26,565	27,411	27,733	27,877	27,479	27,590
Non-specialised wholesale trade	111,279	105,209	115,548	124,286	122,994	121,357	123,297
Retail sale in non-specialised stores with food, beverages or tobacco predominating	437,034	427,551	435,256	438,670	429,818	423,029	415,256
Other retail sale in non-specialised stores	116,445	126,887	135,908	143,923	140,986	135,023	132,956
Retail sale of information and communication equipment in specialised stores	99,768	99,768	99,768	94,571	90,497	90,324	88,931
Retail sale of textiles in specialised stores	77,278	80,110	78,152	77,169	73,302	70,118	68,096
Retail sale of hardware, paints and glass in specialised stores	141,868	138,500	135,325	131,903	131,402	125,655	125,191
Retail sale of electrical household appliances in specialised stores	54,634	55,483	54,486	50,055	46,912	44,204	42,244
Retail sale of furniture, lighting equipment and other household articles in specialised stores	178,372	173,255	168,405	168,813	161,615	154,629	150,479
Retail sale of games and toys in specialised stores	18,993	18,339	19,129	19,276	17,140	18,319	18,378
Retail sale of clothing in specialised stores	350,599	351,688	347,417	341,450	332,799	320,873	315,221

Retail sale of footwear and leather goods in specialised stores	80,338	79,912	81,694	77,665	77,288	71,463	70,910
Retail sale of medical and orthopaedic goods in specialised stores	20,530	21,124	21,191	22,633	24,348	24,781	23,925
Retail sale of cosmetic and toilet articles in specialised stores	47,566	47,566	47,807	48,367	45,409	44,906	45,968
Retail sale of watches and jewellery in specialised stores	70,068	69,637	67,830	69,145	68,839	68,397	67,582
Retail sale via stalls and markets of textiles, clothing and footwear	121,912	130,551	133,446	132,158	131,658	130,878	120,710
Retail sale via stalls and markets of other goods	102,578	94,904	94,904	119,407	119,535	124,217	153,413
Retail sale via mail order houses or via Internet	59,661	70,000	70,000	122,818	144,729	164,936	179,219
Total	**3,873,488**	**3,875,628**	**3,978,894**	**4,082,020**	**4,055,547**	**4,026,424**	**4,048,541**

* When there is no information, data from previous or following year is taken.

Annual detailed enterprise statistics for trade (NACE Rev. 2 G) [sbs_na_dt_r2] – EU 28

Last update	13/01/17
Extracted on	03/02/17
Source of data	Eurostat
INDIC_SB	Value added at factor cost

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
Sale of cars and light motor vehicles	67,556	59,527	63,046	67,581	61,671	60,965	69,474
Sale of other motor vehicles	8,684	5,275	5,886	6,675	6,105	6,816	6,946
Sale of motor vehicle parts and accessories	23,000	22,241	25,119	29,348	25,700	26,012	27,100
Wholesale on a fee or contract basis	41,000	37,052	41,353	44,490	43,524	44,001	43,897
Agents involved in the sale of timber and building materials	2,530	2,240	2,254	2,413	2,264	2,224	2,577
Agents involved in the sale of machinery, industrial equipment, ships and aircraft	6,819	5,860	6,388	6,623	7,230	7,158	7,936
Agents involved in the sale of textiles, clothing, fur, footwear and leather goods	3,650	2,667	3,654	3,832	3,223	3,482	3,765
Agents involved in the sale of a variety of goods	8,364	6,739	7,886	8,654	7,780	7,611	7,533
Wholesale of textiles	4,414	4,145	4,466	4,659	4,355	4,549	4,278
Wholesale of clothing and footwear	20,830	22,133	20,777	23,313	22,125	22,992	24,002
Wholesale of electrical household appliances	18,668	18,081	16,616	17,071	17,826	16,065	17,519
Wholesale of china and glassware and cleaning materials	4,455	5,102	5,608	5,890	5,568	4,981	7,350

Wholesale of perfume and cosmetics	10,035	12,061	12,718	11,610	12,318	12,925	11,118
Wholesale of furniture, carpets and lighting equipment	6,633	6,491	6,326	6,685	6,305	6,261	6,415
Wholesale of watches and jewellery	2,358	2,844	3,146	2,679	2,679	2,597	3,121
Wholesale of other household goods	26,320	26,350	25,446	27,097	25,028	29,780	27,950
Wholesale of information and communication equipment	42,378	42,000	42,000	47,049	48,338	49,000	50,000
Wholesale of agricultural machinery, equipment and supplies	8,450	7,511	7,021	8,836	9,318	10,040	9,815
Wholesale of machine tools	5,043	4,386	4,769	5,366	5,118	5,053	5,986
Wholesale of mining, construction and civil engineering machinery	6,949	5,380	5,167	6,078	6,037	6,065	6,230
Wholesale of machinery for the textile industry and of sewing and knitting machines	489	310	310	410	416	462	412
Wholesale of other office machinery and equipment	5,523	5,351	5,178	4,954	5,273	5,142	5,207
Wholesale of other machinery and equipment	52,298	49,163	54,040	56,977	59,083	56,241	61,163
Wholesale of wood, construction materials and sanitary equipment	39,682	34,768	34,575	37,777	33,676	35,559	36,833
Wholesale of hardware, plumbing and heating equipment and supplies	26,881	23,367	24,255	26,602	26,564	25,080	26,525
Wholesale of chemical products	13,889	13,673	16,141	16,181	16,282	16,576	16,903
Non-specialised wholesale trade	28,079	27,894	25,700	28,000	25,292	25,771	30,243
Retail sale in non-specialised stores with food, beverages or tobacco predominating	122,400	122,400	130,000	130,000	137,560	140,000	140,000
Other retail sale in non-specialised stores	23,684	23,684	23,684	23,684	23,684	23,684	23,684
Retail sale of information and communication equipment in specialised stores	13,105	12,605	11,798	11,000	11,796	10,441	10,723
Retail sale of textiles in specialised stores	2,984	3,014	2,894	2,483	2,470	2,562	2,653
Retail sale of hardware, paints and glass in specialised stores	22,614	21,146	21,496	22,529	20,773	20,603	21,594
Retail sale of electrical household appliances in specialised stores	7,470	6,646	6,370	6,258	5,747	5,691	5,842
Retail sale of furniture, lighting equipment and other household articles in specialised stores	24,437	22,694	23,843	24,201	22,495	22,343	22,853

Retail sale of games and toys in specialised stores	2,326	2,277	2,034	2,225	2,458	2,341	2,428
Retail sale of clothing in specialised stores	44,884	44,259	45,143	45,775	44,605	45,029	48,892
Retail sale of footwear and leather goods in specialised stores	8,516	9,608	10,411	9,619	9,907	9,653	10,005
Retail sale of medical and orthopaedic goods in specialised stores	4,073	4,217	4,254	4,609	4,948	5,245	5,134
Retail sale of cosmetic and toilet articles in specialised stores	8,799	7,339	8,149	8,003	7,589	8,707	9,710
Retail sale of watches and jewellery in specialised stores	6,600	6,070	6,994	7,491	7,603	6,907	7,587
Retail sale via stalls and markets of textiles, clothing and footwear	1,249	988	1,329	1,389	1,149	956	956
Retail sale via stalls and markets of other goods	1,137	1,137	1,137	816	941	941	1,026
Retail sale via mail order houses or via Internet	9,670	11,335	11,919	12,828	13,613	14,383	17,793
Total	**788,920**	**752,028**	**781,296**	**819,757**	**806,432**	**812,894**	**851,175**

* When there is no information, data from previous or following year is taken.

Annual detailed enterprise statistics for trade (NACE Rev. 2 G) [sbs_na_dt_r2] – EU 28

Last update	13/01/17
Extracted on	03/02/17
Source of data	Eurostat
INDIC_SB	Turnover or gross premiums written

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
Sale of cars and light motor vehicles	760,059	668,009.6	679,116.8	708,070.4	673,520.8	664,399.5	719,247.3
Sale of other motor vehicles	60,586	43,837.2	47,761.5	49,151.9	48,233.9	50,932.8	53,036.6
Sale of motor vehicle parts and accessories	139,000	127,835.9	148,145.7	168,249.0	166,000.0	166,923.7	172,000.0
Wholesale on a fee or contract basis	257,000	219,541.9	236,260.9	260,064.7	264,805.1	256,545.4	250,000.0
Agents involved in the sale of timber and building materials	9,312	6,668.8	7,307.3	7,537.8	7,779.7	7,566.7	7,639.0
Agents involved in the sale of machinery, industrial equipment, ships and aircraft	18,382	15,462.4	17,339.7	17,995.2	17,588.2	19,086.6	21,414.8
Agents involved in the sale of textiles, clothing, fur, footwear and leather goods	8,982	7,232.6	8,619.5	9,363.1	8,213.9	9,173.3	9,545.7
Agents involved in the sale of a variety of goods	55,127	48,388.1	50,080.9	56,239.7	56,788.1	55,583.9	52,125.2
Wholesale of textiles	26,859	24,083.2	26,976.5	27,547.6	28,128.7	26,161.3	27,127.3

Wholesale of clothing and footwear	118,896	119,916.3	114,266.3	130,209.0	135,707.4	132,652.0	143,308.2
Wholesale of electrical household appliances	172,804	159,310.6	159,189.8	149,874.2	152,911.3	149,499.5	141,651.1
Wholesale of china and glassware and cleaning materials	26,885	29,288.6	33,515.8	32,680.3	34,042.0	34,548.2	38,172.1
Wholesale of perfume and cosmetics	47,781	55,992.5	54,903.9	56,442.6	57,157.7	59,595.0	55,697.8
Wholesale of furniture, carpets and lighting equipment	43,104	36,819.2	37,328.0	39,905.5	39,427.9	37,175.0	38,934.6
Wholesale of watches and jewellery	14,692	14,715.4	17,317.6	21,205.6	21,205.6	18,641.9	18,065.7
Wholesale of other household goods	168,284	164,405.1	174,628.3	177,353.3	173,752.5	174,316.9	179,279.3
Wholesale of information and communication equipment	332,397	310,000.0	310,000.0	357,979.1	364,816.5	360,000.0	360,000.0
Wholesale of agricultural machinery, equipment and supplies	58,873	52,592.1	53,452.8	64,026.0	68,393.8	68,500.6	71,033.2
Wholesale of machine tools	26,146	22,268.1	25,526.1	28,416.0	27,703.6	27,629.6	29,705.1
Wholesale of mining, construction and civil engineering machinery	42,523	31,106.1	32,182.7	36,297.4	36,234.9	34,161.1	36,993.6
Wholesale of machinery for the textile industry and of sewing and knitting machines	2,840	2,839.7	2,839.7	2,173.8	2,358.4	2,411.1	2,049.6
Wholesale of other office machinery and equipment	26,130	25,766.7	26,040.0	26,261.7	25,125.9	24,913.4	24,939.5
Wholesale of other machinery and equipment	276,610	242,974.4	271,384.6	293,913.8	301,142.1	296,082.2	303,652.5
Wholesale of wood, construction materials and sanitary equipment	277,752	239,684.3	243,814.8	260,567.9	253,973.9	249,293.5	254,307.1
Wholesale of hardware, plumbing and heating equipment and supplies	141,866	131,370.9	141,598.4	150,673.2	150,968.7	142,687.1	144,918.2
Wholesale of chemical products	138,675	120,981.4	139,625.1	156,687.8	165,402.0	167,646.4	168,352.4
Non-specialised wholesale trade	236,577	218,941.2	225,000.0	240,000.0	241,507.9	255,000.0	269,941.8
Retail sale in non-specialised stores with food, beverages or tobacco predominating	922,634	900,000.0	900,000.0	1,000,000	1,021,082	1,000,000	1,000,000
Other retail sale in non-specialised stores	122,943	122,942.8	122,942.8	122,942.8	122,942.8	122,942.8	130,000.0

Retail sale of information and communication equipment in specialised stores	75,369	72,212.4	72,263.0	70,000.0	74,263.1	67,974.0	63,639.1
Retail sale of textiles in specialised stores	12,524	11,630.9	11,479.9	10,646.6	10,657.8	10,874.0	10,751.2
Retail sale of hardware, paints and glass in specialised stores	114,070	107,369.7	110,566.0	114,271.1	108,946.1	104,572.1	108,612.3
Retail sale of electrical household appliances in specialised stores	49,044	44,843.3	42,180.2	40,734.3	42,969.2	41,748.8	42,142.4
Retail sale of furniture, lighting equipment and other household articles in specialised stores	117,991	107,725.5	112,689.8	113,486.7	111,455.2	107,604.8	109,553.2
Retail sale of games and toys in specialised stores	12,363	11,831.5	12,265.1	12,381.0	11,809.1	11,949.2	12,244.7
Retail sale of clothing in specialised stores	187,702	178,158.1	188,552.6	194,066.9	193,236.8	191,531.3	203,719.3
Retail sale of footwear and leather goods in specialised stores	39,713	39,680.3	42,589.9	40,791.7	42,940.8	42,491.9	43,596.8
Retail sale of medical and orthopaedic goods in specialised stores	13,725	13,883.0	13,724.0	14,854.4	15,804.0	16,202.1	16,383.6
Retail sale of cosmetic and toilet articles in specialised stores	40,369	36,889.0	39,766.9	40,347.2	38,177.4	40,631.9	42,699.7
Retail sale of watches and jewellery in specialised stores	25,777	23,015.6	26,052.5	29,965.0	32,248.4	29,324.5	30,926.4
Retail sale via stalls and markets of textiles, clothing and footwear	5,111	3,642.5	4,773.4	5,126.5	4,276.5	3,735.5	3,735.5
Retail sale via stalls and markets of other goods	5,266	5,266.3	5,266.3	5,266.3	3,674.8	3,674.8	3,820.1
Retail sale via mail order houses or via Internet	65,438	67,942.7	67,942.7	67,942.7	67,942.7	67,942.7	67,942.7
Total	**5,298,181**	**4,887,066**	**5,057,278**	**5,411,710**	**5,425,318**	**5,354,327**	**5,482,905**

* When there is no information, data from previous or following year is taken.

Annual detailed enterprise statistics for trade (NACE Rev. 2 G) [sbs_na_dt_r2] – EU 28

Last update 13/01/17

Extracted on 03/02/17

Source of data Eurostat

INDIC_SB Number of persons employed

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
Sale of cars and light motor vehicles	1,492,200	1,462,700	1,399,400	1,416,400	1,366,000	1,330,500	1,335,452
Sale of other motor vehicles	124,200	120,600	120,900	122,000	119,900	123,600	121,601
Sale of motor vehicle parts and accessories	670,000	685,000	674,800	707,400	704,900	706,300	706,230
Wholesale on a fee or contract basis	971,600	1,006,700	1,004,400	1,046,000	1,040,500	1,017,600	1,016,957
Agents involved in the sale of timber and building materials	70,400	69,100	63,900	64,000	63,800	62,500	67,616
Agents involved in the sale of machinery, industrial equipment, ships and aircraft	94,500	105,000	95,100	97,100	100,000	100,400	104,794
Agents involved in the sale of textiles, clothing, fur, footwear and leather goods	84,000	88,100	88,000	90,500	89,400	87,400	80,224
Agents involved in the sale of a variety of goods	236,900	236,800	259,100	276,900	262,900	262,500	263,389
Wholesale of textiles	123,900	122,500	121,100	120,400	121,600	108,800	105,145
Wholesale of clothing and footwear	381,400	399,300	367,900	382,800	377,900	365,700	370,853
Wholesale of electrical household appliances	297,800	275,600	266,900	262,600	255,600	243,500	243,175
Wholesale of china and glassware and cleaning materials	101,600	108,800	109,700	107,400	103,100	98,800	94,825
Wholesale of perfume and cosmetics	169,600	188,200	194,400	186,100	181,100	194,800	187,787
Wholesale of furniture, carpets and lighting equipment	154,000	144,900	142,300	138,500	135,800	134,200	133,442
Wholesale of watches and jewellery	51,100	56,300	56,100	55,900	54,200	56,500	54,802
Wholesale of other household goods	530,200	577,300	553,700	544,400	509,200	521,600	508,582
Wholesale of information and communication equipment	575,500	566,800	574,400	599,900	588,800	585,500	580,000
Wholesale of agricultural machinery, equipment and supplies	152,300	165,700	166,600	174,700	180,100	182,300	186,016
Wholesale of machine tools	79,800	86,200	86,700	91,000	87,200	81,900	85,640
Wholesale of mining, construction and civil engineering machinery	99,400	93,200	88,300	92,400	91,600	88,200	88,167
Wholesale of machinery for the textile industry and of sewing and knitting machines	11,900	10,900	10,900	10,400	10,300	9,200	8,219

Wholesale of other office machinery and equipment	100,900	103,400	101,600	99,300	95,200	94,300	94,688
Wholesale of other machinery and equipment	776,000	823,000	848,000	864,100	856,700	847,000	869,238
Wholesale of wood, construction materials and sanitary equipment	933,300	942,800	892,000	921,100	897,800	865,700	849,093
Wholesale of hardware, plumbing and heating equipment and supplies	483,100	507,100	499,700	536,800	514,500	502,500	483,719
Wholesale of chemical products	197,700	207,400	206,500	212,300	209,000	210,200	203,281
Non-specialised wholesale trade	691,200	685,500	655,800	663,000	673,500	665,700	649,412
Retail sale in non-specialised stores with food, beverages or tobacco predominating	5,452,100	5,818,600	5,609,600	5,778,100	5,780,700	5,783,100	5,803,517
Other retail sale in non-specialised stores	1,064,200	996,000	1,037,600	1,101,400	1,069,300	1,060,700	1,068,017
Retail sale of information and communication equipment in specialised stores	469,200	465,100	453,100	440,000	422,300	405,700	396,919
Retail sale of textiles in specialised stores	191,800	191,400	186,300	180,600	180,100	177,300	170,033
Retail sale of hardware, paints and glass in specialised stores	801,200	769,900	780,300	798,100	765,400	724,200	736,456
Retail sale of electrical household appliances in specialised stores	290,900	291,700	268,800	255,900	251,400	240,500	231,517
Retail sale of furniture, lighting equipment and other household articles in specialised stores	858,700	836,000	838,000	815,900	807,100	763,000	766,580
Retail sale of games and toys in specialised stores	97,400	97,400	101,800	98,900	94,600	94,700	95,506
Retail sale of clothing in specialised stores	1,938,100	1,881,000	1,931,300	1,934,000	1,884,600	1,862,700	1,910,139
Retail sale of footwear and leather goods in specialised stores	423,100	434,300	439,100	433,100	426,700	423,700	419,150
Retail sale of medical and orthopaedic goods in specialised stores	124,900	133,500	134,200	145,500	151,900	159,400	155,627
Retail sale of cosmetic and toilet articles in specialised stores	351,700	345,600	345,300	342,500	322,600	338,000	342,605
Retail sale of watches and jewellery in specialised stores	243,600	241,100	245,300	259,500	267,000	248,200	253,418
Retail sale via stalls and markets of textiles, clothing and footwear	170,100	145,400	162,200	159,000	157,900	154,200	142,466
Retail sale via stalls and markets of other goods	201,400	114,100	121,900	134,100	135,400	137,700	168,107
Retail sale via mail order houses or via Internet	253,500	275,200	315,200	358,700	411,900	440,200	487,773
Total	**22,586,400**	**22,875,200**	**22,618,200**	**23,118,700**	**22,819,500**	**22,560,500**	**22,640,177**

* When there is no information, data from previous or following year is taken.

Regarding the distributive trade by employment, it is important to underline that since data are available at NACE division level (Digit 3 – NACE code), all results should be considered as an upper estimate, as some divisions might contains one or more classes for which harmonised product rules do not exist.

Distributive trades by employment size class (NACE Rev. 2, G) [sbs_sc_dt_r2] – EU 28

Last update	**14.12.16**
Extracted on	**20.02.17**
Source of data	**Eurostat**

Number of enterprises	**2012**	**2013**	**2014**	**Average**	**Percentage**
From 0 to 1 person employed	2.577.519	2.604.470	2.645.964	2.609.318	56,84%
From 2 to 9 persons employed	1.732.022	1.673.011	1.663.731	1.689.588	36,81%
From 10 to 19 persons employed	171.057	164.476	166.101	167.211	3,64%
From 20 to 49 persons employed	86.371	83.625	84.028	84.675	1,84%
From 50 to 249 persons employed	34.862	33.078	32.741	33.560	0,73%
250 persons employed or more	5.993	5.930	5.929	5.951	0,13%
				4.590.303	

Turnover or gross premiums written	**2012**	**2013**	**2014**	**Average**	**Percentage**
From 0 to 1 person employed	394.997	390.950	389.927	391.958	5,22%
From 2 to 9 persons employed	1.072.535	1.020.808	1.088.970	1.060.771	14,12%
From 10 to 19 persons employed	672.167	639.121	645.621	652.303	8,68%
From 20 to 49 persons employed	999.342	945.590	970.937	971.956	12,94%
From 50 to 249 persons employed	1.571.164	1.552.925	1.591.293	1.571.794	20,93%
250 persons employed or more	2.773.586	2.872.213	2.940.377	2.862.059	38,11%
				7.510.841	

Value added at factor cost	**2012**	**2013**	**2014**	**Average**	**Percentage**
From 0 to 1 person employed	47.510	48.323	45.848	47.227	5,07%
From 2 to 9 persons employed	169.918	164.883	173.642	169.481	18,18%
From 10 to 19 persons employed	90.665	89.106	91.725	90.499	9,71%
From 20 to 49 persons employed	116.624	115.022	120.987	117.544	12,61%
From 50 to 249 persons employed	159.881	170.064	181.826	170.590	18,30%
250 persons employed or more	327.393	311.574	371.255	336.741	36,13%
				932.082	

Number of persons employed	2012	2013	2014	Average	Percentage
From 0 to 1 person employed	2.426.329	2.419.255	2.470.014	2.438.533	9,66%
From 2 to 9 persons employed	6.183.691	5.958.154	5.976.103	6.039.316	23,93%
From 10 to 19 persons employed	2.341.761	2.230.178	2.255.139	2.275.693	9,02%
From 20 to 49 persons employed	2.705.197	2.624.023	2.629.549	2.652.923	10,51%
From 50 to 249 persons employed	3.370.595	3.245.546	3.241.023	3.285.721	13,02%
250 persons employed or more	8.498.570	8.541.047	8.607.334	8.548.984	33,87%
				25.241.169	

ANNEX 6: GENERAL OVERVIEW OF THE EU MARKET SURVEILLANCE FRAMEWORK FOR ON NON-FOOD PRODUCTS

Under Regulation (EC) No 765/2008 national market surveillance authorities have clear obligations to proactively control products made available on the market, to organise themselves and ensure coordination between themselves at the national level and to cooperate at the EU level[13]. Economic operators have the clear obligation to cooperate with the national market surveillance authorities and to take corrective action where necessary. National market surveillance authorities have the authority to take sanctions which can include the destruction of products.

Regulation (EC) No 765/2008 integrates the provisions of Regulation 339/93 on control of products from third countries. Such controls are now part and parcel of market surveillance activities and Regulation (EC) No 765/2008 obliges national market surveillance and customs authorities to cooperate in order to ensure a seamless system. Such controls must be carried out in a non-discriminatory manner in line with the WTO rules and under the same rules and conditions as set out for internal market surveillance controls.

It should be noted, however, that most sector legislation contains provisions on the obligations of economic operators vis-à-vis market surveillance authorities and specific procedures and measures when products are found to be non-compliant:

MARKET SURVEILLANCE PROVISIONS IN EU LEGISLATION		
MARKET SURVEILLANCE MEASURES AND STRUCTURES	**REGULATION (EC) No 765/2008**	**SECTOR LEGISLATION**
MARKET SURVEILLANCE PROCEDURES		
Obligations of economic operators vis-à-vis market surveillance authorities	**No**	**Yes**
Cases in which obligations of manufacturers apply to importers and distributors	**No**	**Yes**
Identification of economic operators	**No**	**Yes**
Definition of formal non-compliance	**No**	**Yes**
Procedures for dealing with products presenting a risk at national level	**No**	**Yes**
Market surveillance measures	**Yes**	**No but legislation refers to Regulation (EC) No 765/2008**
Products presenting a serious risk		
Restrictive measures		
Exchange of information — Rapid Information System		
General information support system (ICSMS)		
Union safeguard procedure	**No**	**Yes**

13 The General Product Safety Directive also contains requirements on market surveillance. The relationship between Regulation (EC) No 765/2008 and the General Product Safety Directive is described in detail in the Working Paper of 3 March 2010 available at: http://ec.europa.eu/consumers/safety/prod_legis/docs/20100324_guidance_gspd_reg_en.pdf

MARKET SURVEILLANCE PROVISIONS IN EU LEGISLATION		
MARKET SURVEILLANCE MEASURES AND STRUCTURES	**REGULATION (EC) No 765/2008**	**SECTOR LEGISLATION**
Procedure for compliant products which present a risk to health and safety	**No**	**Yes**
MARKET SURVEILLANCE STRUCTURES		
General requirements for market surveillance	**Yes**	**No but legislation refers to Regulation (EC) No 765/2008**
Information obligations about market surveillance authorities		
Obligations of the Member States as regards organisation of market surveillance		
Principles of cooperation between the Member States and the Commission		
Sharing of resources		
Cooperation with the competent authorities of third countries		
Controls of products entering the Union market		
Release of products		
National measures on products entering the Union market		
Financing provisions for market surveillance	**Yes**	**No**
Penalties	**Penalties for economic operators applicable to infringements of the provisions of the Regulation**	**Penalties for economic operators applicable to infringements of the provisions of sector legislation**

The European Commission has the responsibility to facilitate the exchange of information between national authorities (in relation to their national market surveillance programmes, their risk assessment methodologies, etc.) in order to ensure that market surveillance is effectively EU-wide and that Member States can pool together their means.

1. WHY DO WE NEED MARKET SURVEILLANCE?

Member States have to take appropriate measures to prevent the making available on the market and use[14] of non-compliant products. Market surveillance aims at ensuring that products fulfil the applicable requirements providing a high level of protection of public interests such as health and safety in general, health and safety in the workplace, protection of consumers, protection of the environment and security while ensuring that the free movement of products is not restricted to any extent greater than that which is allowed under Union harmonisation legislation or any other relevant Union rule. Market surveillance entitles

14 Subject to specific Union harmonisation legislation.

citizens to an equivalent level of protection throughout the single market, regardless of the origin of the product. Further, market surveillance is important for the interest of economic operators, because it helps to eliminate unfair competition.

Market surveillance activities are not directed exclusively towards the protection of health and safety but are additionally undertaken with the aim of enforcing Union legislation which seeks also to safeguard other public interests, for example by means of regulating the accuracy of measurement, electromagnetic compatibility, energy efficiency, consumer and environment protection, following the principle of "high level of protection" as laid down in Article 114 (3) TFEU.

Member States must ensure effective surveillance of their market. They are required to organise and carry out the monitoring of the products made available on the market or imported. Member States have to take appropriate measures to ensure that the provisions of Regulation (EC) No 765/2008, of Directive 2001/95/EC and of the other Union harmonisation legislation, as well as non-harmonised, national legislation, in force are respected in the EU and, in particular, to prevent the making available on the market and use of non-compliant and/or unsafe products.

Market surveillance should enable unsafe products or products which otherwise do not conform to applicable requirements set out in Union harmonisation legislation to be identified and kept or taken off the market and unscrupulous or even criminal operators punished. It should also act as a powerful deterrent[15]. For that purpose Member States must:

- correctly implement the provisions of the relevant legislation and allow for sanctions proportional to any infringements;

- survey the products (whatever their origin) introduced on their market in order to ensure that they have been subjected to the necessary procedures, that the marking and documentation requirements have been respected and that they have been designed and manufactured in accordance with the Union harmonisation legislation requirements.

In order to be effective, the market surveillance effort should be uniform across the Union. This is all the more important considering that each point of the Union's external border constitutes an access point for a great quantity of products from third countries. If market surveillance is "softer" in some parts of the Union than others, weak spots are created which threaten the public interest and create unfair trade conditions. Consequently, there must be effective market surveillance along the entire length of the Union's external borders.

In order to guarantee the necessary objectivity and impartiality, market surveillance must be undertaken by the authorities of the Member States. Certain checks (e.g. tests, inspections) can be delegated to other bodies, but the official authorities must retain full responsibility for the decisions taken following these checks. Controls carried out within the framework of market surveillance may be carried out at different times during the life-cycle of a product,

15 According to Article 16 of Regulation (EC) No 765/2008 "Market surveillance shall ensure that products covered by Union harmonisation legislation which, when used in accordance with their intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained, are liable to compromise the health or safety of users, or which otherwise do not conform to applicable requirements set out in Union harmonisation legislation are withdrawn or their being made available on the market is prohibited or restricted and that the public, the Commission and the other Member States are informed accordingly. Member States shall ensure that effective measures can be taken in relation to any product category subject to Union harmonisation legislation".

following its placing on the market, such as distribution, putting into use or final use. It can, therefore, be exerted in various locations, e.g. importers establishments, wholesale or retail distributors, hire companies, users, etc.

2. CONTROLS BY MARKET SURVEILLANCE AUTHORITIES

Market surveillance authorities shall check the compliance of the product with the legal requirements applicable at the moment of the placing of the market or, if relevant, putting into service.

Thus, market surveillance does not formally take place during the design and production stages, which is before the manufacturer has taken formal responsibility for the conformity of the products, usually by affixing the CE marking. However, nothing prevents market surveillance authorities and economic operators to collaborate during the design and production phase. Such collaboration may help taking preventive actions and identifying as early as possible safety and conformity issues.

Other exceptions to the principle that market surveillance can only take place after the manufacturer has taken formal responsibility for the products are trade fairs, exhibitions and demonstrations. Most Union harmonisation legislation allows the showing and display of non-CE marked products at trade fairs, exhibitions and demonstrations, provided that a visible sign clearly indicates that the products may not be marketed or put into service until they have been made to comply, and that adequate measures are taken during demonstrations, where appropriate, to ensure the protection of public interests. Market surveillance authorities must monitor that this obligation is respected.

For market surveillance to be efficient, resources should be concentrated where risks are likely to be higher or non-compliance more frequent, or where a particular interest can be identified. Statistics and risk assessment procedures can be used for this purpose. To be able to monitor products on the market, market surveillance authorities must have the power, competence and resources:

- to regularly visit commercial, industrial and storage premises;
- to regularly visit, if appropriate, work places and other premises where products are put into service[16];
- to organise random and spot checks;
- to take samples of products, and to subject them to examination and testing and
- to require, upon reasoned request, all necessary information.

The first level of control are documentary and visual checks, for example regarding the CE marking and its affixing, the availability of the EU declaration of conformity, the information accompanying the product and the correct choice of conformity assessment procedures. More profound checks may be however necessary to verify the conformity of the product, for example regarding the correct application of the conformity assessment procedure, the

16 This is important for products (for example machinery and pressure equipment) that are directly, after being manufactured, installed and put into service at the premises of the client.

compliance with the applicable essential requirements, and the contents of the EU declaration of conformity.

In practice, individual market surveillance activities can focus on certain aspects of the requirements. Besides market surveillance activities that have as their explicit aim the verification of products made available on the market, other public mechanisms exist that, although not directly designed for that aim, can nevertheless have as a consequence the uncovering of non-compliance[17]. Labour inspectorates that check safety at the workplace, for example, can discover that the design or construction of a machine, or personal protective equipment bearing the CE marking, is not in conformity with the applicable requirement[18].

Information on the compliance of a product at the moment when it was placed on the market can also be obtained during in-use inspections, or by analysing the factors that caused an accident. Complaints from consumers or other users about the product, or from manufacturers or distributors about unfair competition can also provide information for market surveillance purposes.

Monitoring of products made available on the market may be divided between several authorities on the national level, for example functionally or geographically. Where the same products are subject to control by more than one authority (for example customs and a sectoral authority, or local authorities), coordination between services within a Member State is necessary.

Voluntary initiatives, such as product certification or application of a quality management system, cannot be put on the same footing as market surveillance activities carried out by an authority. Still, they can contribute to the elimination of risks and non-compliances. However, market surveillance authorities must be impartial regarding all voluntary marks, labels and arrangements, and they may only be taken into consideration, in a transparent and non-discriminatory way, for the risk and compliance assessment. Accordingly, products should not be excluded from market surveillance operations even if they have been subject to voluntary certification or other voluntary initiatives.

Union harmonisation legislation provides for two different tools that enable market surveillance authorities to receive information on the product: the EU declaration of conformity and the technical documentation. These must be made available by the manufacturer, the authorised representative established within the Union or under certain circumstances by the importer[19].

Other natural or legal persons, such as distributors cannot be obliged to make these available[20]. However, they are expected to assist the market surveillance authority in obtaining them. Further, the market surveillance authority may request the notified body to provide information on the conduct of conformity assessment for the product in question.

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17 According to the Directive on high-speed rail systems, each Member State authorises the putting into service of the structural subsystems in their territory. This is a systematic mechanism to monitor the compliance of subsystems and their inter-operability constituents.

18 Member States are obliged, according to the Directive on the introduction of measures to encourage improvements in the safety and health of workers at work (89/391/EEC), to ensure adequate controls and supervision.

19 Under Decision No 768/2008/EC, module B, Notified Bodies are required to provide, upon request from Member States, European Commission or other Notified Bodies a copy of the technical documentation.

20 Unless the EU Declaration of Conformity is required to accompany the product, in which case the distributor should provide the market surveillance authorities with such document.

The EU declaration of conformity must be made available for the market surveillance authority without delay upon reasoned request[21]. It shall accompany the product where required so by specific Union harmonisation legislation. It can be made available for surveillance purposes in each of the Member States, for instance, by means of administrative cooperation.

The technical documentation must be made available to the market surveillance authority within a reasonable period of time, in response to a reasoned request. The authority cannot request it systematically. In general, it can be requested during random checks made for market surveillance purposes, or when there are grounds for a concern that a product does not offer the level of protection required in all respects.

More detailed information (for example certificates and decisions from the notified body) can, nevertheless, be requested in cases of doubt about the conformity of the product to the applicable Union harmonisation legislation. The full technical documentation should be requested only where clearly necessary, and not, for example, when only a detail has to be checked.

This request has to be evaluated in accordance with the principle of proportionality and, thus, taking into account the need to ensure the health and safety of persons or other public interests foreseen in the applicable Union harmonisation legislation, as well as to protect the economic operators from unnecessary burden. Furthermore, failure to present the documentation in response to a reasoned request by a national market surveillance authority, within an acceptable delay, may constitute sufficient grounds for doubting the conformity of the product with the essential requirements of the applicable Union harmonisation legislation.

In the case of a reasoned request it is sufficient for the manufacturer to provide the part of the technical documentation related to the claimed non-conformity and appropriate for demonstrating whether the issue has been dealt with by the manufacturer. Therefore, the request for translation of technical documentation should be limited to these parts of the documentation. If the market surveillance authority considers a translation necessary, it must clearly indicate the part of the documentation to be translated and allow reasonable time for this to take place. No further conditions may be imposed on the translation, such as a requirement of a translator accredited or recognised by the public authorities.

National authority might accept a language they understand and which is different from the national language(s). The language chosen could be a third language, if accepted by that authority.

It must be possible to make the technical documentation available in the Union. However, it does not need to be kept inside the Union, unless otherwise provided for in the applicable Union harmonisation legislation. The requirement for making it available does not mean that the person who bears this responsibility has to store it himself[22], as long as he is capable of presenting it on request from the national authority. The name and address of the person storing the documentation does not need to be expressly mentioned on the product or on its

21 The reasoned request does not necessarily mean a formal decision by an authority. According to Article 19 (1), paragraph 2 of Regulation (EU) No 765/2008, "market surveillance authorities may require economic operators to make such documentation and information available as appear to them to be necessary for the purpose of carrying out their activities". For a request to be reasoned it is sufficient the market surveillance authority explains the context in which the information is requested (e.g. inspection on specific characteristics of the products, random checks, etc.)

22 For example storing the technical documentation may be delegated to the authorised representative.

packaging, unless otherwise specified. Further, the technical documentation can be kept and sent to market surveillance authorities in paper or electronic form, which allows it to be made available within a period of time commensurate with the risk or non-compliance in question. Member States must ensure that everyone receiving information about the contents of the technical documentation during market surveillance activities is bound to confidentiality according to principles laid down in the national legislation.

3. CONTROL OF PRODUCTS FROM THIRD COUNTRIES BY CUSTOMS

Points of entry to the EU are relevant to stop non-compliant and unsafe products coming in from third countries. Being the place where all products from third countries have to pass by, they are the ideal place to stop unsafe and non-compliant products before they are released for free circulation and subsequently circulate freely within the European Union. Thus, customs have an important role in supporting market surveillance authorities in carrying out product safety and compliance controls at the external borders.

The most effective way to avoid the making available of non-conforming or unsafe imported from third countries on the Union market is to carry out adequate checks during the import control process. This requires involvement of customs and cooperation between customs and market surveillance authorities.

The authorities in charge of the control of products entering the Union market, customs or market surveillance authorities depending on the national organisational structure, are very well placed to carry out initial checks, at the first point of entry, on the safety and compliance of the imported products. There are specific guidelines for import controls in the area of product safety and compliance[23]. To ensure such controls, the authorities in charge of controls of products at the external borders need an appropriate technical support in order to carry out the checks on the characteristics of the products on an adequate scale. They can perform documentary, physical or laboratory checks. They also need appropriate human and financial resources.

Regulation (EC) No 765/2008 on checks for conformity with Union harmonisation legislation in the case of products imported from third countries requires the customs authorities to be closely involved in the market surveillance activities and information systems provided for under EU and national rules. Article 27 (2) of Regulation (EC) No 765/2008 foresees the obligation for co-operation between customs officers and market surveillance officers. Obligations for cooperation are also included in Article 13 of the Community Customs Code which establishes that controls performed with customs and other authorities are undertaken in close cooperation between each other. In addition, the principles of cooperation between the Member States and the Commission established in Article 24 of the Regulation are extended to authorities in charge of external controls, when relevant (Article 27(5)).

Cooperation at national level should allow for a common approach taken by customs and market surveillance authorities during the control process. This should not be hampered by the fact that various ministries and authorities may be responsible for the implementation of Regulation (EC) No 765/2008.

23 These guidelines are available at: http://ec.europa.eu/taxation_customs/resources/documents/common/publications/info_docs/customs/product_safety/guidelines_en.pdf

Customs authorities have the following responsibilities under Regulation (EC) No 765/2008:

- to suspend the release of products when there is a suspicion that the products present a serious risk to health, safety, environment or other public interest and/or do not fulfil documentation and marking requirements and/or the CE marking has been affixed in a false or misleading manner(Article 27(3));

- not to authorise the release for free circulation for the reasons mentioned in Article 29;

- to authorise the release for free circulation for any product in compliance with the relevant Union harmonisation legislation and/or nor presenting risks to any public interest;

- Where the release for free circulation has been suspended, customs have to immediately notify the competent national market surveillance authority which is given three working days to perform a preliminary investigation of the products and to decide:

  – if they can be released since they do not present a serious risk to the health and safety or cannot be regarded as being in breach of Union harmonisation legislation

  – if they must be detained since further checks are necessary to ascertain their safety and conformity.

Customs authorities must notify their decisions to suspend release of a product to the market surveillance authorities, which in turn must be in a position to take appropriate action. Four hypotheses must be distinguished as from the moment of the notification.

The products in question present a serious risk

If the market surveillance authority ascertains that the products present a serious risk, it must prohibit their placing on the EU market. The market surveillance authorities have to request the customs authorities to mark the commercial invoice accompanying the product, and any other relevant accompanying document, with the words 'Dangerous product — release for free circulation not authorised — Regulation (EC) No 765/2008'[24]. Member State authorities may also decide to destroy the products or otherwise render them inoperable, where they deem it necessary and proportionate. The market surveillance authority must use in those cases the system for rapid exchange of information - RAPEX. As a consequence, market surveillance authorities in all Member States are informed, and they may in turn inform the national customs authorities about products imported from third countries, which display characteristics giving rise to a serious doubt as to the existence of a serious risk. This information is of particular importance for customs authorities where it involves measures banning or withdrawing from the market products imported from third countries.

Feedback from market surveillance authorities on whether goods are considered as unsafe or non-compliant is crucial for customs risk management and control processes. It ensures

24 If following the refusal of release for free circulation by customs the products are declared for customs-approved treatment or use other than release for free circulation, and provided the market surveillance authorities have no objections, the same wording must be added, under the same conditions, to the documents relating to that treatment or use.

controls can be concentrated on risky consignments, allowing for the facilitation of legitimate trade.

Furthermore, when non-compliant or unsafe products are found in the internal market, it is often extremely difficult to identify how they entered the EU. Cooperation between customs and market surveillance authorities is encouraged to improve tracing in those cases.

The products in question do not comply with Union harmonisation legislation

In this case the market surveillance authorities must take appropriate measures, if necessary prohibiting the placing on the market under the rules in question. In cases where placing on the market is prohibited, they must ask the customs authorities to mark the commercial invoice accompanying the products, and any other relevant accompanying document, with 'Product not in conformity — release for free circulation not authorised — Regulation (EC) No 765/2008'[25].

- The products in question do not present a serious risk and cannot be considered as not conforming to the Union harmonisation legislation. In this case the products must be released for free circulation, provided that all the other conditions and formalities regarding release for free circulation are met.

- The customs authorities have not been notified of any action taken by the market surveillance authorities.

If, within three working days of the suspension of release for free circulation, the market surveillance authority has not notified customs of any action taken by them, the product has to be released for free circulation provided that all the other requirements and formalities pertaining to such release have been fulfilled.

The entire procedure from the suspension until the release for free circulation or its prohibition by customs should be completed without delay to avoid creating barriers for legitimate trade but does not necessarily have to be completed within three working days. The suspension of release can remain valid for the time required by the market surveillance authority to carry out appropriate checks on the products and allow them to take the final decision. Market surveillance authorities must ensure that the free movement of products is not restricted to any extent greater than that which is allowed under Union harmonisation legislation or any other relevant EU legislation. To that end market surveillance authorities perform their activities regarding products originating from third countries - including the interaction with the relevant economic operators - with the same urgency and methodologies as for products originating from within the EU.

In this case, the market surveillance authority notifies customs within these three working days that their final decision on the goods is pending. The release for free circulation has to remain suspended until the market surveillance authority has made a final decision. That notification empowers customs to extend the initial suspension period. The products will remain under customs supervision even if they are allowed to be stored at another place approved by customs.

25 Also in this case, if following the refusal of release for free circulation by customs the products are declared for customs-approved treatment or use other than release for free circulation, and provided the market surveillance authorities have no objections, the same wording must be added, under the same conditions, to the documents relating to that treatment or use.

4. MEMBER STATES RESPONSIBILITIES

4.1 National infrastructures

Market surveillance is the responsibility of public authorities. This is, in particular, to guarantee the impartiality of market surveillance activities. Each Member State can decide upon the market surveillance infrastructure, for example there is no limitation on the allocation of responsibilities between authorities on a functional or geographical basis as long as surveillance is efficient and covers the whole territory. Member States organise and carry out market surveillance through the establishment of market surveillance authorities[26]. Market surveillance authorities are the authorities of a Member State responsible for carrying out market surveillance on their territory. Surveillance of the market by public authorities is a fundamental element for the good implementation of Union harmonisation legislation.

Member States must ensure that the public is aware of the existence, responsibilities and identity of national market surveillance authorities, and of how those authorities may be contacted. They must also ensure that consumers and other interested parties are given an opportunity to submit complaints to the competent authorities and that these complaints are followed up appropriately.

Member States must entrust market surveillance authorities with the powers, resources and knowledge necessary for the proper performance of their tasks. This is to monitor products made available on the market and, in case of products presenting a risk or other form of non-compliance, to take appropriate action to remove the risk and enforce conformity. As regards personnel resources, the authority has to have, or have access to, a sufficient number of suitably qualified and experienced staff, with the necessary professional integrity. The market surveillance authority should also be independent, and carry out its activities in an impartial and non-discriminatory way. Further, the market surveillance authority should carry out market surveillance respecting the principle of proportionality, for example action must be in accordance with the degree of risk or non-compliance and the impact on the free circulation of products may not be more than is necessary for achieving the objectives of market surveillance.

The market surveillance authority may subcontract technical tasks (such as testing or inspection) to another body, provided that it retains the responsibility for its decisions, and provided there is no conflict of interest between the other body's conformity assessment activities carried out of behalf of economic operators and compliance assessment provided to the market surveillance authority. In doing so the market surveillance authority should exercise great care to ensure that the impartiality of the advice it receives is beyond reproach. The responsibility for any decision to be taken on the basis of such advice should reside in the market surveillance authority.

4.2 National Market Surveillance Programmes (NMSP) and reviews of activities

National authorities are obliged by Article 18(5) of the Regulation (EC) No 765/2008 to establish, implement and periodically update and communicate their NMSP[27]. Programmes may be general and/or sectoral. They should ensure that the overall EU market surveillance

26 A list of market surveillance authorities appointed by the Member States can be found at: http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm

27 A similar provision can be found in the GPSD.

framework is respected. Member States must also communicate the programmes to other Member States and to the Commission and make them accessible to the public via internet, without information that could hamper the effectiveness of the programme if made public. The purpose of these programmes is to allow the other countries' authorities, as well as citizens in general, to understand how, when, where and in which areas market surveillance is carried out. National programmes then contain information on activities planned to improve the general organisation of market surveillance at national level (e.g. mechanisms of coordination between different authorities, resources attributed to them, working methods, etc.) and initiatives in specific areas of intervention (e.g. product categories, risk categories, types of users, etc.)[28]. Both types of information are necessary.

The Commission helped Member States by proposing common templates to lay out their programmes. The use of all relevant templates is recommended to ensure completeness of information provided. This also facilitates the comparability of national market surveillance programmes in specific product or legislation areas and makes it possible for market surveillance authorities to plan cross-border cooperation in areas of common interest.

When establishing national market surveillance programmes, market surveillance authorities should take the needs of customs into account. Programmes should take into consideration the balance between proactive and reactive control activities and any other factors which may influence enforcement priorities. Resource capabilities must be ensured at the border for this purpose.

According to Article 18(6) of the Regulation (EC) No 765/2008, the functioning of market surveillance activities needs to be periodically reviewed and assessed by Member States, at least every four years. The results of this assessment are then communicated to the Commission and other Member States and made available to the public[29].

4.3 Public information

Considering that the aim of market surveillance is to provide a high level of protection of certain public interests, informing the public is an essential element of market surveillance. Therefore, Member States should ensure openness to the public and to interested parties and should ensure public access to the information available to the authorities on product conformity. In accordance with the principle of transparency, information available to the authorities of the Member States or the Commission relating to risks to health and safety or other public interests protected under EU harmonisation legislation posed by products should in general be available to the public, without prejudice to the restrictions required for protecting patents and other confidential business information as well as preserving personal data, and for monitoring and investigation and prosecution activities.[30]

The public should be aware of the existence, responsibilities and identity of national market surveillance authorities, and of how those authorities may be contacted. Also national market surveillance programmes and reviews of activities carried out have to be made available to the public by way of electronic communication and, where appropriate, by other means.

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28 The public national market surveillance programmes can be consulted here: http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm

29 The national reviews and assessments can be found here: http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm

30 See General Product Safety Directive, whereas n. 24 and 35 and Article 16; see also Regulation (EC) 765/2008, Article 19(5).

Among the measures that market surveillance authorities have to take, is the obligation to alert users within their territories within an adequate timeframe of hazards they have identified relating to any product so as to reduce the risk of injury or other damage particularly when the economic operator responsible fails to do so.

5. MARKET SURVEILLANCE PROCEDURES

Market surveillance is carried out through the implementation of a sequence of procedures whose aim is to ensure that an effective and consistent system of market surveillance is established across the EU. Market surveillance authorities follow these procedures when dealing with products presenting a risk to the health and safety or persons or to other aspects of public interest protection, according to Article 16(2) of Regulation (EC) No 765/2008 and in line with Articles R31 and R32 in Annex 1 of Decision No 768/2008/EC, and with products presenting a serious risk requiring rapid intervention, according to Articles 20 and 22 of Regulation (EC) No 765/2008.

An initial event suggesting to market surveillance authorities that a product presents a risk to the health or safety of persons or to other aspects of public interests may trigger the need for closer scrutiny of the product. It may be an accident, the reception of complaints, ex officio initiatives of market surveillance authorities (including custom authorities' control of products entering the EU) as well as information from economic operators on products presenting a risk. When there are sufficient reasons to believe that a product presents a risk, market surveillance authorities carry out an evaluation of compliance with the requirements of the relevant Union harmonisation legislation. They have to perform appropriate checks (both documentary and physical/laboratory checks, as necessary) on the characteristics of the products, duly taking into account the reports and conformity assessment certificates issued by an accredited conformity assessment body provided by the economic operators.

Market surveillance authorities carry out a risk assessment in order to verify if products present a serious risk. According to Article 20(2) of the Regulation an appropriate risk assessment "takes account of the nature of the hazard and the likelihood of its occurrence".[31]

If a product presents a risk to the health or safety of persons or to other aspects of public interests, market surveillance authorities must request without delay to relevant economic operators to:

- take any action to bring the product into compliance with the applicable requirements laid down in the Union harmonisation legislation and/or;
- withdraw the product and/or;
- recall the product and/or;
- stop or restrict supplying the product within a reasonable period.

In case the risk is deemed to be "serious", market surveillance authorities must adopt a rapid intervention following the specific provisions of Articles 20 and 22 of the Regulation.

31 See the Rapid Alert System Guidelines for a more precise definition of "risk" and "serious risk".

The economic operators must ensure that the corrective action is taken throughout the EU. The market surveillance authorities must also inform the relevant notified body (if any) on the decision taken. In case of serious risk requiring a rapid intervention, the market surveillance authority may adopt restrictive measures without waiting for the economic operator to take corrective action to bring the product into compliance. According to Article 21 of the Regulation, the measures adopted by market surveillance authorities have to be proportionate and communicated to the relevant economic operator without delay. The market surveillance authorities must also consult the economic operator prior to the adoption of the measures and, if such consultation is not possible because of the urgency of the measures to be taken, the operator must be given the opportunity to be heard as soon as possible. The market surveillance authorities must withdraw or amend the measures taken if the economic operator demonstrates that he has taken effective action.

When non-compliance is not limited to the national territory, market surveillance authorities must inform the Commission and the other Member States about the results of the compliance evaluation and about the actions required of the economic operator or the measures adopted. In case of serious risk, market surveillance authorities notify to the Commission through the RAPEX system of any voluntary or compulsory measure according to the procedure laid down in Article 22 of the Regulation and/or Article 12 of the GPSD. In the case of products that do not present a serious risk, the Commission and the other Member States will be informed by means of the information support system indicated in Article 23 of the Regulation and/or Article 11 of the GPSD. Market surveillance authorities have to verify that adequate corrective measures have been taken. Otherwise, they adopt appropriate provisional measures, informing the Commission and the other Member States with the procedures detailed above.

In order to broaden the effectiveness of the market surveillance activity launched by the notifying Member State, the other Member States are called upon to follow up on the notification by verifying whether the same product has been made available on their territories and by adopting appropriate measures. They should inform the Commission and the other Member States according to the procedures of the initial notification.

Under Union harmonisation legislation aligned to Decision No 768/2008/EC if the Commission and the other Member States do not raise any objection within a certain period, the restrictive measures are deemed justified and must be adopted without delay by the Member States. In the case of non-compliance due to shortcomings in harmonised standards, the Commission informs the relevant standardisation bodies and brings the matter before the Committee set up under Article 22 of Regulation (EU) No 1025/2012. In light of the Committee's opinion, the Commission can decide to: a) maintain the reference to harmonised standards in the OJEU; b) maintain with restrictions the reference to the harmonised standards in the OJEU; c) withdraw the reference to the harmonised standards in the OJEU. The Commission also informs the relevant European standardisation organisation and, if necessary, requests the revision of the harmonised standards concerned.

If objections are raised, the safeguard mechanism will apply.

Additional information on the procedure allowing Member States to exchange information on measures adopted against products presenting a risk and, if appropriate, for their assessment by the European Commission is provided in sections 7.5.1 and 7.5.2.

6. CORRECTIVE MEASURES – BANS – WITHDRAWALS – RECALLS

According to Union harmonisation legislation, Member States are required to ensure that products are made available on the market only if they comply with the applicable requirements. The latter include both the essential requirements, and a number of administrative and formal requirements. When competent national authorities discover that a product is not in compliance with the provisions of the applicable Union harmonisation legislation, they must take action to ensure it is brought into conformity or taken off the market.

The corrective action depends on the risk or non-compliance and, thus, must be in accordance with the principle of proportionality. Non-conformity to essential requirements must be considered as a substantial non-compliance, because this may lead to the product presenting a potential or actual risk to the health and safety of persons or to other aspects of public interest. In case of a serious risk, Article 20 of Regulation (EC) No 765/2008 sets out the need of prohibiting products from being made available on the market, withdrawing or recalling products.

If a product covered by Union harmonisation legislation is not CE marked, it is an indication that the product does not comply with the essential requirements or the conformity assessment procedure has not been applied and, consequently, the product may endanger the health and safety of persons or harm other public interests protected by that legislation. Only if, following further investigation, the product proves to be compliant with the essential requirements, the absence of the CE marking is to be considered as a formal non-compliance (i.e. the product does not present a risk).

Unless there are reasons to believe that the product presents a risk, there are cases where non-compliance with a number of administrative or formal requirements are defined as formal non-compliance by Union harmonisation legislation. That is the case for the incorrect affixing of the CE marking as regards, for instance, the design, size, visibility, indelibility or legibility, can usually be considered as a formal non-compliance. Examples of typically formal non-compliance could also be the situations where other conformity markings provided for in the Union harmonisation legislation are incorrectly affixed, or where the EU declaration of conformity cannot be provided for immediately or it does not accompany the product when this is mandatory, or the requirement to accompany other information provided for in sectoral Union harmonisation legislation is complied with insufficiently, or, where applicable, the identification number of the notified body has not been affixed to the CE marking.

Enforcement of conformity can be achieved by obliging the manufacturer, the authorised representative, or other responsible persons (importers, distributors), to take required measures. Corrective action can also take place if the necessary measures are taken (for example the product is modified or withdrawn from the market), either as a result of consultations carried out by the market surveillance authority or as a result of formal or informal warnings. In all cases the market surveillance authority must establish accompanying measures to ensure that conformity is enforced. PROSAFE "Guidelines for Businesses to manage Product Recalls & Other Corrective Actions"[32] have been designed to assist businesses to ensure, whenever necessary, the appropriate corrective actions and follow-up

32 http://ec.europa.eu/consumers/archive/safety/rapex/docs/corrective_action_guide_march2012.pdf

once a product has been already made available on the EU market or is coming from third countries.

Actions to prohibit or restrict the placing on the market may first be temporary to allow the market surveillance authority to obtain sufficient evidence about the risk or other substantial non-compliance of the product.

In case of formal non-compliance only (i.e. without a risk), the market surveillance authority should first oblige the manufacturer, or the authorised representative, to make the product intended to be placed on the market and, if necessary, the product already on the market, comply with the provisions and to remedy the infringement within a reasonable time period. If no result can be achieved, the market surveillance authority has to, ultimately, take a further step to restrict or prohibit the placing on the market of the product and, if necessary, to ensure that it is also withdrawn or recalled from the market.

Any decision taken by national market surveillance authorities to restrict or prohibit the placing on the market or the putting into service, to withdraw or recall the products from the market must state the exact grounds on which it is based. The party concerned – in particular, the manufacturer, or the authorised representative established in the Union – must be notified. They must also be informed about remedies available under the national law in force in the Member State in question, and of the time limits to which such remedies are subjected.[33]

Unless the matter is urgent (for example the product presents a serious risk), the manufacturer, or the authorised representative established in the Union, should have an opportunity to be consulted in advance, before the competent authority takes action to restrict the free circulation of products. In practice, it should be considered as sufficient when the manufacturer or the authorised representative has been provided with an opportunity to react.[34] However, it should not delay the proceedings, if the manufacturer or the authorised representative remains passive.

The decision to restrict the free movement of a CE marked product in case of non-compliance with the essential requirements usually invokes the safeguard clause procedure. This procedure is aimed to enable the Commission to keep an overview of such measures, to consider whether or not they are justified and to ensure all Member States take similar measures in relation to the same products. A manufacturer, the authorised representative, or other economic operator may consider himself to have suffered a loss as a result of an inappropriate national measure that restricted the free movement of a product. In such a case he could be entitled to claim damages under the jurisdiction of the Member State which initiated the procedure and accordingly the Commission, at the end of a safeguard clause procedure, where the national measure is considered as non-justified. This may raise the question whether or not a liability case for incorrect implementation of EU law could take place.

33 See Directives relating to simple pressure vessels, toys, machinery, personal protective equipment, non-automatic weighing instruments, active implantable medical devices, gas appliances, potentially explosive atmospheres, medical devices, recreational craft, lifts refrigeration appliances, pressure equipment, ecodesign requirements for energy-related products and in vitro diagnostic medical devices.

34 An explicit provision to consult has been included in Article 21 of Regulation (EC) No 765/2008, as well as in the Directives relating to medical devices and in vitro diagnostic medical services.

7. SANCTIONS

Regulation (EC) No 765/2008 requires Member States to ensure the correct implementation of its provisions and to take appropriate action in the event of infringement. The Regulation requires penalties to be proportionate to the seriousness of the offence and constitute an effective deterrent against abuses.

It is up to the Member States to lay down and implement the mechanism for enforcing the provisions of the Regulation in their territories. According to Article 41 of the Regulation, "the penalties provided for shall be effective, proportionate, and dissuasive and may be increased if the relevant economic operator has previously committed similar infringement".

In addition, Union harmonisation legislation aligned to Decision No 768/2008/EC includes as well a provision requiring Member States to lay down penalties for infringements by economic operators of that particular legislation.

Sanctions are imposed by means of fines, whose sums vary from one Member State to the other. They may also include criminal sanctions for serious infringements.

The most common legal instruments providing for sanctions are general product safety acts and/or sector specific legislation. However, in some Member States sanctions are provided in CE Marking acts, customs code or acts on conformity assessment system.

8. COOPERATION BETWEEN THE MEMBER STATES AND THE EUROPEAN COMMISSION

Cooperation and coordination of action among national authorities is indispensable to obtain effective and consistent surveillance of the Single Market. The EU legal framework provides a number of tools to achieve this goal. The safeguard mechanism included in Union harmonisation legislation obliges to share information about restrictive measures adopted by national authorities so that, if appropriate, follow up action can be taken by other authorities. Mutual assistance based on Regulation (EC) No 765/2008 allows authorities to enforce request of information vis-à-vis economic operators located in another Member State. Administrative cooperation groups (ADCOs), the ICSMS database, the RAPEX Rapid Alert System constitute essential tools to exchange information and optimise work sharing among authorities.

8.1 Safeguard mechanisms

The safeguard clause procedure, based on Article 114(10) TFEU and included in most sectoral Union harmonisation legislation, authorises Member States to take restrictive measures in relation to products presenting a risk to health and safety or other aspects of public interests protection and obliges them to notify those measures to the Commission and other Member States. The safeguard clause procedure is designed to provide a means to inform all national market surveillance authorities about dangerous products, and, accordingly, to have the necessary restrictions extended to all Member States, so as to ensure an equivalent level of protection throughout the EU. Furthermore, it allows the Commission to take a position on the national measures restricting the free movement of products with a view to ensuring the functioning of the internal market.

It is to be noted that the safeguard procedure is distinct from the RAPEX Rapid Alert System procedure because of their different notification criteria and different methods of application[35].

Where, having performed an evaluation, a Member State finds that a product is non-compliant or a product is in compliance but presents a risk to the health or safety of persons or to other aspects of public interest protection, it must require the relevant economic operator to take all appropriate measures to ensure that the product concerned, when made available on the market, no longer presents that risk, to withdraw the product from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

This procedure will be applicable, unless it is established that the risk does not affect a whole series of products manufactured, however limited the series, or that the risk is not due to the product itself but to its misuse, that is, when not used in accordance with their intended purpose or under conditions which can be reasonably foreseen and when not properly installed and maintained.. For an isolated error, limited to the territory of the Member State that has discovered the non-compliance, there is no need to invoke the safeguard clause, since there is no need to take action at EU level. In addition, the risk must be due to the product itself and not to its misuse.

Conformity can be enforced if the national authority requests the manufacturer or the authorised representative to take the necessary measures, or if the product is modified or voluntarily withdrawn from the market. Unless a formal decision is taken in these cases, to prohibit or restrict the making available on the market of the product or to have it withdrawn from the market, the safeguard clause procedure is not invoked. In case there is no compulsory measure; there is no need to invoke the safeguard clause[36].

However, if an economic operator does not take adequate corrective action within the period indicated by a market surveillance authority, the market surveillance authorities have to take all appropriate provisional measures to prohibit or restrict the product's being made available on their national market, to withdraw the product from that market or to recall it.

8.2 The application of safeguard mechanisms step by step

The application of the safeguard clause requires that the competent national authority takes a compulsory measure to restrict or forbid the making available on the market and, possibly, the putting into service of the product, or has it withdrawn from the market where the relevant economic operator does not take adequate corrective action himself. The contents of the decision should relate to all products belonging to the same type, batch or series. It must also have binding legal effect: it is followed by sanctions, if not respected, and can be subject to an appeals procedure. Court decisions, which restrict the free movement of CE marked product within the scope of the relevant Union harmonisation legislation, do not invoke the safeguard clause. However, where administrative proceedings initiated by the surveillance authority

35 The safeguard clause procedures under the Union harmonisation legislation apply independently from Rapid Alert System. Accordingly, Rapid Alert System does not necessarily have to come into play before the safeguard clause procedure is applied. However, the safeguard clause procedure has to be applied, in addition to Rapid Alert System, when a Member State takes a decision to permanently prohibit or restrict the free movement of harmonised products on the basis of a danger or other serious risk presented by the product.

36 Even if it may not constitute a safeguard clause, the market surveillance authorities shall inform the Commission and other Member States of actions taken against non-compliant products where the non-compliance is not restricted to the national territory (see Art. R31(2) of Annex I of Decision No 768/2008/EC.

must be, according to the national law, confirmed by a court, such court decisions are not excluded from the safeguard clause procedure.

The findings that justify the national measure are established either by the market surveillance authority on its own initiative or based on information received from a third party (such as consumers, competitors, consumer organisations, labour inspectorates). Further, the national measure must be based on evidence (for example tests or examinations) that constitutes sufficient proof of errors in the product design or the manufacture to indicate a foreseeable potential or actual danger or other substantial non-compliance, even when the products are correctly constructed, installed, maintained and used in accordance with their intended purpose or in a reasonably foreseeable way. There is a grey zone between correct and incorrect maintenance and use, and it can be considered that, to a certain extent, products should be safe, even if maintained and used for their intended purpose in an incorrect way that can reasonably be expected. In evaluating this, the data supplied by the manufacturer on the labelling, in the instructions, in the user's manual or in promotion materials are to be taken into consideration.

The reason for taking restrictive measures may result, for instance, from differences or failures in the application of essential requirements, incorrect application of harmonised standards or shortcomings in them. The surveillance authority can add or specify other motives (for example failure to comply with good engineering practice) when invoking the safeguard clause, provided that they are directly linked with these three reasons.

Where non-compliance with harmonised standards that give a presumption of conformity is established, the manufacturer, or the authorised representative, must be requested to provide evidence about compliance with essential requirements. The decision of the competent authority to take corrective action must always be based on an established non-compliance with the essential requirements.

The measures taken by authorities have to be proportionate with the seriousness of the risk and the non-compliance of the product and have to be notified to the Commission.

As soon as a competent national authority restricts or forbids the free movement of a product in such way that the safeguard clause is invoked, the Member State must immediately notify[37] the Commission indicating the reasons and justification for the decision.

The information has to include all available details, in particular:

- name and address of the manufacturer, the authorised representative, and in addition – if necessary – the name and address of the importer or other person responsible for making the product available on the market;

- the data necessary for the identification of the product concerned, the origin and the supply chain of the product;

- the nature of the risk involved and the nature of the national measures taken;

37 This notification should be made via ICSMS. A link between the ICSMS database and the GRS RAPEX IT tool will prevent double encoding of information by national authorities for the purposes respectively of the safeguard clause process and rapid alerts according to Article 22 of the Regulation (EC) No 765/2008.

- a reference to the Union harmonisation legislation, and in particular to the essential requirements, against which the non-compliance has been established;

- a comprehensive assessment and evidence to justify the measure (for example harmonised standards or other technical specifications used by the authority, the test reports and identification of the testing laboratory). In particular, the market surveillance authorities must indicate whether the non-compliance is due to either:

  – failure of the product to meet requirements relating to the health or safety of persons or to other aspects of public interest protection; or

  – shortcomings in the harmonised standards conferring a presumption of conformity.

- the arguments put forward by the relevant economic operator;

- If possible, the notification should also include:

- a copy of the declaration of conformity;

- the name and number of any notified body that intervened in the conformity assessment procedure, if applicable;

- a copy of the decision taken by the Member State authorities.

Where objections are raised against a measure taken by a Member State[38], or where the Commission considers a national measure to be contrary to Union harmonisation legislation, the Commission must without delay enter into consultation with the Member States and the relevant economic operator or operators and must evaluate the national measure. On the basis of the results of this evaluation, the Commission decides whether the national measure is justified or not.

The Commission addresses its decision to all Member States and immediately communicates it to them and the relevant economic operator or operators.

If the national measure is considered justified, all Member States must take the measures necessary to ensure that the non-compliant product is withdrawn from their market, and must inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned must withdraw the measure.

Where the national measure is considered justified and the non-compliance of the product is attributed to shortcomings in the harmonised standards, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 concerning the formal objection to harmonised standard.

38 Union harmonisation legislation aligned to Decision No 768/2008/EC provides for a safeguard procedure which applies only in the event of disagreement between Member States over measures taken by a Member State. The aim is to ensure that proportionate and appropriate measures were taken when a non-compliant product is present in their territory and that similar approaches are taken in the different Member States. While in the past a notification of a risk of a product was notified, Commission had to open a case and elaborate an opinion, now, this burden has been removed and a safeguard case is only opened if a Member State or Commission objects to the measure taken by the notifying authority. Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission is required, except where non-compliance can be attributed to shortcomings of a harmonised standard.

Member States other than the Member State initiating the procedure must without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the product concerned, and, in the event of disagreement with the notified national measure, of their objections. Member States must ensure that appropriate restrictive measures are taken in respect of the product concerned, such as withdrawal of the product from their market, without delay.

Where, within a certain period of time of receipt of the information, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure should be deemed justified.

Conversely, should the Commission see no justification for the national action that invoked the safeguard clause, it will ask the Member State to withdraw its action and take immediate appropriate steps to re-establish the free movement of the products in question on its territory.

Whether the action taken by the Member State is considered justified or not, in either case, the Commission keeps the Member States informed of the progress and the results of the procedure.

Once the decision is taken by the Commission, it can be legally challenged by Member States on the basis of Article 263 TFEU. The economic operator directly concerned by the Decision may also challenge it on the basis of article 263 TFEU.

If the initiating Member State does not withdraw the measure in case of non-justification, in this case, the Commission will consider initiating the infringement procedure provided for by Article 258 TFEU.

9. MUTUAL ASSISTANCE, ADMINISTRATIVE COOPERATION AND EXCHANGE OF INFORMATION AMONG MEMBER STATES

The proper application of Union law depends on a smooth administrative cooperation to ensure uniform and efficient enforcement of Union legislation in all Member States. The obligation to cooperate is in line with Article 20 of the Treaty on European Union (TEU) which states that Member States must take all appropriate measures to fulfil their obligations[39], and with Article 24 of Regulation (EC) No 765/2008. Although technical harmonisation has created a single market, where products move over national borders, market surveillance is carried out on a national basis. Administrative cooperation mechanisms between nation- al surveillance authorities, therefore, need to be developed to increase the efficiency of surveillance, to minimise the effect of different surveillance practices and to reduce the overlapping of national surveillance operations. Cooperation between market surveillance authorities can also spread good surveillance practice and techniques across the Union, as it allows national authorities to compare their methods with those of other authorities, for example in the framework of comparisons and joint surveys or study visits. In addition, cooperation can be useful for exchanging views and solving practical problems.

39 An explicit obligation for administrative cooperation is laid down in the Directives relating to pressure equipment and in vitro diagnostic medical devices: Member States are required to take appropriate measures in order to encourage/ensure that the authorities responsible for implementing the Directive cooperate with each other, and provide each other (and the Commission) with information in order to assist the functioning of the Directive.

Administrative cooperation calls for mutual trust and transparency between national surveillance authorities. Member States and the Commission need to be informed about the way enforcement of Union harmonisation legislation, in particular market surveillance of products is organised throughout the single market. This includes information about national authorities in charge of market surveillance for the different product sectors, and about national market surveillance mechanisms to clarify how monitoring of products made available on the market takes place and what corrective actions and other activities the surveillance authority is entitled to use.

Transparency is also necessary regarding the national rules on confidentiality. For the achievement of effective market surveillance in the Union, it is important that national surveillance authorities assist each other. On request, a national authority should make information available and provide other assistance. Without prior request, a national authority may consider sending to the other national authorities all relevant information concerning operations that constitute, or are likely to constitute, breaches of Union harmonisation legislation, which may have an impact on the territory of other Member States. In addition, the national authorities should communicate to the Commission any information they consider relevant, spontaneously or in response to a reasoned request from the Commission. The Commission may then communicate this information to the other national authorities when considered necessary.

Cooperation and mutual assistance according to Article 24(2) of Regulation (EC) No 765/2008 are, in particular, necessary to ensure that action can be taken against all those who are responsible for a non-compliant product being made available on the market. In some cases the authority of the Member State, where the manufacturer, the authorised representative, or other responsible person is established, needs to be contacted. This is to enforce requests of information made to these economic operators, for example to require the EU declaration of conformity or some specified details from the technical documentation, or to request information concerning the distribution chain, and not followed up by them. The Member State under whose jurisdiction the notified body operates (where applicable) needs to be contacted as well. When a national authority acts due to information it has received from another national body, it should report back to this authority on the outcome of the action.

Moreover, market surveillance would be more efficient, at the Union level, if the national surveillance authorities could agree on how to allocate their resources in such a way that a maximum number of different product types could be covered in each sector. To avoid duplication of product tests, or other investigations for market surveillance purposes, national authorities should exchange summary reports of these tests. This can be done by using the Information and Communication System for Market Surveillance (ICSMS). National surveillance authorities should also consider whether or not there is a special need to carry out technical analyses or laboratory tests when another surveillance authority has already done so, and the results are available to those authorities or may at their request be placed at their disposal[40]. It might also be useful to exchange results of periodic inspections on equipment in service, to the extent that they provide information on the compliance of products when they were placed on the market.

Information exchanged between national surveillance authorities has to be covered by professional confidentiality, according to the principles of the national legal system in

40 See Judgement of the Court, cases 272/80 and 25/88.

question, and it has to enjoy the protection extended to similar information under national law. Where a Member States has rules permitting free access by persons to information held by surveillance authorities, this fact must be revealed at the time of the request to another surveillance authority, or during the exchange of information if no such request occurs. If the sending authority indicates that the information involves matters of professional or commercial confidentiality, the receiving authority should ensure that this can be provided for. Otherwise the sending authority is entitled to withhold the information. Coordination and exchange of information between national surveillance authorities need to be agreed by the parties involved and taking into account the needs of the sector concerned. The following principles could be taken into consideration, where appropriate:

- appointing a national communication point or correspondent for every sector, which would coordinate internally as appropriate;

- agreeing about the types of cases for which the communication of surveillance information would serve a useful purpose;

- developing a common approach to issues such as the classification of risks and hazards and their coding;

- identifying of the details which should be communicated in each case, including the request for further information;

- accepting the obligation to respond to enquiries within a given time scale[41];

- transmitting information (requests and responses), as simply as possible, by e-mail, or through a telematic system operated by the Commission (ICSMS) or an external body, and by using standard multi-language forms;

- taking advantage of up-to-date data recording techniques so that enquiries can be easily undertaken and

- treating the information received in complete confidence.

Cooperation between national administrations takes place in working groups set up under the Union harmonisation legislation. Discussions mainly focus on interpretation issues, but questions related to market surveillance and administrative cooperation are also dealt with. Administrative cooperation between national authorities carrying out market surveillance is taking place in the following sectors: measuring instruments and non–automatic weighing instruments (WELMEC), low voltage equipment (LVD ADCO), Eco-Design ADCO Group, electromagnetic compatibility (EMC administrative cooperation), machinery, medical devices (Vigilance Working Group and COEN – Compliance and Enforcement Group), PEMSAC (The Platform of European Market Surveillance Authorities for Cosmetics), Toy-ADCO (The Administrative Cooperation Group of toys), telecommunications terminal equipment (TCAM), recreational craft, personal protective equipment, ATEX equipment, Radio and Telecommunications Terminal Equipment (R&TTE), Cableways (CABLE), Energy Labelling (ENERLAB), Gas Appliances (GAD), Lifts (LIFTS), Marine Equipment (MED), Noise,

41 An information request does not infringe the right of a national authority to take whatever measures are needed to ensure compliance with Union harmonisation legislation within its jurisdiction.

Pressure equipment sector (PED/SVPD), Pyrotechnics (PYROTEC), Chemicals (REACH), Restriction of the use of certain hazardous substances (ROHS), Transportable Pressure Equipment (TPED), Labelling of tyres. There are also groups dealing with more horizontal issues such as PROSAFE (the product safety forum of Europe), the Expert Group on Internal Market for Products (IMP-MSG), a horizontal committee where, for instance, general questions related to the implementation and enforcement of Union harmonisation legislation, such as horizontal aspects of market surveillance, are discussed. The network of the authorities of the Member States competent for product safety, set up under the GPSD, regularly discusses administrative cooperation issues of general interest.

10. RAPID ALERT SYSTEM FOR NON-FOOD PRODUCTS PRESENTING A RISK

The Rapid Alert System used for non-food products allows 31 participating countries (all EEA countries) and the European Commission to exchange information on products presenting a risk to health and safety or other protected interests and on the measures taken by these countries to do away with that risk.

Article 12 of the GPSD provides a legal basis for a general and horizontal system for the rapid exchange of information on serious risks arising from the use of products (RAPEX, Rapid Alert System).

The Rapid Alert System covers consumer and professional products[42]. It is applicable to non-harmonised products and products covered by the Union harmonisation legislation alike[43].

The Rapid Alert System works according to the detailed procedures laid down in annex II to the GPSD and in the Rapid Alert System guidelines[44].

With the entry into force of Regulation (EC) No 765/2008, the scope of the Rapid Alert System system was extended to risks other than those affecting health and safety (i.e. risks for the environment and in the work place, security risks) and also to products intended for professional (as opposed to consumer) use. Member States should ensure that products which present a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, are recalled, withdrawn or that their being made available on their market is prohibited, and that the Commission is informed without delay through Rapid Alert System under Article 22 of Regulation (EC) No 765/2008.

On 16 December 2009, the Commission adopted Decision 2010/15/EU[45] laying down the new guidelines for the management of the Rapid Alert System. Since guidelines were written before 1 January 2010 they refer explicitly only to notifications based on the GPSD. Nevertheless they are the main reference also for notifications based on Regulation (EC) No 765/2008 (see Article 22(4) therein) – professional products and risks other than health and safety.

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42 Under Article 22 of Regulation (EC) No 765/2008, the Rapid Alert System applies to products covered by Union harmonisation legislation.

43 In the field of medicinal products and medical devices, there is a specific information exchange system.

44 Adopted as Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product safety Directive, OJEU L 22, 26.11.2010, p. 1. The Commission is in the process of drafting an EU wide Risk Assessment Methodology which builds on the RAPEX guidelines, developed within the framework of the GPSD and extends risks assessment to products that can harm the health and safety of professional users or other public interests.

45 Decision 2010/15/EU is available at: http://ec.europa.eu/consumers/safety/rapex/docs/rapex_guid_26012010_en.pdf

The Rapid Alert System procedure is as follows:

- When a product (e.g. a toy, a childcare article or a household appliance) is found, for instance, to be dangerous, the competent national authority takes appropriate action to eliminate the risk. It can withdraw the product from the market, recall it from consumers or issue warnings. Economic operators can take such measures also voluntarily which has to be reported by the competent authorities as well. The National Contact Point then informs the European Commission (through IT system GRAS-Rapid Alert System [46]) about the product, the risks it poses and the measures taken by the authority or the economic operator to prevent risks and accidents.

- The Commission disseminates the information that it receives to the National Contact Points of all other EU and EEA countries. It publishes weekly overviews of products posing a risk and the measures taken to eliminate the risks on the Commission's Rapid Alert System website[47].

- The National Contact Points in each EU and EEA country ensure that the authorities responsible check whether the newly notified product is present on the market. If so, the authorities take measures to eliminate the risk, either by requiring that the product is withdrawn from the market, by recalling it from consumers or by issuing warnings.

The safeguard clause procedures under the Union harmonisation legislation apply in addition to the Rapid Alert System. Accordingly, the Rapid Alert System does not necessarily have to come into play before the safeguard clause procedure is applied. However, the safeguard clause procedure has to be applied, in addition to the Rapid Alert System , when the Member State takes a decision to permanently prohibit or restrict the free movement of CE marked products on the basis of a danger or other serious risk presented by the product.

11. ICSMS

ICSMS (Information and Communication System for Market Surveillance) is an IT tool that provides for a comprehensive communication platform between all the market surveillance authorities.

ICSMS consists of an internal (accessible only to market surveillance authorities) and a public area.

11.1 Role

ICSMS offers fast and efficient communication means for market surveillance authorities to exchange information within a short space of time. ICSMS allows information on non-compliant products (test results, product identification data, photographs, economic operator information, risk assessments, accident information, information on measures taken by surveillance authorities etc.) to be quickly and efficiently shared between authorities.

46 General Rapid Alert System for the RAPEX notifications. GRAS-RAPEX replaced RAPEX-REIS (Rapid Exchange Information System for the Rapid Alert System application and extended the scope of Rapid Alert System to professional products and to other risks than health and safety.

47 http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm

The aim is not only to avoid cases where an unsafe product taken off the market in one country to be on sale for a long time in another country but mainly to have a market surveillance policy tool that allows to establish a co-operation mechanism among authorities.

While being aware of the fact that the mere reliable exchange of information is crucial for the market surveillance, it must be acknowledged that the added value of ICSMS stems from its capacity to be the platform for the implementation of the European market surveillance policy.

In this respect whenever a national authority wants to exchange information about a product under investigation with other authorities in order to share resources (e.g. for product checks), carry out common actions or consult other authorities, it must input into ICSMS the relevant information. This must be done as early as possible and certainly well before the decision to adopt measures for products found to present a risk. E.g. if a national authority cannot determine the level of the risk presented by a relevant product and carries out investigations, it must use ICSMS in order to communicate with the competent authorities of the other Member States.

ICSMS is not limited only to non-compliant products, but it gives information also regarding all products checked by authorities even if the result of the checks would be that no non-compliances have been found. This helps authorities avoiding any double (or multiple) checking of products.

Thus the ultimate role of ICSMS is to help the European Union to fulfil one of its major political objectives; i.e. to ensure reliability and coherence in the implementation and enforcement of the European legislation) in order for operators and citizens to benefit from the original intention of full access to the Internal Market.

In particular ICSMS helps market surveillance authorities to:

- proceed to quick and in-time exchange of information on market surveillance measures;
- coordinate their activities and inspections more effectively, especially by focusing on products which have not been inspected or tested yet;
- share resources and have thus more time to concentrate on other products which have yet to be tested;
- carry out wide-scale market interventions wherever products of a dubious nature are concerned using the latest information and avoid thus duplicate and multiple inspections;
- elaborate best practices;
- ensure that market surveillance is efficient and of even rigour in all Member States and avoid thus distortion to competition;
- establish an encyclopaedia of EU market surveillance intelligence.

11.2 Structure

The internal area is destined for market surveillance authorities, customs authorities and the EU. It contains all information available (product description, test results, measures taken etc.). Only ICSMS account holders may access this area.

The public area is destined for consumers, users and manufacturers. The information which is visible to the public provides only the data, which reference the product and its non-compliance and not any internal documents (i.e. information exchange between authority and importer/manufacturer).

ICSMS enables specific searches for non-compliant products. Confidentiality aspects are protected by a system of access authorisations.

Each market surveillance authority can input data about investigated products, which are not already in the database and add information (e.g. additional tests results, measures taken) to an already existing product information file.

The Commission ensures the proper functioning of ICSMS. The use of ICSMS is free of charge.

12. SUMMARY TABLE OF PROVISIONS OF REGULATION (EC) NO 765/2008 RELATED TO MARKET SURVEILLANCE BY MEMBER STATES

Stakeholder	Chapter	Article	Requirement
Member States	Chapter III – EU market surveillance framework and controls of products entering the EU market	16	General obligation to carry out market surveillance and take restrictive measures for product found to be dangerous or in any case non-compliant in relation to any product categories subject to EU harmonisation law and to inform the European Commission and other Member States.
		17	Inform the EC of their national MSAs and their areas of competence.
			Ensure that the public is aware of the existence of national MSAs.
		18	Establish appropriate communication and coordination mechanisms between their national MSAs.
			Establish adequate procedures in order to: - follow up complaints or reports on issues relating to products that may cause risks; - monitor accidents and harm to health which are suspected to have been caused by those products; - verify that corrective action has been taken; - follow up scientific and technical knowledge concerning safety issues.
			Entrust MSAs with the powers, resources and knowledge necessary for the proper performance of their tasks
			Ensure that MSAs exercise their powers in accordance with the principle of proportionality.
			Establish, implement and periodically update their market surveillance programmes.
			Draw up either a general market surveillance programme or sector-specific programmes covering the sectors in which they conduct market surveillance, communicate those programmes to the other MS and the Commission and make them available to the public.
			Periodically review and assess the functioning of their surveillance activities (at least every four year) and communicate the results to the EC, other MS and to the public.
		20	Ensure that products which present a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, are recalled, withdrawn or that their being made available on their market is prohibited, and that the Commission is informed without delay.
		21	Ensure that any measure taken to prohibit or restrict the product's being made available on the market, to withdraw it from the market or to recall it, is proportionate and states the exact grounds on which it is based.
			Communicate restrictive measures without delay to the relevant economic operator, together with the remedies available under the law of the MS concerned and

Stakeholder	Chapter	Article	Requirement
			the time limits to which such remedies are subject.
			Hear the economic operator concerned prior to adoption of restrictive measure
			Withdraw or amend any restrictive measure adopted if the economic operator demonstrates that he has taken effective action.
		22	If considers that the reasons which prompted the restrictive measure or the effects of the measure go beyond its territory, shall immediately notify the Commission of that measure using the market surveillance and information exchange system RAPEX.
			If a product presenting a serious risk has been made available on the market, notify the Commission of any voluntary measures taken and communicated by an economic operator.
		23	Provide the EC with information at their disposal and not already provided on products presenting a risk regarding, in particular, identification of risks, results of testing carried out, provisional restrictive measures taken, contacts with the economic operators concerned and justification for action or inaction.
			Safeguard the confidentiality of the information content.
		24	Ensure efficient cooperation and exchange of information between their MSAs and those of other MS, the EC and the relevant EU agencies. Mutual assistance to supply each other information or documentation and to carry out appropriate investigation or any other measures.
		25	Ensure that their competent authorities participate fully in the training, exchange of experience and best practices, joining the common projects, information campaigns, joint visit programmes.
	Chapter VI – Final provisions	41	Lay down rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements of the provisions of this Regulation and take all measures necessary to ensure that they are implemented.
Market Surveillance Authorities	Chapter III – EU market surveillance framework and controls of products entering the EU market	19	Perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples.
			May require economic operators to make documentation and information available for the purpose of carrying out their activities, and, where it is necessary and justified, enter the premises of economic operators and take the necessary samples of products. MSA may destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary.
			Take due account of test reports or certificate presented by economic operators attesting conformity issued by an accredited conformity assessment body.
			Take appropriate measures to alert users within their territories within an adequate timeframe of hazards they have identified relating to any product so as to reduce the risk of injury or other damage.

Stakeholder	Chapter	Article	Requirement
			Cooperate with economic operators regarding actions which could prevent or reduce risks caused by products made available by those operators.
			In case of decision to withdraw a product manufactured in another Member State, inform the economic operator concerned.
			Carry out its duties independently, impartially and without bias and observe confidentiality in order to protect commercial secrets or to preserve personal data pursuant to national legislation.
			Observe confidentiality where necessary in order to protect commercial secrets or to preserve personal data pursuant to national legislation, subject to the requirement that information be made public under this Regulation to the fullest extent necessary in order to protect the interests of users in the EU.
		26	Cooperate with the competent authorities of third countries with a view to exchanging information and technical support, promoting and facilitating access to European systems and promoting activities relating to conformity assessment, market surveillance and accreditation.
		27	In case of more than one authority is responsible for market surveillance they cooperate with each other, by sharing information relevant to their functions and otherwise as appropriate.
		28	Evaluate the product suspended by the external border controls Authorities. If the product does not present a serious risk to health, safety and other public interest or cannot be regarded as being in breach of EU harmonisation legislation, it shall be released.
		29	Take measures to prohibit that a dangerous product is placed on the market and require the authorities in charge of external border controls to include a commercial invoice accompanying the product and on any other relevant accompanying document.
			Take appropriate action, including the prohibition of the marketing of the product, in case it does not comply with EU harmonisation legislation and require the authorities in charge of external border controls to include the a specific endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document.
			Destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary and proportionate.
			Provide external border controls authorities information on product categories in which a serious risk or non-compliance has been identified.
External border controls Authorities	Chapter III – EU market surveillance framework and controls of products entering the EU market	27	In case of more than one authority is responsible for external border controls, they cooperate with each other, by sharing information relevant to their functions and otherwise as appropriate.
			Carry out appropriate checks on the characteristics of products on an adequate scale, in accordance with the principles set out in Article 19(1), before those products are released for free circulation. Suspend release of a product for free circulation on the internal market when the product (a) displays characteristics which give cause to believe that the product, when properly installed, maintained and used, presents a serious risk to health, safety, the environment or any other public interest, (b) is not accompanied by the written or electronic documentation required by the relevant EU harmonisation legislation or is not marked in accordance with that legislation (c) the CE marking has been affixed to the product in a false or misleading manner and immediately notify the MSAs of any such suspension.

Stakeholder	Chapter	Article	Requirement
			Ensure that any requirements they may impose with regard to the storage of products or the parking of vehicles used for transport are not incompatible with the preservation of perishable products.
			Ensure efficient cooperation and exchange of information among external border controls Authorities.
		28	Release a suspended product if, within three working days of the suspension of release, external border controls Authorities have not been notified of any action taken by the MSAs, and provided that all the other requirements and formalities pertaining to such release have been fulfilled.

ANNEX 7: UNION HARMONISATION LEGISLATION ON NON-FOOD PRODUCTS IN THE EU (2016) AND COMPLIANCE COSTS

1. UNION HARMONISATION LEGISLATION

(1) Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass;

(2) Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles;

(3) Council Directive 75/107/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to bottles used as measuring containers;

(4) Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers;

(5) Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products;

(6) Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC;

(7) Council Directive 92/23/EEC of 31 March 1992 relating to tyres for motor vehicles and their trailers and to their fitting (*valid until 31 October 2017*);

(8) Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels;

(9) Directive 94/11/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer;

(10) Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery;

(11) Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC;

(12) Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors;

(13) Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers;

(14) Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;

(15) Directive 2004/52/EC of the European Parliament and of the Council of 29 April 2004 on the interoperability of electronic road toll systems in the Community;

(16) Regulation (EC) No 552/2004 of the European Parliament and of the Council of 10 March 2004 on the interoperability of the European Air Traffic Management network (the interoperability Regulation);

(17) Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents;

(18) Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC;

(19) Directive 2005/64/EC of the European Parliament and of the Council of 26 October 2005 on the type-approval of motor vehicles with regard to their reusability, recyclability and recoverability and amending Council Directive 70/156/EEC;

(20) Directive 2006/40/EC of the European Parliament and of the Council of 17 May 2006 relating to emissions from air conditioning systems in motor vehicles and amending Council Directive 70/156/EEC;

(21) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery;

(22) Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC;

(23) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;

(24) Directive 2007/45/EC of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for pre-packed products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC;

(25) Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles;

(26) Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information;

(27) Directive 2008/2/EC of the European Parliament and of the Council of 15 January 2008 on the field of vision and windscreen wipers for wheeled agricultural or forestry tractors (Codified version);

(28) Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community;

(29) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;

(30) Directive 2009/34/EC of the European Parliament and of the Council of 23 April 2009 relating to common provisions for both measuring instruments and methods of metrological control;

(31) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys;

(32) Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products;

(33) Regulation (EC) No 78/2009 of the European Parliament and of the Council of 14 January 2009 on the type-approval of motor vehicles with regard to the protection of pedestrians and other vulnerable road users, amending Directive 2007/46/EC and repealing Directives 2003/102/EC and 2005/66/EC;

(34) Regulation (EC) No 79/2009 of the European Parliament and of the Council of 14 January 2009 on type-approval of hydrogen-powered motor vehicles, and amending Directive 2007/46/EC;

(35) Regulation (EC) No 595/2009 of the European Parliament and of the Council of 18 June 2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC;

(36) Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor;

(37) Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer;

(38) Regulation (EC) No 1222/2009 of the European Parliament and of the Council of 25 November 2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters;

(39) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products;

(40) Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel;

(41) Directive 2010/30/EU of the European Parliament and of the Council of 19 May 2010 on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products;

(42) Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment;

(43) Regulation (EU) No 1007/2011 of the European Parliament and of the Council of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products and repealing Council Directive 73/44/EEC and Directives 96/73/EC and 2008/121/EC of the European Parliament and of the Council;

(44) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment;

(45) Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products;

(46) Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE);

(47) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products;

(48) Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles;

(49) Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles;

(50) Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles;

(51) Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC;

(52) Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses;

(53) Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels;

(54) Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility;

(55) Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments;

(56) Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments;

(57) Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts;

(58) Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres;

(59) Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits;

(60) Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC;

(61) Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment;

(62) Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC;

(63) Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006;

(64) Regulation (EU) No 540/2014 of the European Parliament and of the Council of 16 April 2014 on the sound level of motor vehicles and of replacement silencing systems, and amending Directive 2007/46/EC and repealing Directive 70/157/EEC;

(65) Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC;

(66) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC;

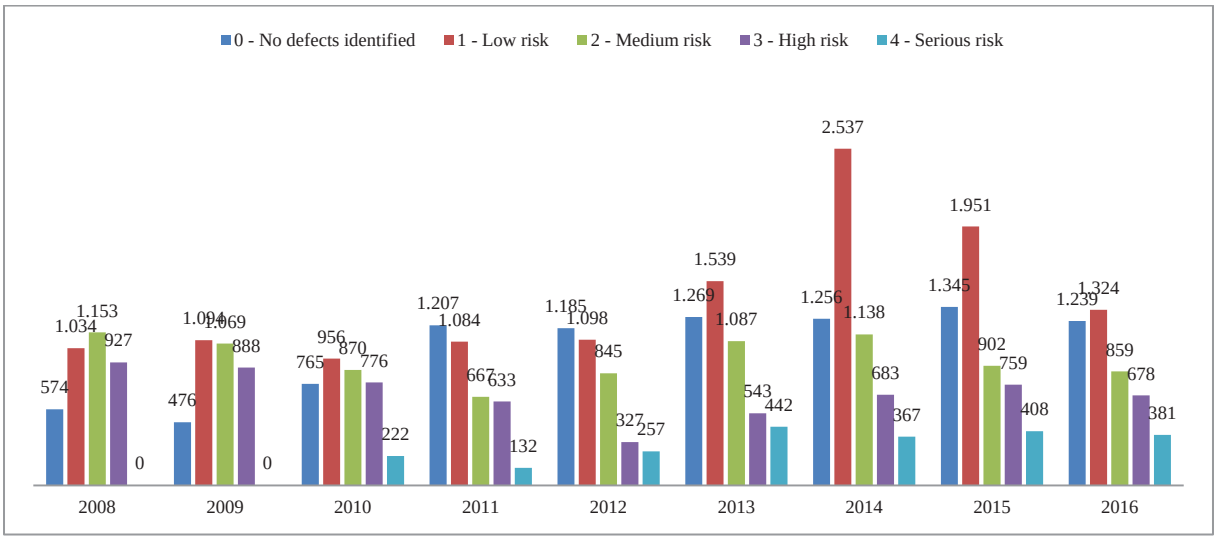
(67) Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC;

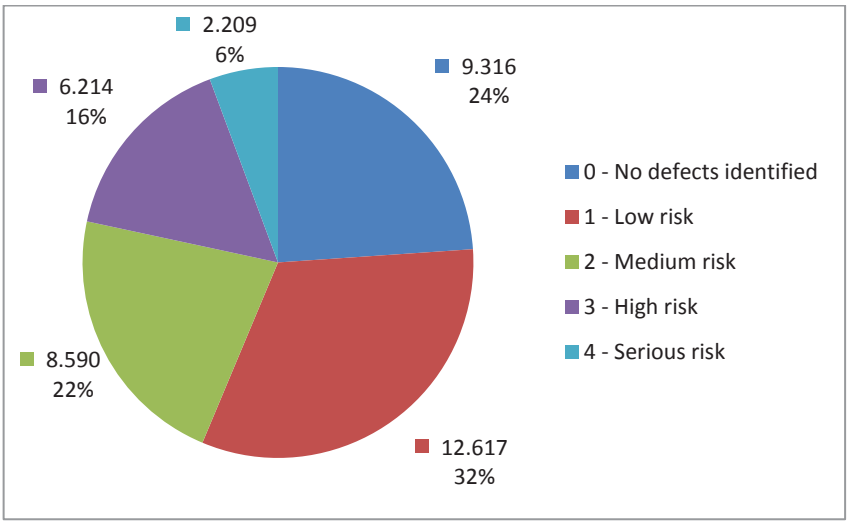
(68) Directive (EU) 2016/802 of the European Parliament and of the Council of 11 May 2016 relating to a reduction in the sulphur content of certain liquid fuels.

2. EVIDENDE OF NON-COMPLIANCE AT EU LEVEL

2.1 Data from the Information Communistation System for Market Surveillance (ICSMS)

	0 - No defects identified	1 - Low risk	2 - Medium risk	3 - High risk	4 - Serious risk
2008	574	1.034	1.153	927	0
2009	476	1.094	1.069	888	0
2010	765	956	870	776	222
2011	1.207	1.084	667	633	132
2012	1.185	1.098	845	327	257
2013	1.269	1.539	1.087	543	442
2014	1.256	2.537	1.138	683	367
2015	1.345	1.951	902	759	408
2016	1.239	1.324	859	678	381
	9.316	**12.617**	**8.590**	**6.214**	**2.209**





GUIDELINE	RISK	COUNT
2000/14/EC Outdoor Noise Emissions Directive	0 - no defects identified	179
	1 - Low risk	151
	2 - Medium risk	70
	3 - High risk	17
	4 - Serious risk	9
	5 - not specified	142
2000/9/EC Cableways Directive	1 - Low risk	1
	2 - Medium risk	1
	3 - High risk	1
	5 - not specified	2
2001/95/EC General Product Safety Directive (GPSD)	0 - no defects identified	1418
	1 - Low risk	1790
	2 - Medium risk	2645
	3 - High risk	2673
	4 - Serious risk	510
	5 - not specified	8225

GUIDELINE	RISK	COUNT
2002/95/EC Restriction Use of Hazardous Substances Directive (RoHS)	0 - no defects identified	236
	1 - Low risk	69
	2 - Medium risk	68
	3 - High risk	8
	4 - Serious risk	16
	5 - not specified	190
2002/96/EC Waste Electrical & Electronic Equipment Directive (WEEE)	0 - no defects identified	28
	1 - Low risk	64
	2 - Medium risk	23
	3 - High risk	5
	4 - Serious risk	13
	5 - not specified	58
2003/2003/EC Fertilizers Directive	5 - not specified	1
2004/108/EC Electromagnetic Compatibility Directive (EMC)	0 - no defects identified	163
	1 - Low risk	2068
	2 - Medium risk	133
	3 - High risk	82
	4 - Serious risk	62
	5 - not specified	357
2004/22/EC Measuring Instruments Directive (MID)	0 - no defects identified	15
	1 - Low risk	11
	2 - Medium risk	14
	3 - High risk	3
	5 - not specified	10
2004/42/EC Deco-paint Directive	1 - Low risk	1
	2 - Medium risk	1
	5 - not specified	2
2004/49/EC Railway Safety Directive	5 - not specified	2

GUIDELINE	RISK	COUNT
2006/42/EC Machinery Directive	0 - no defects identified	475
	1 - Low risk	601
	2 - Medium risk	541
	3 - High risk	365
	4 - Serious risk	145
	5 - not specified	704
2006/66/EC Batteries and Accumulators Directive	0 - no defects identified	1
	1 - Low risk	1
	2 - Medium risk	2
	3 - High risk	2
	4 - Serious risk	2
	5 - not specified	3
2006/95/EC Low Voltage Directive (LVD)	0 - no defects identified	2053
	1 - Low risk	2566
	2 - Medium risk	3367
	3 - High risk	2426
	4 - Serious risk	568
	5 - not specified	6586
2007/23/EC Pyrotechnic Articles Directive	0 - no defects identified	41
	1 - Low risk	17
	2 - Medium risk	13
	3 - High risk	4
	4 - Serious risk	8
	5 - not specified	143
2007/45/EC Pre-packed Products Directive	1 - Low risk	1
2007/46/EC Motor Vehicles Directive	4 - Serious risk	1
	5 - not specified	2
2009/105/EC Simple Pressure Vessel Directive	0 - no defects identified	14

GUIDELINE	RISK	COUNT
	1 - Low risk	44
	2 - Medium risk	18
	3 - High risk	5
	4 - Serious risk	7
	5 - not specified	32
2009/125/EC Energy Related Products Directive	0 - no defects identified	774
	1 - Low risk	156
	2 - Medium risk	431
	3 - High risk	4
	4 - Serious risk	7
	5 - not specified	627
2009/142/EC Gas Appliances Directive (GAD)	0 - no defects identified	40
	1 - Low risk	60
	2 - Medium risk	84
	3 - High risk	78
	4 - Serious risk	9
	5 - not specified	195
2009/23/EC Non-Automatic Weighing Instruments Directive	0 - no defects identified	2
	1 - Low risk	7
	2 - Medium risk	3
	3 - High risk	2
	5 - not specified	2

GUIDELINE	RISK	COUNT
2010/30/EU Energy Labelling Directive	0 - no defects identified	27
	1 - Low risk	53
	2 - Medium risk	52
	3 - High risk	9
	4 - Serious risk	7
	5 - not specified	54
2010/35/EC Transportable Pressure Equipment Directive	0 - no defects identified	5
	1 - Low risk	2
	3 - High risk	2
	4 - Serious risk	1
	5 - not specified	15
2010/62/EU Tractor Directive	0 - no defects identified	1
	2 - Medium risk	1
2011/65/EU Restriction of Hazardous Substances RoHS	0 - no defects identified	230
	1 - Low risk	81
	2 - Medium risk	115
	3 - High risk	7
	4 - Serious risk	13
	5 - not specified	99
2012/19/EU Waste Electrical & Electronic Equipment Directive	0 - no defects identified	3
	1 - Low risk	1
	2 - Medium risk	1
	3 - High risk	1
	4 - Serious risk	2
	5 - not specified	7

GUIDELINE	RISK	COUNT
67/548/EEC Dangerous Substances Directive	0 - no defects identified	7
	1 - Low risk	88
	2 - Medium risk	80
	3 - High risk	29
	4 - Serious risk	1
	5 - not specified	115
75/324/EEC Aerosol Dispensers Directive	0 - no defects identified	20
	1 - Low risk	38
	2 - Medium risk	45
	3 - High risk	2
	5 - not specified	42
76/211/EEC Pre-packed Products Directive	5 - not specified	1
76/768/EEC Cosmetics Directive	0 - no defects identified	5
	1 - Low risk	25
	2 - Medium risk	7
	3 - High risk	5
	4 - Serious risk	23
	5 - not specified	202
76/769/EEC Marketing and Use Directive	0 - no defects identified	10
	1 - Low risk	36
	2 - Medium risk	98
	3 - High risk	205
	5 - not specified	142
87/357/EEC Consumer Products appearing to be other than they are Directive	3 - High risk	1
	4 - Serious risk	13
	5 - not specified	7

GUIDELINE	RISK	COUNT
88/378/EEC Toy Directive	0 - no defects identified	983
	1 - Low risk	1289
	2 - Medium risk	1063
	3 - High risk	1348
	4 - Serious risk	135
	5 - not specified	2808
89/106/EEC Construction Products Directive	0 - no defects identified	58
	1 - Low risk	24
	2 - Medium risk	15
	3 - High risk	2
	5 - not specified	308
89/336/EEC Electromagnetic Compatibility Directive (EMC)	0 - no defects identified	250
	1 - Low risk	1321
	2 - Medium risk	248
	3 - High risk	172
	4 - Serious risk	9
	5 - not specified	130
89/686/EEC Personal Protective Equipment Directive (PPE)	0 - no defects identified	650
	1 - Low risk	1292
	2 - Medium risk	669
	3 - High risk	156
	4 - Serious risk	39
	5 - not specified	649
91/414/EEC Plant Protection Products Directive	0 - no defects identified	1
	2 - Medium risk	1
	3 - High risk	1
	5 - not specified	1
93/15/EEC Civil Explosives Directive	2 - Medium risk	1

GUIDELINE	RISK	COUNT
	5 - not specified	7
93/42/EEC Medical Devices Directive	0 - no defects identified	6
	1 - Low risk	7
	2 - Medium risk	4
	3 - High risk	1
	4 - Serious risk	2
	5 - not specified	53
94/11/EC Footwear Directive	0 - no defects identified	1
	5 - not specified	1
94/25/EC Recreational Craft Directive	0 - no defects identified	13
	1 - Low risk	35
	2 - Medium risk	12
	3 - High risk	5
	5 - not specified	44
94/62/EC Packaging and Packaging Waste Directive	0 - no defects identified	2
	1 - Low risk	12
	5 - not specified	3
94/9/EC Equipment for Use in Potentially Explosive Atmospheres (ATEX)	0 - no defects identified	4
	1 - Low risk	6
	2 - Medium risk	20
	3 - High risk	5
	4 - Serious risk	4
	5 - not specified	15

GUIDELINE	RISK	COUNT
95/16/EC Lift Directive	1 - Low risk	18
	2 - Medium risk	5
	3 - High risk	8
	4 - Serious risk	1
	5 - not specified	9
96/98/EC Marine Equipment Directive	5 - not specified	6
97/23/EC Pressure Equipment Directive	0 - no defects identified	51
	1 - Low risk	58
	2 - Medium risk	78
	3 - High risk	47
	4 - Serious risk	12
	5 - not specified	64
97/68/EC Directive on Emissions of off-road engines	0 - no defects identified	2
	2 - Medium risk	4
	3 - High risk	1
	5 - not specified	3
98/37/EC Machinery Directive	0 - no defects identified	268
	1 - Low risk	627
	2 - Medium risk	1246
	3 - High risk	915
	4 - Serious risk	12
	5 - not specified	633

GUIDELINE	RISK	COUNT
98/8/EC Biocidal Products Directive	0 - no defects identified	27
	1 - Low risk	193
	2 - Medium risk	103
	3 - High risk	12
	4 - Serious risk	3
	5 - not specified	201
99/36/EC Transportable Pressure Equipment Directive	0 - no defects identified	3
	2 - Medium risk	2
	3 - High risk	5
	5 - not specified	6
99/45/EC Dangerous Preparations Directive	0 - no defects identified	61
	1 - Low risk	561
	2 - Medium risk	426
	3 - High risk	132
	4 - Serious risk	10
	5 - not specified	621
99/5/EC R&TTE - Radio and Telecommunications Terminal Equipment Directive	0 - no defects identified	143
	1 - Low risk	1800
	2 - Medium risk	88
	3 - High risk	109
	4 - Serious risk	13
	5 - not specified	277
Commission Delegated Regulation (EU) No 1059/2010 energy labelling of household dishwashers	0 - no defects identified	1
	1 - Low risk	6

GUIDELINE	RISK	COUNT
Commission Delegated Regulation (EU) No 1060/2010 energy labelling of household refrigerating appliances	0 - no defects identified	8
	1 - Low risk	17
	2 - Medium risk	7
	5 - not specified	2
Commission Delegated Regulation (EU) No 1061/2010 energy labelling of household washing machines	0 - no defects identified	1
Commission Delegated Regulation (EU) No 1062/2010 energy labelling of televisions	0 - no defects identified	2
	1 - Low risk	5
	5 - not specified	1
Commission Delegated Regulation (EU) No 626/2011 energy labelling of air conditioners	0 - no defects identified	1
	1 - Low risk	2
	2 - Medium risk	1
	5 - not specified	4
Commission Delegated Regulation (EU) No 65/2014 energy labelling of domestic ovens and range hoods	1 - Low risk	1
	5 - not specified	5
Commission Delegated Regulation (EU) No 665/2013 energy labelling of vacuum cleaners	0 - no defects identified	4
	1 - Low risk	2
	3 - High risk	1
	5 - not specified	1
Commission Delegated Regulation (EU) No 874/2012 energy labelling of electrical lamps and luminaires	0 - no defects identified	12
	1 - Low risk	35
	2 - Medium risk	42
	3 - High risk	5
	5 - not specified	5

GUIDELINE	RISK	COUNT
Construction Products Regulation (EU) No 305/2011	0 - no defects identified	10
	1 - Low risk	5
	2 - Medium risk	1
	3 - High risk	4
	4 - Serious risk	2
	5 - not specified	34
Directive 2009/48/EC on the safety of toys	0 - no defects identified	1239
	1 - Low risk	585
	2 - Medium risk	369
	3 - High risk	542
	4 - Serious risk	293
	5 - not specified	1376
Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (recast) Text with EEA relevance	1 - Low risk	3
	2 - Medium risk	16
	3 - High risk	2
	4 - Serious risk	1
Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) Text with EEA relevance	0 - no defects identified	6
	1 - Low risk	8
	2 - Medium risk	6
	3 - High risk	1
	5 - not specified	3
Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments Text with EEA relevance	2 - Medium risk	3

GUIDELINE	RISK	COUNT
Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making av2ilable on the market of electrical equipment designed for use within certain voltage limits Text with EEA relevance	0 - no defects identified	44
	1 - Low risk	31
	2 - Medium risk	112
	3 - High risk	83
	4 - Serious risk	39
	5 - not specified	3
Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC Text with EEA relevance	0 - no defects identified	9
	1 - Low risk	3
	5 - not specified	1
Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment Text with EEA relevance	1 - Low risk	3
	3 - High risk	1
Non Harmonised Product / No directive applies	0 - no defects identified	96
	1 - Low risk	73
	2 - Medium risk	53
	3 - High risk	36
	4 - Serious risk	16
	5 - not specified	63
REGULATION (EC) No 1007/2011 Textiles Regulation	0 - no defects identified	14
	3 - High risk	2
	4 - Serious risk	2
	5 - not specified	6
REGULATION (EC) No 107/2009 ecodesign for simple set-top boxes	0 - no defects identified	5
	2 - Medium risk	2
REGULATION (EC) No 1222/2009 Tyre Labelling	0 - no defects identified	12
	1 - Low risk	3
Regulation (EC) No 1223/2009 on cosmetic	0 - no defects identified	129

GUIDELINE	RISK	COUNT
products	1 - Low risk	37
	2 - Medium risk	49
	3 - High risk	50
	4 - Serious risk	15
	5 - not specified	25
Regulation (EC) No 1223/2009 on cosmetic products - Article 23	0 - no defects identified	12
	2 - Medium risk	1
	4 - Serious risk	2
	5 - not specified	55
Regulation (EC) No 1272/2008 Classification, Labelling & Packaging (CLP)	0 - no defects identified	74
	1 - Low risk	174
	2 - Medium risk	149
	3 - High risk	108
	4 - Serious risk	43
	5 - not specified	237
REGULATION (EC) No 1275/2008 ecodesign for electrical and electronic household and office equipment	0 - no defects identified	110
	1 - Low risk	11
	2 - Medium risk	13
	5 - not specified	11
Regulation (EC) No 1907/2006 (REACH)	0 - no defects identified	402
	1 - Low risk	306
	2 - Medium risk	556
	3 - High risk	322
	4 - Serious risk	119
	5 - not specified	982

GUIDELINE	RISK	COUNT
REGULATION (EC) No 244/2009 ecodesign for non-directional household lamps	0 - no defects identified	20
	1 - Low risk	26
	2 - Medium risk	32
	4 - Serious risk	1
	5 - not specified	8
REGULATION (EC) No 278/2009 ecodesign for external power supplies	0 - no defects identified	266
	1 - Low risk	61
	2 - Medium risk	105
	5 - not specified	26
REGULATION (EC) No 528/2012 Biocidal Products	0 - no defects identified	5
	1 - Low risk	53
	2 - Medium risk	32
	3 - High risk	18
	4 - Serious risk	1
	5 - not specified	31
REGULATION (EC) No 640/2009 ecodesign for electric motors	1 - Low risk	6
	5 - not specified	2
REGULATION (EC) No 642/2009 ecodesign for televisions	0 - no defects identified	8
	1 - Low risk	6
REGULATION (EC) No 643/2009 ecodesign for household refrigerating appliances	0 - no defects identified	7
	1 - Low risk	1
	2 - Medium risk	6
REGULATION (EC) No 648/2004 Detergents	0 - no defects identified	6
	1 - Low risk	24
	2 - Medium risk	6
	3 - High risk	1
	5 - not specified	10

GUIDELINE	RISK	COUNT
REGULATION (EC) No 689/2008 Export and Import of Dangerous Chemicals	1 - Low risk	2
Regulation (EC) No 765/2008 Accreditation & Market Surveillance	0 - no defects identified	56
	1 - Low risk	44
	2 - Medium risk	16
	3 - High risk	3
	4 - Serious risk	9
	5 - not specified	52
REGULATION (EC) No 850/2004 Persistent Organic Pollutants	0 - no defects identified	15
	1 - Low risk	3
	2 - Medium risk	3
	3 - High risk	2
	4 - Serious risk	3
	5 - not specified	17
REGULATION (EU) No 1015/2010 ecodesign for household washing machines	0 - no defects identified	1
REGULATION (EU) No 1194/2012 ecodesign for directional lamps, light emitting diode lamps and related equipment	0 - no defects identified	12
	1 - Low risk	27
	2 - Medium risk	35
	5 - not specified	2
REGULATION (EU) No 206/2012 ecodesign for air conditioners and comfort fans	0 - no defects identified	1
	1 - Low risk	2
	2 - Medium risk	2
	5 - not specified	1
REGULATION (EU) No 617/2013 ecodesign for computers and computer server	0 - no defects identified	1
	5 - not specified	6
REGULATION (EU) No 66/2014 ecodesign for domestic ovens, hobs and range hoods	2 - Medium risk	6
	5 - not specified	5
REGULATION (EU) No 666/2013 ecodesign	0 - no defects identified	5

GUIDELINE	RISK	COUNT
for vacuum cleaners	1 - Low risk	2
	3 - High risk	1
	5 - not specified	3
REGULATION (EU) No 932/2012 ecodesign for household tumble driers	0 - no defects identified	2

2.2 Reviews and assessments of the functioning of market surveillance activities

Member States reviewed and assessed the functioning of their market surveillance activities carried out for the 2010 to 2013 period. These reports were drafted pursuant to Article 18(6) of Regulation (EC) 765/2008.

http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation_en

The Commission combined the provided information into a single report.

http://ec.europa.eu/DocsRoom/documents/15241/attachments/1/translations

A more detailed analysis of data provided by member States is contained in Annex 9 section 5.

2.3 Joint market surveillance authorities in different sectors

- Toys intended for children under 3 years

  http://www.prosafe.org/images/Documents/JA2013/JA2013_Toys_Final_Technical_Report_24-02-2016.pdf

- LED lighting equipment

  http://ec.europa.eu/DocsRoom/documents/9868

- Active electric energy meters and heating meters

  http://ec.europa.eu/DocsRoom/documents/20422

- Electromagnetic Compatibility

  http://ec.europa.eu/DocsRoom/documents/9869

  http://ec.europa.eu/DocsRoom/documents/8064

- Radio and Telecommunications Equipment

  http://ec.europa.eu/DocsRoom/documents/9922

http://ec.europa.eu/DocsRoom/documents/7718

http://ec.europa.eu/DocsRoom/documents/13343

- REACH and CLP

  https://echa.europa.eu/about-us/who-we-are/enforcement-forum/forum-enforcement-projects

3. COSTS OF COMPLIANCE

3.1 Terminology

ATEX	Directive on Equipment and protective systems intended for use in potentially explosive atmospheres
CPR	Construction Products Regulation
EMC	Electromagnetic Compatibility Directive
GAD	Gas Appliances Directive
IM	Internal Market
LD	Lifts Directive
LVD	Low Voltage Directive
MD	Machinery Directive
MID	Measuring Instruments Directive
OED	Outdoor Equipment Directive
PED	Pressure Equipment Directive
PPE	Personal Protective Equipment Directive
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical substances Regulation
R&TTE	Radio and Telecommunications Terminal Equipment Directive
RoHS	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment
SPVD	Simple Pressure Vessels Directive

3.2 Introduction

This section outlines the process by which industry complies with the legislation and attempts to identify and quantify the costs incurred in compliance[48]. More specifically, the analysis has

48 For further details, see Commission Staff Working Document SWD(2014)23.

attempted to estimate the costs of compliance with Union harmonisation legislation faced by firms. This task has been undertaken through case studies of specific product groups. The table below lists the product groups covered by the case studies.

No	Product	Applicable Legislation
Harmonised product groups		
1	Electric motors	Core Directives - LVD, EMC, ATEX Other applicable IM legislation: REACH, RoHS, Ecodesign
2	Laptops	Core Directives - R&TTE, LVD and EMC Other applicable IM legislation: Ecodesign, RoHS, Packaging and Packaging Waste Directive
3	Domestic refrigerators and freezers	Core Directives - LVD, EMC Other applicable IM legislation: REACH, Ecodesign, Energy labelling, RoHS, Regulation on materials in contact with foodstuff
4	Lifts for persons	Core Directives - Lifts[49], LVD and EMC
5	Gardening equipment	MD, EMC, Outdoor noise, Non-road mobile machinery Emissions, RoHS, REACH
6	Fuel dispensers	MID, LVD, EMC
7	Air conditioners	MD, EMC, LVD, CPR, RoHS, Energy Labelling, PED[50], Ecodesign, Regulation 2000/2037/EC on Ozone Depleting Substances Regulation 2006/842/EC on Fluorinated Greenhouse Gases Regulation 2007/1494/EC on Labelling Requirements
8	Integrated circuits	LVD, EMC, ATEX, RoHS

For each of these product groups, the relevant legislation was reviewed, sectoral data on market size and structure was analysed and firms were interviewed in depth in order to identify the processes followed in compliance and the costs incurred. Data on costs was then analysed using the Standard Cost Model in order to draw conclusions around the cost of

49 The Machinery Directive applies to lifts for goods and to other types of lifts not covered by the Lifts Directive, the Cableways Directive applies to lifting appliances installed in outdoor mountain or urban sites.

50 The SPVD is also applicable but only to certain types of air conditioners.

compliance. Finally, macro-economic impacts were assessed through the application of a macro-economic model.

Attempting to quantify the costs of compliance is clearly not without its challenges:

- **Establishing the baseline:** whilst many firms have provided an indication of the situation prior to the introduction of Union harmonisation legislation, none were able to provide quantitative data on costs, given the time that has elapsed; similarly, it has not seemed useful to compare current costs against a hypothetical scenario in which no Union harmonisation legislation exists;

- **Availability of data:** data on costs can clearly be commercially sensitive and many firms were unwilling to participate or reluctant to provide data; even where firms were willing, many simply did not collect data relating to certain costs of compliance; it was relatively straightforward to obtain data on the level of human resources working directly on compliance with administrative obligations, whereas data on product design and development and testing was less available;

- **Disaggregation of data:** for most of the products in question, several pieces of IM legislation are applicable; moreover, most of the firms interviewed produced a range of products or models for both EU and global markets; it thus became difficult to isolate the cost of compliance with particular pieces of legislation from other costs and to relate those costs solely to production for the EU28 market;

- **Establishing the "business-as-usual" scenario**, namely the costs that would be incurred in the absence of legislation; many firms found it difficult to accurately estimate the proportion of costs that they would incur in the absence of legislation, i.e. as part of the normal process of product design, development and testing.

A distinction should be made between administrative and substantive compliance costs:

- **Administrative costs** - relate to the costs of preparing documentation and direct fees; and

- **Substantive compliance costs** - relate to any specific investments firms must make in order to comply with the law.

It is widely recognised that there may be nuances and an unclear demarcation between the two types of costs because such costs are part of a continuum. Most notably, in the case of testing carried out as part of conformity assessment modules to comply with Union harmonisation legislation, the aim is neither to obtain an authorisation or certification. Rather, it is to demonstrate compliance with the essential requirements. Nevertheless, the guidelines suggest that conformity assessment should still be treated as a substantive compliance cost, even if the current definition does not exactly fit this area. However, some elements of the conformity assessment process are administrative, such as preparing the technical file and issuing the Declaration of Conformity. Therefore, the following methodological distinctions were made:.

Type of costs	One-off costs	Recurring costs
Administrative costs	• Familiarisation with Union harmonisation	• Development and updating of technical files

	legislation and standards • Notified Bodies fees for Union harmonisation legislation and mandatory testing	• Production of a DoC and CE marking • Conformity assessment: preparation of technical files in parallel with testing activities
Substantive compliance costs	• Modifications to product design (during new product development phase/ R&D) • Modifications to product design once products have been placed on the market • Costs of temporarily or permanently withdrawing products from the market	• Conformity assessment: preparation of technical files in parallel with testing activities testing for conformity with the applicable modules defined in Union harmonisation legislation

Source: CSES

The extent of administrative and substantive compliance costs was estimated for four stages in the process of compliance with Union harmonisation legislation:

- Preparatory actions and familiarisation with the applicable legislation and relevant administrative obligations for economic operators
- Substantive compliance: Introduction of processes or changes to product design and production processes to ensure compliance with substantive obligations
- Conformity assessment procedures and the preparation of relevant technical documentation
- Declaration of Conformity or other statement of compliance and CE marking

Costs incurred at each stage are now presented in the sub-sections that follow. Although a common approach was adopted to the cases, in some instances it has been difficult to compare findings from the different cases due to the data limitations already described. Cost are estimated at sectoral level, for firms of different size and for public authorities.

3.3 Preparatory actions and familiarisation with the legislation

Familiarisation with Union harmonisation legislation and the respective requirements is an important and ongoing task for all firms. Even though the amount of time that firms spend on familiarisation was found to vary, most firms indicate that they spend quite a lot of time on such activities, commonly 15-20% of the total in terms of human resources.

Many large firms have staff specialising in regulatory compliance (commonly around 2-4 staff). Since monitoring legislation is part of their everyday business, as part of the familiarisation process, they follow and input to EU policy and legislative-making processes. The firms interviewed recognised that it was in their direct interest to participate in shaping the form, content and implementation of Union harmonisation legislation. Furthermore, many of the large firms interviewed are actively involved in standards development processes. They

are involved in discussions at the policy level and have a clear view of relevant developments, and of the dates for the introduction of new requirements or changes to relevant technical standards.

Among small firms, there is more of an ad-hoc approach to the familiarisation step, i.e. whenever there are major legislative developments or changes to standards, SMEs seem to find out about what changes are being introduced. They then assess whether any modifications are necessary for existing products or for new product development. SMEs find out about forthcoming changes through a number of information sources, particularly the relevant national and/ or EU industry associations – which charge a membership fee but provide updates on relevant legal developments.

Some firms interviewed also maintain a database that identifies the relevant legislation and relevant/applicable standards for each of their products. Once developed, however, such a database is useful across different business functions since an overview of legal requirements is required by laboratory staff involved in testing, production engineers and product development departments. Some larger firms were found to have developed a more sophisticated database / information management system that goes beyond a simple spreadsheet. However, this can be costly and time consuming both to set up and to maintain. A suggestion was made that it would be very helpful if there were an online database or web portal where product group specific information about compliance, such as forthcoming legislative developments and the dates of updates to standards coming into effect was provided.

Firms in a few product sectors covered also referred to costs for staff attending training courses, either organised internally or through the use of external consultants. The true cost of such training is difficult to identify, since it may often be incorporated into wider staff training activities. In the case of petrol pumps, one company suggested that it accounted for 15% of the total costs of familiarisation, whilst another suggested a figure of 25%.

In small firms, the familiarisation step typically accounted for less than one full time equivalent (FTE), but sometimes additional external support was needed. For larger firms, given their engagement in EU policy and legislative-making processes and standardisation-related activities, the costs are often much higher, usually around 3-4 FTE (although in one case, as many as 15 staff were involved, although only part of their time was involved in familiarisation). This reflected a much more active approach to monitoring and shaping the development of Union harmonisation legislation and technical standards.

Among other preparatory actions that involve cash costs for firms are the purchase of harmonised standards which, in the majority of cases, represent the preferred route to ensuring conformity with the applicable requirements. The costs of the purchase and/or update of standards for a specific product group does not account to more than €2,000 on an annual basis, and in many cases less than €1,000.

The amount of time for familiarisation varies depending on the year and what type of legislation has been introduced. For instance, long-established Union harmonisation legislation was seen as much less burdensome during this step, compared with the introduction of new legislation. For example, for the laptops case, a significant resource input was required to input to the preparation of RoHS and once adopted, to ensuring that companies were RoHS-ready. In the case of air conditioners and air conditioning systems, the Ecodesign implementing regulations required substantial familiarisation time.

Currently, SMEs and large firms obtain information about Union harmonisation legislation, technical standards and administrative requirements from a variety of sources, such as the legislative authorities, suppliers, industry and trade associations, market surveillance authorities, etc. However, among SMEs and especially micro firms, there is a low level of knowledge about Union harmonisation legislation, and the specific requirements for different economic operators in the value chain (manufacturers, importers and distributors). Therefore, there seems to be a need to ensure that there is an easily identifiable "first port of call" available for firms in each Member State, particularly SMEs, to find out more about which Union harmonisation legislation is applicable to their products and which standards could be applied to meet the essential requirements. Although the European Enterprise Network could potentially help in providing a signposting function, the European Information Centres (EICs) can only provide very general advice and are non-specialised, as is the case for the SOLVIT network, whereas PCPs have at least some specialist knowledge, since they are often located within national Ministries that are responsible for different national competent authorities.

Quite a number of manufacturers that took part in the case studies stated that one of the most significant challenges in respect of the familiarisation step is keeping track of changes in legislation and updates to standards, since there is a high cumulative frequency of changes. They suggested that an online web portal could be developed at EU level funded by the Commission to provide a single reference point for firms to find out more about which legislation applies to their product, and what changes are being made to legislation and updates to standards.

3.4 Substantive compliance with Union harmonisation legislation

Having understood and familiarised themselves with the applicable essential requirements under Union harmonisation legislation for their product, firms then need to comply with these requirements (often using a voluntary technical standard) and with the appropriate conformity assessment procedures and CE marking requirements.

Either in the case of the development of new or modification of existing product models, this typically includes a period of largely overlapping research and development activities and product testing, the latter providing feedback on the former. The main cost drivers are the costs of human resources (research, engineers), materials, investment in testing facilities and in the costs of testing. Ensuring compliance with the requirements is sometimes the main driver of R&D and testing activities or may be only one among a number of considerations in new product development. The aim is to satisfy market demand and to ensure product quality. Thus, the share of these costs associated with meeting legal requirements (substantive compliance costs) can vary greatly. This is reflected in the input provided through the interview programme and case studies.

Aspects related to product safety may be linked to specific legal provisions but many firms indicate that such activities would take place even in the absence of Union harmonisation legislation. In most case studies, the firms responded that testing for the Machinery Directive, Lifts Directive, Low Voltage Directive or the EMC Directive is largely part of their business as usual costs, i.e. what firms would do irrespective of whether European harmonised product legislation was in place. For instance, lift manufacturers undertake their own extensive product testing both during development and installation so as to ensure high levels of quality and safety. In most cases, these checks, which are often part of internal quality management systems, readily encompass the minimum essential requirements set out in the legislation.

In contrast, firms very often consider that none of the costs of compliance with environmental (emissions, noise, energy efficiency) requirements are business-as-usual costs. An exception identified in this regard (material handling equipment) indicated that the share of investment in R&D and testing activities directly linked to Union harmonisation legislation has recently increased from a typical 10-20% to more than 60% of the total R&D budget. . Another exception is the energy efficiency of domestic refrigerators and freezers [cf. case study].

The main reason indicated is the need to ensure compliance with Non-road Mobile Machinery Emissions and the Outdoor Noise Directives, both of which require dedicated testing facilities (the costs of a sound chamber to test for outdoor noise can be more than €1 million). However, there are also benefits and potential trade-offs with products' performance, requiring additional product design costs. In comparison, firms in the gardening equipment sector – a sector also covered by the NRMM and the Outdoor Noise Directives - indicated that 10-35% of product development and testing costs could be avoided in the absence of Union harmonisation legislation.

Another Directive considered by some stakeholders as having created significant compliance costs for SMEs is the Ecodesign Directive, under which implementing regulations are adopted in relation to specific product groups. The evaluation of the implementation of the Ecodesign Directive in 2012[51] suggested sizeable costs for R&D, testing facilities and possible changes in production. The Ecodesign implementing regulations however only require redesign of the worst-performing products.

A survey organised by the Finnish Industry Association indicated that, on average, for each firm the one-off costs of setting up the necessary test labs were around €200,000 with an additional 1-2 FTE for relevant personnel. In the case of SMEs that use external labs to assess conformity, the cost per product is, according to information from the impact assessments, around €1,000 per product model-family. The testing of products also includes investment in testing facilities. Large firms usually invest in their own testing facilities while smaller firms use external labs more commonly, often those of accredited organisations that provide certification services (Notified Bodies). The costs involved are higher, but smaller firms often have no choice because they cannot afford the major upfront investment to set up a suitable laboratory and to purchase testing equipment.

Whether directly or indirectly linked to legal provisions, an important point identified through a number of the case studies (laptops, lifts) is that a high percentage of substantive compliance costs are integrated into firms' product design cycle. Large manufacturers account for a very significant market share and since they follow legislative-making processes leading to the adoption of Union harmonisation legislation, they are typically aware well in advance of the adoption of the legislation what the requirements are likely to be, and they can therefore factor these in to R&D and design processes well in advance of the legislation coming into effect. A number of firms therefore indicated that even the costs for compliance with the Ecodesign implementing regulations could be significantly reduced when firms are given significant lead times and can integrate the design and testing activities into their normal product development cycle[52]. It should be noted however that the product development cycle varies among sector. For example, in the case of laptops it is typically no

51 CSES(2012), Evaluation and review of the Ecodesign Directive, http://ec.europa.eu/enterprise/policies/sustainable-business/ecodesign/review/index_en.htm

52 It should be noted that the product development cycle varies among sector. For example, in the case of laptops it is typically no more than 6 months, while in the case of air-conditioners it can be up to 3 years.

more than 6 months, while in the case of air-conditioners it can be up to 3 years. Product development cycles are usually considered in the regulatory process establishing Ecodesign implementing regulations.

In contrast, frequent changes to requirements and standards can lead to sizeable costs for industry. It was also noted that regulatory changes for IM legislation are less frequent than changes to environmental legislation. However, the interaction between (and cumulative regulatory impacts of) Union harmonisation legislation on the one hand and environmental legislation on the other can sometimes lead to additional administrative costs for industry.

While in general many safety-related directives are not viewed as particularly costly, frequent changes to the requirements or relevant standards can have cost implications requiring the sudden withdrawal and redesign of products. While it was not argued that individual pieces of Union harmonisation legislation change too frequently (usually legislation is reviewed once every 10 years) since multiple legislation is applicable to a given product, and legislative review processes are carried out at different times, there is an almost constant process of monitoring for revisions. This is especially the case for technical standards, where amendments to standards can be especially frequent.

An example of the implication of changes to standards was provided in the laptop case study where a large multinational had to withdraw a specific desktop PC model that did not meet Amendment 1 of standard IEC 60950-1, a standard set of electronic safety requirements. Similarly, a manufacturer of air-conditioners estimated that it will need to use 75% of its development resources over a 12-18 month period to make necessary adjustments to meet the recently introduced requirements for fans under the Ecodesign Directive.

After the initial adjustments are made, the burdens associated with the Directive are expected to significantly reduce. A lift manufacturer suggested that any technical adaptation required by the legislation would cost around €500k-€1m in terms of new product development. Such costs would relate to ensuring conformity of design, a physical examination of 8-10 different product platforms to be certified but also additional documentation for the conformity assessment process, costs for sales companies, training for sales and production staff, updating sales literature.

Moreover, economic operators referred to additional risks arising for R&D and early stage product development investment if they do not know how Union harmonisation legislation will develop over time, and the form that its implementation may take in future. It is difficult to provide typical values of substantive compliance costs across the whole industry. They vary depending on the product category and the firm strategy. The following table provides some illustrative examples from the case studies.

Product category	**Example(s)**
Domestic Refrigerators	A large firm typically spends 1-1.5 year FTE / firm, 80-90% of which is allocated to product development and product quality testing. Another large firm indicated that a typical product development project - leading to the development of a basic model with multiple variants – takes 3 years and requires and a budget of up to €100 million.

Gardening equipment	A large firm producing close to one million units indicated that around 3% of annual R&D budget of €50-60 million that is invested to the development of a new product is directly related to ensuring compliance with internal market legislation (circa €4 million). A small firm producing 15,000 units indicated investments for product design of €200-300k
Pumps and dispensers	A large producer of pumps and dispensers (over 1000 employees) estimated total compliance costs of €3.2m over the last five years, €2m on changes to product design and €1.2m to production processes.

3.5 Conformity assessment procedures

The conformity assessment procedure most commonly followed by manufacturers interviewed was the Supplier's Declaration of Conformity (SDoC). Among the steps needed as part of conformity assessment are carrying out product testing, the preparation of the technical file and the preparation of the DoC and the required information manual and CE marking. For product groups that have legislation that requires mandatory third party testing, an inspection by Notified Bodies and appropriate certification is required.

According to the common requirements set out in Decision 768/2008/EC, following the placing on the market, this information needs to be kept for 10 years following the placing on the market and to be updated whenever there are changes. This can require significant time and resources, for instance, checking and updating DoCs every few months, as and when legislation and standards are updated.

Significant time is often dedicated to the collection of information from suppliers of specific components or finished products. The estimated time for the preparation of a technical file for a gardening equipment product ranges from 40-100 hrs. The costs for conformity can vary depending on the need or not for third party certification. The data from the case studies suggests that the annual budget of firms for services of Notified Bodies is in the range of €30-80k, around €4,000 for certification of a single product and representing 20-25% of the total estimated costs for compliance. Similar figures were provided by manufacturers of fuel dispensers. Manufacturers of fuel dispensers – a product that requires third party certification - estimated that Notified Bodies fees represented 55% of the conformity assessment costs, 35% relating to initial inspections and 20% to periodic inspections. Data from the evaluation of the Gas Appliances Directive[53] also refer to certification costs in the range of €1000/product. However, the input from a number of firms (gardening equipment, air conditioners, refrigerators) is that firms use NBs services to support them in testing and ensuring compliance even when third party certification is not mandatory.

The provision of relevant information in the instruction manuals and translation costs are also part of the administrative costs. Data for translation costs of these manuals to cover all EU countries ranged around €3,000 for each gardening equipment model. It should be noted here that every change to relevant standards or requirements lead to costs for the replacement of manuals. A producer of domestic appliances selling around 2 million units indicated that

53 RPA (2011), Ex-Post Evaluation of the Gas Appliances Directive: http://ec.europa.eu/enterprise/dg/files/evaluation/03_2011_finalreport_gas_en.pdf

every time there is new legislation new information manuals need to be printed. The estimated cost at an annual basis was around €100,000k/year.

Sectors covered by the Outdoor Noise Directive (e.g. gardening equipment) need also to submit information included in the DoC to the national and European authorities. Estimates from the gardening equipment case were that it took approximately 80 hours for the 20 different models in its production line. The REACH Regulation and the RoHS Directive do not directly affect firms in the manufacturing sector that are downstream users. The main task is the collection of information from suppliers so as to ensure that no substances of high concern are included in any component.

Some large manufacturers may test components but more typically, the approach followed is to request and collect appropriate certificates from suppliers, to allocate part of a FTE on an annual basis for this activity. According to the recent review of the REACH Regulation[54], 50-70% of downstream users of chemicals (mostly in the non-food manufacturing industry with the exception of chemicals and plastics) have experienced an increase in the costs of managing information along the supply chain, typically in the form of additional workload for existing staff (small firms) or the hiring of extra staff (large firms).

As in the case of product design and testing, additional costs may also arise from the changes to regulatory requirements and the updating of relevant standards. There is a need to adopt information manuals and technical files. This can be particularly problematic for small firms that do not have the structures and mechanisms to follow developments on an on-going basis. The feedback provided suggests that it is mainly these changes that create important adjustment costs rather than the actual information obligations. This is seen as particularly problematic for small firms.

Frequent changes make the legal environment unpredictable but also introduce costs – sometimes sizeable – for firms that try to follow all development and to fit their information collection systems to the information obligations. The feedback provided suggests that it is mainly these changes that create important adjustment costs rather than the actual information obligations. This is seen as particularly problematic for small firms. It was noted that regulatory changes for Union harmonisation legislation are less frequent than changes to environmental legislation. However, the interaction between and cumulative regulatory effects associated with the two can sometimes lead to additional administrative costs for industry.

A further finding was that although economic operators may not always be able to quantify costs, most firms were able to comment on the level of staffing involved and the broad cost parameters. There were however concerns regarding those areas of the regulatory framework where there is potential future uncertainty for economic operators with regard to the future costs of compliance, such as REACH. Given the very significant level of investment and long lead times required in order to bring some types of new products to market, there are concerns that the situation may change in the interim with potentially very high costs for industry.

A large global components manufacturer in the electronics sectors expressed concern as to whether particular chemicals would still be in use in 10 years' time, and whether if not, substitute products are likely to be available. Product R&D operates according to long lead

54 CSES (2012), Functioning of the European chemical market after the introduction of REACH http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/chemical_market_en.htm

times and significant investment in the product development cycle is required to bring new innovative products to market. Economic operators, especially larger companies operating globally have to be inherently forward-looking in assessing how the regulatory landscape will evolve over time.

The firm interviewed commented that "there is a great deal of legal uncertainty from a downstream user perspective. There is a substance called gallium arsenide and currently microchips cannot be made without it, but there is no viable substitute product. The substance is currently being reclassified under the CLP 5th ATP. There is a risk that the substance could be fast-tracked to being subject to an authorisation, which would impose major costs on industry. If a particular substance requires authorisation or is banned, then this could really disrupt the supply chain, and lead to legal uncertainty. REACH is delivering in terms of identifying harmful substances, but there should be a greater focus on assessing the impacts on impacts on downstream users."

3.6 Estimates of costs at sectoral level

On the basis of data inputs from firms across the eight sectors examined, we estimated compliance costs – administrative and substantive – at a sectoral level. In the table that follows, we provide summary information drawing on the data from the case studies focusing on:

- Total annual compliance costs (excluding business as usual costs) and their share in the sector turnover;

- The main cost drivers (phases of the process, type of activity) of administrative costs.

Various caveats should be added before presenting the summary findings with regard to the costs of compliance of Union harmonisation legislation across 8 harmonised product groups. Firstly, there were difficulties in obtaining reliable quantitative data on cost parameters across all variables. Secondly, there were specific issues and assumptions made regarding cost drivers for each case study. These are indicated in the footnotes for the Table below that provide an aggregate of sectoral cost estimates for each case and explained in greater detail in the respective case studies.

The total estimated annual costs of compliance of Union harmonisation legislation across the 8 harmonised product cases were estimated at €342 million.

Product group	**Total annual compliance costs for the sector and share in annual turnover (%)**	
Electric motors	€ 33.2 million	0.3% of annual turnover
Laptops	€ 28.1m	2.0% of annual turnover
Domestic refrigerators/freezers	€ 86.0 million	0.4% of annual turnover
Lifts	€ 26.0 million	0.9% of annual turnover
Gardening equipment	€ 98.5 million	3.9% of annual turnover**
Petrol pumps	€ 12.2 million	1% of annual turnover
Air conditioners	€ 50.1 million	1% of annual turnover
Integrated circuits	€ 7.7 million	<0.1% of annual turnover
Total	€ 342 million	

**Notes (i) the reasons for this outlier are explained in the case study on gardening equipment (ii) reference should be made to the footnotes in the case studies setting out the quantitative findings in all cases, since the assumptions made underlying the data, any gaps and imputations used for particular cases needs to be spelled out.*

It is also important to note that it has not always been possible to clearly distinguish between administrative and substantive compliance costs in the quantitative assessment. There are grey areas where the delineation between different types of costs is unclear. For example, while conformity assessment costs are classified as being substantive costs, there are aspects of conformity assessment where administrative costs are incurred in parallel, such as the preparation of a technical file. Where possible to do so, a differentiation between the two was made in individual case studies.

This being said, we can still observe wide divergence in compliance costs between different harmonised product groups. In most cases, total annual estimated compliance costs do not exceed 1% of annual turnover. The notable exceptions in this regard were gardening equipment (3.9%) and laptops (2.0%). The explanatory factors as to why compliance costs were higher in these sectors were explored through the research. In the case of gardening equipment, the higher level of compliance costs was mainly because of the costs associated with environmental Union harmonisation legislation (the Outdoor Noise Directive, non-road mobile emissions). In contrast to safety-related requirements which are very often considered to be "business as usual", costs of compliance with environmental legislation are considered additional for the firms in the sector and, according to most firms, rather demanding, particularly in terms of the testing required.

For gardening equipment, administrative costs were found to be only a small part of total compliance costs. This seems to be the case generally for many consumer products (gardening equipment, domestic refrigerators and air conditioners). Substantive compliance costs are the main driver of compliance costs because important aspects of product design and testing for safety are not considered by firms to be business-as-usual costs. In comparison, in the case of the lifts and electric motors, both products primarily addressed at professional users, substantive compliance costs (product design and testing) are generally considered to be business as usual and, as a result, the main focus of firms is on the administrative costs of the legislation,

In the case of laptops, the estimates provided may over-estimate the total compliance costs associated with Union harmonisation legislation. Since the industry is dominated by a small number of global manufacturers, it was difficult for them to provide compliance costs disaggregated by geographic region because they tend to design products for global markets and sometimes for multiple – or at least dual – regulatory requirements with some customisation of the product itself to local markets.

Ecodesign was perceived as costly by some manufacturers that took place in the electric motors case study. However, there was found to be a difference between perception amongst industry about the main cost drivers in terms of the type of legislation, and the actual costs. The Ecodesign Regulations do not require all products to be redesigned, only the lowest-performing electric motors (typically 20% of existing models). Since other major global jurisdictions, such as the US, already had strict requirements, many motors already complied and the Ecodesign regulations has simply prevented the dumping of poorly efficient electric motors on the EU market. Compliance costs only equated to 0.3% of turnover in the electric motors sector.

3.7 Compliance costs by firm size

There were differences between firms in the level of compliance costs (administrative, substantive) by firm size, although this was difficult to substantiate based on the limited

numbers of SMEs that agree to take part in the study. SMEs were found to experience significantly higher costs / unit for regulatory compliance compared with large firms that are better able to spread the costs across a high number of units. SMEs also appear to have a higher percentage of staff involved in compliance-related activities (familiarisation, testing) than large firms, although few are able to have individual staff members working full-time on compliance. Micro and small firms were also more likely to have to rely solely on external third party conformity assessment since many do not have their own in-house laboratory and testing facilities.

SMEs are also at a comparative disadvantage because large firms follow EU legislative-making and standardisation development processes more closely. As a result, they are more aware about proposed changes to Union harmonisation legislation in advance and can factor in anticipated regulatory requirements prior to new IM regulatory requirements coming into effect at the product design stage, which lowers substantive compliance costs. Even if the number of SMEs that participated in the case studies was limited, the quantitative findings on compliance cost differentials were substantiated by a number of SME and industry associations in particular sectors (e.g. lifts, air conditioning).

The administrative burdens of compliance with Union harmonisation legislation were sometimes found to be disproportionate for micro enterprises. For instance, any manufacturer wishing only to place a product on the domestic market must still comply with Union harmonisation legislation (including DoC and CE marking requirements) if their product is in the harmonised sectors. An example cited by a European SME association of the burdens were the Finnish woodcutters, where micro enterprises of 2 persons only producing products for the local domestic market had to go through the conformity assessment procedures and to CE mark, even though the products were sold untreated. Nevertheless, they are still subject to the REACH Regulation.

3.8 Costs for public authorities of monitoring product safety and regulatory enforcement

Quantification of expenditure on national support mechanisms, structures and activities to support the implementation of Union harmonisation legislation, such as on market surveillance, was impossible. However, some data was available in this regard through previous studies and impact assessments.

As far as public authorities are concerned, the available estimates on the number of product safety enforcement activities provided by national authorities suggest that a total of 3,000-4,000 product inspectors across EU28 are engaged in market surveillance and regulatory enforcement activities, with an annual budget of enforcement activities in the range of €100-150 million[55]. These figures are quite a high estimate, as they include enforcement activities relating to non-harmonised products. In addition, in order to assess the overall costs of the implementation of Union harmonisation legislation, other costs related to national implementation are the human resource costs for policy coordination through the role of national competent authorities, for instance, in the transposition of Union harmonisation legislation, in the appointment of Notified Bodies, etc.

The feedback provided points to market surveillance as being the most resource-intensive

55 Commission Staff Working Document - Annexes to the Impact Assessment Accompanying the document : Product Safety and Market Surveillance Package, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2013:0033(52):FIN:en:PDF

aspect of the implementation of Union harmonisation legislation for public authorities. From the small number of Member States that provided data on the resources allocated to Union harmonisation legislation, more than 80% appears to be allocated to market surveillance activities. Compared to the situation prior to the introduction of the Union harmonisation legislation, national authorities may have experienced some cost savings. According to the evaluation of the MID, for instance, many authorities indicated a substantial decrease in their workload in terms of dealing with applications for national certification. This reduction was most notable in countries with a small number of manufacturers of measuring instruments or where measuring instruments are imported on the basis of certification undertaken in other countries.

3.9 Conclusions on the costs of compliance with Union harmonisation legislation for industrial products

Whilst most manufacturers could highlight the most costly compliance steps and pieces of legislation, few were able to quantify the costs incurred at each step with any accuracy. However, as the overall volume of Union harmonisation legislation has grown, it was clear that the task of ensuring compliance with legislation and technical requirements set out in harmonised standards is resource-intensive.

A certain proportion of compliance costs were 'BAU' and would have been incurred by industry regardless as to whether there was a European regulatory framework in place. Many firms have well-developed internal safety testing procedures as part of quality assurance procedures and use third party testing for reputational reasons, even where not mandatory.

In all sectors, the process of adaptation to new technical requirements can be costly for manufacturers short-term, particularly when the transition period is relatively short. In the long-run, substantive compliance costs fall over time as manufacturers become more familiar with the requirements of the legislation. Industry is highly familiar with compliance requirements for long-established directives, such as the Machinery Directive, Low Voltage Directive and EMC Directive. Since the technical standards and administrative requirements are well-known, these can be factored in to design requirements from the outset.

Some legislation is more costly than others to implement. Ecodesign implementing regulations were often mentioned as costly, both because of the need for changes to be made to the worst-performing products. However, it should be noted that under Ecodesign Regulations, this does not mean redesigning all existing models, rather only the worst-performing, typically 20% of existing models. Moreover, products that have already been placed on the market are not effected by ecodesign; components and parts are not a specific aspect: ecodesign requirements are generic to the whole product. Substantive costs vary by sector. In sectors characterised by rapid technological innovation, the substantive requirements can usually be "designed into" the product; in that sense, the legislation sets parameters regarding what is possible without increasing the costs of design and production.

In other sectors, substantive costs tend to account for a relatively high proportion of total compliance, depending on the duration of the product lifecycle. For example, it is more difficult for manufacturers of products with a long lifecycle because they are more likely to have to make modifications – or to identify alternatives or substitutes - to products already on the market. This is more costly than factoring these into the initial design phase during the R&D process.

It is also worth noting that there has been a gradual accretion of Union harmonisation legislation in the previous 25 years and this has led to cumulative effects of regulatory compliance. While it has long been the case that multiple pieces of legislation may be applicable to a given product, when the New Approach was first adopted, it was perhaps not foreseen that the body of internal market legislation would grow to the level that it has. Moreover, the past decade has seen the introduction of a number of Union harmonisation directives and regulations that apply horizontally across all product groups (e.g. REACH, RoHS, Ecodesign and Energy Labelling). The cumulative effects of regulatory compliance stem from the fact that manufacturers of industrial products must comply with a growing body of internal market and environmental legislation. It is the cumulative frequency of these changes and updates to legislation itself and to (voluntary) technical standards that result in cumulative effects and impose additional costs, for instance, familiarisation time to keep track of changes, integrating new requirements into R&D and the product design phase, making modifications to products already on the market.

Findings from the case studies

- Familiarisation with the legislation accounts for a significant proportion of the total costs of compliance, estimated at around 15-20% for many firms. Much of these costs are in the form of staff time, around 2-4 FTEs in a typical large firm and >1 FTE in an SME.
- Ensuring compliance with IM legislation is sometimes a key driver of R&D and testing activities or may be only one among a number of considerations in new product development
- Testing equipment can account for massive costs that manufacturers might not otherwise incur. These affect SMEs disproportionately, as the cost is spread over at lower volume of production.
- In the long-run, a high proportion of substantive compliance costs are integrated into firms' product design cycles and are therefore negligible. In that sense, the legislative requirements tend merely to set parameters around what is possible rather than imposing additional substantive compliance cost
- In contrast, frequent changes to legislative requirements and standards can impose sizeable adaptation costs on industry, albeit one-off and short-term in nature.
- A significant proportion of the costs of conformity assessment relates to the task of collecting information from suppliers, preparing technical files, checking and updating DoCs and maintaining technical files for 10 years. Such costs are greatly increased when there are changes to the legislation or the standards.
- The costs of conformity assessment depend very largely on the need for third-party certification. Certification of a single product typically costs around €4k in NB fees, though annual certification of systems would be much higher.
- In most sectors the costs of compliance do not exceed 1% of annual turnover, provided that much of the costs of product design and testing for safety can be considered business-as-usual costs.

- SMEs experience higher compliance costs relative to their turnover, though few have individual staff members solely devoted to compliance. They are also more likely to rely on external third-party conformity assessment and less likely to follow and participate in the process of developing legislation and standards at EU level.

- Market surveillance activities are estimated to occupy 3,000-4,000 product inspectors across EU28 at a cost of around €100-150m per annum. This accounts for around 80% of the total cost to national authorities of developing, implementing and enforcing IM legislation.

- The gradual accretion of IM legislation has required manufacturers to comply with a growing body of internal market and environmental legislation. Frequent updates to legislation itself and standards risk imposing cumulative costs, for instance, related to familiarisation time to keep track of changes, integrating new requirements into R&D and the product design phase, making modifications to products already on the market, updating DoCs, etc.

3.10 Case studies

3.10.1 Case Study 1 – Electric motors

Introduction

The product group examined in this case study is electric motors. The rationale for the selection of these product groups was that:

- Electric motors are covered by a large number of Union harmonisation Directives and Regulations;

- There is a large number of professional users in the sector;

- The sector represents a high share of total manufacturing (see industry structure below). Hence demand for electric motors is closely related to manufacturing processes and investments in the manufacturing industry[56].

The case study is based on desk research and interviews with two national industry associations representing manufacturers of electric motors and nine in depth interviews with manufacturers of electric motors operating in Europe, four large size manufacturers, one medium and four small.

Product definition and description of structure of the sector

Product definition

The product group examined in this case study is electric motors. An electric motor is a device which converts electric energy into mechanical energy[57]. These types of motors are widely used in machine tools, household appliances, power tools and other electrical

56 Report 'Trends and segments for electric motors' by the Dutch Center for Encouraging import from Developing Countries (CBI) – 2011. http://www.cbi.eu/system/files/marketintel/Trends_and_segments_for_electric_motors.pdf

57 Definition taken from 'EUP Lot 11 Motors' by de Almeida, Ferreira, Fong and Fonseca (2008). See http://www.eup-network.de/fileadmin/user_upload/Produktgruppen/Lots/Final_Documents/Lot11_Motors_FinalReport.pdf

appliances and equipment. There are two main types of electric motors. These are the so-called AC and DC motors. Around 50% of the demand in the European Union is for AC motors. Further distinctions can be made by output in kW or by type of motor (single-phase, multi-phase).

Electric motors are covered under PRODCOM code 27.11 that includes the following 21 different sub-categories:

- 27111010 - Electric motors of an output <= 37.5 W (including synchronous motors <= 18 W, universal AC/DC motors, AC and DC motors)
- 27111030 - DC motors and generators of an output > 37,5 W but <= 750 W (excluding starter motors for internal combustion engines)
- 27111053 - DC motors and generators of an output > 0,75 kW but <= 7,5 kW (excluding starter motors for internal combustion engines)
- 27111055 - DC motors and generators of an output > 7,5 kW but <= 75 kW (excluding starter motors for internal combustion engines)
- 27111070 - DC motors and generators of an output > 75 kW but <= 375 kW (excluding starter motors for internal combustion engines)
- 27111090 - DC motors and generators of an output > 375 kW (excluding starter motors for internal combustion engines)
- 27112100 - Universal AC/DC motors of an output > 37,5 W
- 27112230 - Single-phase AC motors of an output <= 750 W
- 27112250 - Single-phase AC motors of an output > 750 W
- 27112300 - Multi-phase AC motors of an output <= 750 W
- 27112403 - Multi-phase AC motors of an output > 0,75 kW but <= 7,5 kW
- 27112405 - Multi-phase AC motors of an output > 7,5 kW but <= 37 kW
- 27112407 - Multi-phase AC motors of an output > 37 kW but <= 75 kW
- 27112530 - Multi-phase AC traction motors of an output > 75 kW
- 27112540 - Multi-phase AC motors of an output > 75 kW but <= 375 kW (excluding traction motors)
- 27112560 - Multi-phase AC motors of an output > 375 kW but <= 750 kW (excluding traction motors)
- 27112590 - Multi-phase AC motors of an output > 750 kW (excluding traction motors)
- 27112610 - Alternators of an output <= 75 kVA

- 27112630 - Alternators of an output > 75 kVA but <= 375 kVA
- 27112650 - Alternators > 375 kVA but <= 750 kVA
- 27112670 - Alternators of an output > 750 kVA.

Industry structure

Enterprises

According to data from Eurostat there were around 14,000 enterprises in the electric motors sector in the period of 2008 – 2010, which were concerned with the manufacturing of these motors. As mentioned before this concerns NACE code is 27.11 (Manufacture of electric motors, generators and transformers), which is broader than only electric motors.

Table 7-1: Number of enterprises – electric motors, generators and transformers sector (NACE 27.11)

2008	2009	2010
14,697	14,272	14,544

Source: Eurostat, Structural Business Statistics.

The following table shows the production value for the years 2009 and 2010. It shows a sharp increase from 2009 and 2010. This is not in line with the number of employees, which stayed stable around 2.5 million during the same time period.

Table 7-2: Production value (in million €) – electric motors, generators and transformers (NACE 27.11)

2009	2010
45,530.38	53,606.02

Source: Eurostat.

Products

Based on the Eurostat PRODCOM data for 2009, the total market size for electric motors was around 733.5 million units or EUR 10.5 billion in production value[58]. In the following table an overview is provided of the different PRODCOM indicators and their export/import value for the year 2009. In Europe 293.2 million electric motors, generators and transformers were produced. The corresponding production value was 12.3 billion euro's. The sector has exported a value of 4.2 billion, while imports amounted to 2.4 billion. This confirms the view that most motors are still produced in (Western) Europe given the highly automated production processes present in those countries[59]. Table 7-A1 in the Annex gives a detailed description of all codes and the production, import and export values.

58 Including production and import, excluding export.

59 Report 'Trends and segments for electric motors' by the Dutch Center for Encouraging Import from Developing Countries (CBI) – 2011. http://www.cbi.eu/system/files/marketintel/Trends_and_segments_for_electric_motors.pdf

Table 7-3: Production, import and export value – electric motors, generators and transformers (2009), PRODCOM CODES: 2711010 to 27112670[60]

	Quantity (units)	Values (€)
Production	293,264,097	12,309,392,520
Import	543,812,581	2,433,820,520
Export	103,498,097	4,261,409,780
Total EU market (Production + imports - exports)	733,578,581	10,481,803,260

Source: Eurostat PRODCOM.

Tables 7-4 and 7-5 show numbers of units sold and value data for the four most common technologies of motors. 91% of all electric motors sold in Europe in 2010 are small power range motors, namely under 750W. In this year, only 0.01% of the motors sold had a very large power range, 9% were medium range motors.[61]

Table 7-4: Electric motors and generators sold by type in EU27 (thousand units, 2010)

Technology	Power range					
	≤ 750 W		> 0,75 ≤ 375 kW		> 375 kW	
	units	%	units	%	Units	%
DC Motors and Generators	12,176	56	4,417	21	1	5
AC Single-Phase	67,019	29	6,379	30	n/a	n/a
AC Multi-Phase	11,700	5	10,175	49	28	95
Universal	23,288	10	n/a	n/a	n/a	n/a
Total	230,123	100	20,970	100	30	100

Source: EuP lot 30: Electric Motors and Drives (2012)

Table 7-5: Revenue data for electric motors and generators by type EU27 (millions €s, 2010)

Technology	Power range					
	≤ 750 W		> 0,75 ≤ 375 kW		> 375 kW	
	Value €	%	Value €	%	Value €	%
DC Motors and Generators	1,762	39	515	11	64	5

60 The table in the appendix provides an overview of the data of per PROD-COM CODE.

61 Source: EuP lot 30: Electric Motors and Drives (2012), table 2-3 and 2-4 - http://www.eco-motors-drives.eu/Eco/Documents_files/EuP-Lot30-Task-2-2-Dec-2012.pdf

AC Single-Phase	1,365	30	805	17	n/a	n/a
AC Multi-Phase	805	18	3,384	72	1,142	95
Universal	576	13	n/a	n/a	n/a	n/a
Total	4,508	100	4,705	100	1,207	100

Source: EuP lot 30: Electric Motors and Drives (2012).

Analysis of applicable legislation and standards

Electric motors are covered by seven different pieces of legislation. This legislation is divided into three categories:

- Health and safety (Low Voltage Directive, Machinery, RoHS Directive on hazardous chemicals, REACH, ATEX directive),
- Electromagnetic compatibility (EMC Directive); and
- Energy consumption (Eco-design and the respective implementing measures)

The following directives are applicable to electric motors:

- Low Voltage Directive: LVD is applicable to all electric motors, except extra low voltage and high voltage;
- Machinery Directive: the MD is applicable for high voltage electric motors (high voltage electric motors are considered as partly completed machinery). It should be mentioned that in general electric motors are used in machines, for which the MD is applicable. So, although the MD is not applicable to most electric motors, MD is applicable to the machines with electric motors;
- Directive on Electromagnetic Compatibility (EMC): EMC is applicable to all electric motors. Some interviewees mentioned that EMC is not relevant to electric motors, because electric motors do not cause disturbances. There only might arise problems when other components are added (such as control units).
- ATEX: ATEX is only applicable to electric motors that are used in specific areas (explosive atmospheres).
- RoHS: Refers to the use of chemicals (such as lead).
- Reach: Refers to the use of chemicals (such as copper lamination).
- Ecodesign: Ecodesign is applicable to a large part of the electric motors (see below).

The table in the appendix provides an overview of relevant Union harmonisation legislation for the electric motors, including the basic administrative requirements.

The most important directives is terms of impacts are considered to be the Ecodesign (EuP for IEC-motors) and ATEX. ATEX (if applicable) is considered the most burdensome since it requires third party certification.

Ecodesign is a relatively new Directive in relation to electric motors. Electric motors which have to comply with the Ecodesign directive are called IE-motors or IEC-motors. For these motors there are rules for energy efficiency. EC Regulation 640/2009 implements the European Ecodesign Directive for electric motors. It contains requirements for the design of electric motors. The Regulation was published on 23 July 2009 and entered into force on 12 August 2009. There are several efficiency levels in the regulation. Minimum requirements are IE2 from 2011, IE3 or IE2 combined with a variable speed drive (VSD) for motors above 7.5 kW from 2015 and IE3 or IE2+VSD for motors above 0.75 kW from 2017. Because of the clear timetable enterprises can anticipate on the new efficiency levels. Also international standards are developed before a new level comes into force. Every new level means for enterprises that they have to design new electric motors, which stimulates innovation. Some interviewee noticed that the new efficiency levels are used in the market as a commercial tool.

Analysis of costs of compliance

Introduction

The information presented in this section is based on the in-depth interviews with nine manufactures of electric motors. The firms range in terms of size and production volume. From six respondents data on administrative costs were collected, four large size manufacturers, one medium and one small.

Table 7-6: Basic information on the firms interviewed

Firm	Specific/main product	Firm size	Annual sales from product	Main markets
A	Electric motors	Large (>1000 employees)	3,500,000 units	--
B	Electric motors	Large (>1000 employees)	25,000 units	100% of sales in the EU
C	Electric motors	Large (>500 employees)	900,000 units	80% of sales in the EU
D	Electric motors	Large (>500 employees)	260,000 units	60% of sales in the EU
E	Electric motors	Medium (250-500 employees)	600,000 units	98% of sales in the EU
F	Electric motors	Small (<250 employees)	15,000 units	80% of sales in the EU
G	Electric motors	Small (<250 employees)	40,000 units	100% of sales in the EU
H	Electric motors	Small (<250 employees)	20,000 units	100% of sales in the EU
I	Electric motors	Small (<250 employees)	20,000 units	100% of sales in the EU

Before we briefly discuss the process steps some remarks need to be pointed to understand the typical situation for electric motors:

- In this case study we identified seven directives which are applicable to electric motors. But in general not all directives are applicable to all electric motors. The applicable directives for electric motors differ between companies, depending on which type of motors they produce. For example, the ATEX directive is only applicable to motors which are used in explosive atmospheres.

- Lots of companies do not produce bare electric motors. Often frequency converters, controllers, software, etc. are added to the electric motors. These added components are often also covered by legislation individually or in combination with the electric motor. For example, some interviewees mentioned that electric motors themselves do not produce interferences and the EMC directive actually is not very relevant, but when frequency converters or controllers are added this causes interferences which make the EMC directive very relevant. Another interviewee mentioned that the Machinery directive was not applicable to the electric motors they produce, but that their customers use the electric motors in their machines. These machines are covered by the Machinery directive. This leads to customer requirements with regard to the supplier of the electric motors in line with the Machinery directive. In general, interviewees indicated that it is difficult for them to distinguish between the processes to comply with the obligations for the electric motors and the processes to comply to the obligations for the added components, because for the manufacturers it is one integrated process.

- Most of the directives relevant for electric motors exit already for a relative long time. They do not change that much and companies are used to comply with these directives. It is incorporated in their processes. Only the Ecodesign implementing regulation is relatively new and has at the moment the largest impact on companies. The regulation requires that electric motors, covered by the regulation, have to reach certain levels of energy efficiency in several steps. For some manufacturers/models [as indicated in section 1.6 the requirements are not more stringent than elsewhere in the world and do not mean that all models need to be redesigned, only a number of them. Typically ecodesign means redesign for 20% of the existing models. Since other jurisdictions such as the US already had strict requirements, many motors already complied and the ecodesign regulation simply stopped the dumping of the poor efficiency ones on the EU market], this does not require simple adjustment of existing models, but complete electric motors have to be redesigned. When asking about internal market legislation for electric motors, most interviewees start with the Ecodesign regulation, because this regulation is the current issue and has the major impact on the companies. Other directives are more viewed as business as usual. The Ecodesign regulation causes extra costs for the companies, but on the other hand most interviewees use the new requirements as strategic issues in their markets. They recognize the impact of electric motors on energy use in the world and that improving the energy efficiency of electric motors is very important. They try to be the first with the development of more efficient motors in the market.

The following steps can be identified in the process of placing electric motors to the market:

- Familiarisation with applicable/relevant obligations

- Introduction of processes or changes to product design and production processes to ensure compliance with substantive obligations
- Conformity assessment procedures and relevant documentation
- Declaration of conformity or other statement of compliance and CE marking

Familiarisation with applicable/relevant obligations

To comply with the applicable internal market legislation companies need to have knowledge of the applicable directives and of the standards. As mentioned, the applicable directives for electric motors differ between companies, depending on which type of motors they produce. For example, the ATEX directive is only applicable to motors which are used in explosive atmospheres and the Ecodesign directive is not applicable to all motors because this directive includes several exceptions.

In general, the companies are linked to information sources on Directives and on standards or they have their own system. For example a smaller Dutch producer is a member of the NEN-connect network. This is a digital platform which shows the different standards and directives which are of interest for producers of electric motors. The platform sends an automatic message when the standards are updated and changes need to apply. When this message arrives, the firm examines the change and decides if they have to change their design. Furthermore, companies buy standards and get all technical features to comply with.

One interviewee mentioned that they participate in standardisation groups to be informed in a very early stage about the backgrounds of the legislation and standards. For them these backgrounds are necessary for the correct application of the requirements.

The average costs for familiarisation with applicable/relevant obligations of the interviewed companies amount to approximately 0.2% of turnover. More than 90% of these costs are cost of human resources.

Introduction of processes or changes to product design and production processes to ensure compliance with substantive obligations

For developing new electric motors and production processes the companies have to comply with the requirements of relevant directives. For most directives working in accordance with the relevant standards is incorporated in the development, testing en production processes of the enterprises. At the moment the Ecodesign implementing regulation requires that electric motors are more and more energy efficient in several steps. To comply with these efficiency requirements enterprises have to redesign some models [as indicated in section 1.6 the requirements are not more stringent than elsewhere in the world and do not mean that all models need to be redesigned, only a number of them. Typically ecodesign means redesign for 20% of the existing models. Since other jurisdictions such as the US already had strict requirements, many motors already complied and the ecodesign regulation simply stopped the dumping of the poor efficiency ones on the EU market. Although this causes extra costs,

several respondents mentioned that these developments also offer new opportunities in their markets.

For most producers of electric motors testing is the most costly step to comply with the relevant Directives. But on the other hand most interviewees would also test a lot when there were no directives and standards. This is needed to develop and sell safe products. This is especially the case for ATEX-motors because these motors are used in explosive atmospheres.

The average costs for compliance with requirements (product design and testing) of the interviewed companies amount to approximately 0.6% of turnover. 74% of these costs are cost of human resources, 23% are costs for testing equipment and 3% are costs for third parties.

Conformity assessment procedures and relevant documentation

This step is concerned with preparing technical documentation, which causes costs for employees of the enterprises, and with conformity assessment. Conformity assessment is especially related to inspection of notified bodies. This is the step that causes most of the external costs. This is especially relevant for ATEX-motors. For ATEX- motors it is mandatory that a notified body inspects the designs of these motors and test motors to get the required marking. This is only needed when companies produce motors that are to be used in explosive atmospheres.

The average costs for conformity assessment procedures and relevant documentation of the interviewed companies amount to approximately 0.3% of turnover. 57% of these costs are cost of human resources, 32% are costs for third parties and 11% are costs for testing equipment.

Declaration of conformity or other statement of compliance and CE marking

Drawing up declarations of conformity and CE marking is not viewed a big issue for the interviewees. Compared to the other steps this is a minor step, not very complex and not very costly. The average costs for declaration of conformity or other statement of compliance and CE marking of the interviewed companies amount to approximately 0.1% of turnover. More than 90% of these costs are cost of human resources.

Business as usual

Companies were asked to differentiate between Business As Usual cost (BAU) and cost specifically due to the internal market regulation. Part of the activities obliged by IM legislation companies would perform anyway. For example, a firm may carry out product testing so as to check the quality and safety of products. Such costs are known as ‘business as usual’ (BAU) costs. Respondents mentioned that the largest shares of the activities that cause the administrative costs are business as usual. If there were no directives and standards the enterprises would have their own quality and safety standards. To meet these standards companies also have to test their products. Some enterprises mentioned that without directives they would spend less on some external tests (costs of third parties). On average, 73% of the costs of human resources spent on compliance activities is considered as business as usual by the interviewed companies. For the costs of third parties this average is 67% and for the costs of testing equipment 87%.

Assessment of costs of Union harmonisation legislation for the whole sector

Data collection

Based on the information provided by interviewees, the average costs of complying with Union harmonisation legislation have been estimated. Out of six respondents, data on costs were collected, four large size manufacturers, one medium and one small. In principle the respondents are manufacturers. But some of them also have some trading activities (import of motors). Cost data have been collected for activities relating to electric motors, especially manufacturing, but the respondents could not distinguish between the compliance costs for the manufactured and the imported motors. The data collection was focussed on the costs to comply with the following legislation: Low Voltage Directive, Machinery Directive, the Directive on Electromagnetic Compatibility (EMC), ATEX, RoHS, Reach and Ecodesign.

The six interviewed companies were asked to give estimates of the costs of human resources, costs of third parties and costs of testing equipment for total compliance activities (top down approach). Also data on time and tariff were asked (bottom up approach), but this did not result in sufficient usable data. For the testing equipment the costs for the last five years are collected to calculate the average cost per year. Next the interviewees were asked to distribute these costs of human resources, costs of third parties and costs of testing equipment over the identified steps of the compliance process (familiarisation, compliance with requirements, conformity assessment, DoC and CE marking and other) and they were asked which parts of these costs are considered as business as usual.

Estimation of costs

All costs are collected as totals for enterprises. The cost estimates for the whole sector are based on turnover. All costs were calculated as percentages of turnover and this was then used to weight the results. The data collected with two SMEs did not show clear differences – in terms of costs as a percentage of turnover - as compared to the data for large enterprises. Therefore, there were no grounds for making a distinction in the calculations. In other words, it has been assumed that the compliance costs as a percentage of turnover are the same for large enterprises and for SMEs.

Based on the results from the six respondents, in Table 7-7 the estimates of compliance costs for the sector of electric motors are presented as percentages of turnover. The costs were standardised by calculating averages of the percentages. To estimate the compliance costs for the whole sector of electric motors we followed the following steps:

- for each type of costs (cost of human resources, costs of third parties and costs of testing equipment) the costs were calculated as a percentage of the turnover of electric motors, averaged over respondents (first row in Table 7-7)

- the distribution of the costs over the different process steps is again an average of the estimated distribution from the respondents, as a percentage of the annual compliance costs (see distribution over process steps in Table 7-7)

- we then determined the average percentages of business as usual (as percentage of annual compliance costs, per cost type), to distinguish between the total compliance costs and the regulatory burden related to the internal market legislation (last 2 rows in table 7-7).

Table 7-7: Estimate of average compliance costs (%)

	Cost of human resources for total compliance activities	Costs of third parties	Costs of testing equipment	Total
Annual costs (% of turnover)	0.95%	0.13%	0.18%	1.26%
Of which (% of annual costs; is the distribution over process steps)				
- Familiarisation	19.17%	8.50%	2.50%	15.65%
- Compliance with requirements (product design and testing)	49.00%	15.00%	80.00%	50.16%
- Conformity assessment	16.67%	71.50%	16.67%	22.15%
- DoC and CE marking	13.50%	5.00%	0.83%	10.79%
- Other	1.67%	0.00%	0.00%	1.26%
And of which (% of annual costs)				
- Business As Usual (BAU)	73.33%	68.00%	86.67%	74.76%
- Regulatory burden	26.67%	32.00%	13.33%	25.24%

Source: CSES study

To calculate an estimate of the overall costs for the whole sector we used the value of the total EU market according to Eurostat PRODCOM, namely € 10,5 billion in 2009 (see table 7-3). Applying the percentages in table 7-7, led to the figures presented in the table 7-8.

Table 7-8: Estimate of compliance costs for the whole sector of electric motors (€)

	Cost of human resources for total compliance activities	Costs of third parties	Costs of testing equipment	Total
Total Annual costs	€ 99,175,627	€ 13,159,638	€ 19,368,345	€ 131,703,610
Distribution over process steps:				
- Familiarisation	€ 19,008,662	€ 1,118,569	€ 484,209	€ 20,611,440
- Compliance with requirements (product design and testing)	€ 48,596,057	€ 1,973,946	€ 15,494,676	€ 66,064,679
- Conformity assessment	€ 16,529,271	€ 9,409,141	€ 3,228,057	€ 29,166,470
- DoC and CE marking	€ 13,388,710	€ 657,982	€ 161,403	€ 14,208,094

- Other	€ 1,652,927			€ 1,652,927
- Business As Usual (BAU)	€ 72,728,793	€ 8,948,554	€ 16,785,899	€ 98,463,246
- Regulatory burden	€ 26,446,834	€ 4,211,084	€ 2,582,446	€ 33,240,364

Source: CSES study

Overall conclusions

The case study examined alternative and direct current electric motors. Total EU market for electric motors in 2009 was 733.5 million units and €10.5 billion in value. 91% of all electric motors sold in Europe in 2010 are small power range motors, namely under 750W.

Electric motors are covered by seven different pieces of Union harmonisationlegislation covering aspects of health and safety (Low Voltage Directive, Machinery, ATEX), electromagnetic compatibility (EMC), energy consumption (Ecodesign Directive) and chemicals use (RoHS Directive on hazardous chemicals, REACH).

Based on the information collected during the study it is estimated that the total annual costs of compliance with Union harmonisation legislation for the firms in the sector are around €130 million, although more than 70% of this is considered to be part of business as usual, namely costs incurred even in the absence of legislation. The estimated net annual costs directly linked with the legislation are around €33 million, no more than 0.3% of the annual turnover of the sector. Substantive compliance costs are significant (around 50%) of the total and are primarily linked with ensuring compliance with the Ecodesign and the ATEX Directives. Still, there are also important costs for familiarisation with the legislation (15%) and conformity assessment procedures, including in particular the costs for notified bodies in relation to the ATEX Directive.

Sources of information

Publications

- Report 'Trends and segments for electric motors' by the Dutch Center for Encouraging import from Developing Countries (CBI) – 2011. www.cbi.eu/system/files/marketintel/Trends_and_segments_for_electric_motors.pdf
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- Almeida, Ferreira, Fong and Fonseca (2008), 'EUP Lot 11 Motors'. www.eup-network.de/fileadmin/user_upload/Produktgruppen/Lots/Final_Documents/Lot11_Motors_FinalReport.pdf
- Anibal de Almeida, Hugh Falkner, João Fong and Keeran Jugdoyal (November 2012), 'EuP lot 30: Electric Motors and Drives, 2nd Draft'. www.eco-motors-drives.eu/Eco/Documents_files/EuP-Lot30-Task-2-2-Dec-2012.pdf

- Eurostat PRODCOM

Interviews:

- 2 with national industry associations
- 9 interviews with enterprises (especially producers); from 6 respondents data on administrative costs were collected.

Annex

Production, import and export value per PROD-COM CODE

Table 7-A1: Production, import and export value – electric motors, generators and transformers (2009), PROD-COM CODES: 2711010 to 27112670

PRODCOM CODE/ INDICATORS	Export values (000s)	Import values (000s)	Production Quantity (000s)	Production Value (000s)	Total
27111010 - Electric motors of an output <= 37.5 W (including synchronous motors <= 18 W, universal AC/DC motors, AC and DC motors)	429,581,300	814,922,340	74,545,678	825,041,147	1,210,382,187
27111030 - DC motors and generators of an output > 37,5 W but <= 750 W (excluding starter motors for internal combustion engines)	278,747,230	386,366,040	104,390,496	1,407,085,735	1,514,704,545
27111053 - DC motors and generators of an output > 0,75 kW but <= 7,5 kW (excluding starter motors for internal combustion engines)	49,647,610	55,532,980	6,000,000	261,370,719	267,256,089
27111055 - DC motors and generators of an output > 7,5 kW but <= 75 kW (excluding starter motors for internal combustion engines)	31,837,520	15,936,700	1,000,000	200,000,000	184,099,180
27111070 - DC motors and generators of an output > 75 kW but <= 375 kW (excluding starter motors for internal combustion engines)	41,158,050	20,115,000	21,021	45,698,243	24,655,193
27111090 - DC motors and generators of an output > 375 kW (excluding starter motors for internal combustion engines)	43,932,440	36,989,480	1,600,000	61,635,219	54,692,259
27112100 - Universal AC/DC motors of an output > 37,5 W	140,273,990	121,276,880	21,783,407	495,727,677	476,730,567
27112230 - Single-phase AC motors of an output <= 750 W	120,770,450	129,836,810	56,520,199	1,195,803,791	1,204,870,151
27112250 - Single-phase AC motors of an output > 750 W	50,438,620	49,425,060	6,300,000	132,175,642	131,162,082

PRODCOM CODE/ INDICATORS	Export values (000s)	Import values (000s)	Production Quantity (000s)	Production Value (000s)	Total
27112300 - Multi-phase AC motors of an output <= 750 W	191,938,140	77,272,170	10,000,000	667,498,083	552,832,113
27112403 - Multi-phase AC motors of an output > 0,75 kW but <= 7,5 kW	324,722,000	133,198,120	6,359,618	1,455,629,073	1,264,105,193
27112405 - Multi-phase AC motors of an output > 7,5 kW but <= 37 kW	198,759,480	62,888,110	1,189,773	663,563,780	527,692,410
27112407 - Multi-phase AC motors of an output > 37 kW but <= 75 kW	110,315,070	43,175,790	192,619	304,180,879	237,041,599
27112530 - Multi-phase AC traction motors of an output > 75 kW	91,719,690	11,825,180	14,000	300,000,000	220,105,490
27112540 - Multi-phase AC motors of an output > 75 kW but <= 375 kW (excluding traction motors)	171,106,750	49,028,550	54,834	422,095,148	300,016,948
27112560 - Multi-phase AC motors of an output > 375 kW but <= 750 kW (excluding traction motors)	111,558,390	24,443,830	21,331	454,592,720	367,478,160
27112590 - Multi-phase AC motors of an output > 750 kW (excluding traction motors)	630,921,610	55,401,750	11,593	1,003,373,605	427,853,745
27112610 - Alternators of an output <= 75 kVA	114,769,970	85,838,450	3,142,975	326,940,309	298,008,789
27112630 - Alternators of an output > 75 kVA but <= 375 kVA	63,040,220	29,373,550	66,725	177,975,375	144,308,705
27112650 - Alternators > 375 kVA but <= 750 kVA	75,541,500	10,966,450	18,434	135,533,843	70,958,793
27112670 - Alternators of an output > 750 kVA	990,629,750	220,007,280	31,394	1,773,471,532	1,002,849,062
Electric Motors, generators and transformers	**€4 ,261,409,780**	**€2,433,820,520**	**293,264,097 units**	**€12,309,392,520**	**€10,481,803,260**

Source: Eurostat PRODCOM database, all values (€s, units) are in thousands

Summary of Union harmonisation legislation covering electric motors

Table 7-A2: Summary of Union harmonisation legislation covering electric motors

Name of legislation	Main issue addressed	Who is responsible?	Requirements for economic operators
LVD 2014/35/EU *Directive on low voltage machines*	Health & Safety (low voltages machines)	Technical documentation should be provided by the manufacturer. Declaration of conformity procedures	According to the directive, all products should meet the safety requirements set out in annex I.

Name of legislation	Main issue addressed	Who is responsible?	Requirements for economic operators
		and CE marking can be followed by both the manufacturer or his authorized representative (art. 8)	-Testing according to relevant standards -Development of technical file -Declaration of conformity and CE marking -Mark with information (type, voltage, etc,) -Installation instructions and manual for final consumer (with translations)
Machinery 2006/42/EC *Directive on machinery*	Health & Safety (machinery)	Manufacturers or his authorized representative (art. 5)	- Ensure satisfaction of health and safety requirements Annex I - Technical file (Annex VII) -Provide necessary information (instruction) - Conformity procedures (art. 12, art. 13 for not finished machines) - CE marking (art. 16) - EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery - Construction file and risk assessment which contains: (i) a list of the essential health and safety requirements applied and fulfilled (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks,

Name of legislation	Main issue addressed	Who is responsible?	Requirements for economic operators
			(ii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards, (iv) any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorized representative, (v) a copy of the assembly instructions for the partly completed machinery
EMC 2014/30/EU *Directive on Electromagnetic Compatibility*	Electromagnetic compatibility	Manufacturer (and, for the CE marking his authorized representative)	- fulfill the protection requirements mentioned. -Testing according to standards -Development of technical file -EC Declaration of conformity and CE marking -Installation instructions and manual for final consumer -Meet essential requirements -Other marks and information
ATEX 2014/34/EU *Directive on Equipment and protective systems intended for use in potentially explosive atmospheres*[62]	Health & Safety (equipment and protective systems intended for use in potentially explosive atmospheres)	The directive carries obligations for the person who places products on the market and/or puts products into service, be it the manufacturer, his authorized	-Risk assessment -Products should meet the health and safety requirements as set out in the Directive; -Meet the required testing to relevant

62 http://ec.europa.eu/enterprise/sectors/mechanical/files/atex/guide/atex-guidelines_en.pdf

Name of legislation	Main issue addressed	Who is responsible?	Requirements for economic operators
		representative, the importer or any other responsible person	standards -Development of technical documentation for testing purposes -CE Marking
RoHS (2011/65/EC) *Restriction use of hazardous substances*	Use of hazardous chemicals (Health and environment – art. 1)	Manufacturers are mainly responsible (art. 7) Secondly, art. 8 lists responsibilities of authorized representatives. Thirdly, art. 9 lists obligations of importers. Lastly, art. 10 lists obligations for distributors.	-Assure no substances listed in annex II are used (art. 4) The following measures are required from the *manufacturers*: -Assure production in line with requirements directive (art. 4 and 7a) -Collect compliance statement from suppliers (material declarations) -Technical file with supplier declarations and own analysis tests (internal production control, art. 7b) -Declaration of conformity (art. 7c) -Declaration of conformity to be kept for 10 years (art. 7d) -CE marking of the product -Procedures for production to remain in conformity (art. 7e) -Register of non-confirming and recalled products and informing distributors (art. 7f) -Identification mark on each product (art. 7g and 7h) -Take measures if they have reason to believe non-conformity (art. 7i)

Name of legislation	Main issue addressed	Who is responsible?	Requirements for economic operators
			-Provide information if so requested by a competent national authority (art. 7j)
REACH (1907/2006/EC) *Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals*	Use of chemicals (Health and safety)	Manufacturing, authorized representative (art. 4) or importer.	Collect statement from suppliers stating that he is in compliance with requirements (REACH compliance statement) Register and notification of the substances to the Agency.
Eco-Design Directive 2009/125/EC and Implementing Regulation 640/2009 *(Design and sustainability)*	Energy consumption/ efficiency	Manufacturer or his authorized representative is in general responsible. However, art. 4 of the directive lists specific requirements for the importer if the manufacturer is not established within the community.	Meet the ecodesign requirements as described in Annex I (art. 3 regulation) -Testing (conformity assessment – art. 4 regulation) -Declaration of Conformity and CE marking (art. 3&5 regulation) -Complying with the mentioned conformity procedure in the appendix, -Information in instruction manual for minimizing energy-use -Comply to the proper energy efficiency levels (IE2 or 3) -Instructions for consumers on sustainable use

3.10.2 Case study 2 – Laptops

Introduction

The aim of the product cases is to assess how Union harmonisation legislation for industrial products affects economic operators (manufacturers, importers and distributors). The applicable Union harmonisation legislation specific to each product is mapped out and the costs of regulatory compliance (administrative and substantive) in meeting Union harmonisation regulatory requirements are then assessed.

The rationale for the selection of laptops[63] as a product group was that:

- A key issues highlighted in the specifications was how far Union harmonisation legislation is 'fit for purpose' in facilitating – or at least not hindering - process / product innovation. Since laptops are characterised by a high level of innovation and technological change, they provide scope to explore this issue.

- Laptops are dominated by a small number of global manufacturers. This allows us to consider how Union harmonisation legislation affects multinational companies that produce laptops for both the European internal market and other markets globally.

The case study was carried out using desk research and interviews. With regard to data sources, the main sources used were Eurostat SBS (2 digit NACE code level) and Prodcom data (8 digit NACE), sectoral studies and market research reports.

Product definition and description of structure of the sector

Information and data on market size and structure for the laptop industry is presented. Recent industry developments and market trends are also summarised.

Product definition and data availability

The product group within scope is laptops (also commonly referred to as notebooks). Other types of IT products, such as palm-top organisers, desktops and printers are outside the scope.

Eurostat SBS and Prodcom data extends more widely than laptops alone[64] and covers the manufacture of computers and peripheral equipment. It was therefore only possible to obtain data at a sufficient level of disaggregation for some variables. In order to supplement Eurostat data and to compensate for data gaps, we have also made use of industry data from industry associations and other market data available through previous studies.

Market size and structure

The size and structure of the laptops market is now considered. The main variables presented are the number of enterprises, employees and production value, and the value of imports and exports. According to data from the PRODCOM database[65], the total market for laptops is around €24.6 billion. Market studies available provided similar estimates (€24.4 billion)[66]. According to the same data source, a total of 79 million laptops units are sold annually within the EU.

63 Laptops can be defined as a portable computer to be operated for extended periods of time without a direct connection to an AC power source.

64 NACE codes 2620 includes: Laptop PCs and palm-top organisers, Point-of-sale terminals, ATMs and similar machines capable of being connected to a data processing machine or network Desk top PCs and Laptop PCs and palm-top organisers, among other categories of peripherals.

65 It is not clarified by the definition but it is also possible that this category covers portable tablets.

66 Data from the 2011 Euromonitor report for computers.

Table 7-9: EU laptop market size (2011) – estimate based on PRODCOM data for product code 26201100 - Laptop PCs and palm-top organisers

Exports quantity (million units)	Value of exports (billion €s)	Imports quantity (million units)	Imports value (billion €s)	Production quantity (pairs)	Production value (billion €s)	**Consum-ption volume (million units)**	**Consum-ption value (billion €s)**
8.8	3.3	80	25.6	7,800,000	2.25	**79**	**24.6**

Source: Eurostat Prodcom data

A leading EU industry association suggested a lower figure for laptops alone. According to industry data, the current market size for laptops can vary significantly and is about 32 million - 48 million units per annum. This is a more accurate figure since palm-top organisers were not examined. PRODCOM data confirms that laptops manufacturing is mainly carried out outside the EU, commonly in East Asia. The value of imports into the EU is more than 9 times greater than of imports.

Global laptop producers are commonly involved throughout the value and distribution chain (e.g. from initial design, through to manufacturing and direct distribution to consumers and businesses). In recent years, since the price of laptops has gone down considerably, manufacturers have had to adjust the value chain. Accordingly, there is strong reliance of manufacturers on ODMs (Original Designed Manufacturers). ODMs are suppliers that supply parts or final parts for laptops and under the modular approach to complying with IM regulations (see later in this case), may assume responsibility for the compliance of the particular product modules/ parts that they produce.

Industry structure and employment

A small number of major global laptop producers dominate manufacturing and distribution activities. It was estimated that there are only about 20 large firms in total and industry data shows that five multinationals have approximately a 60% share of the global market (Hewlett-Packard, Dell, Acer, Lenovo and Toshiba).

Additional information about market share in Europe was obtained by searching the Amadeus database (now called ORBIS) of Bureau Van Dijk on laptops. This confirmed that top manufacturers have a very high market share. For example, HP has an estimated 21.5% share of the market, ACER 11.4%, Lenovo: 11.4% and Asus 11.2%. Data for other firms was not available.

Looking beyond the leading global manufacturers, there are also SMEs in the laptops sector. These build bespoke desktops and notepads in relatively small volume (as little as a few hundred units). Data from Eurostat's Structural Business Statistics were of limited use since NACE code 2620 "Manufacture of computers and peripheral equipment" extends well beyond laptops. This shows that there were 6,963 enterprises in 2008. An alternative data source was the ORBIS database (Bureau Van Dijk) which provides information on active enterprises in Europe.

The ORBIS database lists a total of 7094 firms under NACE code 2622 for 2013 – similar to the Eurostat figure. However, a keyword search with the "economic activity description" field with the term "laptops" produced a list of 66 manufacturers. 3 of these are large firms and the

remaining 63 are SMEs. 8 of these firms were the headquarters of firms and the remainder were branches and included as one or more subsidiaries of the large manufacturers. In total, on the basis of the information collected, we consider that the number of firms resulting from the use of the ORBIS database provides a realistic estimate of the number of firms affected by internal market legislation.

In terms of employment, the total computers and peripheral equipment sector employed almost 1.1m people across Europe in 2008. There had been a reduction in employment to 884,000 by 2010. However, this relates to the whole of NACE 2620 (including desktops, palmtop organisers and many other types of IT equipment). The European industry association interviewed confirmed that the number of employees in the laptops sector involved in manufacturing is very low. Nevertheless, laptops are an important industry, when combining different aspects of the value chain from manufacturing through to distribution (wholesale, retail) and aftersales and servicing activities.

Key industry trends and challenges

This case does not allow for a detailed review of key industry trends and challenges. However, recent developments and key features of the laptop industry are worth noting. These are, in summary:

- The importance of economies of scale and scope to be competitive, with a high level of market concentration in manufacturing and distribution among a handful of leading global firms.

- A decline in laptop sales and prices in a maturing industry. Increasing competition from product groups such as tablets, smart phones and the advent of alternative data storage solutions such as cloud computing, which reduces the need for high computing power in portables.

- Convergence between the mobile phone and ICT markets (including the entrance of new manufacturers that have diversified away from Smart Phones into tablets and notebooks.

- Strong capacity for innovation and technological change[67].

- Changes to the business model and organisation of the value chain within the laptop industry:

    - Increased use of ODMs in manufacturing processes.

    - Leading brand names moving away from selling hardware alone to combining these with add-on services such as technical support.

67 Examples of technological change are increased processing power with reduced power consumption through investment in energy-efficient technologies

Analysis of applicable Union harmonisation legislation and standards

Summary of applicable legislation

A mapping exercise was undertaken to identify relevant applicable Union harmonisation legislation for laptops. In summary, the main legislation that is applicable is:

- The Low Voltage Directive (LVD)
- Electromagnetic Compatibility Directive (EMC)
- Radio equipment Directive
- RoHS Directive (2011/65/EC)Ecodesign for Energy-related products Directive (ErP) 2009/125/EC
- REACH Regulation (EC 1907/2006)
- Packaging and packaging waste (2004/12/EC)

The detailed mapping of applicable legislation is provided as an annex. This summarises the main issues addressed through the legislation (e.g. product safety, energy-efficiency), the key administrative requirements for manufacturers and examples of relevant (voluntary) technical standards. The mapping of the legislation was based on desk research and discussions with individual manufacturers. It should be noted that environmental legislation applicable to laptops such as the WEEE Directive (design for end of life and recyclability) is outside the scope.

Overall, the Union harmonisation regulatory framework affecting laptops was regarded by interviewees as being relatively stable in terms of the core applicable legislation. For instance, the EMC Directive has been in place since 1989 and although this was recast in 2004, there were no major changes. The LVD is one of the oldest Single Market Directives and was adopted even before the "New" or "Global" Approach came into being in the early 1970s. The R&TTE Directive has been in place since 1999.

However, further successive Union harmonisation regulations applicable to laptops have been adopted in the last decade, such as the RoHS Directive and REACH Regulation and the setting of Ecodesign requirements for energy-related products (ErPs). Firms interviewed stated that the introduction of new IM regulations have had a much greater impact on the industry than their predecessors.

There are currently general requirements common to electrical products used in households and offices, and concern standby and off-mode electric power consumption and Power consumption for information technology equipment (ITE). However, specific requirements will soon apply following the adoption of Regulation 617/2013 (Ecodesign requirements for computers and computer servers), of which some requirements will be mandatory from 1 July 2014 and others from 1 July 2016. In addition, there exists a voluntary energy labelling for laptops used as office equipment, called 'Energy Star'. This is an endorsement label for the most efficient appliances developed by the US, which is also applied in the EU for office equipment).

Conversely, standards are always changing and being updated, which requires technical work both during the development stage and in order to comply with new or updated technical requirements.

Alternative routes to regulatory compliance - laptops

There are two alternative routes to regulatory compliance for laptops. If a laptop is defined by the manufacturer as a **"radio product"**, then the Radio Equiment Directive alone can be applied. Since the Directive incorporates requirements relating to electrical safety and checking for Electromagnetic Compatibility, this means that the LVD and EMC Directives themselves do not need to be applied, since this would be duplicative.

However, if the laptop is considered to be a piece of "**electrical equipment"** containing a radio part within it, then a modular approach can be followed in which the R&TTE, LVD and EMC Directives are treated separately for compliance purposes. This can be especially beneficial for manufacturers in a situation in which different manufacturers and / or ODM suppliers are responsible for producing different parts of the product since they can then assume responsibility for the compliance of specific product modules rather than for the whole product. An explanation as to how these approaches work in practice, and the advantages and disadvantages of each approach from the perspective of manufacturers is highlighted in the following table.

Table 7-10: A modular approach to compliance with IM regulations

Compliance route	*Description*	*Compliance requirements – analysis of differences*	*Advantages and disadvantages*
Radio Equipment Directive alone	Complying with Union harmonisation regulations using the RED only. This means that the whole laptop is treated as a single radio product.	• DoC must be placed together with the product • Product must be CE marked Notification requirements for non-harmonised radio frequencies Laptops with Wifi Radio Module Class 1 and 2 must include an alert mark next to the CE mark	*Advantages* • Only one Directive is applicable rather than three • Legal clarity - responsibility for whole product is sole responsibility of manufacturer *Disadvantages* • Cannot divide up compliance responsibilities between different components / parts manufacturers. • Additional labelling marking requirements compared to the EMC-D/LVD (e.g. alert mark next to

			CE mark, information on restrictions of use, etc…). • Making information available for the user which are not required for the LVD and the EMC (e.g. DoC placed with the product).
A modular approach - RED, EMC and LVD Directives applied separately	Modular approach - the laptop itself is treated as a non-radio product and the RED is only applied to the radio module. Other parts of the laptop are subject to the EMC and the LVD	DoC must be placed together with radio module Only the radio module would potentially need the alert sign (Class 2) Notification requirements for radio frequencies (only for radio module part)	*Advantages* • Division of responsibility for compliance between manufacturers responsible for different components / parts of laptop • Manufacturer producing other parts of laptop under LVD and EMC don't need to consider requirements specific to the R&TTE Directive e.g. alert sign, DOC with product[68] • Manufacturers of other parts do not need to provide a DoC to user (only upon request by a MSA)

Feedback is now provided by manufacturers interviewed about their views on the overall Union harmonisation regulatory framework and their experiences of complying with Union harmonisation legislation. There are different views among industry as to which approach is preferable. Firms interviewed all appreciated the flexibility afforded by Union harmonisation legislation to determine whether to follow the RED alone, or to adopt a modular approach as and when appropriate. Interview feedback is now considered on this matter.

Firm C treats laptops as a single radio product and complies with the RED alone and assumes responsibility for the product's compliance. The LVD and EMC Directives are not applicable

68 A DoC only needs to be provided with the product by manufacturer responsible for radio part (since only R&TTE Directive has this requirement).

because the essential requirements under these Directives are already included within the RED. *"The main benefit of a modular approach was dividing up responsibility among manufacturers for different parts of the laptop, depending on the module concerned. However, as a manufacturer, we prefer to take sole responsibility for regulatory compliance".* This was considered as beneficial when considering their obligations towards consumers and in terms of minimising risks.

Conversely, in Firm A and Firm B, the modular approach is followed and compliance with the LVD, EMC and RE Directives respectively is addressed separately. The modular approach was considered to be more efficient in a situation in which multiple manufacturers are involved in producing the end product since the manufacturer of each part is able to assume responsibility for their specific part. In a competitive market place, it was considered that suppliers need to take responsibility for the quality of their product lines and it was believed that this had helped to strengthen standards in the components market.

In Firm A, a different member of the regulatory compliance team deals with each of these Directives and conformity assessment testing is also carried out separately by different teams. The firm pointed out that under the modular approach, the manufacturer of the final product retains ultimate responsibility for product compliance. In the full version of the DoC[69], a list of all modules that can be used for each product model is provided. This has been made available online by all leading laptop manufacturers. The modular approach was however seen as an effective mechanism for optimising regulatory compliance processes and procedures, with advantages in allocating responsibility to different manufacturers at different modules/ stages in the production process.

Firm A commented that *"Since due diligence needs to be carried out on each product, the modular approach allows us to provide better information to Market Surveillance Authorities about how compliance has been achieved through each product module. If an MSA asks for further information or raises questions about a product, then the manufacturer or ODM supplier concerned that carried out conformity assessment tests and produced technical documentation relating to that specific module can provide technical information as to how regulatory compliance has been achieved under that module".*

According to an industry association, most but not all laptop manufacturers follow the modular approach. This depends on the manufacturer's business model and how the manufacturing of laptops is organised. Some laptops are designed and manufactured by a single manufacturer, whereas others are produced by multiple manufacturers and ODM suppliers, each responsible for different parts / modules and components within the laptop. For example, Firm C is directly involved in all aspects of manufacturing and does not generally outsource production (although it may source components from suppliers), whereas most firms in the sector (including Firms A and B) use an increasing amount of outsourcing to ODM suppliers for manufacturing. This trend has been accelerated by downward pricing pressure for laptops and competition from smartphones, tablets and cloud computing.

Analysis of costs of compliance with Union harmonisation legislation

This section contains:

69 In the laptops industry, it has been agreed that an abbreviated version of the DoC is provided together with the product with more detailed regulatory compliance information provided online.

- A summary of how laptop manufacturers meet Union harmonisation compliance requirements from a business process point of view, highlighting any differences in approach between manufacturers.

- An estimate of the costs of complying with Union harmonisation regulations (administrative and substantive compliance costs)

Interview programme

In order to carry out the quantitative research, four interviews have been carried out with global manufacturers (three with laptops manufacturers and one with a leading manufacturer of chips and processors)[70]. In addition, two discussions were carried out with a European industry association. An overview of the firms interviewed is provided in the following table:

Table 7-11: Overview of firms interviewed - laptops

Firm	Product category	Firm size	Annual sales from product in the EU
A	Laptop manufacturer	Large	3 million units/ annum. Market share - 19-20% of EU market
B	Laptop manufacturer	Large	4 million units/ annum. Market share – 25-26% of EU market
C	Laptop manufacturer	Large	NA - but circa 8-10% of EU market
D	Components manufacturer	Large	NA - but no. of laptop chips and components numbered in the millions/ annum

Although there were challenges in persuading firms to take part, the firms interviewed are all globally recognised players in the laptops industry and account for a market share of c.a. 50-55% of the total market. There are an estimated total of 15m annual laptop sales in Europe. Unlike for other products, no SMEs were interviewed, since the laptops industry is dominated by large manufacturers (see Section 2).

Overview – how do laptops manufacturers manage regulatory compliance?

In this section, a description is provided of the way in which laptops manufacturers manage compliance with Union harmonisation regulations. Five main steps were identified in harmonised product sectors in order to place products on the EU market. These five steps were defined for all the harmonised product cases and have been used as the basis for carrying

70 There were difficulties in persuading more firms to participate. Some companies approached were concerned about commercial sensitivities, while others did not believe that they would be able to collect such complex data at the product level because they produce so many different product platforms.

out discussions with manufacturers to ascertain information about how they manage compliance processes and the costs involved:

- Familiarisation with the applicable/relevant obligations – preparatory actions
- Introduction of processes or changes to product design and production processes to ensure compliance with substantive obligations
- Conformity assessment procedures and relevant documentation
- Declaration of conformity or other statement of compliance and CE marking
- Other activities related to obligations posed by authorities

The way in which manufacturers manage each of these five steps and feedback received on the type of costs involved is now provided.

Reference should also be made to the previous section, which highlighted that there are alternative routes to achieving compliance for laptops. Clearly, whether a given manufacturer has decided to follow the R&TTE-D alone, or a modular approach in which they comply with the RED, EMC-D and the LVD-D separately will have implications in terms of the way in which manufacturers organise their business processes relating to compliance and testing.

Step 0 – Engagement in EU policy and legislative-making processes and in standardisation-related activities

The firms interviewed recognised that it was in their direct interest to participate in influencing the form, content and implementation of Union harmonisation legislation. Since large manufacturers dominate the laptops sector, they commonly participate directly in EU legislative-making and standardisation development processes, for instance by taking part in working groups meetings on particular Directives and in standardisation processes. They also make an indirect contribution, for instance, by providing feedback through the main European industry association, Eurodigital, who in turn participate in EU regulatory processes and in consultations on specific Union harmonisation regulations.

The aim of this participatory approach is to ensure that industry feedback influences and shapes the form of new Union harmonisation legislation. Taking part in policy and legislative-making processes enables firms to better anticipate regulatory developments affecting laptops well in advance of the entry into force of Union harmonisation legislation. It also allows industry to shape the requirements for manufacturers, which is especially important when the potential burden could be significant and other appropriate but equally effective solutions are possible. Among the examples of legislation where industry input was felt to be especially important were RoHS, REACH and the drawing up of Eco-design implementing regulations.

Firm B agreed that active participation in EU regulatory development processes was vital and stressed that they invest considerable time in monitoring key developments well in advance of new regulations and technical standards being adopted and coming into force. Firm C commented that *"In order to ensure that we are effective in managing compliance, we take part in the policy-making process and this facilitates our understanding of how regulatory requirements should be interpreted and implemented. It is important to have both direct and indirect communication channels with legislators (e.g. participating in industry associations,*

responding to public consultations, attending meetings and workshops, direct email contact etc.)".

The preparatory phase prior to legislation and standards being adopted requires human resources. Firm B commented that they worked approximately 75% FTE on Union harmonisation legislation and that they spent a lot of time following new regulatory developments. This requires attending 6 industry meetings in Brussels per year of 2 days' duration, contributing to the preparation of industry responses to proposed EU regulatory developments, etc.

However, although this does take some time and resource commitment on the part of industry, the scale of administrative costs incurred should be set in context. It is in industry's strong interest to monitor EU regulatory developments and standardisation processes closely as part of an active approach to managing compliance with Union harmonisation regulations. This helps manufacturers to better anticipate how changes in the regulatory regime applying to the products that they manufacture is likely to affect their industry. This can in turn help to reduce substantive compliance costs by ensuring that upcoming or new requirements are factored into the product design process from the outset.

Moreover, large global manufacturers also employ thousands (and sometimes tens of thousands) of staff and can spread the cost of engaging in EU policy and legislative-making processes across sales volumes that amount to millions of units per year in the EU. Although there are only a few laptop manufacturers that are SMEs, such firms may find it more difficult to dedicate resources to Step 0.

Step 1 - Familiarisation with applicable legislation and relevant information obligations.

Taking part in the early stages of the formulation of legislation as part of preparatory work to help laptops manufacturers better anticipate forthcoming legislative developments, updates to technical standards, etc. (Step 0) is closely linked to Step 1, which is concerned with familiarisation with the applicable legislation and relevant information obligations once Union harmonisation regulations have been adopted.

Manufacturers invest considerable human resources in familiarisation with the applicable regulatory and administrative requirements. Since the sector is dominated by approximately 10 large global manufacturers, these firms have dedicated regulatory compliance departments who not only work on familiarisation, but brief their colleagues in other departments as to (i) which legislation is applicable (ii) which technical standards could be utilised (iii) whether there are any forthcoming regulatory changes likely that need to be considered in product design (iv) preparatory work needed on documentation (mainly the preparation of a DoC and of a technical file for each product.

There was a lot of variance in the percentage of time firms estimated that familiarisation took as a proportion of total time spent by internal staff over the 5 process steps. For instance, Firm A estimated that about 10% of staff time was devoted to familiarisation, whereas the equivalent figure for Firm C was 15%. For Firm B, however, this was estimated at 40% (Firm D did not provide an estimate).

Such divergence among manufacturers will depend on the role and perceptions of the interviewee and how the amount of time spent on compliance is divided between different compliance activities and business functions. Since in many cases, the interviewee was

located in Europe, and was themselves involved in monitoring regulatory developments, they did not always have the details of the amount of human resources involved in testing activities for compliance, which are often carried out in a different Member State or outside the EU. It was interesting to note that requesting data from colleagues particularly those located outside Europe was seen as challenging and would take considerable time and that the quality of the information eventually provided may not be well thought through.

More generally, it was difficult to quantify how many staff are working on compliance for any given product group, since most laptop manufacturers produce a wide range of electrical and IT products. Regulatory compliance teams typically work across a number of different product groups, are overseeing different applicable Union harmonisation regulations, as well as differences in the technical standards which are specific to particular product groups. This means that it is often difficult to estimate precisely how much staff time is spent on familiarisation broken down to a particular product group. This was the case for instance with Firm C, which has a team of 13 FTE staff working on compliance with Union harmonisation regulations and a further 13 FTE staff with EU environmental regulations.

Laptop manufacturers interviewed noted that they spent much less time on familiarisation in regard to long-established IM legislation, such as the LVD and EMC Directives, where the requirements have not changed that fundamentally in 20-30 years. They spent much more time preparing their firms to meet new regulatory requirements stemming from recently adopted IM legislation. Examples cited in this regard from the past few years were the RoHS Directive (RoHS II was adopted in 2011), the REACH Regulation (which entered into force on 1st June 2007). For instance, Firm D, a global manufacturer of microchips and compressors commented that there had been a lot of preparatory work for RoHS and REACH. There was a need for specialist compliance staff to liaise internally across different business functions such as R&D in order to ensure that the firm was fully compliant and REACH-ready.

The introduction of new implementing regulations for Ecodesign specific to laptops was viewed by firms interviewed as being likely to require significant familiarisation time. An Ecodesign implementing measure was adopted in 2013 for computers and servers in June 2013[71]. Laptops manufacturers already have some familiarity with Ecodesign requirements through the requirements on Standby and Off-mode (Regulation EC 1275/2008) which apply to electronic devices generally.

.Lastly, in order to help industry to minimise the burden of EU legislation, the development of guidance materials was seen as invaluable in saving time for familiarisation costs. For instance, a components manufacturer in the laptops industry commented that the development of guidance for Ecodesign requirement on standby and off-mode was especially important, given the technical complexity involved. However, aspects related to standby and off-mode for laptops are now included in the new ecodesign regulation for computers and computer servers and no longer in the horizontal regulation on standby and off-mode.

Step 2 - Changes to processes or changes to product design and production processes

Like other industrial products, laptop manufacturers have to incorporate regulatory requirements into R&D and product design processes. However, it was difficult to obtain cost

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estimates from manufacturers. In instances when data was not available at all, the main reasons were that:

- Where manufacturers carry out conformity assessment testing internally, the testing often takes place in laboratories outside Europe for global consumer products such as laptops. Since laboratories work on products designed for the global market, data on testing costs specific to European Union harmonisation regulations is often not collected by the manufacturer.

- Laptops manufacturers are increasingly reliant on ODM suppliers to carry out testing at the product design stage. ODM suppliers do not usually break down their prices to reveal the specific costs of regulatory compliance (and associated conformity assessment tests) since they provide their client(s) with a total estimated price.

- Manufacturer that make extensive use of ODM suppliers carry out random "spot" testing of products as part of quality control procedures but only at the point when a product model is already on the market (e.g. checking of product batches about to be shipped).

Industry found it difficult to quantify expenditure on substantive design costs. Firm A pointed out that the business model makes it difficult for laptops manufacturers to disaggregate costs. "There is lot of global leveraging and in the notebook business a lot of manufacturing is outsourced this work is, the certification are more and more included in the final price offer and not always quantified, if it is quantified, the price is on global scale mixing a lot of items. In addition, there are difficulties in calculating the leveraged cost of testing modules, which nowadays are carried out on an outsourced basis by OEM suppliers. Consumer notebooks are now totally managed by the outsourcing partner and therefore we totally lost control of that type of costs especially as annual aggregate and related to EU. Somehow by passing the ball we avoid to ask to avoid the risk to have our outsourced partner to revise the agreements, assuming that it is their task to keep tests costs low".

Even in those instances when data was available to the manufacturer, they were unwilling to share this data because it was considered to be commercially sensitive. Although some data imputations have been made by our team (see table quantifying these costs), the feedback received was mainly qualitative.

It was observed that **by anticipating changes to Union harmonisation regulations, firms are able to help minimise substantive compliance costs**. As noted above, large firms follow EU regulatory development processes closely, and are usually aware about changes to Union harmonisation legislation and administrative requirements well in advance of these becoming mandatory and also follow standards development processes. Since laptop products are designed with knowledge of current requirements under Union harmonisation regulations (and those likely in future) in mind, and the core legislation has been relatively stable in the past decade, this helps to avoid lots of changes to produce design or to products already on the market due to changes in requirements.

Another observation from the research was that some types of costs, such as substantive changes to product design once products have already been placed on the market in the EU are probably lower for laptops than for say air conditioners due to **differences in the product development lifecycle and the duration of the product's lifecycle post-placement on the**

market. Whereas for an air conditioner, this lifecycle is typically 10-12 years (see Ecodesign Preparatory Studies[72]), for laptops it is around 2-4.

If changes are required due to changes in Union harmonisation regulations (and/ or updates to voluntary technical standards), these are usually identified well in advance by laptop manufacturers. Any necessary changes can therefore be factored into the design phase when new product models under development, which helps to reduce substantive compliance costs.

It is less common – though not unknown - for laptops to have to be temporarily withdrawn from the market or for modifications to have to be made to existing models. Rather, new laptop platforms under development take these changes into account directly and existing models are simply phased out in line with their planned product timeframe.

Some examples of substantive costs were however identified over and above the initial R&D and product design phase. For instance, interviewees stated that the introduction of some Union harmonisation regulations had resulted in them incurring substantial additional costs, even if these were difficult to quantify. For instance, under REACH, there was a need for chip makers supplying laptop manufacturers to invest in R&D to identify and test possible substitute chemicals for use in the production of micro-chips.

The **most costly pieces of Union harmonisation regulations were perceived as being those IM regulations introduced in the past five – ten years**. This is partly because new Union harmonisation regulations require more familiarisation time, but mainly because whereas the classical New Approach Directives were concerned with product safety, more recent regulations have more environmental and health-focused requirements in their objectives (e.g. concerned with restricting the use of dangerous chemicals, hazardous substances, and ensuring improved levels of energy efficiency).

There may therefore be a need under these regulations to make significant changes and to plan for these changes, for instance, in respect of product design and specifications, the type of components and parts used, the substances and chemicals used, etc.

Both Firm B and Firm D regarded the introduction of RoHS and REACH as having been burdensome for laptops manufacturers and components makers (e.g. of chips and micro-processors) respectively. Firm D commented that while recognising the environmental benefits, there were significant costs associated with achieving REACH compliance. These are examined in Table 7-12.

Table 7-12: Industry concerns about legal uncertainty for downstream users under REACH regulation

A concern among industry in relation to the REACH regulation was that there was perceived legal uncertainty as to which substances might be outlawed in future following substance evaluation or subject to restrictions and authorisation requirements. These concerns are particularly acute in terms of the potential cost implications from a downstream user perspective. There is not only uncertainty as to whether chemicals that are currently critical for some laptops components could be banned or restricted, and replacing

72 Preparatory studies for Eco-design Requirements of EuPs, Lot 3 Personal Computers (desktops and laptops) and Computer Monitors, IVF Industrial Research and Development Corporation, 2007 (for the European Commission's DG TREN)

them with alternatives could potentially be costly.

This was viewed as especially problematic by Firm D. For instance, the substance, gallium arsenide, is widely used and without it microchips cannot be produced. However, there is no viable product substitute. The substance is currently being reclassified under the CLP Regulation as part of the Adaptations to Technical Progress (ATP) to the CLP. This specific substance is currently also being assessed under the Community rolling action process substance evaluation by Latvia. However, there are presently no common criteria for undertaking substance evaluation in order to fast-track particular chemicals. In Firm D's view, before banning or requiring authorisation for substances that could really disrupt the supply chain, there should be a more detailed impact assessment for downstream users.

Since REACH is at a relatively early stage in the process of identifying harmful chemicals that need to be subject to authorisation, restrictions and phased out, there is considerable legal uncertainty and unpredictability for downstream users at the present time. Currently, manufacturers cannot plan for the future effectively and this was said to impose costs.

Firm D noted that since a technology-driven development cycle from basic R&D through to high-volume manufacturing takes 10 years. Planning is therefore needed as to which substances can be legally used under Union harmonisation regulations for the next 15-20 years and investment decisions need to be taken about semi-conductor production facilities which can be very high-cost. Such legal uncertainty may deter investment.

There can also be substantive compliance costs associated with **ensuring that products already placed on the market meet requirements set out in updated harmonised technical standards**, even though there is a transition period before new standards must be used for products and products that have used the former standard to be slowly phased out. For instance, in the area of electrical safety, in March 2013, a large multinational announced that it had temporarily withdrawn a desktop PC product from the market because it was not compliant with Amendment 1 of IEC 60950-1, an updated standard on electrical safety. The firm concerned was reported to be redesigning the product in order to allow it to continue to be sold in future.

Table 7-13: Differences in the cost of modifying products to reflect the updating of standards – a comparison between Europe and the US

There are differences between Europe and the US as to whether products can remain on the market once new and updated technical standards have been introduced. Firm B commented that the differences between the US and European regulatory systems affects the costs of modifying products in order to update technical standards, once these are placed on the market.

In the EU, there is a transition period during which manufacturers that apply harmonised standards must update products in accordance with the new technical standard, usually within 2-3 years of a product being placed on the market. This imposes costs on the European laptops industry compared with other geographic regions. In contrast, in the US, once a product is already on the market[73], then even if a new, updated technical standard has

73 There is no direct equivalent to the concept of "placing a product on the EU's internal market" as set out in Decision 768/2008

been introduced, products using the old standard can continue to be legally sold in the US . However, any new products in the development pipeline are required to conform with the new, updated standard.

Step 3 - Conformity assessment procedures and relevant documentation.

The applicable **conformity assessment** modules that need to be followed will depend on which alternative route to compliance the manufacturer has decided to select. As set out in detail in Section 3, if the modular approach is applied, then appropriate testing will need to be carried out for the EMC-D, LVD-D and the RED respectively, whereas if the product is classified as a radio product, then only the CA procedures applicable under the RED will need to be applied[74].

The laptop manufacturers interviewed use the Suppliers' Declaration of Conformity (SDoC) as the main conformity assessment route to meet the essential requirements for applicable IM regulations. Many manufacturers also choose to use a third party to carry out testing in respect of some IM directives, although this is not mandatory. This is a common approach (for instance for the LVD to check electrical safety) since many manufacturers prefer to use external conformity assessment bodies either to carry out all the testing or to check a sample of products that have already been checked by the manufacturer using internal testing. This approach was seen as helpful in minimising risks and in reassuring consumers, which is important, since there are reputational management issues at stake.

Industry confirmed that the flexibility of carrying out conformity assessment internally using the SDoC was appreciated. Since the majority of laptops are produced by global manufacturers using large in-house testing facilities, it was felt that manufacturers could ensure product safety equally as well as third party conformity assessment. Firm B commented that *"there is no evidence that SDoC makes products any less safe compared with the use of mandatory third party testing, so long as the system is underpinned by robust market surveillance".*

There were difficulties in obtaining data on the costs of internal and external Conformity Assessment Procedures, for the reasons already set out in Step 2 (e.g. commercial sensitivity of data, internal testing costs not shared between different business divisions globally, difficulty in obtaining accurate data when testing carried out outside EU by manufacturer or when outsourced to ODMs).

Nevertheless, some estimates on the annual costs of external conformity assessment, were obtained. For instance, Firm A estimated that across the 30-40 different product platforms launched annually on the EU market, it spends approximately 800000– 1m EUR per year on third party conformity assessment. In addition, it estimated that in-house testing costs approximately 10000 EUR / regulatory model. A distinction was drawn here between a "regulatory model" on which compliance is built and a "marketing model" i.e. a firm may develop many different models for marketing purposes, but there are a much smaller number of basic platforms on which basic compliance is built. However, it was not possible to obtain

74 The conformity assessment procedures that are applied by manufacturers under the R&TTE-D are in summary (II) Internal production control (iii) Internal production control plus specific apparatus tests (IV) Technical construction file and (V) Full quality assurance).

estimates of the one-off and recurring costs of internal laboratories and testing and of the purchase equipment.

The applicable conformity assessment mechanism is defined in each implementing measure and conformity is generally based on internal design control or on a quality assurance management system. Implementing measures may also make provision for modules, but this is typically Module A unless explicitly stated otherwise. In the case of the forthcoming Ecodesign requirements for computers and computer servers (Regulation 617/2013), when these start to apply, the applicable conformity assessment procedure will be the internal design control system set out in Annex IV of the Ecodesign Directive or the management system for assessing conformity set out in Annex V of the Directive.

Since large firms dominate the laptops market, no SMEs were able to be interviewed. Some feedback was nevertheless obtained on SMEs. According to the industry association, Eurodigital, it can be challenging for SMEs to test products for Ecodesign requirements. Firm D, which is a global manufacturer of chip and micro-processors confirmed that it assists smaller manufacturers in carrying out testing to meet Ecodesign requirements, which currently apply only to standby power mode), but will be replaced by requirements applying to computers and computer servers as a whole through Ecodesign implementing regulation 617/2013.

Feedback was received from two global laptops manufacturers on the costs of standards. It was pointed out that a distinction needs to be made between harmonised standards and wider standards and technical specifications that are used by the industry but which are not directly linked to complying with Union harmonisation legislation.

Although the purchase of harmonised standards is voluntary, since the leading laptops manufacturers follow these standards, they are regarded as being part of the overall costs of compliance (even if they only account for a small percentage of the overall costs). There are just a few harmonised standards that meet the essential requirements set out in Union harmonisation legislation and are included in the Declaration of Conformity (DoC) for laptops. In analysing costs, only the purchase of these harmonised standards should be considered. The same standards can often be applied not just to other types of laptop models but also to other product devices horizontally. For instance, ETSI EN 300 328 relates to 2,4GHz WiFi technology, regardless as to whether the device concerned is a laptop or an MP3 player. We therefore asked firms to estimate the proportion of the costs of standards solely relating to laptops and to IM legislation.

Firm A stated that the cost of purchasing a single standard, especially those related to the EMC and to electrical safety under the LVD is typically around 80 EUR. There are cheaper prices when obtaining updates for standards that have already been purchased. A manufacturer of laptops will typically follow some 30-40 standards in total (of which only a few are harmonised standards needed to build compliant products). However, as noted above, once a complete set of standards has been purchased, these can then be used across multiple laptop models.

An alternative option for large manufacturers is to purchase a company license, which then gives them the right to purchase a certain number of single licenses (typically 50 licences for all IEC standards purchased). The cost is approximately 40,500 EUR, which is a one-off cost, but which can be used to cover multiple laptop products (and other devices). The cost of purchasing standards specific to the laptops segment of Firm A were estimated to be in the

order of 5000 EUR per year across multiple product models. The cost is higher for large firms than for SMEs because SMEs can purchase standards with a single user license, whereas to share the knowledge internally, large firms must by a company license, or at the least a license for multiple users.

One of the interviewees commented that "companies need to operate smartly in terms of the way in which they deal with buying standards otherwise they may waste money, even if the cost of standards is a relatively small part of the whole. The cost of buying standards is not normally attributed to the cost of an individual product, rather that the purchase of a complete set of standards is needed in order to build multiple laptop platforms". In this respect, there are similarities to the costs of purchasing laboratory equipment in that this is a pre-requisite and part of the "set up" costs for being a manufacturer in the sector.

According to the interviewee in Firm A, "some European Standardization Organisations such as ETSI adopt a more industry-friendly approach since the standards that they develop are free (in effect, they are paid for by industry who pay to participate in the standards development process for ETSI standards. The amount payable is dependent on the type of membership, the size of the company, and the participation that it has in the standards development process". Firm C noted that *"some companies are more CENELEC-oriented and either purchase individual standards or have a subscription, whereas others are more ETSI-oriented and pay subscriptions to be involved in the standardization process (as standards are indeed freely available). Other laptops manufacturers are involved in the development of both CENELEC and ETIS standards, so the cost of their participation in standardisation making processes (and in purchasing standards) is higher".*

Step 4 - Declaration of Conformity (DoC) or other statement of compliance and CE marking.

Producing documentation - the DoC and the technical file

In common with other industrial products, having first carried out conformity assessment procedures, laptop manufacturers are required to produce a DoC and technical file and to keep this updated for 10 years following placement on the market.

The preparation of the DoC itself is straight forward since this involves producing a sheet of A4 setting out the applicable Union harmonisation regulations, and commonly also a list of the voluntary harmonised standards that have been applied in order to meet the essential requirements. However, there are administrative costs associated with the regulatory checking and updating of DoCs due to the high cumulative frequency of regulatory changes, both legislative and those resulting from updates to harmonised technical standards. Decision 768/2008 states that DoCs shall be kept "continuously updated".

Internal systems and procedures need to be put in place to ensure that these documents are updated regularly. Updating DoCs between two and four times each year – depending on the firms' internal procedures – is a significant burden in terms of human resource costs. Industry noted that although producing an individual DoC was not difficult, the cumulative effects can be burdensome, since global firms have hundreds of different product models (and variants of each product model) and each DoC then has to be kept under continual review.

In Firm A, the dedicated European compliance team working on Union harmonisation regulations includes 4 staff solely involved in the development and updating of compliance

documentation, with regular internal review procedures put in place for (i) checking, maintaining and updating DoCs and (ii) checking that technical files are as complete as possible. This was regarded as resource-intensive.

There was a perception that there is now a longer timeframe to check that product documentation is administratively compliant with the applicable Union harmonisation regulations. It was noted that while it previously took 5 days to undertaken an internal procedures to review DoCs and technical documentation and check that these are up to date, the procedure now takes up to 20 days. This was attributed to Union harmonisation legislation becoming more numerous and complex, for instance, as a result of the introduction of the RoHS, EuP and Ecodesign Directives.

Although some firms viewed the requirement to provide a paper copy of the DoC together with the product under the RED as burdensome, the administrative costs are not that significant thanks to an agreement with TCAM for manufacturers to use the so-called "short form of a Declaration of Conformity". This is an abbreviated compliance statement localised in all languages and a weblink is provided to the full declaration which is available in English only, but can be translated at the specific request of MSAs.

Translation requirements for DoCs – uncertainty for manufacturers?

Two laptops manufacturers interviewed commented that they faced legal uncertainty since it is unclear whether there is a formal requirement that DoCs should be translated into local languages or should continue to provide a local language version of a DoC upon request as has been the case for many years.

The wording in the NLF has led to uncertainty for industry as to what translation requirements apply to DoCs in order to meet compliance requirements. There is ambiguity in the wording in Decision 768/2008 which states that "The DoC shall be translated into the language or languages required by the Member State in which market the product is placed or made available". This ambiguous wording causes uncertainty for the laptop industry, which had previously produced DoCs in English only. One firm commented that *"If a translation requirement were to become compulsory, this would be administratively burdensome. Also, for whose benefit would this be, since regulatory compliance information – unlike an instruction booklet which is directly is concerned with consumer safety –is only to help facilitate the work of MSAs*". The argument put forward is that it is cheaper for global businesses to produce DoCs in English only and the benefits of translating the DoC are minimal given that the applicable legislation is well known and is available translated in all EU languages.

A further concern related to translation was that since the NLF, upon reasoned request by a Market Surveillance Authority (MSA), part of the technical file may be required to be translated. While the reasons for this were understood, since many test reports and other important information for MSAs may not even be in a European language, there were concerns that this could constitute a significant administrative burden for manufacturers. The problem is that there is no clear definition as to what constitutes a "reasoned request".

Step 5 - Other activities related to Union harmonisation information obligations.

Traceability requirements

The Commission has strengthened traceability requirements for industrial products in order to better enable MSAs to trace the provenance of products and to be able to contact the manufacturer to obtain regulatory compliance information, and parts of the technical file such as tests reports more easily. In Decision 768/2008, there is a specific requirement for products (at least for the packaging) to provide addressee information for the manufacturer and importer(s).

The move towards strengthening traceability is understandable since so many products are manufactured in third countries and MSAs need to be able to contact the manufacturer that produced the product more easily. However, industry has concerns about the administrative burdens that this might impose and also the constraints on product design if such information has to be provided on the product itself.

However, both the industry association and two firms were concerned about the potential administrative burdens of traceability requirements and the difficulty of conforming with such requirements, while at the same time producing attractive, consumer-appealing products. This point extends beyond laptops alone to other products such as smart phones. It was argued that traceability requirements may risk compromising product aesthetics from an industrial design point of view (in instances where labelling has to be provided on the product itself). E-labelling was viewed as a possible solution to avoiding having to have too much information on products and packaging.

A further issue identified relating to information obligations related to marking requirements under the RED. This affects laptops using Class II Wifi devices.

Table 7-14: Marking requirements affecting laptops using Class II wifi devices

Alongside the CE mark, an additional alert mark (a circle with an exclamation mark in the middle) has to be provided on laptops next to the CE mark. This was regarded by Firm C, which follows the R&TTE-D alone as unnecessary first because the CE mark should already cover all safety-related aspects of products and secondly since the alert mark is not understood by consumers. Although the costs involved in adding labels to products are small, the multiplication of labelling requirements (linked to IM regulations and product safety, but also energy-efficiency, waste disposal) has cumulative effects. For example, it places constraints on manufacturers as to where the marking and labelling information should be placed in order to ensure compliance, and may serve to detract from producing an appealing product (again, this depends whether there is scope to put such information discretely on the product e.g. on the underside of the product, under the battery, etc).

Assessment of costs of Union harmonisation legislation for the whole sector

In this section, the costs of complying with Union harmonisation legislation in the laptops sector are assessed. The data is based on data and supporting qualitative information provided by four manufacturers. Although the analysis is based on a small number of firms, these can be considered as representative, since they collectively account for a significant share of the

market. In the case of laptops, the three firms that took part collectively account for 45-50% of the market and all four participants are global manufacturers.

There were challenges in carrying out the analysis since there were data limitations as regards the costs of product testing, for reasons already explained in our assessment of the five steps in Section 4. Nevertheless, it was possible to arrive at quantitative estimates, since some manufacturers were able to provide more detailed information than others.

Extrapolation of costs and cost saving from the firms to the sector

The following table summarises the costs per unit and total estimated costs for industry. A list of key assumptions made is provided in footnotes. The cost estimates take into account information provided by the firms that took part in relation to the five process steps described in Section 4.

The costs are related to turnover. In the first column, we seek to distinguish between different types of costs. The distinction between one-off and recurrent costs has been taken into account in the analysis, and some costs, such as the costs of purchasing laboratory equipment have been annualised[75].

Table 7-15: Summary of main costs of compliance for laptops manufacturing industry

Types of cost	Unit of measurement	Unit cost[76]	Total quantity	Total costs (annualised)
Compliance with admin. requirements				
Familiarisation	(Manufacturers / cost per year)	€ 402,000	10[77]	€ 4,020,000
Preparation of DoC and technical documentation	Manufacturers / cost per year)	€ 1,206,000	10	€ 12,060,000
Standards purchase	No. of standards	€ 80	30-40	€ 5000[78]

75 These costs were annualised in order to arrive at comparable annual costs, using a system similar to firms' accounting for depreciation. For some questions, we also asked questions in the SCM questionnaire about how much they spent on testing equipment over a 5 year period, which had to be annualised.

76 All unit costs are based on the interviews with at least 3 respondents answering each figure.

77 Turnover is used to upscale the parameter estimates. The average respondent has a market share of about 10%. The same approach was adopted for the DoCs.

78 Approximately 30-40 standards need to be purchased in order to develop a compliant laptop product. However, once purchased, these standards can then be used across multiple product platforms. We have assumed an average annualised cost of 5000 EUR since larger firms may purchase a group license rather than buy standards individually.

Types of cost	Unit of measurement	Unit cost[76]	Total quantity	Total costs (annualised)
Substantive compliance and Conformity assessment (internal)[79]				**€ 9,000,000**
R&D and Product design	Models	€ 800,000	10[80]	€ 8,000,000
Testing (internal)	Models	€ 5,000	200[81]	€ 1,000,000
Testing equipment[82]				No data
Conformity assessment (external)				**€ 3,000,000**
Consultancy/advisory services (product design)				€ 0
3rd party Conformity Assessment by notified bodies	Models	€ 15,000	200	€ 3,000,000
Total (excluding testing equipment)				**€ 28,080,000**

The total estimated costs of regulatory compliance by the laptops industry are in the order of 28m EUR on an annualised basis. However, it should be noted that there was difficulty in obtaining data from firms on all the variables (for reasons explained in our assessment of the five steps in Section 4 and in some cases, further expanded upon below). For example, there were difficulties in obtaining estimates of BAU and for the purchase of testing and laboratory equipment.

Business as Usual (BAU) costs were not taken into account in the calculations (these are the costs that firms would be undertaking anyway regardless as to whether internal market legislation was in place, for instance product performance testing and safety testing as part of internal quality management procedures). The main problem was the lack of consistency in

79 Here, substantive compliance costs are concerned with building in compliance requirements to product design during new product development phase and where necessary, making modifications to products that have already been placed on the market.

80 Based on one respondent and its market share, the total number of models was estimated at 200. The average respondent runs 20 models, so the quantity is 10 (200/20).

81 Number of models (see above footnote). The same is done for 3rd parties.

82 No data was available on the costs of purchasing testing equipment because for commercial sensitivity reasons, the firms concerned were unwilling to share this data.

the estimates provided by firm and the absence of firms being willing to provide quantitative estimates generally in two cases.

Among the two firms that did provide data, there was divergence in interpretation among firms as to whether compliance costs meet the requirements of Union harmonisation legislation. Firm A estimated that approximately 30% of the time spent by internal staff on regulatory compliance would be necessary anyway as part of the internal planning and quality management procedures necessary to ensure a safe product and to produce documentation about the product and safety elements. Conversely, Firm C commented that *"since all compliance-related activities are ultimately related to Union harmonisation legislation, there is no element of compliance costs that can be considered as BAU".*

Some costs are one-off costs, whereas other costs are recurring. Other types of costs are more nuanced, and represent a combination of one-off and recurring costs. Examples of costs that are clearly one-off include the purchase of laboratory and testing equipment, R&D costs, third party conformity assessment costs and the purchase of standards. Other costs are evidently recurrent, such as the recalibration of testing equipment. However, the picture is more nuanced for other types of compliance costs, which are both one-off and recurring. For example, the cost of the preparation of a DoC and technical documentation mainly occurs prior to a product being placed on the market. However, in addition to these one-off costs, there are also recurring costs linked to the need to update and maintain a DoC for 10 years post-placement on the market. In addition, there is a need to update technical documentation, for instance, to reflect new spare parts and components that are introduced as replacements once a product is already on the market. As regards product design, the costs are mainly one-off, but there could also be recurrent costs if regulatory changes are made and modifications to product design are needed once the product is on the market.

With regard to the total estimate of firm size, although the total number of firms in the industry was estimated to be approximately 60, the top 10 firms account for a very high market share, so the calculations have been made based on compliance cost data provided by leading global firms and then extrapolated. It was estimated that compliance with administrative requirements amounts to 57.2% of total costs (14.3% for the familiarisation stage and 42.9% for the preparation of technical documentation associated with the product and the DoC. Another major cost was the substantive compliance costs associated with the R&D and product design phase to ensure that compliance requirements are factored into new product development. These were significant and estimated to be circa 8m EUR per annum (28.5% of the total).

No substantive compliance costs were identified linked to withdrawing laptops from the market and making modifications to products due to changes in regulatory requirements and/ or in technical standards among the firms that participated (although one or two examples of product withdrawals resulting from regulatory requirements were identified through the desk research. The low incidence of product withdrawals and design modifications reflects the fact that leading global; manufacturers are fully aware of regulatory changes well in advance of these being introduced, and factor these into the R&D and design phase. This is made possible due to the fact that there are relatively short development lead times for laptops, so current models on the market do not have to be replaced, since they rapidly become old models and are superseded by new models that are compliant with new regulatory requirements.

A further significant cost was carrying out conformity assessment. Although the SDoC procedure was usually followed by manufacturers, as noted earlier, several interviewees stated that they made use of a combination of in-house laboratory and testing facilities and external conformity assessment services. This depended on the individual Directive concerned. For instance, it was common to outsource at least some aspects of testing for standards relating to the LVD to a third party, since these relate to electrical safety.

As noted earlier, it was difficult to obtain data on the costs of setting up testing laboratories (one-off costs) and on the recurrent annual costs of recalibration. The reasons for the absence of data were explained earlier and include the commercial sensitivity of the data, the lack of data availability internally within organisations because the information is not shared between different business divisions globally and because testing costs are hidden due to the use of OEM and ODM suppliers.

The costs of internal testing were estimated to be 3.5% and the costs for external testing in the region of 10.7% of the total regulatory costs of compliance. However, the estimates of internal testing costs are probably an under-estimate and reflect the staff time involved in carrying out testing and some laboratory costs. The quantification exercise took into account information concerning the 'Business as Usual' (BAU) scenario, i.e. the estimated percentage of compliance costs linked to IM regulations that related to activities that the firm would undertake anyway irrespective of whether there was Union harmonisation legislation.

Overall Conclusions

- Laptop manufacturers appreciate the flexibility provided by Union harmonisation legislation and the fact that there are alternative routes to achieving regulatory compliance (following the RED alone vs. a modular approach).

- The compliance costs for manufacturers that follow several individual pieces of Union harmonisation legislation under the modular approach are broadly similar to the costs of following a single Directive (RED), since similar product safety tests are required under the RED (e.g. to ensure electrical safety, electro-magnetic compatibility).

- A modular approach can however be advantageous in allowing compliance responsibilities to be divided up between different manufacturers specific to the part of the laptop that they produce and the corresponding applicable module, while the manufacturer retains ultimate responsibility for compliance of the final whole product.

- There were difficulties in obtaining data on substantive compliance costs during the R&D and product design phase, especially for testing costs. This was due to commercial sensitivity reasons in some cases, and the extensive use of ODM and OEM suppliers by most laptop manufacturers in others.

- Qualitative feedback suggests that substantive costs are lower for laptops than for certain other types of industrial products (e.g. air conditioners) when regulatory changes are introduced because the lifecycle of a laptop model is shorter. Therefore, new requirements can be built into the development and customisation of new models, rather than having to adapt or replace components or to adapt product platforms used as the basic building block for developing new products variants.

- There is strong support among manufacturers for the increased provision of compliance information to Market Surveillance Authorities (MSAs) and users/ consumers electronically and for e-labelling. This may offer scope for efficiency savings and a reduction in the administrative costs of updating compliance information.

- There are concerns that since the adoption of the NLF, there is legal uncertainty for manufacturers resulting from the ambiguous wording in Decision 768/2008 as to the translation requirements for DoCs.

- Since the DoC is primarily intended for MSAs rather than for users/ consumers, if this requirement were to be interpreted in a stricter way in future, then there is a risk that this would result in considerable additional administrative costs. The current practise is that the translation of DoCs is only available upon request by MSAs.

- Divergent requirements for DoCs between Union harmonisation regulations can cause uncertainty when manufacturers are shipping mixed products in large containers, some of which require a DoC together with the product under the RED, while other products do not because they do not contain a radio part. There is a risk that different administrative requirements for different types of products may confuse customs authorities and lead to unnecessary and costly delays.

Sources of information

References

- Eurostat Structural Business Statistics Database and PRODCOM
- Data from the 2011 Euromonitor report for computers.
- Lot 3 Personal Computers (desktops and laptops) and Computer Monitors Final Report (Task 1-8)
- Guidance documents on the LVD and EMC Directives

Interviews

- Interviews with 4 global manufacturers, 3 of laptops and one of computer chips
- Several interviews with the European industry association, Digital Europe.

Annex 1 –Mapping of Union harmonisation Legislation (Laptops)

Table 7-16: Mapping of applicable Union harmonisation legislation and administrative requirements for manufacturers

Name of legislation	*Main issues addressed (safety, environment, other)*	*Main administrative requirements for manufacturers*	*Relevant standards (note: illustrative only)*
Core legislation			
Low Voltage Directive	Health & Safety	Supplier's Declaration of	EN 60950-1:2006

(LVD) -	(electrical)	Conformity (SDoC) Testing according to relevant harmonised standards or alternative means of achieving presumption of conformity Preparation of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations)	Information technology equipment - Safety -- Part 1: General requirements
Electromagnetic Compatibility Directive (EMC)	Electromagnetic compatibility	Testing according to relevant harmonised standards or alternative means of presumption of conformity Development of technical file Declaration of conformity and CE marking	Electrical safety standards IEC 60950 (IT equipment safety), EN 60950 (and American standard UL 60950)[83]. EN 55024:2010 IT equipment (Immunity characteristics) Limits and methods of measurement CISPR 24:2010 EN 61000-3-2:2006 - Part 3-2: Limits for harmonic current emissions (equipment input current <= 16 A per phase) EN 55022, (Radiated emissions), IEC 61000-2-2 and IEC 61000- 3-3, EN 61000-3-3:2008 - limitation of voltage changes, voltage fluctuations and flicker

83 These standards are similar and can be considered broadly harmonised.

			in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection IEC 61000-3-3:2008[84].
Radio equipment Directive	Radio bandwidth frequency	Manufacturers must carry out testing to ensure that RE devices do not cause any harm to PST Networks and do not violate power and frequency spectrum allocations on a country by country basis. Declaration of conformity and CE marking	The RED is applicable to laptops that include radio devices e.g. modems and/or wireless communications interfaces (e.g. WiFi, Bluetooth). EN 55024:2010 Information technology equipment - Immunity characteristics - Limits and methods of measurement CISPR 24:2010 EN 55022:2010 Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 22:2008 (Modified)
RoHS Directive (2011/65/EC)	Use of hazardous chemicals	Collect compliance statement from suppliers (material declarations) Technical file with supplier declarations and own analysis tests Declaration of conformity to be kept for 10 years	Although the 2002 RoHS Directive did not require CE marking, the new 2011 Directive does so.
Ecodesign for Energy-related Products Directive (ErP) 2009/125/EC.	Ecodesign requirements		The ErP establishes a framework for setting Ecodesign requirements for energy-related products (ErPs). Through product-specific Implementing Measures, mandatory, Ecodesign requirements are set.

84 When designing a computer or laptop, EMC technical standards influence the design phase because they set the parameters as to what is possible or not.

			Two implementing measures are currently applicable under the ErP. External power supplies that are shipped with the notebook (Regulation 278/2009/EC with regard to ecodesign requirements for no-load condition electric power consumption and average active efficiency of external power supplies) General requirement applicable to electrical electronic office equipment on standby and off-mode power consumption (Regulation 1275/2008/EC with regard to Ecodesign requirements for standby and off-mode electric power consumption of electrical and electronic household office equipment. The above are applicable to general electrical products. However, for laptops these implementing regulations will be superseded by Regulation 617/2013 (Ecodesign requirements for computers and computer servers) which will be mandatory from 01.07.2014.
Wider applicable legislation where CE marking does not apply			
REACH Regulation (EC 1907/2006)	Use of chemicals	REACH compliance statement from suppliers	
Packaging and packaging waste (2004/12/EC)	Packaging	Declaration of Conformity	

Annex 2 - Voluntary environmental labels

In addition to Union harmonisation legislation, there are a number of voluntary environmental labels at European and national levels relevant to laptops such as the EU Ecolabel for portable computers[85]. Examples of the requirements in order to qualify and be able to display energy efficiency markings on products are that "Power management settings should be 10 minutes to screen off (display sleep); 30 minutes to computer sleep".

There are also national voluntary labelling schemes within the EU such as Blue Angel (Der Blaue Engel), a German certification system for environmentally-friendly products and services and Nordic Swan, the official sustainability Ecolabel for the Nordic countries. There are also international voluntary energy-efficiency labels such as Energy Star (US), which is for office equipment also applied in the EU. Other schemes include TCO Certified, an international sustainability certificate for IT products which incorporates a range of criteria to ensure that the manufacturing, use and recycling of IT products is carried out in an environmentally-friendly, socially responsible and sustainable manner. Such labelling initiatives have strong potential to promote resource efficiency, and are often adhered to by major manufacturers, even if there is no regulatory requirement to do so. There are links here with IM regulations that require manufacturers to assess the energy efficiency of products, notably the Ecodesign implementing regulation for computers and computer servers, for which the setting of the requirements took into account the work done for the development of Energy Star.

3.10.3 Case study 3 – Domestic Refrigerators and Freezers

Introduction

The product groups examined in this case study are refrigerators and freezers for domestic use, also known as cold appliances. The rationale for the selection of these product groups was that:

- Refrigerators and freezers are covered by a large number of Union harmonisation Directives and Regulations, 8 in total;

- The sector is dominated by a few (around 20) large manufacturers; and

- The conclusions drawn from an assessment of these specific products could be used to draw conclusions on the compliance costs for a broader category of electric domestic appliances since most of the products within this group are covered by the same pieces of legislation.

The case study is based on desk research, the interview with the EU industry association representing manufacturers of refrigerators and freezers (CECED) and three detailed interviews with manufacturers of domestic appliances, one medium size firm (350 employees and total turnover of 150 million) and two large multinationals selling over 2million units and occupying more than 2000 employees. The final text of the analysis was reviewed by CECED that provided additional comments. However, this should not be considered as an endorsement of the conclusions from the side of CECED.

85 The Ecolabel for portable computers can be awarded for desktops or laptops with a system unit, display and keyboard combined in a single case which can be used with an internal battery. This product group also covers devices equipped with touch screen keyboard.

Product definition and description of the sector

Product definition (products included/excluded)

The product group examined in this case study are refrigerators and freezers for domestic use, also known as cold appliances. According to standard EN 153 they are "electric mains-operating refrigerating appliances". According to standard EN 15502:2006 refrigerating appliances are "factory-assembled insulated cabinets with one or more comportments and of suitable volume and equipment for household use, cooled by natural conversion or a frost-free system whereby the cooling is obtained by one or more energy consuming means". There are two main type of refrigerating appliances, compression type and absorption type. The main appliance categories are:

- Simple refrigerators (no freezer compartment);
- Refrigerator-freezer (with at least one refrigerator and one freezer compartment);
- Food freezers; and
- Frozen-food storage cabinets

Data on the market size of the specific product group are derived mainly from Eurostat PRODCOM database and are complemented by market studies. In the PRODCOM database the specific products are covered under the code 27.51.11 (Refrigerators and freezers of household type) with the following subcategories:

- 27511110 - Combined refrigerators-freezers, with separate external doors
- 27511133 - Household-type refrigerators (including compression-type, electrical absorption-type)
- 27511135 - Compression-type built-in refrigerators
- 27511150 - Chest freezers of a capacity <= 800 litres
- 27511170 - Upright freezers of a capacity <= 900 litres

According to PRODCOM database data for 2011 the total market for refrigerators was close to 24.6 million units with a value of the market of EUR 4.8 billion sold/annum. Other data sources suggest a somewhat smaller market size of 17-20 million[86] cold appliances sold on an annual basis. Refrigerators represent around 42% of the market, combined units 38% and freezers 20%.

The majority of domestic refrigerators are electric powered. However, gas refrigerators and freezers (of the absorption type) are also available used either as mobile (e.g. for camping, recreation vehicles and boats) or fixed at home. Data on the specific market segment are not available since PRODCOM codes do not differentiate depending on the source of power. According to the Evaluation of the gas appliances Directive[87] there are a few large firms in

86 Topten (2012), Cold appliances: recommendations for policy design May 2012, http://www.topten.eu/uploads/File/Recommendations_Cold_May%202012.pdf

87 RPA (2011), Ex-Post Evaluation of the Gas Appliances Directive- Final report

Europe producing gas refrigerator. The 2005 preparatory study for the development of Ecodesign implementing measures for domestic refrigerators and freezers[88] refers to a total of 0.7-0.8 million of absorption refrigerators sold annually in Europe, 0.3 million of which were gas refrigerators. A according to the competitiveness report of the gas appliances sector they do not have a noteworthy role in the total market.[89]

Available PRODCOM data also indicate that the total volume of production within Europe is around 15 million units with a value of €3.8 billion. Of these, 3.4 million units are exported (value of €0.9 billion) while there are also around 12.7 million units imported from third countries (estimated value of €1.9 billion). Thus, according to the PRODCOM, imported refrigerators represent around 50% of the market of refrigerators and freezers. However, it should be noted that a significant part of leading refrigerators and freezers brand are designed in Europe but manufactured outside Europe and subsequently imported.

Industry structure

Concerning the structure of the industry, Eurostat Structural Business Statistics are not particularly helpful. The relevant NACE statistical code covers the whole range of domestic appliances (27.51 - Manufacture of domestic appliances[90]) and as a result they do not allow developing an accurate picture of the sector (e.g. number of firms, turnover, employment). Nonetheless, there were 2,200 enterprises[91] active in the manufacturing of electric domestic appliances (annual turnover of 41 billion and close to 195 thousand people employed in 2011), 31,000 wholesalers of electric appliances (€159 billion turnover and 267,000 people employed). Some guidance on the share of the refrigerators and freezers sub-sector may be provided by PRODCOM data according to which refrigerators and freezers represented around 15% in terms of value sold of all domestic appliances[92]. This would imply a total number of 29,000 employees in the manufacturing of refrigerators and freezers.

Table 7-17: Data on market size and industry structure for cold appliances

Parameter	Data
EU Market size	PRODCOM (2011): € 4.8 billion (24.6 million units) Market reports: 17-20 million (2010)
Production volume/value in Europe	PRODCOM (2011): € 4.8 billion (15 million units)
Imports	PRODCOM (2011): €1.9 billion (12.7 million units)
Exports	PRODCOM (2011): €0.9 billion (3.4 million units)
Number of enterprises (2010)	Market reports: 10 large multinational firms with multiple brands cover around 85% of EU market sales

88 ISIS (2007), Preparatory studies for Ecodesign Requirements of EuPs – Lot 13: Domestic refrigerators and freezers – Final report

89 Ecorys (2009), Study on the Competitiveness of the EU Gas Appliances Sector - Within the Framework Contract of Sectoral Competitiveness Studies – ENTR/06/054 - Final Report, http://ec.europa.eu/enterprise/sectors/pressure-and-gas/files/study_competitiveness_eu_gas_appliances_final_en.pdf

90 Besides refrigerators and freezers this category includes a range of appliances including: dishwashers and washing machines, vacuum cleaners, hair dryers, radiators and heaters, microwave ovens, electric ovens, grills and toasters, coffee makers, electric cookers, food grinders and mixers, electric blankets.

91 The data from Eurostat refer to individual enterprise units, many of which are subsidiaries of the few large manufacturers that dominate the refrigerators market and are present in most EU national markets.

92 All products for which the first 4 digits of the PRODCOM code is 2751.

Parameter	Data
	Eurostat: Manufacturing (NACE 27.51): 2,212 (all electric domestic appliances); Wholesale (NACE 46.43): 30,900; Retail (47.54): 54,500
Number of employees (2010)	NACE 27.51: 194,200 (all electric domestic appliances) Wholesale (NACE 46.43): 267,000 Retail (47.54): 269,000

Source: Eurostat

According to data from Euromonitor market research for 2012, 10 large size companies – most of them present in the market with multiple brands – represent more than 85% of the market in Western and Eastern Europe. At the product/brand-name level the market is rather fragmented since only 1%[93] of the models are sold under the same name in all EU markets.

Additional information for the number of firms can be derived from the ORBIS database of Bureau Van Dijk. From the total of 2,568 enterprises active in the 27.51 a search within the economic activity description field using the keywords "refrigerators" OR "freezers" produced 101 records. The list included all major producers as well as smaller manufacturers some of which are active in the commercial refrigerators and freezers market. A market share list from Euromonitor market research database suggested that 22 manufacturers capture 98% of the market in Western Europe and 90% in Eastern Europe (including non-EU countries). Thus, we consider that a total number of 100 firms provide an upper limit in terms of firms affected by the relevant IM legislation for refrigerators and freezers.

Analysis of applicable Union harmonisation legislation and standards

Desk research and the input from firm interviews identified the list of applicable pieces of Internal Market legislation, the basic administrative requirements and the relevant harmonised standards that can be used by manufacturers to meet the essential requirements. According to the input from industry 95-99% of manufacturers do make use of the standards in the case of refrigerators, and more general for domestic appliances.

Refrigerators are covered by 9 different pieces of Union harmonisation legislation covering a range of aspects:

- **Health and safety** (Low Voltage Directive, Regulation on materials and articles that come in contact with food, RoHD Directive on hazardous chemicals,). In the case of gas refrigerators and freezers the Gas appliances Directive is applicable. Furthermore, the Pressure Equipment Directive applies for those refrigerators and freezers that include piping and other pressure vessels (compressors, containers of refrigerants, heat exchangers) with internal pressure above 0,5 bar.

- The General product safety Directive is also applicable but does not introduce additional requirements to refrigerators since these are covered by the other more specific pieces. It does introduce however other obligations, mainly of administrative nature;

93 Electra report - Twenty solutions for growth and investment to 2020 and beyond, http://ec.europa.eu/enterprise/sectors/electrical/files/electrareport_en.pdf

- **Electromagnetic compatibility** (EMC Directive); and
- **Energy consumption and noise** (Eco-design and Energy labelling Directives and the respective implementing measures).

In addition, certain requirements arise from the F-GAS Directive concerning the use of fluorinated gases used in refrigerators, as downstream users of chemicals included in articles under REACH Regulation and also in relation to the use of packaging (Packaging Directive). We should also note that the WEEE Directive is also applicable to refrigerators - and is identified as rather burdensome for manufacturers - but it is a piece of legislation that is outside the scope of this study.

Table 7-18: Summary of Union harmonisation legislation covering refrigerators and freezers and the relevant standards

Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
LVD	Health & Safety (electrical, flammable refrigerants)	Testing according to relevant standards or alternative solutions Development of technical file Declaration of conformity and CE marking Include information ensuring that the product can be used safely and in applications for which it was made	IEC/EN 60335-1 IEC/EN 60335–2- 24
Directive 2009/142/EC on Appliances Burning Gaseous Fuels (GAD)	Health and safety of gas appliances	Testing according to relevant standards or alternative solutions Development of design documentation Declaration of conformity and CE marking	EN 732

Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
General product safety Directive	Health & Safety	Provide identification of the product by a product reference Carry out sample testing of products, keep a register of complaints and keeping distributors informed of such monitoring (voluntary) Inform authorities of dangerous products and actions taken to prevent risk Co-operate with the authorities upon request	
Pressure equipment Directive	Health & Safety	Testing according to relevant standards or alternative solutions Development of design documentation Declaration of conformity and CE marking	EN 378-2:2008+A2:2012[94] EN 12178:2003[95] EN 12263:1998[96] EN 12284:2003[97] EN 14276-1:2006+A1:2011[98] EN 14276-2:2007+A1:2011[99]
Regulation on materials and articles that come in contact with foodstuff 1935/2004 and Regulation 10/2011 on plastic materials and articles intended to come into contact with food	Health & Safety	Chemical analysis and migration tests of the materials used (in cabinet, door, shelves and accessories) Establish information collection system providing information on the source of materials (traceability) Declaration of compliance	

94 Refrigerating systems and heat pumps - Safety and environmental requirements - Part 2: Design, construction, testing, marking and documentation
95 Refrigerating systems and heat pumps - Liquid level indicating devices - Requirements, testing and marking
96 Refrigerating systems and heat pumps - Safety switching devices for limiting the pressure - Requirements and tests
97 Refrigerating systems and heat pumps - Valves - Requirements, testing and marking
98 Pressure equipment for refrigerating systems and heat pumps - Part 1: Vessels - General requirements
99 Pressure equipment for refrigerating systems and heat pumps - Part 2: Piping - General requirements

Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
EMC 2004/108/EC	Electromagnetic compatibility	Testing according to standards Development of technical file Declaration of conformity and CE marking	EN 55014-1 EN 55014-2 EN 61000
Eco-Design Directive 2009/125/EC (Implementing Regulation 643/2009 related to domestic cold appliances)	Noise	Testing Declaration of Conformity and CE marking Information in instruction manual for minimising noise	IEC 60704-1 IEC 60704-2-14 IEC 60704-3 ISO 8960
	Energy consumption/ efficiency	Testing Technical file with results of studies and explanations of design choices made and the management system Declaration of Conformity to be kept for 10 years and CE marking Information in instruction manual for minimising energy-use	EN 62301 - IEC 60301 EN 153/ EN ISO 15502
Energy Label Directive 2010/30/EU and implementing Regulation 1060/2010	Energy consumption/ efficiency	Testing according to harmonised standard Technical file with results of studies and explanations of design choices made and the management system Development of product fiche Placing of energy label	IS015502
F-GAS on fluorinated gases 842/2006	Climate change	Information on the gas contained in the instruction manual and relevant label on product	

Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
RoHS (2011/65/EC)	Use of hazardous chemicals	Collect compliance statement from suppliers (material declarations) Technical file with supplier declarations and own analysis tests Declaration of conformity to be kept for 10 years	
REACH	Use of chemicals	Collect statement from suppliers stating that he is compliance with requirements REACH compliance statement	
Packaging and packaging waste (2004/12/EC)	Packaging	Declaration of Conformity	Standard EN 13427

The analysis and the discussions with manufacturers did not indicate the presence of conflicting requirements that could be seen as creating either or uncertainty or problematic trade-offs in relation to the design of the product.

Turning to the administrative requirements, a number of applicable pieces of Union harmonisation legislation (LVD, EMC, Eco-design and Energy-Label, Regulation concerning articles in contact with foodstuff, RoHS) require the development of a technical files following testing, which in most cases is done according to the specific technical standard. The discussions did not point to any conflicts or overlapping activities in relation to the development of these technical files. The main concern is the size of these files and the work required to develop and update them. It is also often difficult to keep all the required information and to get from suppliers the complete technical files. Suppliers sometimes send only parts of the technical file (e.g. the test reports, energy consumption reports) or do not provide technical information at all (only the DoC) due to concerns about confidentiality and this means that certain testing needs to be redone.

The General Product Safety Directive also introduces certain requirements including the mandatory product identification or the voluntary conduct of tests of marketed products and the keeping of a register of complaints.

The review of the requirements of the Declaration of Conformity indicate minor differences in terms of the terminology used (e.g. under the LVD there is a reference to the "description of the product" whereas under the EMC, the "identification of the apparatus") or similar but the same requirements in terms of the information to be provided (e.g. under LVD it is required to provide the date when the CE mark was affixed to the product whereas under the EMC, the date that the declaration of conformity was signed). However, the discussions so far did not suggest any conflicts or problems for the manufacturers.

Analysis of costs of compliance with Union harmonisation legislation

The information presented in this section is based on the in-depth interviews with 3 manufactures, one small and two large size firms[100].

Table 7-19: Basic information on the firms interviewed

Firm	Firm size	Annual sales from product in the EU	Main markets
A	Small (ca. 350 employees)	Ca. 350 thousand units	Ca. 100% of sales in the EU
B	Large (>1000 employees)	2 million units	Ca. 100% of sales in the EU
C	Large (>4000 employees)	1.8 million units	80% of sales in the EU

On the basis of the discussion with firms the process followed by manufacturers of refrigerators to ensure compliance with the Union harmonisation legislation includes:

- familiarisation with the applicable Union harmonisation legislation and the respective requirements, identification and purchase of relevant standards and in some cases other preparatory actions in training of staff.
- introduction of changes to the product design and the production process to ensure compliance with the requirements
- conformity assessment procedures including the relevant testing and the development of the technical file, the use of notified bodies for certification if/when required, preparation of declaration of conformity (DoC), CE marking and placing in the market
- other activities in response to requests of the market surveillance activities

Preparatory actions: Familiarisation with relevant legislation and purchase of standards

A common practice among most economic operators (not only manufacturers but also distributors) is to develop a database where all applicable legislation is indicated, the relevant harmonised standards are listed along with links to the technical file which demonstrates how the essential requirements are met (see below). The databases are continuously updated to reflect changes in the legislation, to standards or any information related to the technical files. In the case of both small firm A and large C around 1 FTE is allocated solely to the management and update of the database which covers all domestic appliances products produced by the firm. Additional staff working in product development and testing makes use of the database and contribute to maintaining and storing information in the database.

Sophisticated relational databases are also used among larger size companies[101] in order to manage the complexity of keeping track with Union harmonisation legislation, standards and amendments, but equally ensuring that relevant links are kept under each product group to technical documentation required by the firm itself for monitoring regulatory compliance, risk management and quality assurance purposes.

100 It has not been possible to collect data from a manufacturer of gas refrigerators. However, some data on costs of the gas appliances were available in the evaluation of the Gas appliance Directive and are included in the relevant sections of the report.

101 In 2012, the firm interviewed had a turnover of EUR 150 million and 350 employees. Around 10% of the turnover came for the sales of refrigerators. The firm is a subsidiary of a larger enterprise

The majority of manufacturers in the sector rely on the use of European harmonised standards in order to meet the essential requirements. In the case of refrigerators the number of mandatory harmonised standards is around 20 but additional standards (e.g. related to quality management) are also often used by firms. While there is no fixed period for revisions of those standards, their average life span is around 6-8 years. Data from two firms indicate that the average annual expenditure for purchase and/or update of technical standards is usually in the range of €700-1,000.

Compliance with the applicable Union harmonisation legislation

Ensuring compliance with the applicable Union harmonisation legislation often requires changes to existing product design or new product development. Furthermore, the introduction of new products requires product design work and testing to ensure that the new products are in compliance with requirements.

The small size firm A indicated that in total around 7-8 engineers work full time in product design and quality for all products in the production line, around 10% of which focusing on refrigerators (0.8 FTE). However, since Firm A outsources most of the manufacturing to OEM suppliers in third countries, suppliers absorb most of the compliance costs in their own design process prior to production. Nonetheless, around 0.5-1 FTE is allocated to the testing of all products which includes testing according to harmonised standards and also reliability checks on a periodical basis. Tests for the EMC and LVD Directives take place in the firm's premises while other tests are conducted outside. It was estimated that the total annual costs for testing and certification for all products produced account to €200k/year including the expenditure for testing equipment with costs for refrigerators around €20-30K for the 20-30 models of refrigerators that are placed in the market on an annual basis (around €1k/model).

For large firms B and C, 5% of the total number of employees in the specific product line is working on product development activities, around 100 for firm B and close to 300 for Firm C. For the development of a new product Firm B usually spends 1-1.5 year (i.e. 100-150 FTE), 80-90% of which is allocated to the product development and product quality testing. Firm C indicated that a typical product development project - leading to basic model with multiple variants – has duration of 3 years and a budget of up to €100 million. For the large size firm B, testing for product quality and internal market legislation are rather closely linked and it was not possible to get specific estimates of testing costs.

Thus, some of the above costs are not directly linked to Union harmonisation legislation and firms select to incur as part of their own product quality strategy. However, it was not possible to get estimates of the shares of costs that should be linked to IM legislation. For Firm C more than 60% of the total costs are linked with product design activities, around 50% of which (€30 million) is directly linked to compliance with Internal market legal requirements.

Among the different tests, the firms made reference to those related to RoHS which require an examination of the substances in the materials used for fridge appliances. Firms B and C stated that the most costly tests linked to the IM legislation are those related to the Ecodesign Directive for energy efficiency and noise. A typical noise chamber costs around €1 million while for the costs of equipment for energy efficiency testing for the Ecodesign Directive – which is used for a range of products – are around €100 k. Of course, these are generally one-off investments on equipment that may last for more than 5 or 10 years. The tests for EMC and LVD Directives were also considered as costly due to equipment costs but no specific

figures were made available. According to Firm B a rather problematic point appears to be the tests concerning the Regulation on the materials and articles the come in contact with foodstuff. The current provisions of the legislation are considered as rather unclear (making reference to materials that "may" come in contact with foodstuff) and often lead firms to perform a broader range of tests than what could be the case if the provisions were more specific.

Conformity assessment procedures

The last part of the process includes the preparation of the technical file, the inspection of the notified bodies and certification, preparation of the DoC and the required information manual and the placing of the CE marking.

The results of the necessary tests is also brought together in a technical file and the remaining documentation, parts of which also need to be translated to English. According to Union harmonisation legislation this information needs to be stored for at least 10 years and updated whenever there are changes. Significant time is often dedicated for the collection of information from suppliers of specific components or finished products.

While not necessary for all the pieces of applicable Union harmonisation legislation, Firm A uses the services of a third party (Notified body) for conformity assessment. This is part of the firm's risk management strategy and introduces costs that are higher than those necessary to meet the minimum requirements imposed by Union harmonisation legislation. The costs for certification for all products is included in the €200k/year indicated earlier.

Large Firm B indicated that around €100k is spent on an annual basis for third party services that most often go beyond the minimum required (e.g. testing of production facilities) while Firm C tries to keep the costs of third party to the minimum and spends no more than €10-20k for third party certification. Firm C also stated that there are 3 FTE working on the preparations of DoCs and ensuring that CE marking is appropriately applied in all products. In total, while a specific figure was not provided, Firm C estimated that the conformity assessment procedures and preparation of documentation represents no more than 15% of the total budget allocated to the development of a new model. Firm C also indicated that the requirement for placing an energy label on each appliance adds a cost of around €1/appliance.

Firm A suggested that there is some confusion in relation to the information and level of detail to be included in the DoCs and whether legislation and the relevant standards need to be included but this was not shared by the representatives of large Firms B and C. Still, even for small Firm A this part does not represent a sizeable cost. The firms interviewed did not indicate any problem with the requirement for a single declaration. However, CECED indicated that some of manufacturers may find it problematic as they have separate departments each having responsibility for preparing conformity statements within their own competence. In such case, the requirement for a single DoC may introduce some costs for changes to structures and procedures. Unfortunately, none of the firms was able to provide more specific estimates of the time and resources allocated to these activities. However, on the basis of the information provided this did not appear to represent sizeable part of the total costs.

In relation to gas refrigerators falling under the Gas Appliances Directive, the evaluation of the Directive found that the introduction of GAD led to additional costs, particularly with regard to testing/certification and labelling/CE marking. 102 However, the costs of testing and certification for all types of gas appliances – not only gas refrigerators – were estimated at around 0.1% of the annual sales value of gas appliances. Response to market surveillance authorities

Market surveillance authorities make requests for technical information and possibly for testing of products approximately once a month although this varies significantly among countries. The amount of time dedicated to respond to enquiries from market surveillance authorities varies depending on the nature of the request (e.g. what information is required from the technical file, which Directive the request relates to, or whether information in relation to conformity of all applicable legislation has been asked for). Typically, authorities give to firms 10 days to respond to requests. The Ecodesign, RoHS, EMC and energy labelling Directives are those for which there are most often requests for information by the market surveillance authorities. A common perception is that big firms tend to be asked more frequently than SMEs to provide technical information. The large firm interviewed indicated that the related resources dedicated are difficult to estimate but are generally part of the work of the 10 FTE dedicated to compliance.

Business as usual

All firms indicated that they would probably conduct large part of the tests, primarily those related to product safety, even in the absence of the legislation and that production quality management would still be part of internal procedures irrespective of the regulatory framework requirements. Even parts of the costs for tests from third parties could be considered as part of a business as usual (no Union harmonisation legislation) scenario. Even more demanding product reliability tests – that are voluntary under the GPSD - are often conducted by established firms that want to ensure the quality of their products. Similarly, given that issues such as energy efficiency are the focus of consumer organisations related tests would also have to take place – even if not demanding – in the absence of relevant requirements under the Ecodesign and Energy labelling Directive. Thus, large parts of the testing costs incurred – on average up to 50% - are considered as business as usual. Even the product design is in most respects not driven by the legislation but primarily by the general product development process. The main concern for manufacturers is when requirements introduced do not provide sufficient lead time in which case these design costs cannot be integrated in the product design cycle.

Assessment of costs of Union harmonisation legislation for the whole sector

On the basis of the information provided we have attempted to estimate the costs of compliance for the whole refrigerators sector. The provided figures include the information concerning the Business as usual scenario. Assumptions have been made concerning the number of firms affected since, besides the 10 large firms indicated by EGMF there are also a number of smaller size manufacturers particularly in the professional market segment. As indicated in section 2, the calculations for the whole sector were based on an estimated number of 100 firms, an annual turnover of €4.8 billion and a number of units sold/year of €24.6 million.

102 RPA (2011), Ex-post evaluation of Directive 2009/142/EC on appliances burning gaseous fuel, http://ec.europa.eu/enterprise/dg/files/evaluation/03_2011_finalreport_gas_en.pdf

The table overleaf summarizes the analysis of the costs for different aspects. The main point is that the estimated cost for compliance activities for the whole of the domestic refrigerators and freezers sector is around €160 million/year. Around 60% of this (€86 million) is considered as directly resulting from the internal market legislation while the remaining 40% are costs that would most probably occur even in the absence of legislation. Total substantive compliance costs – product designs related activities, testing and testing equipment – are estimated between 80-90% of the total compliance costs while administrative costs (information collection, preparation of technical files, DoC) represent 10-20%.

Table 7-20: Summary of main costs of compliance for domestic refrigerators industry

	Unit of measurement	**Average cost/unit**	**Total quantity**	**Industry wide costs/year**
Own human resources occupied on compliance activities				
Total	Per annual turnover	2.9% of turnover	€4.8 billion	€140 million
Familiarisation with legislation				5-10%
Share of product design and testing activities				80-90%
Conformity assessment (technical file preparation, information manual, DoC and CE marking)				5-10%
Share of human resources costs in absence of IM legislation (BaU)				40%
Net human resources compliance costs				€86 million
Costs of testing equipment				
Total	Per annual turnover	0.33% of turnover	€4.8 billion	€16 million
Share of expenses even in absence of IM legislation		Ca. 48%		
Net costs for testing equipment				€8.3 million
Costs of third parties				
Total	Per annual turnover	0.5% of turnover	€4.8 billion	€2.6 million
Net third party costs – only for IM		60%		€1.8 million
Total annual compliance costs	**Per firm**	**€1.59 million**	**100**	**€158.6 million**

Total net compliance costs		**€ 0.86 million**	**100**	**€86 million**
Substantive compliance costs				80-90%
Administrative costs				10-20%
Share in total industry turnover				**0.2%**
Basic assumptions:	Total units sold: 24.6 million/year Market size: €4.8 billion Number of firms affected: 100 (20 large and 80 small)			

Overall conclusions

The product groups examined in this case study are refrigerators and freezers for domestic use, also known as cold appliances. The total market for refrigerators in 2011 was close to 24.6 million units with a value of the market of EUR 4.8 billion sold/annum. Refrigerators represent around 42% of the market, combined units 38% and freezers 20%. The total volume of production in Europe is around 15 million units with a value of €3.8 billion while imports represent around 50% of the market. Significant part of leading refrigerators and freezers brand are designed in Europe but manufactured outside Europe and subsequently imported. In total, around 10 large size companies – most of them present in the market with multiple brands – represent more than 85% of the market in Western and Eastern Europe and 22 manufacturers capture 98% of the market in Western Europe and 90% in Eastern Europe (including non-EU countries).

Cold appliances are covered by 9 different pieces of IM legislation that cover health and safety aspects (Low Voltage Directive, Regulation on materials and articles that come in contact with food, RoHD Directive on hazardous chemicals), electromagnetic compatibility (EMC Directive), energy consumption and noise (Ecodesign and Energy Labelling Directive). The Gas appliances Directive and Pressure Equipment Directive are also applicable to a small share of cold appliances.

The analysis suggests that cost for compliance activities for the whole of the domestic refrigerators and freezers sector is around €160 million/year, representing no more than 0.2% of annual turnover. Around 60% of this (€86 million) is considered as directly linked to the implementation of the internal market legislation while the remaining 40% are costs that would most probably occur even in the absence of legislation (business as usual). Substantive compliance costs – costs related to product design, testing and testing equipment – are estimated between 80-90% of the total compliance costs while administrative costs (information collection, preparation of technical files, DoC) represent 10-20% of the total. The compliance costs are driven primarily by the compliance with environmental legislation (mainly the Ecodesign Directive) which, in contrast to health and safety aspects, is not considered as business as usual.

Sources of information

References

- Eurostat Structural Business Statistics Database and PRODCOM

- Euromonitor Market research data on consumer appliances
- Text of applicable IM legislation and relevant standards
- Guidance documents of LVD and MC Directives
- Input from one medium and one large manufacturer/importer of refrigerators and freezers.

Interviews

- Interview with industry association: CECED
- 3 interviews with manufacturers of refrigerators/freezers

3.10.4 Case study 4 - Lifts

Introduction

This case study assesses how Union harmonisation legislation affects different economic operators involved in the manufacture, import and distribution of lifts for persons (covered under the Lifts Directive). In order to help shed light on the interaction between different types of Union harmonisation legislation, and issues around whether there are sufficiently clear demarcations between such legislation, it also however addresses other types of lifts covered through the Machinery Directive 2006/42/EC, including lifting hoists, lift platforms and escalators and certain types of lifts for goods not covered by the Lifts Directive. The applicable Union harmonisation legislation specific to each product is mapped out and the administrative costs – and to the extent possible substantive compliance costs – in meeting these regulatory requirements are then assessed.

The rationale for the selection of lifts was that:

- The lifts sector, while dominated by four large firms, has a large number of small and medium-sized enterprises ("SMEs");
- The lifts sector has longstanding experience of implementing Union harmonisation legislation since the first Lifts Directive was adopted in 1995;
- The Lifts Directive is one of nine Directives that formed part of the Alignment Package. It is important to examine stakeholder views on how the alignment process has had an impact on strengthening the coherence of Union harmonisation legislation; and
- The case demonstrates the advantages of having a clear delimitation in Union harmonisation legislation in defining the borderline between different Directives in order to ensure legal clarity for economic operators.

The case study is based on interviews of EU-level and national industry associations, manufacturers and installers of lifts and manufacturers of safety components for lifts, as well as analysis of key legislative documents and published reports.

Product definition and structure of the sector

The lift industry is dominated by four very large companies (Kone, Otis, Schindler, ThyssenKrupp Elevator), of which three are European (one non-EU) and one from the USA. These four companies and their subsidiaries have a high combined share of the European market, estimated at 60%.

The lifts industry has undergone substantial changes as a result of globalisation, with evidence of increased industry consolidation in statistics on market structure.[103] The estimated size of the lifts market in Europe, according to the Europe SME lifts association (EFESME) was about €15 billion in in 2009. However, this extends beyond manufacturing and the placing of products on the market (covered by IM legislation). Lift manufacturing and installation only accounts for one third of the total market size, while the remainder is made up of after-sales services (maintenance 41%, repair 7%, and modernisation 18%). The total number of lifts in operation in the EU was estimated at about 4.7 million units. Further data has been obtained for 2009 from NACE and PRODCOM on the size and structure of the lifts industry. "Lifts and escalators" fall within the NACE classification "manufacture of lifting and handling equipment".

NACE data shows that there are over 9,500 enterprises in the lifts sector, the great majority of which are SMEs, although there has been a decline in the number of lifts companies in the 2008-2010 period (the latest period for which data was available), reflecting on-going industry consolidation processes.

Table 7-21: Number of enterprises – lifts sector

Nace Code	2008	2009	2010
28.22	9,970	9,720	9,525

Source: Eurostat

The production value of lifts is shown in the following table. The data shows that in parallel with the economic and financial crisis there was a major downturn in the lifts industry but that the production value has since stabilised.

Table 7-22: Production value of the lifts sector (€ thousands)

Nace Code	2008	2009	2010
28.22	59,072.38	42,603.23	43,688.83

Source: Eurostat

In the following table, Prodcom data shows that a total of about 255,000 lifts (and skip hoists) were produced in Europe in 2012, of which the majority were electrical lifts and the remainder hydraulic.[104]

103 http://www.lift-report.de/index.php/news/361/373/Industry-report---Lifts-and-escalators-an-industry-in-flux

104 It should be noted that skip hoists are not lifts and are not subject to the Lifts Directive. However, Eurostat does not provide further disaggregation of Prodcom data.

Table 7-23: Sales volumes for lift manufacturing industry (2012)

	Units	Median price (€)	EU27 production value (€000)
Sales volumes			
28221630 (electrically-operated lifts and skip hoists)	133,000	18,242	2,157,000
28221650 (lifts and skip hoists excluding electrically-operated)	122,000	14,207	802,766
Total sold volume	255,000	-	2,959,766

Source: Eurostat

Manufacturing in the lifts sector is strongly export-oriented and has generated a significant volume of exports, although the interviews found that a lot of manufacturing that used to take place within the EU has been moved to lower-cost producer countries outside the EU. The table below provides a summary.

Table 7-24: Production value – lifts sector (2010)

	Export values (000s)	Import values (000s)	Production Value (000s)	Apparent consumption (Production+ Imports- Exports)
28221630 - Electrically operated lifts and skip hoists	599,774,450	37,947,640	2,343,821,623	1,781,994,813
28221650 - Lifts and skip hoists (excluding electrically operated)	165,383,210	17,338,000	628,899,470	480,854,260
Total	**765,157,660**	**55,285,640**	**2,972,721,093**	**2,262,849,073**

Source: Eurostat

With regard to employment, various industry surveys indicate a total European workforce in the lifts for persons sector (manufacturing, installation and servicing) of between 15,000-18,000 people.[105]

Analysis of applicable Union harmonisation legislation and standards

This section maps out relevant Union harmonisation legislation since the study seeks to

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provide estimates of the costs associated with complying with Union harmonisation legislation (dividing these costs into administrative costs and substantive compliance costs). Reference is also made to applicable environmental legislation where this has a major impact on manufacturers of industrial goods. However, in the quantitative analysis, we do not seek to quantify the impact of such legislation, rather only Union harmonisation legislation for industrial products.

In the first table, relevant applicable Union harmonisation legislation for lifts for persons is mapped out. The table shows that, unlike some of the other product cases, the lifts sector is subject to relatively few pieces of Union harmonisation legislation.

Table 7-25: Legislation applying to lifts

Applicable legislation	Scope of products included	Main administrative requirements for economic operators
Lifts Directive	Lifts for persons, persons and goods or goods alone (if the carriers is accessible) with speeds of more than 0.15 m/s	• Conformity assessment - obligation of the installer of lifts or manufacturer of safety components • Produce a DoC (note: DoC required for both installation of lifts and for each safety component) • Keep technical documentation copies of EC type-examination certificates and their additions for a period of 10 years from the date on which the safety component was last manufactured or the date on which the lift was placed on the market • 'CE' marking - must be visibly affixed to lifts or to certain safety components of lifts • Rules relating to manufacturing apply to both installers of lifts and to manufacturers of lift safety component (or authorized representatives)
		All economic operators Traceability obligations - identify name of installer, manufacturer, name / ID number of Notified Body having carried out conformity assessment **Installers and manufacturers** Conformity assessment remains the obligation solely of the installer or the manufacturer of safety component **Importers** • Verify that the manufacturer of safety

Applicable legislation	Scope of products included	Main administrative requirements for economic operators
		components has carried out the applicable conformity assessment procedure and has drawn up a technical documentation. • Verify that the safety components for lifts are correctly marked and accompanied by the required documents. • Keep a copy of the DoC and indicate their name and address on the product, or where this is not possible on the packaging or the accompanying documentation.
EMC Directive	Applies to lifts for persons	Testing products for Electromagnetic Compatibility interference Conformity assessment procedure for apparatus mandatory CE marking on apparatus required in accordance with Annex V.
Machinery Directive 2006/42/EC	Lifts for goods only Slow-moving lifts (speed less than 0.15 m/s) Construction site hoists Lifting platforms for persons with impaired mobility	<u>Manufacturers</u> • Ensure conformity assessment procedure for lifting machinery carried out • Produce a DoC (note: DoC required for both installation of lifts and for manufacture of each safety component) • Keep technical documentation copies of EC type-examination certificates and their additions for a period of 10 years 'CE' marking - must be visibly affixed to lifts or to certain safety components of lifts • Construction file and risk assessment. The latter should contain: (i) a list of the essential health and safety requirements applied and fulfilled; (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks;

Applicable legislation	Scope of products included	Main administrative requirements for economic operators
		(iii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards; (iv) any technical report giving the results of the tests carried out either by the installer or manufacturer or by a body chosen by the manufacturer or his authorised representative; and (v) a copy of the assembly instructions for the partly completed machinery.

The Lifts Directive covers Lifts for persons (and goods). Article 1(1) states that the lifts to which the Directive applies are those "serving buildings and constructions". The Directive is clear as to whether spare parts and components are included, since it covers both lifts and safety components for lifts, both of which must be CE-marked. Likewise, other Directives that apply to different types of lifts such as Directive 2000/9/EC relating to Cableways (e.g. chair lifts, drag lifts) also applies to safety components and also to sub-systems.

A number of different types of lifts are **excluded from the Directive's scope**, namely:

- lifting appliances whose speed is not greater than 0,15 m/s;
- construction site hoists;
- cableways; including funicular railways;
- lifts specially designed and constructed for military or police purposes;
- lifting appliances from which work can be carried out;
- mine winding gear;
- lifting appliances intended for lifting performers during artistic performances;
- lifting appliances fitted in means of transport;
- lifting appliances connected to machinery and intended exclusively for access to workstations including maintenance and inspection points on the machinery; and
- rack and pinion trains, escalators and mechanical walkways.

The legislation applies to goods alone if the carrier is accessible i.e. a person may enter it without difficulty, and fitted with controls situated inside the carrier or within reach of a person inside the carrier. Other types of lifts to carry goods are included within the scope of the Machinery Directive 2006/42/EC.

Analysis of costs of compliance with Union harmonisation legislation

Feedback was obtained on how companies in the lifts sector ensure compliance with the relevant Directives (listed in Table 7-25 above). In order to ensure their compliance with the legislation, the large manufacturers tend to employ specialist staff at their research and development centres and production sites, as well as in their distributing companies (typically nationally-based) that are responsible for installation, service and maintenance. Compliance must be ensured at the design and development stage (typically a one-off task for each new or revised product) as well as at the installation stage for each individual lift unit. It should be noted that the EU legislation only relates to new products; service, maintenance and renovation (including of lifts pre-dating the Lifts Directive) is covered by national legislation that differs from country to country.

Lifts differ from many other industrial products in that compliance has to be undertaken in three main phases, which may take place at different sites in different countries. New lift models are, firstly, *designed* to take into account Union harmonisation legislation. For the big four manufacturers, design tends to be undertaken at specialist research and development (R&D) centres, given the obvious economies of scale. For example, one of the firms interviewed has eight R&D centres globally, of which three are in the EU. Second, new lifts must be *manufactured* to comply with the legislation. Again, the manufacturing of lifts may often be done centrally to make use of economies of scale. The same firm has multiple global production sites, of which three are in the EU. Last, the installers of lifts must ensure that *installed* products satisfy a proper conformity assessment undertaken on site before they become operational. In contrast to the design and manufacturing of lifts, installation is typically done by nationally-based firms given the need for proximity. The four large firms have operating companies or authorised distributors in each of the 27 Member States and in many other countries worldwide. SMEs clearly differ from the four global players in that respect, since design and production is more likely to take place at the same site.

At each phase, the task of ensuring compliance is very different. Designing a new lift product or model is clearly a lengthy task, undertaken some considerable period before the product is placed on the market. The design process involves intensive testing, whether required by the legislation or not. At the design stage, the requirements of the legislation must be taken into account and thus limit the options for design but without creating a specific additional stage in the process; the requirements are "designed in" to the product. The manufacture of lifts in compliance with the legislation is relatively straightforward, provided that the product has been designed to comply and provided that the lift is made according to the specification. However, the installation of lifts tends to require numerous refinements to ensure the lift functions well within its environment. These refinements result in a corresponding need for repeated checks to ensure compliance with the legislation, as well as with health and safety requirements in general.

The particular nature of this production chain also creates specific costs and benefits compared to other products. There is the need for specialist staff that have expert knowledge of the legislation at all sites, i.e. the locations where R&D, production and installation take place. This is in contrast to a product such as mobile phones, for which there is no separate "installation" phase; once such products leave the production site, the manufacturer can be sure that the product is compliant (unless it is tampered with at a later stage). Compliance is thus a "decentralised" task, creating the need for communication between disparate sites at different points in the production chain, e.g. for feedback from installers to designers about the practical difficulties faced in complying with the legislation at the point of installation.

However, the nature of the product (i.e. physically large and fixed in a certain location) facilitates enforcement of the regulation and market surveillance; products can be tracked and traced much more easily than other products, making it hard for rogue or ill-informed manufacturers to place non-compliant products on the market. Similarly, end-users are unlikely to purchase non-compliant products inadvertently, e.g. via a website.

The size of the four largest manufacturers enables them to employ specialist compliance staff in-house. As a result, the general approach in the lifts industry is to gain approval of the installer's full quality assurance system under Module H, which avoids the need for EC type-approval of each unit installed. However, the system used tends to vary according to the nature of the building; other Modules tend to be used for unusual buildings. Two of the companies interviewed pointed out that they would tend to comply with the harmonised standards as much as possible, reflecting the fact that the Lifts Directive covers a very specific product, unlike some other directives. Compliance with harmonised standards also makes exporting easier to third countries that have unilaterally adopted the EU standards (e.g. many of the Asia-Pacific countries) and also simplifies maintenance.

Feedback from industry associations was that European standards play an important role in supporting the compliance of SMEs with EU legislation, since almost all SME producers of lifts use ropes and follow such technical standards. However, the four large manufacturers do not use standards in order to comply with the essential requirements, since they use belts. There is a reluctance among the biggest industry players to be involved in standardisation because of concerns about maintaining competitive edge and because newer types of lifts are patented.

Preparatory actions: familiarisation with relevant legislation and purchase of standards

For the two large companies interviewed, the process of **familiarisation with legislation** was not unduly costly. Their very large size makes it affordable to employ staff specialising in EU and other legislation. For example, such staff are a very small part of the workforce for the big four players with more than +40,000 employees worldwide. Moreover, the availability of specialist staff allows the large companies to be well-connected to the European Commission and to participate in various forums and working groups at EU level, which helps familiarisation.

The greatest costs related to familiarisation with the legislation tend to occur when there are changes in the harmonised standards or in the interpretation of those standards, e.g. by national authorities. One interviewee reported that the cost of familiarisation with applicable requirements was not particularly costly, nor was purchasing the relevant standards. (Standards in the UK typically cost between £50 and £300 each). However, reviewing the existing harmonised standards could take time, as could the process of familiarisation across a large company, given the need for constant communication of the information obligations of the legislation to a much wider group of people. For example, the requirements of the legislation are just one part of the knowledge required by those installing lifts; those staff would not necessarily be as pro-active as the compliance officers in ensuring that their knowledge remained up-to-date, hence the need for continued communication as well as regular training. None of the companies interviewed incurred costs in using external consultants to support preparatory work.

Compliance with the applicable Union harmonisation legislation

Changes to the requirements of the legislation or to the standards have the greatest potential to impose costs on manufacturers where they require changes in **processes and product design**. Indeed, the nature of lifts requires very considerable investment to be undertaken in the design and development of new products over long time-periods. Where changes occur in the legislation on a regular basis or at short notice, they have the potential to impose substantial costs on manufacturers.

However, the companies interviewed pointed out that the costs of adapting processes and product design are much less where changes in the legislation are announced some time before they come into effect. In general, lift products are continually evolving, e.g. in response to technological innovations and the R&D centres of the large companies are constantly seeking to improve their products, whether through new models or new versions of existing models. The development process involves constant checking of prototypes to ensure safe and effective functioning, as well as compliance with the legislation. Whilst such checks are time-consuming, they are seen as part of the overall development cost. Indeed, it becomes hard to separate out the cost of checking compliance with the legislation from the cost of other checks. As one interviewee stated, "the product specification is not costly as you have to do it anyway; in that sense, the Directive just limits your options, it doesn't create costs".

Conformity assessment procedures

The companies interviewed were unanimous in highlighting the additional costs imposed by **conformity assessment procedures** both in development and installation. The development of a new or revised model tends to require continual refinements to the product. When a product is designed, it has to be considered by a notified body and go back each time it is revised (as part of the overall development process). Manufacturers/installers are required to retain the product certification at each stage of development, which creates a cost. It would appear therefore that it is not so much the cost of the developing a product that conforms to the legislation which is burdensome but the cost of checking conformity. Such costs tend to be additional and therefore costly. As noted above, approval of the installer's full quality assurance system under Module H avoids the need to have each individual unit checked.

Within the conformity assessment procedure, it would appear that the main costs are imposed by the requirement to collect all information required for technical reports. For example, collecting information from third party suppliers of components can be particularly burdensome due to the lifecycle of the product. The compilation of test reports is equally important and burdensome but tends to be viewed as a "business as usual" cost, since the manufacturers operate their own test procedures and compile test reports in any case. Similarly, product identification requirements (e.g. serial number) and the maintenance of technical information for at least ten years tend also to be seen as "business as usual" costs, in the latter case, because the life-cycle of a lift is 25-30 years. It may be possible to reduce some costs by allowing increased use of electronic documentation.

The large manufacturers tend to undertake their own tests themselves, using in-house staff and following quality assurance systems approved under Module H. Clearly, such costs are significant, given the need for full-time staff. However, the cost of notified bodies tends to be modest; one manufacturer reported that third party notified body inspections are only used to verify its quality assurance system. No company reported their own internal reviews of technical documentation to be particularly burdensome, given the availability of in-house

staff; one of the companies mentioned that such reviews were undertaken by the global headquarters. In the case of lifts, periodic inspections of installed products are the responsibility of the customer and, in any case, fall under national rather than EU legislation.

Declaration of Conformity and CE marking

Overall, the **Declaration of Conformity and CE marking** do not appear particularly burdensome for manufacturers, except for the requirement to keep information up to date, e.g. in relating to changes in the harmonised standards or in the legislation. Since each lift installed represents a unique product, the information has to be created every time, which creates an administrative burden if the DoC is to be kept up-to-date. However, since the CE marking and DoC also have to cover the equipment and environment surrounding the lift, this step can be particularly burdensome in a minority of installations. Since, typically, the lift manufacturer will not have constructed the surrounding environment, e.g. the hoist way, the process of issuing the DoC and CE marking can prove problematic. For example, one company reported that some customers may pressure the lift installer to issue a DoC (e.g. by withholding payment) in cases where the customers themselves have not fulfilled their own obligation to develop a compliant environment for the lift.

Other activities necessary to comply with Union harmonisation legislation

None of the companies interviewed referred to costs resulting from any **other activities** required by the legislation.

Analysis of administrative costs for each relevant step indicated

Since the Lifts Directive refers to a very specific product, this Directive accounts for the majority of administrative costs. However, the administrative costs tend to be minimised by the fact that the harmonised standards of the Lifts Directive have been developed to take into account the regulatory compliance requirements applicable to lifts set out in other relevant directives, notably the Electromagnetic Compatibility Directive (EMC). This means that if a manufacturer follows the standard and carries out a conformity assessment based on the standard, they will have met their regulatory obligations across all relevant pieces of legislation.

Similarly, products covered by the Machinery Directive (e.g. escalators) and using the harmonised standards of that Directive will in meeting these requirements have also complied with the EMC requirements since they are incorporated into the standard. Two companies referred to the need to take into account the Ecodesign Directive, with respect to the buildings in which lifts are installed. One of the companies also referred to the need to comply with the ATEX Directive on occasions, i.e. in potentially explosive atmospheres.

None of the firms were able to provide detailed costs for every step in the process. However, we can make some statements based on the evidence available.

- **Familiarisation with legislation** is undertaken in-house by the large companies using specialist staff; one company stated that each of its national subsidiaries had at least one compliance officer and one final inspector, both of which would possess in-depth knowledge of the legislation and would keep themselves up-to-date; the same company estimated that the total number of compliance and inspection officers across the EU to be around 100. The other company referred to six specialist staff ("Blue collar"

operators, i.e. technicians and associate professionals) in one of its nationally-based distributing companies (in a medium-size country).

- **Processes and product design**: the large manufacturers tend to undertake their own tests, using in-house staff and following quality assurance systems approved under Module H, which serves to minimise cost; in addition, one large company suggested that changes to the legislation could incur costs of €550k-€600k if they require changes to the reference numbers for lift products.

- **Conformity assessment procedures**: The Lifts Directive is the most burdensome piece of legislation, particularly the requirement for compulsory third party conformity assessment procedures and the supporting technical documentation; this is much more detailed than the other Directives. Lift manufacturers undertake their own extensive testing of their products both in development and in installation to ensure quality and safety; in most cases, such checks can readily encompass the requirements of legislation. To a large extent, the testing required by conformity assessment would therefore tend to represent a "business as usual" cost rather than an additional cost imposed by the legislation.

- The administrative requirement related to conformity assessment procedures undertaken in the product development stage are quite high initially, but occur only once (for each model or version). The larger companies do not incur costs of notified bodies in the installation of lifts, except in special cases where those lifts do not follow the harmonised standards; one national subsidiary in a medium-sized country referred to the need to use a notified body for the certification of lift units around 3 or 4 times per year at a cost of €500 per time, i.e. €2k per year – a cost described as "minimal compared to the cost of installing lifts". The administrative burden associated with conformity assessment is quite high as inspections have to be undertaken for each new lift installed. There is also the cost of buying and maintaining testing equipment; one subsidiary of a large company reporting that cost to be around €5k per year depending on the frequency of tests.

- **Declaration of Conformity and CE marking**: in general, this task is not seen as particularly costly, except that gathering the information required for the DoC takes time. The possibility to issue a single DoC covering all Directives significantly reduces the administrative costs of this step.

Compliance costs

As for administrative costs, most compliance costs relate to the Lifts Directive, which in any case requires compliance with the EMC Directive. Again, no firm was able to provide detailed costs for every step in the process. However, we can make some general statements based on the evidence available.

Where changes occur in the legislation on a regular basis or at short notice, they have the potential to impose substantial costs on manufacturers in the design and development of products and production processes. For example, one manufacturer suggested that any technical adaptation required by the legislation would cost around €500k-€1m in terms of new product development; such costs would relate to ensuring conformity of design, a physical examination of 8-10 different product platforms to be certified, additional documentation for the conformity assessment process, costs for sales companies, training for sales and

production staff, updating sales literature.

In the long run, particularly where changes in the standards or in the legislation are introduced with sufficient notice, the costs of compliance are inseparable from the "business-as-usual" costs of designing and developing new products and production processes. It may be that the legislation or the standards exclude some options for design or production that would have delivered cost-savings, but these potential "missed savings" were not specifically mentioned by the companies interviewed.

Conclusions

It would appear that the main determinants of the level of compliance costs are the regularity and notice period of any changes in the legislation or in the harmonised standards. New or revised models are continually being designed and developed to reflect technological advances. Provided that changes are not made too frequently and are signalled well in advance, manufacturers appear able to design and develop compliant products without incurring additional compliance costs; to a certain extent, compliance is "designed in". Changes brought in at short notice can impose very significant costs, as units already in production have to be revised; this can prove particularly problematic where contracts have already been agreed with customers. Frequent changes in the legislation or, particularly, in the harmonised standards also impose a significant compliance cost by requiring extensive information and retraining of staff to ensure that "front-line" staff, e.g. lifts installers are aware of, and apply the revised standards.

For the large companies interviewed, it is clear that the administrative burden represents a somewhat modest financial cost compared to total costs/turnover, as evidenced by the number of specialist staff compared to the total workforce. SMEs may face a difficult choice between incurring the overhead involved in having specialist staff and not keeping up to date with changes in the legislation. Moreover, they rarely have the capacity to engage in the various processes at EU level related to setting standards.

Overall, it would appear that the various Directives applying to lifts are consistent and streamlined, i.e. compliance with harmonised standards of the Lifts Directive implies compliance with the other Directives. This consistency limits the costs of compliance and, particularly, the administrative burden associated with the legislation. It may therefore be safe to conclude that any negative cumulative impacts of the legislation are modest. Moreover, it is reasonable to assume that most, if not all, Member States would introduce legislation covering lifts in the absence of the Lifts Directive, given the risks to safety inherent to this product. The EU legislation may therefore have reduced compliance costs and the administrative burden by enabling the application of harmonised standards and a consistent compliance process across all Member States. However, EU legislation does not apply to services, maintenance and renovation. Any risks to safety must therefore be covered by national legislation, which will inevitably vary from country to country. It may be worthwhile for the Commission to explore the possibility of bringing service, maintenance and renovation of lifts within the scope of EU legislation or to find ways to encourage a gradual, voluntary convergence in the requirements of national legislation.

Assessment of costs of Union harmonisation legislation for the whole sector

On the basis of the information provided, we have attempted to estimate the costs of compliance for the installation of lift units, including electrically-operated (NACE 28221630)

and other (NACE 28221650). In offering such estimates, we have taken into account certain characteristics of the sector and of firms therein.

First, companies involved in the manufacture and installation of new lifts typically also undertake modernisation, repair and maintenance, which are not subject to EU legislation. For that reason, we have estimated costs of compliance as a proportion of production value rather than of the total revenues of such companies. Total revenues for manufacture and installation are based on multiplying median prices (sourced from PRODCOM) against the total number of units sold by each company.

Second, the estimates in the table below do not include data from manufacturers of components. Of course, the manufacturers of components must comply with the relevant legislation and this imposes a certain cost. However, those compliance costs differ in nature from the costs incurred by manufacturers and installers of lift units and are therefore excluded from the table.[106] For example, conformity assessment of new components is a one-off event, whereas each new lift unit must be assessed at the installation stage. Information from the interviews of such companies has instead informed the qualitative text above.

Third, the companies interviewed were generally unable to separate substantive compliance costs (in product design, manufacture and installation) from business-as-usual costs. All interviewees agreed that changes in the legislation or in the standards introduced at short notice tended to impose very significant substantive compliance costs. In particular, any units already in production or already manufactured but not yet installed required technical adaptations in order to be compliant with the legislation, which proved costly. However, the level of any short-term adaptation costs would depend entirely on the precise nature of the change. Moreover, manufacturers are continually innovating in search of higher quality and lower costs (not least in response to demand) and average production costs tend to be falling (e.g. due to increasing economies of scale). In this dynamic situation, the companies interviewed tended to report that, given time to adjust, they could "design in" the requirements of the legislation without necessarily incurring substantive compliance costs. None of the companies was able to state how their products would be different in the absence of legislation. For those reasons, the table below offers no estimate of substantive compliance costs.

Fourth, the companies interviewed stressed that they undertake extensive testing during the installation process for reasons of safety and quality and would do so in the absence of EU legislation. Although the conformity assessment process imposes a significant cost in terms of staff time required to check installations (e.g. under Module H) and compile technical reports, such costs tend to be inseparable from business-as-usual costs. In that sense, it might be possible to conclude that the conformity assessment process determines the format of testing during the installation without necessarily being more expensive than the tests that installation companies would undertake in the absence of EU legislation. SMEs may differ in that respect, as they are more likely to use Notified Bodies and thus incur a direct financial cost, which can be significant; of course, many reputable SMEs would submit their products for third-party testing in the absence of EU legislation, so it is impossible to determine the additional burden imposed by the legislation.

106 To a certain extent, the compliance costs incurred by manufacturers of components might be passed on to the manufacturers and installers of lift units through higher prices for components. However, it is beyond the scope of this study to determine the extent to which that happens.

The table below suggests that the costs of compliance may be around £26m p.a. for a production volume of 255,000 units. This represents around 0.89% of total revenue of €2,960m from manufacture and installation of whole units in the EU. To this cost must be added the significant but unquantifiable costs just described. However, the companies interviewed were unanimous in reporting that the cost of complying with EU legislation was less than under a "benchmark" scenario in which national legislation differed from country to country.

Table 7-26: Summary of main costs of compliance for installation of lift units

	Unit of measurement	Average cost/unit	Total quantity	Industry wide costs/year	*Explanatory notes*
Human resources expended on compliance					
Familiarisation with legislation	Per annual turnover	0.26%	€2,959.766 m	€7.696m	*Staff responsible for participating in EU-level processes, identifying legislative requirements and informing the wider company, e.g. Codes Officers.*
Informing and training staff in legislative requirements					*Significant cost but impossible to quantify, typically consisting of small amounts of time spent by a large number of individuals*
Product design and testing activities					*Inseparable from business-as-usual costs. Significant in the short-term (i.e. adaptations to changes in the legislation or in the standards). Negligible in the long-run.*
Checking compliance in design and production	Per annual turnover	0.16%	€2,959.766 m	€4.736m	*Compliance and inspection officers at sites responsible for R&D & production*
Conformity assessment (technical file preparation, information manual)					*Inseparable from business-as-usual costs*
Declaration of Conformity & CE marking	Per annual turnover	0.00%	€2,959.766 m	€0.000m	*Negligible*
Total human resources compliance cost				€12.432m	*In addition to non-quantified costs of training, product design and testing, etc.*

	Unit of measurement	Average cost/unit	Total quantity	Industry wide costs/year	*Explanatory notes*
Costs of testing equipment					*Cost of testing for reasons of quality, health & safety are impossible from costs of testing required by the legislation. Production sites typically serve EU and global markets, therefore impossible to separate cost of testing equipment required by EU legislation from testing equipment that would be needed in the absence of legislation.*
Costs of third parties					
Purchasing standards[107]	Per annual turnover	0.01%	€2,959.766 m	€0.296m	*Typical cost = €2k per company per year.*
External consultants	Per annual turnover	0.00%	€2,959.766 m	€0.000m	*No reported instances of use of external consultants*
Notified Bodies (Module H)	Per annual turnover	0.04%	€2,959.766 m	€1.184m	*Typical cost is €25-30k for a national subsidiary of a major manufacturer (responsible only for installation).*
Notified Bodies (fees for testing specific products)	Per unit	€200-1000	n/a	n/a	*Units deviating from the standards require specific approval but typically form a very small proportion of total installations.*
Total annual compliance costs	**Per annual turnover**	**0.89%**		**€26.344m**	
Total net compliance costs				n/a	*Inseparable from business-as-usual costs.*
Substantive compliance costs				n/a	*Inseparable from business-as-usual costs.*

107 As an indicative example, UK standards under the Lifts Directive are typically priced between £50 and £300. See: http://shop.bsigroup.com/.

	Unit of measurement	Average cost/unit	Total quantity	Industry wide costs/year	*Explanatory notes*
Administrative costs				**€26.344m**	*Excludes substantive compliance costs, which are inseparable from business-as-usual costs*
Share in total industry turnover				**0.89%**	
Basic assumptions:	Total units sold: 255,000 units per year (NACE: 28221630 and 28221650) Market size: € 2959.766 million (PRODCOM) Weighted median price per unit: €16,312 (NACE 28221630 and 28221650)				

Overall conclusions - lifts

Lifts for persons are a harmonised product group for which there is one overarching piece of legislation. The Lifts Directive incorporates different elements of product safety (including electrical safety) that for other product groups would be covered separately by the LVD. Other Directives, such as the EMC Directive also apply. IM legislation affecting the lifts sector was found to be coherent with no specific gaps overlaps, inconsistencies or duplication identified. The Machinery Directive 2006/42/EC (MD) applies to certain types of lifts, but the delimitation between the two Directives is clearly specified in the 2006 recast of the MD. This ensures mutual exclusivity between Directives and clarity for economic operators.

The "big four" lift manufacturers account for some 60% of the EU market, estimated at €15 billion in in 2009 (EFESME). NACE data shows that there are over 9,500 enterprises in the lifts sector, the majority of which are SMEs. A particular characteristic of the lifts sector is that the manufacturing of lifts only accounts for one third of total market size, while the remainder is made up of after-sales services (maintenance 41%, repair 7%, and modernisation 18%). Whereas manufacturing activities and initial installation are regulated through IM legislation, once installed, lifts fall under national in-service inspection regimes. The costs of lifts maintenance and the costs linked to periodic servicing once in use are a significant cost, but are note linked to European legislation.

The Lifts Directive accounts for the majority of administrative costs, although such costs are minimised by the fact that the relevant harmonised standards take into account the compliance requirements of other relevant directives, notably the Electromagnetic Compatibility Directive (EMC). This means that if a manufacturer follows the standard and carries out a conformity assessment based on the standard, they will have met their regulatory obligations across all relevant pieces of legislation. Familiarisation with legislation is undertaken in-house by the large companies using specialist staff. When developing products, the large manufacturers tend to undertake their own tests, using in-house staff and following quality assurance systems approved under Module H, which serves to minimise cost. The requirement for compulsory third party conformity assessment procedures and the supporting technical documentation tends to be the most burdensome requirement of the legislation. However, the firms emphasised that much of the required testing would be undertaken in the absence of legislation, for reasons of product safety and quality. The administrative requirement related to conformity assessment procedures undertaken in the product development stage are quite high initially, but occur only once. In contrast, the administrative requirement related to conformity assessment procedures in the installation process are higher, as as inspections have to be undertaken for each new lift installed. The task of producing the Declaration of Conformity and CE marking is not particularly costly.

Based on the research, the costs of compliance may are estimated at €26m p.a. for a production volume of 255,000 units across the EU. This represents around 0.89% of total revenue of €2,960m from manufacture and installation of whole units in the EU. However, the companies interviewed were unanimous in reporting that the cost of complying with EU legislation was less than under a "benchmark" scenario in which national legislation differed from country to country. Clearly, these costs are more onerous for SMEs than for large companies that can spread compliance costs among a large number of units.

Sources of information

References

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- Text of applicable IM legislation and relevant standards
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- Dispan, J. (2007), Industry report - Lifts and escalators – an industry in flux, IMU Institute Stuttgart
- Elevators and Escalators - A Global Strategic Business Report 10/12

Interviews:

- 3 EU industry associations: European SMEs in the lift industry (EFESME), European Lifts Association (ELA), European Lifts Components Association (ELCA)
- 1 national lift association
- 8 manufacturers of lifts
- 2 manufacturers of lift components

3.10.5 Case study 5 – Gardening equipment

Introduction

The case study examines gardening equipment with focus on three specific categories, chain saws, lawn mowers and brush cutters. Gardening equipment can be electric, battery powered or petrol based and they are used both by consumers and professionals. The rationale for the selection of these product groups was that:

- Lawn mowers are covered by a rather large number of Union harmonisation Directives and Regulations, 8-10 depending on the type of product;
- The sector is dominated by a few large manufacturers; and
- The conclusions drawn from an assessment of these specific products could be used to assess with some level of confidence the administrative and compliance costs to the broader category of domestic appliances since most of the products within this group are usually covered by the same pieces of legislation.

The case study is based on desk research and interviews with the EU industry association representing manufacturers of gardening equipment (EGMF) and five in depth interviews with manufacturers of gardening equipment operating in Europe, two large manufacturers, two medium and one small.

Product definition and description of structure of the sector

The focus of case study has been three types of gardening equipment, chain saws, lawn mowers and brush cutters. These categories represent the main sales volume of the broader garden machinery equipment group of products that also includes various types of trimmers, vacuums and blowers, leaf blowers, leaf collectors, motor hoes (<3 kW), scarifiers, shredders/chippers and pruners. Gardening equipment are used both by consumers and professionals although there are often differences in terms of engine power and features and some products that are typically used by professionals (e.g. garden tractors). The following paragraphs provide a more formal definition of the three products under examination on the basis of the relevant EN standards:

Lawn mowers[108]

According to EN standard EN836 a lawnmower is "a walk-behind or ride-on grass cutting machine or a machine with grass-cutting attachment(s) where the cutting device operates in a plane approximately parallel to the ground and which uses the ground to determine the height of cut by means of wheels, air cushion or skids, etc., and which utilises an engine or an electric motor for a power source. The cutting devices are either rigid cutting elements or non-metallic filament line(s) or freely pivoting non-metallic cutter(s)". A lawnmower may be a walk-behind or ride-on grass cutting machine or a machine with grass-cutting attachment(s) where the cutting device is rotating about a horizontal axis to provide a shearing action with a stationary cutter bar or knife (cylinder mower).

108 The definition comes from EN 836

Chain saws

A chainsaw (or chain saw) is a portable mechanical saw, having teeth that are linked to form an endless chain, rotated about two pivot points by a power mechanism that can be an electric motor, a gasoline engine, compressed air, hydraulic power.

Brush cutters[109]

A brush cutter is a combustion-engine driven portable hand-held unit fitted with a rotating blade made of metal or plastic intended to cut weeds, brush, small trees and similar vegetation. The cutting device operates in a plane approximately parallel to the ground.

Market size and industry structure

Data available from Eurostat PRODCOM database already provide relatively detailed data on the level of production and trade of chain saws, lawnmowers and cutters. The following PRODCOM codes fit rather well with the specific product groups under examination:

- 28241180 - Electro-mechanical hedge trimmers and lawn edge cutters
- 28304010 - Electric mowers for lawns, parks, golf courses or sports grounds
- 28304030 - Mowers for lawns, parks or sports grounds, powered non-electrically, with the cutting device rotating in a horizontal plane
- 28304050 - Motor mowers for lawns, parks or sports grounds, powered non-electrically, with the cutting device rotating in a vertical plane or with cutter bars
- 28304070 - Non-motorized mowers for lawns, parks, golf courses or sports grounds (such as push cylinder mowers) (excluding with the cutting device rotating in a horizontal plane)
- 28241123 - Electro-mechanical chainsaws
- 28241260 - Chainsaws with a self-contained non-electric motor

The data analysis suggests a total market size (production+ imports – exports) of around €2.5 billion for those categories with a total volume of 23 million chain saws, lawn mowers, trimmers and cutters sold. Imports are, according to PRODCOM, close to 60% of to total consumptions. Our interviews with manufacturers suggest that this is a reflection of the important role of non-EU producers (US firms are particularly strong in certain segment) but also the fact that many EU producers have transferred part of their production capacity outside Europe but with most of the production re-imported to the EU. Along with the US market (50% of the global sales), the European market remains the most important market for gardening equipment (35%).

109 The definition comes from EN ISO 11806

Table 7-27: PRODCOM data for Lawn mowers, trimmers, cutters and chain saws (2010)

Product code	Export quantity (000s)	Export value (millions)	Import quantity (000s)	Import value (million €s)	Production quantity (000s)	Production Value (million €s)	Total quantity (000s)	Total Value (million €s)
28241180	650	23	5,881	122	1,510	63	**6,741**	**162**
28304010	340	28	1,461	64	2,826	169	**3,947**	**205**
28304030	264	62	1,774	389	3,375	862	**4,885**	**1189**
28304050	7	11	194	88	21	36	**208**	**113**
28304070	49	4	187	6	150	23	**288**	**25**
28241123	180	16	1,317	49	517	51	**1,654**	**84**
28241260	99	13	2,817	192	2,341	564	**5,059**	**743**
Total	**1,589**	**157**	**13,631**	**910**	**10,740**	**1,768**	**22,782**	**2,521**

Source: Eurostat

Data from the European garden machinery federation (EGMF) deviate slightly from PRODCOM suggesting a EU market size of around 15.1 million gardening equipment products of which around 6 million are lawnmowers and 3 million are brush-cutters. There are also 3 million hedge-trimmers and 4.5 million chainsaws sold on an annual basis[110]. According to another study[111], around 4.5 million lawnmowers are sold annually in the EU with chain saws, hedge trimmers and lawn trimmers also being at a 7-digit level.

According to an earlier study[112] around 90% of sold lawnmowers on the European market are of the walk-behind type with cutting blade widths up to 50 cm, while the sales of ride-on is around 300,000 units.

Data from the UK[113] indicate that the consumer market represents around 60% of the total gardening products market with the remaining directed to professional users. Another study[114] raised the consumer segment in the whole of the EU to 75%. Lawn mowers represent around 40% of the consumer gardening equipment market in the UK (based on retail sales) with another 35% going to various types of power tools such as chain saws, cutters and trimmers.

110 http://www.egmf.org/en/economic-information/

111 Data from the UK indicate that the consumer market represents around 60% of the total gardening products market with the remaining directed to professional users. Lawn mowers represented around 40% of the consumer gardening equipment market in the UK (based on retail sales) with another 35% going to various types of power tools such as chain saws, cutters and trimmers.

111 According to the EGMF, its members sell in Europe more than 6 million lawnmowers, 4.5 million chainsaws, 3 million brush-cutters and 3 million hedge-trimmers on annual basis

111 http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/iastudy_noise_finrep_en.pdf

112 'Lawn Mover Noise and Vibration Control' study (Tetteroo & Bockhoff, 2006) cited in http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/iastudy_noise_finrep_en.pdf

113 http://www.britishgardenshed.co.uk/uk_market.htm

114 NOMEVAL (TNO, 2007)

Professional equipment has a relatively short lifespan of 2 years with an average usage of 150 hours per year. Consumer equipment has a lower usage rate of around 5 hours per year with a typical lifespan of several years[115].

Table 7-28: Data on market size and industry structure

Parameter	Data
EU Market size (2012)	EGMF: 10 million units for the whole Europe (39 countries) PRODCOM : 22.7 million units, € 2.5 billion
Production in EU27	PRODCOM : 10.7 million units, € 1.8 billion
Imports	PRODCOM : 13.6 million units, € 0.9 billion
Exports	PRODCOM : 1.6 million units, € 0.16 billion
Number of enterprises (2010)	20 large firms
Number of employees (2012)	30,000 employees (EGMF) 120,000 in dealers

Source: Eurostat

Industry structure

Eurostat data are not particularly useful when it comes to analysing the structure of the industry. There are two relevant NACE codes (28.24 - Manufacture of power-driven hand tools; 28.30 - Manufacture of agricultural and forestry machinery) which are much broader in scope and do not allow for meaningful conclusions.

The information provided by EGMF suggests that the consumers market is dominated by 20 large size companies that occupy around 30,000 employees. This has been the result of a significant consolidation phase in the last twenty years which has led to few large players bringing together small and medium size manufacturers while retaining the brand names and the production units across Europe. Brand awareness is relatively high among consumers, and technological barriers also make it difficult for new competitors to enter the market. The tendency is explained by the high fixed costs faced by individual product lines. According to one estimates that development costs correspond to 5% of its turnover[116]. The 13 members of EGMF- including both large multinationals and smaller size firms - cover almost 75% of the European market. The main players in the market – although this may differ in the different sub-sectors – are Husqvarna (SE), Stihl (DE), Bosch (DE), Global Garden Products (IT), MTD (US), Toro (US), John Deere (S), Stanley Black and Decker (US), Echo (DE), TTI (HK) and Makita. [117]

In the professionals market there are a few SMEs producing a wide variety of models and there are 147 brands and 1500 models for lawnmowers. Still, around 80% of the European market for professional handheld internal combustion engine powered equipment is covered

115 http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/tno_nomevalrep12-12-07_en.pdf

116 SME Test Study on possible policy options for reviewing the Noise Directive + Impact Assessment Study on possible policy options (concerning conformity assessment procedures) for reviewing the Noise Directive), http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/smetest_noise_finrep_en.pdf (p.59)

117 Data retrieved from Euromonitor international Passport database (accessed from British library)

by 4 European companies. SMEs are niche players, with specialised knowledge of specific client needs.

Analysis of applicable Union harmonisation legislation and standards

Chain saws, lawn mowers and brush cutters (gardening equipment) are covered by a large number of Union harmonisation Directives and Regulations covering a range of aspects:

- **Health and safety**: The Machinery Directive (2006/42/EC) is the main applicable legislation for all products. In the case of electricity/battery powered products requirements of the Low Voltage also apply but not the procedures and information obligations that are covered by the Machinery Directive. In the case of lawn mowers, brush cutters self-certification (Module A) can be used for conformity assessment. In the case of chain saws which are included in Annex IV, third party certification from a notified body is required.

- The **General Product Safety Directive** (2001/95/EC) is also applicable but does not introduce additional requirements to refrigerators since these are covered by the other more specific pieces of legislation. It does introduce however other obligations, mainly of administrative nature;

- **Electromagnetic compatibility**: The EMC Directive applies to all powered gardening equipment.

- **Noise**: The Outdoor Noise Directive (2000/14/EC) is particularly relevant to gardening equipment and introduces requirements concerning the sound power level which needs to be measured under specific conditions. It also requires that manufacturers submit a copy of the Declaration of Conformity (DoC) to the Member State authorities and the Commission.

- **Pollutant Emissions**: Gardening equipment have been covered by the Directive 2002/88/EC on Gaseous Emissions of non road mobile machinery (NRMM) since 2004. It covers spark ignited (SI) engines (petrol engines) up to 18 kW for engines installed in and held and non-handheld equipment such as lawn and garden machines. Certain small SI engine applications (including some trimmers) were exempted from the Stage II emission limits but these exemptions expired at the end of the first quarter of 2011. However, it should be noted that many manufacturers of gardening equipment purchase the engines from dedicated suppliers which have the responsibility to ensure compliance with the NRMM.

- **Chemicals**: Both RoHS Directives and REACH Regulation certain obligations to manufacturers of gardening equipment in terms of the chemicals included in the equipment. As downstream users, under REACH gardening equipment manufacturers need to ensure that the products do not contain substances of very high concern and, if they do, they need to pass information to their customers.

In addition, for certain type of gardening equipment products there are additional pieces of Union harmonisation legislation applicable:

- for battery based products the Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators

- for products with remote control features using wireless technology, the RED is also applicable

The following table analyses the main requirements arising for economic operators as a result of the different pieces of IM legislation and indicates the relevant harmonised and other standards applicable.

Table 7-29: Summary of Union harmonisation legislation covering refrigerators and freezers and the relevant standards

Name of legislation	Issue addressed	Requirements for economic operators	Relevant standards[118]
Machinery (2006/42/EC)	Safety	Requirements concerning safety and health of lawn mowers Information warnings and pictograms Conformity assessment on the basis of self-certification (module A) – Except for chain saws Develop technical file to be available upon request of authorities Declaration of conformity Marking of product (CE marking, name of manufacturer, type, series, year of construction)	EN 836 [119] EN ISO 5395-1/2/3 [120] EN 11681-2[121] EN ISO 11806 EN 60335-2-91/ EN 60335–2-77/EN 60335-2-107/EN 60745-2-13
LVD	Health & Safety	Testing according to relevant standards or alternative solutions (other requirements under Machinery)	EN 60335-1
General product safety Directive	Health & Safety	Provide identification of the product by a product reference Carry out sample testing of products, keep a register of complaints and keeping distributors informed of such monitoring (voluntary) Inform authorities of dangerous products and actions taken to prevent risk Co-operate with the authorities upon request	
EMC	Electromagnetic compatibility (for electric powered equipment)	Testing according to standards Development of technical file Declaration of conformity and CE marking	EN 61000-6-1 EN 61000-6-2 EN 61000-6-3 EN ISO14982

118 The list of standards is not exhaustive. Furthermore, not all standards identified are applicable to all products.
119 safety of powered lawnmowers
120 safety of electrically powered lawn mowers
121 Machinery for forestry - Portable chain saws - Safety and testing requirements

Name of legislation	Issue addressed	Requirements for economic operators	Relevant standards[118]
NRMM Emissions (97/68/EC and amendments)	Emissions of ride-on combustion engine powered lawn mowers	Application for type approval of engine or engine type Information dossier Testing of engines Approval by technical service Affix label with EC type approval marking with ID number and information on engine type and trade mark	
Outdoor noise Directive (2000/14/EC)	Noise	Meet sound level requirements (Stage II levels for most gardening equipment) Conformity assessment (Modules A and control by notified bodies, G,H) Declaration of conformity Place CE marking and marking of the guaranteed sound power level Send copy of DoC with information on measured and guaranteed sound to national authorities and the Commission (complete information in database)	EN ISO 3744[122]: **1995** ISO 10884:1995/ISO 9207:1995/ISO 11094:1991[123] EN ISO 22868[124] EN ISO 11094[125] EN ISO 4871[126]
REACH	Use of chemicals	Collect statement from suppliers stating that products are in compliance with requirements concerning chemical content of components Test the content of articles of products for substance of very high concern (not mandatory) Issue REACH compliance statement	
RoHS	Use of hazardous chemicals	Collect compliance statement from suppliers (material declarations) Develop technical file with supplier declarations and own analysis tests Declaration of conformity to be kept for 10 years	

122 Determination of sound power levels and sound energy levels of noise sources
123 Test area standard for different categories
124 noise test for internal combustion lawn mowers, brush cutters, trimmers
125 test code of airborne emissions for powered mower
126 Declaration and verification of noise emission values of machinery and equipment

Name of legislation	Issue addressed	Requirements for economic operators	Relevant standards[118]
Batteries Directive (2006/66/EC)	Heavy metal content and labelling of batteries	Forbids placing on the market batteries/ accumulators containing mercury or cadmium Design products so that batteries can be removed Information on the type of battery used Contribute to costs for establishment of battery collection schemes at national level (applies in some cases)	
Packaging and packaging waste	Packaging	Declaration of Conformity	Standard EN 13427

The review of the various requirements and the discussions with manufacturers pointed to a few issues in relation to the implementation of the legal framework and the requirements:

- large number of applicable pieces of legislation makes the whole system complex and increases legal uncertainty. The changes to the different pieces of legislation or the relevant standard in different periods also means that, quite often, firms need to introduce changes to product design, procedures, declaration forms or produced information manual which larger or smaller cost implications;

- an area of concern indicated by some firms is the problematic relationship between the Machinery and the outdoor noise Directive. A key issue indicated is that for the measurement of sound power level which falls under the Outdoor Noise Directive there is still reference to the outdated 1995 version of the ISO/EN 3744 standard while, for those products not covered by the outdoor noise, but covered by the Machinery Directive the most recent 2010 version is used. More generally, in the recent consultation[127] 80% of the respondents expressed the wish to merge the methods of measuring noise emissions required under both directives into a single Harmonised Standard;

- duplication in parts of the certification process – mainly the fees to the third parties - in the case where manufacturers sell to other firms products similar to those they sell under their own brands with only minor- cosmetic – differences (e.g. different color). For these products, which are identical with those that have already undergone conformity assessment but have a different name (model number), manufacturers are required to pay additional fees;

- firms indicate that, while there have been clear benefits from the harmonisation of the applicable legislation, there are significant problems with market surveillance which, in their view, means that much cheaper, lower quality and arguably non-compliant products circulate in the market;

127 Public consultation on the revision of Directive 2000/14/EC on noise from outdoor Equipment, http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/public-consultation/report_en.pdf

- the review of the requirements of the Declaration of Conformity indicate minor differences in terms of the terminology used or the type of information to be provided. However, the discussion with industry did not suggest important conflicts or problems. Still, the alignment process across all Directives is considered rather welcome.

Analysis of costs of compliance with Union harmonisation legislation

The information presented in this section is based on the in-depth interviews with 5 manufactures of gardening equipment. The firms range in terms of size and production volume. They also have different approaches in terms of the level of testing and other R&D activities they perform that are not a direct result of the legislation which is a reflection of their size and position in the market.

Table 7-30: Basic information on the firms interviewed

Firm	Specific product considered	Firm size	Annual sales from product	Main markets
A	Brush cutters	Large (>1000 employees)	1 million units	50% of sales in the EU
B	Lawn mowers	Large (>1000 employees)	1 million units	90% of sales in the EU
C	Lawn mowers	Medium (250-500 employees)	200,000 units	90% of sales in the EU
D	Lawn mowers	Small (<250 employees)	15,000 units	100% of sales in the EU
E	Chain saws	Medium size (250-500)	100,000 units	50% in the EU

On the basis of the discussion with firms the process followed by manufacturers of gardening equipment to ensure compliance with the Union harmonisation legislation includes:

- familiarisation with the applicable Union harmonisation legislation and the respective requirements, identification and purchase of relevant standards and in some cases other preparatory actions in training of staff.

- introduction of changes to the product design and the production process to ensure compliance

- conformity assessment procedures including the relevant testing and the development of the technical file, the use of notified bodies for certification if/when required, preparation of declaration of conformity (DoC), CE marking and placing in the market

- other activities in response to requests of the market surveillance activities

Preparatory actions: Familiarisation with relevant legislation and purchase of standards

Familiarisation with Union harmonisation legislation and the respective requirements represents a first task for all firms. Almost all firms indicated that this is not a particularly demanding part of the process and it usually corresponds to no more than 0.1-0.2 FTE of a member of the legal compliance team. However, most firms also indicated that the R&D or homologation departments try to monitor developments in the legislation and one of them even performs a scenario analysis aiming to prepare for alternative scenarios.

All firms interviewed indicated that they maintain a database of the relevant pieces of legislation which is continuously updated and also includes information in relation to the relevant/applicable standards. Maintenance and update of the database usually occupies an employee of the firms compliance/homologation department on a part-time basis. The sophistication of the database tends to be greater for larger size firms.

In relation to use of standards all firms consider them crucial in the conformity assessment process. The information provided suggest that firms typically spend €500-€2,000 on an annual basis for the purchase and update of standards and the reading licences for their various departments for a single product line (e.g. lawn mowers), for which 15-20 different standards are applicable.

Compliance with the applicable Union harmonisation legislation.

Ensuring compliance with the applicable Union harmonisation legislation often requires changes to existing product design or new product development. Furthermore, the introduction of new products requires product design work and testing to ensure that the new products are in compliance with requirements. While in most cases new product development is driven by market demand there are also cases where product development and R&D activity are primarily driven by legal requirements. More specifically, most firms indicated that the Non-Road Mobile Machinery (NRMM) and the Outdoor Noise Directives have led to significant level of investment. In the case of the NRMM, some firms purchase the combustion engines from suppliers and do not perform own research.

Large size Firm A indicated that around 3% of its annual R&D budget of €50-60 million invested to the development of a new product is directly related to ensuring compliance with internal market legislation (circa €4 million). On top of that they have made one of investments of around €10 million in tooling/equipment during the last five years. Small size firm D indicated annual costs for product design of €200-300k while medium size Firm C around €2 million. The amounts invested on product design vary depending on the firms' size but, on the basis of the data provided, the total investment on an annual basis is around €500,000 for every 100,000 units of production.

Testing of products is an important part of these costs. It includes tests directly related to the Union harmonisation legislation but also product performance and durability. For the large scale producers, these tests take place primarily in-house on an ongoing basis while for smaller firms these are often outsourced. Firm B suggested that around 15% of the budget and time of the 30 researchers and engineers working full time in the R&D department with around 30 FTE allocated to tests required by IM legislation for product homologation. The other firms indicated costs in the range of €200-700k.

Certain directives (NRMM, Outdoor noise) require specific testing facilities. Large size manufacturers may purchase for their internal controls while in other cases these may be outsourced to specialised labs. Estimates for the one-off costs for the purchase of testing equipment from large Firm A are around €30 million covering all products in the product line and all applicable Directives. €5 million were spent for chemical analysis equipment for REACH testing and €5 million for a sound chamber for outdoor noise tests. However, it should be noted that REACH related testing is not mandatory and it reflects the specific policy of this company that is not replicated among the smaller size manufacturers. Most other firms indicated smaller size investments in the range of 100-1,000,000 which were also confirmed from another data source (€0.6 million for noise measuring room).

The discussion with firms suggest that, on average, around 50% of the testing activities are directly related to Union harmonisation legislation while the remaining is part of the quality and durability testing of products. The outdoor noise and the NRMM are for most firms the pieces of Union harmonisation legislation that introduce most costs.

Conformity assessment procedures

The information provided from manufacturers is that the whole process of conformity assessment of a new product tends to last around 9 months in total. This includes the preparation of the technical file, the inspection of the notified bodies and certification, preparation of the DoC and the required information manual and the placing of the CE marking.

The estimated time for the preparation of technical file for a single product ranges from 40-100 hrs[128] with around half of the time required whenever there are significant changes to legislation.

In terms of the use of notified bodies, which is mandatory in the case of the Outdoor Noise Directive, all firms indicated that they are used even when a third party is not mandatory. The data provided suggest that the annual budget of firms for services of Notified Bodies is in the range of €30-80k, around €4,000 for a single product.

The costs for notified bodies increase for firms that produce multiple variants of the same model with the same technical characteristics. Customs authorities often do not allow the placing of products on the market if the model is not the same as that indicated in the label attached. As suggested, the current label does not allow for the provision of information that will allow to identify both the basic model and its variant. There is additional administrative work created for every new variant of the same basic model (i.e. same product with only differences in colours and brand name). This also means costs for new labels, changes to relevant references in the instruction manual and fees (around €700/product and additional time of around 4 weeks) to notified bodies every time they need to certify that the initial technical file is also appropriate for the new model.

The interaction of the CE marking with other labelling appears also somehow problematic for some of the firms and introduces costs that, in principle they need not incur. More specifically Firm B indicated that while the firm did not consider it necessary to apply for the German GS mark, it was in practice obliged in order to be able to sale in the German market as many

128 One firm indicated 300hrs but this deviated from all others.

retailers do not accept products without the GS mark. The cost for the GS mark certification of each model is around €1,200 and this needs to be renewed every 5 years for a bill of around €700. There is also a €800 annual fee charged by GS. In total, the annual bill for Firm B to get the GS mark certificate for all its lawn mower products placed in the German market is around €32,000.

Provisions of relevant information in the instruction manuals are also included in all Directives. There were no specific data provided for the time to develop the information manual. For most firms these are seen as part of the overall time for the conformity assessment process. Translation costs are also relevant here with average costs of around €3,000 for each different model.

In the case of products covered by the Outdoor Noise Directive additional information provision obligations arise since firms are required to submit information included in the DoC to the national and European authorities. One firm estimated that it can take up to 80 hours for the 20 different brush cutter models in its production line.

Certain information collection obligations arise from REACH Regulation. The main work is the collection of information from suppliers to ensure that no SVHCs are included. In the case of Firm A, around one FTE is allocated to the collection of this information from suppliers. One of the firms also conducts its own testing of the chemical content of certain components with annual costs for all products are around €500k. However, this is rather the exception. Most other firms are limited to the collection of declaration of conformity from their suppliers which is the responsibility of the purchases department.

Finally, under the NRMM there is the obligation to submit data to the national and European Database. While there are some problems with the process – sometimes difficult to update and problematic when introducing a new model with lower noise emissions – firms could not provide specific data on the specific time allocated and suggested that it is part of the work of the compliance/homologation department.

Business as usual

The discussion with firms indicates that a rather important part of the activities and the respective costs would not have taken place in the absence of the legislation. Firms estimated that, in total, between 10% and 35% of the compliance costs (substantive and administrative) would have incurred even in the absence of any legislation

Assessment of costs of Union harmonisation legislation for the whole sector

On the basis of the information provided we have attempted to estimate the costs of compliance for the whole of the gardening equipment sector. The provided figures include the information concerning the Business as usual scenario (i.e. the fact that 10-35% of the product development costs should be expected to occur irrespective). Certain assumptions have been made concerning the number of firms affected since, besides the 20 large firms indicated by EGMF, there are also a number of smaller size manufacturers particularly in the professional market segment.

The table below summarizes the main costs per unit and for the total of the industry. As is evident costs for product design and testing represent more than 85% the total costs of compliance.

Table 7-31: Summary of main annual costs of compliance for gardening equipment manufacturing industry

	Unit of measurement	Average unit cost	Total quantity	Industry wide costs/year
Familiarisation with legislation/support actions				
- human resources	per manufacturer	€ 11,520	100[129]	€ 1,152,000
- costs of purchase of standards	per manufacturer and per product line	€ 1,250	500[130]	€ 625,000
Compliance with IM-legislation requirements				
- Product (re)design and testing	per 100.000 units	€ 500,000	22.7 million/year	€ 113,500,000
Share of product design and testing costs that would apply even in the absence of the legislation				10-35%
Net product design and testing costs				**73,775,000-€102,150,000**
- Testing equipment[131]	per manufacturer	€ 100,000	100[21]	€ 10,000,000
Share of product design and testing costs that would apply even in the absence of the legislation				10-35%%
Net costs for testing equipment				**€1,000,000-€3,500,000**
Conformity Assessment				
- Preparation of technical file	per single model	€ 2,100	375[132]	€ 787,500
- Costs of notified bodies	per single product	€ 4,000	375[23]	€ 1,500,000
- requirement for new labelling	per single model (once in four years)	€ 700	375[23]	€ 262,500

129 We have assumed 20 large size firms (members of the EGMF) and 30-80 small firms
130 On the basis of an average of 5 product lines on average per manufacturer
131 Investment in testing equipment is usually one-off and last for at least 5 years. The costs provided here have been estimated on an annual basis.
132 Number based on an assumption of 15 models/firm once in four years

	Unit of measurement	Average unit cost	Total quantity	Industry wide costs/year
- translation costs	per single model (once in four years)	€ 3,000	375[23]	€ 1,125,000
Other				
- Submission of information for outdoor noise Directive	per manufacturer	€ 2,400	100[21]	€ 240,000
- Collection of REACH information	per manufacturer	€ 25,000	100[21]	€ 2,500,000
Total				**€85,467,000-111,342,000**

The estimated costs for the sector are in the range of €85-112 million/year which represent 3-5% of the total annual turnover of 2.5billion of the sector. This is a rather high share but the administrative costs – namely excluding product design and testing - are no more than 10%-15% of the total costs and less than 0.3% of the annual turnover of the sector.

Conclusions

Gardening equipment covered in this case study includes chain saws, lawn mowers and brush cutters. These categories represent the main sales volume of the broader garden machinery equipment group of products which also includes various types of trimmers, vacuums and blowers, leaf blowers, leaf collectors, motor hoes, scarifiers, shredders/chippers and pruners. The total annual market size of gardening equipment is estimated at around €2.5 billion for those categories with a total volume of 23 million sold. The consumer segment of the gardening equipment market is dominated by 20 large size companies while in the case of professional equipment there is a greater number of SMEs serving niche segments.

Gardening equipment is covered by more than 10 different pieces of Union harmonisation legislation (Directives and Regulations) covering a range of aspects including health and safety, environmental aspects (noise, pollutants, toxic from batteries).

For the whole sector the estimated annual costs are in the range of €85-112 million which represent a rather significant 3-5% of the total annual turnover of €2.5billion of the sector. This is driven by the high compliance costs associated with the environmental IM legislation (outdoor noise, outdoor emissions) both of which required changes in the design and rather sizeable costs for testing equipment (one-off) and on-going testing of products, only a small proportion of which is considered to be "business as usual" for most firms. Administrative costs – such as costs for documentation, fees to notified bodies, the preparation and updating of technical files, purchasing standards, the development of manuals - are no more than 10%-15% of the total costs and no more than 0.3% of the annual turnover of the sector.

Sources of information

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- 5 interviews with manufacturers of lawn mowers, chain saws and brush cutters

3.10.6 Case study 6 – Fuel Dispensers (Measuring Instruments)

Introduction - objectives of the study

This case study focuses on fuel dispensers which are classified as instruments and appliances for measuring, testing and navigation (hereinafter measuring instruments) and are covered under the Measuring Instruments Directive (MID). The manufacturing of fuel dispensers is also regulated by a number of other pieces of EU legislation, such as ATEX and the Petrol Vapour Recovery Directives.

The rationale for the selection of fuel dispensers was that:

- The sector, while dominated by four large firms, also includes a large number of SMEs;
- The legislation allows for the use of internationally-agreed normative documents, as an alternative to the use of harmonised standards;
- The MID is one of the Directives that form part of the Alignment Package; and
- The case has the potential to demonstrate the advantages of coherent interaction and clear demarcations between different pieces of legislation, in order to ensure legal clarity for economic operators.

The information presented in this case study was obtained from a variety of sources including Eurostat data, official EU documents, industry association documents and interviews with four major firms in the sector.

Product definition and description of structure of the sector

Product definition

Fuel dispensers are classified under NACE code 28.13 (manufacture of other pumps and compressors) and correspond solely to the PRODCOM Code 28131105: petrol and oil dispensing pumps.

Fuel dispensers are described as machines combining a pump and point-of-sale (POS) system and pumping fuel into motor vehicles. A Point of Sale (POS) system is a system for managing the sales of goods. The term refers to the software and hardware associated with check -out stands, and all of the bundled features which are included.

A modern fuel dispenser is typically divided into two main parts: an electronic part containing an embedded computer to control the action of the pump, drive the pump's displays, and communicate to a sales system; and secondly, the mechanical section which in a self-contained unit has an electric motor, pumping unit, meters, and valves to physically pump and control the fuel flow.

Market size

Fuel dispensers have an annual life cycle of 12 years and, on this basis, there are currently

around 300,000 fuel dispensers installed across the EU[133]. The size of the European market can be estimated on the basis of a total production value of around €360 million in 2012 based on a unit price of around €1,100[134]. According to PRODCOM data on fuel dispensers, around 16% of the production of Europe is exported outside EU while imports represent no more than 3% of the market.

PRODCOM data shows that a total of about 350,000 petrol and oil dispensing pumps were produced in Europe in 2012. Manufacturing in this sector is strongly export-oriented and has generated a significant volume of exports, although the interviews found that a lot of manufacturing that used to take place within the EU has been moved to lower-cost producer countries outside the EU.

Table 7-32: Production and value of petrol and oil dispensing pumps in EU27 in 2012 – PRODCOM Code 28131105

Export Quantity (Units)	Export Value (€)	Imports Quantity (Units)	Imports Value (€)	Production Quantity (Units)	Production Value (€)	Consumption Value € (Production + Imports - Exports)
347,309	148,672,970	245,102	15,171,090	349,038	357,890,334	224,388,454

Source: Eurostat

Industry structure

There are around 20 producers of fuel dispensers for petrol stations[135]. The major manufacturers include Gilbarco, Tokheim, Petrotec and Dresser Wayne with a presence across Europe and more than 60% market share[136]. The remaining manufacturers are present in only a few Member States. It is also estimated that the main companies in the sector employ around 10,000 employees without referring to importers or local distributors[137]. Altogether, the petrol pump sector employs about 14,000 to 16,000 workers[138].

Analysis of applicable Union harmonisation legislation

As noted above, the manufacture of fuel dispensers is covered by the Measuring Instruments Directive and by a number of other Directives, such as ATEX and the Petrol Vapour Recovery Directives. The table below provides a summary.

133 Figure also obtained after analysing PRODCOM annual production statistics
134 PRODCOM data from 2012
135 CSES (2010), Interim Evaluation of the Measuring Instrument Directive
136 Ibid;
137 Ibid;
138 PRODCOM data, 2010; cf. CSES (2010), Interim Evaluation of the Measuring Instruments Directive, page iii

Table 7-33: EU Legislation applicable to fuel dispensers

Applicable legislation	Issue addressed	Requirements for economic operators
Directive on Measuring Instruments (MID)	Legal metrological control	• Conformity assessment: obligation of the installer/manufacturer • Produce a DoC • Keep technical documentation copies of EC type-examination certificates and their additions for 10 years • CE marking and additional metrology marking must be visibly affixed to products
ATEX Directive	Risks relating to equipment used in potentially explosive atmospheres	• Conformity assessment – either by the manufacturer or a subcontractor of the manufacturer to a Notified Body • Produce a DoC • Keep technical documentation copies of EC type-examination certificates and their additions for a period of 10 years • CE marking must be visibly affixed to products • Additional markings of certain components for safety purposes
Petrol Vapour Recovery Directive (94/63/EC)	Reduction of emissions	• Conformity assessment with administrative fee charged by the Member State • Marking (pictogram sticker) certifying the equipment includes a petrol vapour recovery system
National Emission Ceiling Directive (2001/81/EC)	Reduction of emissions	• Same as above given that the directive relates to the reduction of emissions of volatile organic compound (VOC), i.e. petrol vapour • Administrative requirements depend on specific national measures
EMC Directive	Electromagnetic compatibility (for electric powered equipment)	• Testing products for Electromagnetic Compatibility interference • Conformity assessment procedure for apparatus mandatory • CE marking on apparatus required in accordance with Annex V.
LVD	Health and safety	• Conformity assessment – either by the manufacturer or a subcontractor of the manufacturer to a Notified Body • Develop a technical file (see Annex IV of LVD) • Produce a DoC • Keep technical documentation copies of EC type-examination certificates and their additions for a period of 10 years • CE marking must be visibly affixed to products • Provide installation instruction manual for installers

The nature of fuel dispensers is such that they require regulation covering different perspectives, notably accuracy and reliability in measurement, minimisation of the risks of explosion and protection of the environment. This inevitably requires multiple pieces of legislation, creating the risk that the overall framework is not coherent.

The interviews with the major companies in the sector suggest that the EU legislative framework pertaining to fuel dispensers has in fact become more coherent over the years,

albeit with some gaps and inconsistencies remaining. Whilst EU legislation on measuring instruments dates back to the early 1970s, MID represented a considerable simplification, since it replaced eleven previous directives, all covering different products.

The ATEX Directive was introduced in 1993. Hitherto, manufacturers were required to satisfy different national legislative requirements in each country in which they operated, whilst meeting European requirements on MID. Since the introduction of ATEX, each manufacturer has been able to gain certification from one Notified Body for its sales across the EU. MID and ATEX side-by-side have thus served to reduce barriers to the free movement of goods in the internal market – as evidenced by the process of consolidation in the industry over the last two decades, as manufacturers exploit economies of scale. Indeed, the technical parts of fuel dispensers now tend to be the same across different Member States. Moreover, the credibility of this legislative framework has also assisted manufacturers in their efforts to export to third countries. MID was also reported to be consistent and complementary to the more recent RoHS Directive.

The consistency of the legislative framework for fuel dispensers is also enhanced by the use of internationally-agreed normative documents, namely those of the International Organization of Legal Metrology (OIML). This has tended to make European products immediately marketable to third countries that apply the OIML standards. The one downside of this approach is, however, that EU manufacturers exert less influence on the specification of the standards than they do on EU standards, such as those of the ATEX Directive.

Despite this generally positive situation, there are still some inconsistencies among the applicable Directives and Regulations. More specifically, the definition of "large-scale fixed installation" within RoHS is criticised as being too vague. Definitions applicable to fuel dispensers also appear to differ between Directives, with for instance the EMC Directive treating a dispenser as a single machine, whereas MID treats it as a collection of several measuring instruments[139].The MID Annex MI-005 distinguishes between individual measuring systems (i.e. fuel dispensers) and self-service arrangements (of fuel dispensers).

There remains debate over the desirability of having an annex of the MID devoted exclusively to fuel dispensers. Annex MI-005 covers "measuring systems for continuous and dynamic measurement of quantities of liquids other than water"[140] and defines and covers all the relevant essential requirements for metrology (and refers to voluntary standards that give presumption of conformity can be more specific). It therefore can be applied to the case of fuel dispensers and, indeed, it defines flow ranges specifically for fuel dispensers. However, the industry associations and manufacturers consulted were of the view that an annex specifically devoted to fuel dispensers would be preferable and ease the process (and thus the costs) of compliance.

It was also reported by the companies interviewed that some fuel dispenser products or components covered by ATEX and PED are not covered by MID, e.g. automatic feed nozzles and pressure valves. Although these components are not directly relevant to measuring, they can have an effect on accuracy of measurement. As a result, certification requirements can differ for each piece of legislation. According to the companies and industry associations interviewed, this can lead to conflicts between approval bodies which results in an unnecessary multiplication of conformity tests and an increase in administrative work.

139 EMC Article 2 (a) (b) (c), Annex MI-005
140 Annex MI-005

A major issue is the fact that EU legislation does not address the connection between fuel dispensers and forecourt point-of-sale (POS) systems, which are not covered by EU legislation. Indeed, it was reported that it was impossible for MID-approved fuel dispensers to be connected to equipment with national certificates only such as pre-MID POS systems. . Since retailers, including small supermarkets, have contracts with POS systems providers, this can cause difficulties[141]. Moreover, the legislation does not cover the provision of regular checks and recalibration of fuel dispensers once installed; as with other New Approach Directives, MID is only concerned with the placement of a product on the market and its installation. Whilst this does not affect the free movement of products, it does affect the free movement of services, with such services tending to be provided mostly by nationally-based operators.

It was also proposed by some of the companies interviewed that the legislative framework (notably MID) needs to be extended to cover additional types of fuel dispensers, particularly compressed natural gas dispensers (CNGD), which are currently subject to national legislation. Although mutual recognition under Art 34 of the TFEU applies to CNGD, this is only valid when countries accept this. CNG is regulated under OIML R139[142] and for many years, each country has required its own type approvals. Whilst mutual recognition could be a means of allowing products to circulate freely, the risk is that national authorities to allow such products to be placed on the market in the absence of national certificates. In contrast, liquid natural gas dispensers (LNGD) are subject to MID despite accounting for lower volumes of trade. There are around 5,000 to 10,000 petrol stations equipped with CNGD while there are only around 100 stations equipped with LNGD across Europe. CNG is for cars while LNG is for trucks. CNGD are available in petrol stations along with normal MID-approved fuel dispensers and LPG dispensers, while LNGD are most likely to be found in dedicated petrol stations. Given the barriers to the circulation of CNGD products, the risk is that manufacturers face higher costs than if such products were covered by EU legislation and are be unable to exploit economies of scale in production.

Analysis of costs of compliance with Union harmonisation legislation

Analysis of the costs of compliance has been based on interviews with four large companies that serve the EU27 market and export globally, as well as two industry associations. The table provides information on the firms interviewed.

Table 7-34: Basic information on the firms interviewed

Firm	Specific/main product (if a specific sub category)	Firm size	Annual sales from product	Main markets
A	Pumps & dispensers	Large (4,000 employees)	10,000 units	50% of sales in the EU
B	Pumps & dispensers	Large (>1,000 employees)	15,000 units	82% of sales in the EU

141 There is a period of transition up till 2016, after which all new POS must be MID compliant
142 International Organisation of Legal Metrology (OIML) R139: Compressed gaseous fuel measuring systems for vehicles

Firm	Specific/main product (if a specific sub category)	Firm size	Annual sales from product	Main markets
C	Gasoline Dispensers, payment solutions for petrol stations	Large (5,400 employees globally)	Not known	60% of sales in the EU
D	Fuel management and dispensing systems, service station hardware	Large (3,200 employees)	15,000 units	33% of sales in the EU

Step 1: Familiarisation with the legislation and relevant obligations, as well as preparatory actions

For all the companies interviewed, identifying and reviewing the requirements of the legislation, the relevant standards and the resultant information obligations is a relatively costly activity. Two companies offered an estimate of the relative share of this task in the overall cost of Step 1: 50% and 60% respectively. Membership of the relevant industry associations at EU and/or national level, e.g. CECOD, is vital to this task and, of course, involves a membership fee. Whilst membership of industry associations serves a wider purpose (and is thus a business-as-usual cost), much of the rationale for and benefit of membership is related to receiving information about the legislation and the standards – and also to being able to influence the legislation and the standards at the EU level.

As well as receiving information through the industry associations, all the companies employed at least one staff member dedicating most or all of their time to this task. These individuals typically participate in the various working groups and committees relating to the legislation (e.g. through CEN) and within the relevant industry associations. Although such participation is costly, this investment of time is considered to be worthwhile by the companies, given the benefit arising, i.e. in terms of being able to influence the legislative process and receive information in good time.

For the companies interviewed, the cost of identifying the legislation and the relevant standards and reviewing its requirements mostly consisted of the staff costs of these individuals. For example, Firm A employed three staff (out of 4,000) with responsibility for overseeing compliance: one in the UK (also the European head office), one in Germany and one in Italy. Firm D employed one person in each of the 5-6 different national offices, each spending perhaps 50% of his/her time on this task. Similarly, Firm C employed between 3 and 5 heads at senior engineering level (out of a total workforce of 5,4000) to understand the legislation and train manufacturing people and QA people – as well as to undertake tasks related to other steps, i.e. checking the manufacturing process, finding practical solutions to compliance issues, gaining approvals, etc.

Training staff was seen as the next most costly element of Step 1. It is routinely provided by all the companies interviewed, for new staff and for existing staff, as and when there are changes to the legislation and/or the standards. The true cost of such training can be hard to identify, since it may often be incorporated into wider training of staff. One Firm suggested it accounted for 15% of the costs of Step 1, whilst another suggested a figure of 25%.

Use of external consultants to aid the familiarisation and preparatory process appears to vary widely between the companies interviewed. Two companies stated that they very rarely used consultants, whilst two others suggested that the use of consultants accounted for around 10% of the costs of Step 1. One Firm stated that it only used consultants when entering new national markets, which might thus explain this discrepancy. It might be safe to conclude that consultants are rarely used for the "routine" task of ensuring familiarity with the legislation but can be used when additional support is needed to identify the requirements relating to new products or new markets.

Purchasing the standards (of Directives other than MID) also presents a direct financial cost for all companies interviewed (although the MID normative documents are made available free-of-charge on the Europa website), although participation in standards committees at EU level sometimes provides access to the standards free-of-charge. For the companies interviewed – all large – the cost of standards was not seen as prohibitive. Two suggested it accounted for only 5% of the costs of Step 1. Another quoted a figure of €1.2k for each standard purchased, which was not seen as particularly burdensome relative to its revenues. However, such costs would inevitably be more burdensome for SMEs.

Two companies, as well as one EU-level industry association, highlighted that the most significant costs in Step 1 resulted from having to address differing interpretations of the legislation and of the standards in different countries. Such difficulties were said to arise not from the text of the legislation or of the standards, but from insufficiently clear guidance or, indeed, a lack of guidance. The resulting costs tended to relate to the time spent negotiating with national authorities, market surveillance authorities and Notified Bodies, as well as delays in placing products on the market (although neither firm was able to specify the precise cost, which is not therefore included in the table below).

Overall, all the companies and the industries associations interviewed highlighted the fact that most of the costs incurred in Step 1 were no higher than the previous situation in which national legislation applied. Indeed, the fact that the MID standards are also based on the internationally-agreed OIML normative documents means that there has been a degree of continuity in the processes followed, with the EU legislation reducing costs by bringing a more uniform approach. Given this situation, it would seem that the main scope for reducing costs associated with Step 1 relate to facilitating a more uniform interpretation of the legislation applying to fuel dispensers (i.e. MID, ATEX, EMC, etc.) and encouraging a more consistent application and enforcement in different Member States.

Step 2: Changes to product design and production processes to ensure compliance with substantive obligations

The nature of fuel dispensers and related products is such that design, development and manufacture require extensive testing for the purposes of safety, accuracy and reliability. It is clear that national legislation already imposed quite stringent requirements in most countries, particularly those where national standards were based on internationally-agreed normative documents. The EU legislation also places stringent requirements on manufacturers, with a consequent need for extensive testing and risk analysis, as well as subsequent changes to product design and production processes. For example, the one firm offering an estimate of substantive compliance costs, Firm B, reported that substantive compliance costs had amounted to €3.2m over the last five years (equal to around 3% of turnover), of which €2m on changes to product design and €1.2m on changes to production processes. Whilst these are one-off costs for each specific product that is certified, the fact that each large firm is

continually bringing new products to market mean each incurs such costs on an annual basis.

It is, however, impossible to separate such costs from the business-as-usual scenario, particularly in a context of on-going technological development and innovation. Indeed, reputable manufacturers of high-quality products undertake extensive testing and risk analysis of any new product in any case. To a certain extent, such activities therefore represent a business-as-usual cost. Overall, the legislation has perhaps represented more of a burden for manufacturers of poorer-quality products, who have had to operate to higher standards, with less potential to undercut other suppliers on the basis of low price.

Of the companies interviewed, all agreed that testing related to compliance with substantive obligations posed a considerable cost. Indeed, testing and risk analysis is undertaken throughout the year at all the companies interviewed, involving a mix of internal staff and external costs. Firm D suggested that testing might account for up to €1m of its annual revenue of €15m (i.e. just less than 7%). Firm B reported that testing accounted for around €500k out of annual revenues of €20m (i.e. 2.5%). Firm C reported annual testing costs of €50-€150k for each of its four European factories, i.e. €200-600k p.a. Whilst such costs are clearly significant, it is not possible to separate them from a situation in which national legislation prevails or from the "business-as-usual" cost, given the emphasis that reputable manufacturers would place on product safety, accuracy and reliability.

In general, the companies were unable to give accurate data on the cost of testing equipment related to compliance with the EU legislation. For example, Firm D stated that most testing was undertaken at the firm's main laboratory in the USA; the cost of testing for the EU market was therefore inseparable from the cost of testing products for all global markets – particularly, where international, rather than EU standards apply. Firm A reported that it spent around €40k p.a. on testing equipment for the purposes of compliance (mostly linked to the EMC Directive) in relation to sales of around 10,000 fuel pumps per annum (equivalent to an average cost of €0.25 per unit).

Firm A did, however, highlight one very specific cost arising from the legislation and which could not be considered as a business-as-usual cost. One effect of the MID has been to require calibration of fuel dispensers (e.g. to match fuels) to take place in the factory rather than on-site (i.e. at the fuel retailer's forecourt). Previously, this calibration would take place on site, with the appliance then checked by a local trading standards officer, which Firm A considered to be easier. Although the fee for the local trading standards officer was not cheap (e.g. €50 per nozzle, so €300 for a pump with six nozzles), it was paid by the customer. However, under Module B (type approval) of MID, the Notified Body now has to verify the product and the calibration has to be undertaken at the factory. This creates difficulties as the precise conditions of the installation environment (i.e. the retailer's forecourt) cannot be known and recreated in the factory. Enforcement authorities tend not to allow subsequent adjustments to be made on site, whereas previously the manufacturer could send staff to tweak the product on site. Whilst Module F allow verification and calibration at the forecourt, this option

As a result, Firm A reported that it was required to spend a lot of time in the factory, continually refining weights and measures equipment to ensure the product is legal. Overall, the legislation was reported to have introduced a liability for the manufacturer, for which no obvious practical solution had been found. The consequent cost included €120k on testing facilities for LPG, as well as around €250k in staff time over the last six years, equivalent to perhaps €100 extra per dispenser under MID compared to the previous situation.

Step 3: Conformity assessment procedures

Under the MID, manufacturers can choose from a number of conformity assessment procedures, namely Modules B+F, B+D, H1 or G. This creates a variety of approaches and therefore differing costs, with some manufacturers subject to periodic inspections of their quality systems by Notified Bodies (e.g. under Modules D and H1) and others having the conformity of specific products verified, e.g. under Modules B and F.

The companies interviewed were unanimous in reporting that the fees of Notified Bodies represented the costliest element of Step 3. The one firm that offered an estimate of the proportion of total costs in this step accounted for by Notified Bodies fees suggested a figure of 55%, of which 35% relating to initial inspections and 20% to periodic inspections. All the companies offered estimates of the financial costs of the fees of Notified Bodies and those estimates demonstrating a degree of consistency. An initial inspection of a fairly routine nature (e.g. permeation tests or other minor adjustments) was said by two companies to cost up to about €4k, whereas testing of components such as valves, motors or junction boxes was said by another firm to cost €10-20k. The same firm reported that it undertook around six of such tests each year, representing a total cost of about €100k in Notified Body fees (i.e. 0.5% of total turnover). More extensive tests for entirely new products or processes might cost €40k-50k each. In addition to the initial inspections, it is also necessary for each firm to have periodic inspections by Notified Bodies in order to retain their certification. Figures quoted by one firm included €15k-25k for both the MID and the ATEX Directives, with another firm quoting a figure of around €30k for such periodic inspections across its three European facilities for the same two Directives.

Whilst the cost of Notified Bodies' fees was reported to be high, the companies agreed on the benefits of gaining certification. One firm made a favourable comparison to the situation prevailing before the introduction of the New Approach Directives, stating that the current costs were relatively low. The same firm reported that it was able to use its MID and ATEX certification globally, in the former case because of the use of OIML standards by MID. Moreover, it was also reported that OIML certification from some EU Member States tended to have more credibility than certification gained in some third countries.

Manufacturer's own internal checks were also reported to be costly, albeit less than the cost of Notified Bodies. However, to a large extent, these tended to be a business-as-usual cost, with such checks undertaken continuously and routinely – and likely to be undertaken in the absence of legislation.

Similarly, the preparation of technical documentation in advance of conformity assessment, compilation of test reports, production identification requirements and maintenance of technical information for ten years were reported to be costly in terms of internal staff time. Indeed, one firm suggested that such activities could account for several hundred thousand euros each year in staff time, whilst another suggested that such activities could account for around 35% of the total costs of conformity assessment. Preparation of technical documentation related to ROHS was said by one firm to pose a particularly high cost. In addition, two companies reported very high costs of translation of documents related to conformity assessment, although such costs may be inextricable from the general costs of translating instruction manuals – estimated at around €100k p.a. by one firm (against sales of 10,000 units and turnover of "tens of €millions" per year).

Step 4: Declaration of Conformity and CE marking

The companies interviewed were unanimous in reporting that the Declarations of Conformity and use of the CE marking were much less costly than Steps 1, 2 and 3. However, the preparation of a Declaration of Conformity could be made more complicated – and therefore more costly – by the need to collect information, DoCs and compliance statements from suppliers of components. Depending on the number of components and of suppliers, this could in some cases be costly and manufacturers need to build such requirements into their contracts with suppliers.

The compliance statements that will be required under ROHS and REACH were expected by one firm to impose a significant cost as and when they become mandatory. However, at this stage it was not possible to estimate the cost of producing such statements.

The requirement to apply CE marking was reported by all the companies to pose very little cost. Indeed, it was easily incorporated into the manufacturing process. None reported any particular additional financial cost. However, the companies and industry associations reported some confusion around the application of CE marking. This included a lack of clarity around whether the CE marking needed to be placed only once on each pump installation or on each nozzle. It was also suggested that consumers had limited awareness of the significance of the CE marking, with national standards, such as the British Standard markings, being more widely-recognised in each country.

As with the technical documentation, translation of the Declaration of Conformity was reported to be expensive. Three of the four companies reported a very high cost of translation, whilst another reported it to be moderately high. One firm reported that it was necessary to translate Declarations of Conformity four times a year, at a cost of around €8k p.a. In order to minimise costs and the potential for error, another firm reported that it replicated the text from the various language versions of the official documentation as far as possible. Again, such translation costs are bound up with the wider cost of translating instruction manuals. However, given that fuel dispensers are sold only to businesses and not to consumers, one firm suggested that there should perhaps be flexibility over the requirement (imposed by most Member States under the terms of Article 6 of the MID) to provide such documentation in the language of the customer, provided that the customer has sufficient numbers of staff fluent in the language proposed by the manufacturer. In that way, it might be possible to reduce the number of translations required, particularly into the less-spoken EU languages where it less difficult to spread the cost of translations over a large volume of sales.

Conclusion/Summary

On average, around €800k per year are spent by major manufacturing groups on activities linked to compliance. Direct administrative compliance costs represent just over 10% of the total costs of compliance-related activities. Investments in terms of product design, manufacturing equipment represent major compliance-related expenditures (around 35-40%).

Assessment of costs of Union harmonisation legislation for the whole sector

On the basis of the information provided, we have attempted to estimate the costs of compliance for the whole sector. The figures in the table below include information concerning the "business-as-usual" (BAU) scenario.

Table 7-35: Summary of main costs of compliance for the firms interviewed

	Firm 1	Firm 2	Firm 3	Firm 4	Average	Total
Turnover	€ 20m	€ 20m	€ 600m	€ 15m		€ 1,091,666,667
Compliance Costs FTE						
- costs FTE yearly	€ 72,000	€ 260,000	€ 420,000	€ 330,000		
- costs FTE yearly / turnover	0.36%	1.30%	0.07%	2.20%	1%	€ 5,372,250
Business As Usual (BAU) FTE		30%	30%		30%	€ 1,611,675
Compliance costs FTE		70%	70%		70%	€ 3,760,575
Compliance Costs - third party fees	€ 41,667	€ 500,000	€ 500,000	€ 1,000,000		
- costs third parties / turnover	0.21%	2.50%	0.08%	6.67%	2.4%	€ 12,367,014
Business As Usual (BAU) third parties		50%	50%		50%	€ 6,183,507
Compliance costs third parties		50%	50%		50%	€ 6,183,507
Compliance Costs - testing equipment	€ 160,000	€ 100,000	€ 500,000			
- costs testing equipment/turnover	0.80%	0.50%	0.08%		0.46%	€ 2,773,519
Business As Usual (BAU) test equipment		20%	20%		20%	€ 554,704
Compliance costs test equipment		80%	80%		80%	€ 2,218,815
Total compliance costs	€ 273,667	€ 860,000	€ 1,420,000	€ 1,330,000		€ 20,512,782
Business As Usual (BAU)		€348,000	€476,000		41%	€ 8,349,886
Compliance costs		€512,000	€944,000		59%	€ 12,162,897
Total compliance costs as % of Turnover	1.5%	4.5%	0.25%	9%		

The assessment of costs of Union harmonisation legislation for the whole sector is based on the figures obtained from the four major companies in the sector representing 60% of the market. The figures in the far right column are an extrapolation of the data obtained from the four major firms and represent the total turnover and compliance costs for the whole of the EU petrol pumps sector.

The annual turnover for the whole sector is estimated at €1.1bn. Total compliance costs are estimated at €20.5M for all the companies in the sector, representing around 2% of their combined turnovers. For the largest of all four companies (firm 3) compliance costs represent 0.25% of the turnover. For the smallest (firm 4), compliance costs amount to around 8.5% of the total turnover. Across the four companies, around 60% of the compliance costs relate to compliance with EU Internal Market legislation.

Administrative compliance costs FTE represent around 0.5%-1% of companies' annual turnover on average. Costs range from just under €100,000 to over €400,000 for larger companies. On average, they make up 30% of Business As Usual costs to a firm on a yearly

basis. The remaining 70% relate to EU IM legislation compliance requirements.

Administrative and non-administrative compliance costs towards third-parties are of around €500,000 on average for the companies in the sector. These costs represent around 2.5% of companies' annual turnover and make up 50% of their Business As Usual costs.

Testing equipment costs for compliance activities averaged around €100,000 per firm annually. For larger companies, testing equipment can cost over €500,000. These costs are also dependent on the number of factories owned by companies. These costs represent around 0.5% of companies' annual turnover in the sector and make up 20% of Business As Usual costs. In other words, testing equipment expenditures at firm level mostly relate to the necessity to comply with the MID requirements and other environment-related requirements introduced by various EU legislative measures.

According to PRODCOM data, the production value of each individual petrol pump unit ranges between €1,000 and €2,000. This corresponds with the data obtained from the individual companies when dividing their annual turnover by the number of units they produce per year. When dividing the individual companies' annual turnover by their total compliance costs, it is possible to see that compliance costs account for between 0.25% and 9% of the production value of a single unit (See Table 7-35).

Overall conclusions

This case study focused on fuel dispensers which are machines combining a pump and point-of-sale (POS) system and pumping fuel into motor vehicles. In other words, fuel dispensers combine an electronic part containing an embedded computer measuring fuel sales and a mechanical section to physically pump and control the fuel flow.

There are around 20 manufacturers of fuel dispensers in Europe, amongst which are four major players with more than 60% of the market share in Europe and a significant presence worldwide. The total production value for petrol pumps in Europe was of around €360 million in 2012 based on a unit price of around €1,100. A total of about 350,000 petrol and oil dispensing pumps were produced in Europe in 2012. The manufacture of fuel dispensers is mainly covered by the MID and by a number of other Directives, namely: ATEX, the Petrol Vapour Recovery Directive, the EMC Directive, the Low Voltage Directive and the National Emissions Ceiling Directive. The nature of fuel dispensers is such that regulations covering different perspectives are required, notably on accuracy and reliability in measurement, minimisation of the risks of explosion and protection of the environment.

The assessment of costs of Union harmonisation legislation for the whole sector was based on the figures obtained from the four major companies in the sector representing 60% of the market. Total compliance costs are estimated at €20.5M for the four major companies in the sector, representing around 2% of their combined turnovers. Around 60% of the compliance costs relate to compliance with EU Internal Market legislation (€12M) whilst the remaining €8.5M relate to business-as-usual compliance costs.

Administrative and non-administrative compliance costs towards third-parties are of around €500,000 on average. Familiarisation costs are reported to be significant in this particular sector. This is due to the need for company to address differing interpretations of the MID legislation and of national standards in different countries. Testing equipment costs for compliance activities averaged around €100,000 per firm annually. For larger companies,

testing equipment can cost over €500,000. In summary, investments in terms of product design, manufacturing equipment represent major compliance-related expenditures (around 35-40%) for companies in the sector.

List of interviews

- 2 interviews with industry associations: CECOD, PEIMF
- 5 interviews with manufacturers
- 1 interview with the European Commission DG Enterprise and Industry

3.10.7 Case study 7 – Air Conditioners

Introduction

Common aims

The aim of the case studies is to assess the way in which Union harmonisation legislation for industrial products affects different economic operators across selected product groups. Union harmonisation legislation applicable to each product group is first mapped out and an assessment of any gaps, loopholes, inconsistencies and duplication is provided. The compliance costs in meeting these requirements are then assessed.

Specific aims of case

The rationale for the selection of air conditioners and air conditioning systems as a product group was that:

- Air conditioners and air conditioning systems are a significant industrial sector, particularly in southern European countries, with a large volume of products sold.
- There are only a relatively small number of firms overall in most market segments, and large firms dominate the market.
- The sector is one in which there is a high level of internationalisation in manufacturing and non-EU firms dominate some segments of the European market (especially for smaller and portable air conditioners). This has allowed market access issues to be considered.

The case study was carried out using a combination of desk research and interviews. The main data sources used were Eurostat SBS (2 digit NACE code level) and Prodcom data (8 digit NACE), sectoral studies and market research reports. Work carried out recently on Ecodesign requirements for air conditioners and air conditioning systems was also used, since this provides useful data on market size and structure[143].

143 For instance, the F-Gas regulation (Regulation 842/2006 on certain fluorinated greenhouse gases) relating to greenhouse gases was considered by some air conditioning stakeholders interviewed to be one of the most burdensome pieces of legislation affecting the sector.

Product definition and description of market structure

This case study focuses on air conditioners and air conditioning systems (both comfort air conditioning in buildings and portable air conditioning systems). There are a number of different types of air conditioners such as air-to-air, water-to-air, evaporatively-cooled, split and multi-split air conditioners air-to-air, water-to-air, and VRF (Variable Refrigerant flow) systems. Industrial chillers are also covered, wherever these incorporate air conditioning systems. The focus is on electrically-driven air-conditioning appliances although gas burning appliance designs placed on the market were also taken into account, since a different legal regime applies under the GAD.

Selected sub-sectors within the wider HVAC industry, and heat and industrial pumps have also been included, but only where these are part of air conditioning and heating systems. There is a trend towards convergence of cooling and heating systems so air conditioning manufacturers often produce these items.

Data and information sources

An overview of sectoral data and key trends is now provided, drawing on Eurostat Structural Business Statistics (SBS) and Prodcom data. Since Eurostat datasets can be misleading in that they present data at a very high level of aggregation, we have also drawn on market research reports. Where data gaps have been identified, for instance, an accurate estimate of manufacturing employment in the sector, we have taken feedback from industry associations and individual manufacturers into account about since they have provided insights on market size and structure, recent industry developments and market trends.

Industry structure and employment

In the first table, we provide an overview of the sector, although it should be noted however that the data is at a higher level of aggregation than for air conditioners and air conditioning systems alone. Eurostat SBS data under NACE 28.25 includes the manufacture of refrigerating or freezing industrial equipment, including assemblies of components, the manufacture of air-conditioning machines, including for motor vehicles, non-domestic fans, heat exchangers, machinery for liquefying air or gas manufacture of attic ventilation fans (gable fans, roof ventilators, etc.).

Table 7-36: Manufacture of non-domestic cooling and ventilation equipment sector (NACE 28.25)

	2008	2009	2010
Number of enterprises	9,913	8,984	9,190
Number of employees	254,200	228,800	219,700
Production value	48,083.16	37,624.77	38,645.77

Source: Eurostat's SBS

The European industry association – Eurovent – speculated that Eurostat data may also extend to firms and employment relating to the installation and maintenance of air conditioners and air conditioning systems, not only to manufacturing. Given the unreliability of official data

sources on the number of enterprises and employment, it has therefore been necessary to rely on market studies that provide industry data and on information provided by industry associations.

The **manufacturing industry for small air conditioners (<12 KwH) and comfort cooling systems is dominated by a small number of global manufacturers, especially from East Asia**. The market for single and multi-split air conditioners is dominated by Asian manufacturers and brands.[144] The five largest brands of air conditioners for domestic use in Europe are all Asian: Mitsubishi (Japan), Daikin (Japan), LG Electronics (South Korea), Hitachi (Japan) and Toshiba (Japan). Outside East Asia, a number of other international manufacturers have a strong market share of the global air conditioner market such as Amana, Carrier, Lennox and Trane (US). In BRIC economies, such as China and India, there are also large manufacturers with high sales volumes, such as Haier, Gree and Midea (China) and Blue star and Voltax (India). Chinese companies also export a lot of small air conditioning products to Europe under an array of different, less well known brands.

It was not possible to obtain accurate data on the level of employment within the sector. However, it was noted by the industry association that there is a significant level of employment – greater than in manufacturing – relating to the installation, servicing and maintenance of air conditioners and air conditioning systems. Employees in these sectors are only indirectly affected by IM legislation, they are much more affected by environmental legislation, for instance, European legislation pertaining to the F-Gas regulation and pursuant legislation[145] setting out minimum requirements and the conditions for the mutual recognition for the certification of companies and personnel.

Some data on employment in Europe by international manufacturers was however obtained. It is important to point out that although non-EU firms dominate many areas of manufacturing and although a significant proportion of manufacturing also takes place outside Europe, manufacturers originating from East Asia have made a significant investment in setting up some manufacturing facilities in Europe, which has created a significant amount of European direct employment and indirect employment (suppliers/subcontractors of e.g. pumps and fans. According to Eurovent, an EU industry association, about 5000 direct jobs have been created and an estimated 15000 indirect jobs. A significant proportion of total employment in the EU in the air conditioning sector is for the subsidiaries of large international companies. Japanese, Korean and US air conditioning companies are well-represented.

For instance, the market leader Daikin has a factory in Belgium and two in the Czech Republic. Mitsubishi Electric has a factory in Scotland, whilst Hitachi has a factory in Spain. Among the reasons why global manufacturers are investing in developing manufacturing capabilities in Europe are: proximity to market, a need to strengthen their market share in Europe and to embed their position in the European market. Consequently, these companies are keen on monitoring and participating in European decision making processes, including the development of Ecodesign and Energy Labelling regulations.

It is **difficult to obtain a clear picture by country of origin of the brands of air conditioning manufacturers** since lesser-known brands sold on European markets can be

144 Preparatory study on the environmental performance of residential room conditioning appliances (airco and ventilation), Economic and Market analysis, July 2008

145 For instance, pursuant to The F-Gas Regulation (EC) No 842/2006, Commission Regulation (EC) No 303/2008 of 2 April 2008 establishes minimum requirements and the conditions for mutual recognition for the certification of companies and personnel as regards stationary refrigeration, air conditioning and heat pump equipment containing certain fluorinated greenhouse gases

subsidiary companies of international holding companies. However, a previous study for DG ENTR on the air conditioning sector citing Eurovent data[146] estimated that East Asia (particularly Japan and Korea), have a dominant market share with 60% and 13% respectively. These data estimates were checked, for instance with JRAIA (The Japan Refrigeration and Air conditioning Industry). They estimated that Japanese manufacturers share of the market is in the region of 50-60% in Europe.

The US has a 10% share of production, the EU has only an estimated 7% share, whilst Israel has 6% and China 5%. Notwithstanding the points above regarding international manufacturers setting up manufacturing facilities in the EU, a 2008 market study for the Commission confirmed that the majority of small air conditioners for domestic use are manufactured and assembled outside Europe[147], with the exception of mini-chillers, where Europe has a stronger manufacturing base (although international manufacturers with manufacturing plants in Europe are also present in the market).

Although in absolute terms, Europe's market share is relatively low, European manufacturers have a higher market share in the production of high-end air conditioning systems produced in lower volume, and in specialised market segments. For example, an interviewee from a European manufacturer commented that "while East Asian manufacturers dominate small air-conditioning systems for comfort and office cooling, European manufacturers have a higher market share of large-scale industrial cooling systems. Europe also has a significant market share for other types of air conditioners such as precision air conditioning and chillers. For instance, the UK and Germany have a strong market position in respect of precision air conditioning (such as cooling systems for data centres). Although disaggregated data is difficult to obtain, interview feedback found that European manufacturers and the US also have a strong market share in respect of industrial refrigeration. For instance, Italy is strong in the chillers market. It is not possible to provide accurate data on the percentage of firms that are SMEs in the air conditioning industry. As noted above, at 4 digit NACE code level, it is difficult to obtain sufficient disaggregation through Eurostat. Discussions with industry associations confirmed however that at least for smaller air conditioners for domestic use, small comfort coolers and for portable air conditioners, the market is dominated by large firms. A further market study from 2012 (Lot 6, Ecodesign)[148] was only able to identify small numbers of SMEs manufacturing air conditioning systems, chillers and fan coils (not quantified).

Market size

Before providing information on the European air conditioner and air conditioning systems market, we first provide an indication of the size of the market globally.

Market research data was obtained by CSES directly from the industry on the air conditioning market globally in 2013. The data shows the relative importance of different geographic markets in million units and their respective global market share.

146 It should be noted that this data is not publicly available, since it is proprietary.
147 Idem.
148 Sustainable Industrial Policy – Building on the Ecodesign Directive – Energy-Using Product Group Analysis/2 Lot 6: Air-conditioning and ventilation systems, Part 2 Market Study, July 2012

Table 7-37: World market for air conditioning in 2013

Geographic region	*No. of units (m. units)*	*Percentage share*
China	41.2	42.0
United States	14.35	14.6
Japan	9.58	9.8
Latin America	6.95	7.1
Europe	6.65	6.8
South East Asia	6.2	6.3
India subcontinent	4.87	5.0
Middle East	4.57	4.7
Africa	2.86	2.9
Oceania	0.91	0.9
Total	**98.14**	100.0

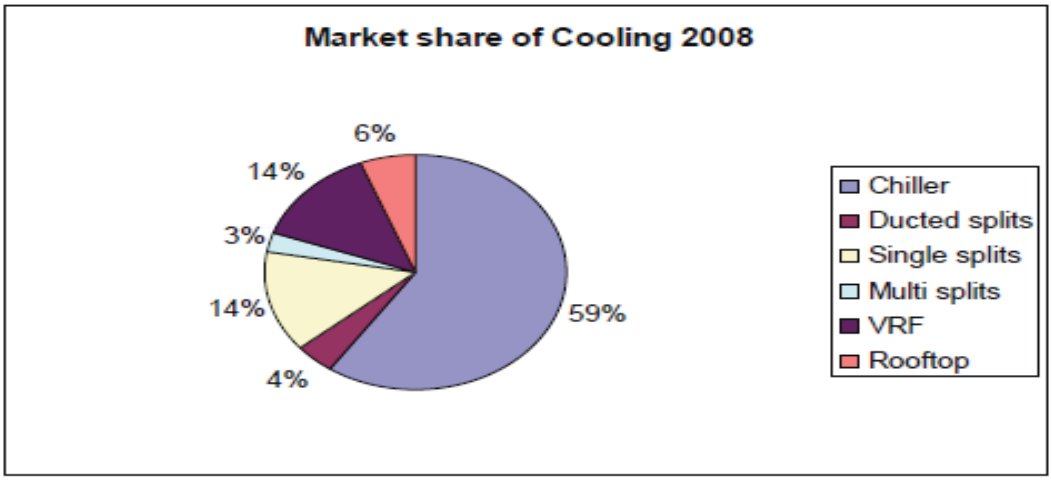
Source: JARN, the "Japan Air Conditioning, heating and refrigeration news" magazine, 25 May 2013

The data shows that 98.1m units were sold globally annually. The data confirms that China is the world's largest air conditioner market, although, as noted earlier, Japan and Korea are the biggest manufacturing companies for air conditioners sold on the European market. The **estimate of 98.1m units sold globally compares with about 6.65m units sold in Europe in 2012**, according to Eurovent figures. As will be demonstrated below, although European manufacturers have a relatively low market share globally in terms of sales volume, they have a higher market share for non-domestic air conditioning systems and for chillers.

A study undertaken for the Commission in 2008[149] noted that Southern European countries accounted for a large share of demand within the EU, reflecting climatic factors as a key demand driver. In the figure below, a breakdown of the market share for different air conditioning systems by type and cooling capacity is provided. The figure shows that chillers with air conditioning in them account for 59% of the market, and other types of air conditioning a much lower proportion. Single splits and VRF splits (ducted splits are not so easy to install in European households since most do not have duct space) each with a 14% share of the market respectively.

149 Preparatory study on the environmental performance of residential room conditioning appliances (airconditioning and ventilation), ECODESIGN Lot 10, July 2008

Figure 7-1: Market Share - Air Conditioning Systems by type and cooling capacity



Source: Sustainable Industrial Policy – Building on the Ecodesign Directive, July 2012 (*Note: single splits below 12 kW are excluded from the graph.)*

A 2012 study[150] on the impact of the Eco-design Directive provides an assessment of current market size and structure. However, according to the study "Extra EU-27 trade and Intra EU-27 trade are only available in Prodcom at the even more aggregated level of Procom code 28251 Non-domestic cooling and ventilation equipment. The Prodcom data are therefore of limited value for this analysis, being too aggregated"[151].

Prodcom data in respect of different types of air conditioning systems is now provided. The "apparent production" values are derived from the reported figures and do not take into account possible stock levels between production or import and sale). The first category of Prodcom data relates to air conditioning systems, self-contained or split-systems. The data shows that European manufacturing exports account for a small proportion of total sales.

Table 7-38: Window or wall air conditioning systems, self-contained or split-systems, Prodcom category 28251220, Million Euros

Year	*2003*	*2004*	*2005*	*2006*	*2007*	*2008*	*2009*
Exports	87	96	98	147	173	155	119
Imports	620	1,032	924	944	1,389	1,255	668
Production	1,148	1,343	1,264	1,101	1,396	935	682
Apparent consumption	1,681	2,279	2,089	1,898	2,612	2,034	1,231

Source: Eurostat, Prodcom

150 Sustainable Industrial Policy – Building on the Ecodesign Directive – Energy-Using Product Group Analysis/2 Lot 6: Air-conditioning and ventilation systems, Part 2 Market Study, July 2012

151 The relevant Prodcom categories are: 28251220: Window or wall air conditioning systems, self-contained or split-systems. These products are within the scope of this case when used for comfort cooling and over 12 kW cooling capacity: smaller units are under Prodcom code 28251250: Air conditioning machines with refrigeration unit (excluding those used in motor vehicles, self-contained or split-systems machines). This category includes comfort-conditioning air conditioning chillers and chillers used for other air conditioning applications, and other products, 28251270: Air conditioning machines not containing a refrigeration unit; central station air, handling units; boxes and terminals, constant volume units and fan coil units (including air handling units and terminal units – including fan coil units - but also other component parts of central air conditioning systems).

Prodcom data in respect of air conditioning machines with refrigeration units is now provided. Again, the level of imports considerably exceeds exports.

Table 7-39: Prodcom category 28251250: air conditioning machines with refrigeration unit (excluding those used in motor vehicles, self-contained or split-systems machines), million Euros

	2003	*2004*	*2005*	*2006*	*2007*	*2008*	*2009*
Exports	375	404	422	430	502	631	509
Imports	1,299	1,949	1,594	1,203	1,657	1,384	881
Production	1,607	1,779	1,566	1,699	2,095	2,364	1,651
Apparent consumption	2,532	3,324	2,738	2,473	3,250	3,117	2,023

Source: Eurostat, Prodcom (note – data on exports was not available in earlier years).

Lastly, the third Prodcom category examined was air conditioning machines not containing a refrigeration unit. Here, unlike in the first two areas, European manufacturing is comparatively stronger, with exports considerably exceeding imports.

Table 7-40: Prodcom 28251270: Air conditioning machines not containing a refrigeration unit; central station air handling units; vav boxes and terminals, constant volume units and fan coil units, million Euros

	2003	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**
Exports	188	215	244	270	344	390	328	344	467	459
Imports	167	292	251	254	357	274	207	224	258	200
Production	1,474	1,270	1,253	1,531	1,682	1,777	1,465	1,550	1,676	1,736
Apparent consumption	1,453	1,347	1,260	1,516	1,696	1,661	1,344	1,429	1,466	1,477

Market research data

In the following table, data on the number of units sold annually in the EU based on product sales data from market research are now provided. The Prodcom figures are larger, which reflects the wider scope of Prodcom classifications.

Table 7-41: Comparison of Prodcom and Market Research Data (2009)

Air conditioning products	*Market Research (no. of units sold annually in EU)*	*Prodcom value*	*Prodcom category*
Chillers	85000	2384000	28251250
AHUs for air conditioning and fan coil units	184,000 + 1,140,000 = 1,324,000	1716000	28251270

Source: Market research data and Prodcom, Analysis presented in Sustainable Industrial Policy – Building on the Ecodesign Directive (DG ENTR).

The data presented above from the market research report draws on a number of sources, such as Eurovent sales data for EU27 for 2008 and 2009, market research reports from BSRIA for

six countries (an extrapolation was made for EU27). Although the data is from 2008 and 2009, market research data provides a more accurate picture than Prodcom data since it is disaggregated for air conditioning and fans and for chillers[152].

Key industry trends and challenges

A number of key industry trends were identified through the research. These are, in summary:

- The adverse impact on the market of the global economic and financial crisis, with a significant drop in the numbers of air conditioning units sold in the European Union in 2008, 2009 and 2010, albeit with a recovery in 2011 and 2012.
- Convergence of cooling and heating products and systems.
- The integration of more energy-efficient technologies into air conditioners and cooling systems.

Annual turnover in the sectors under review has declined due to the **global economic and financial crisis**, in particular due to lower levels of construction activity. This has led to reduced demand for new air conditioning systems. However, demand for maintenance and repair services has been relatively steady during this period. Although initiatives to reduce energy consumption at EU and Member State level will help to boost demand for the installation of new, energy-efficient units in future, the number of units sold in the European market has declined overall in the past five years. The number of units has fallen sharply across the EU to 9.2m units in 2007, and further still to only 5m units in 2009. It has recovered somewhat during 2010 and 2011, but declined again to 6.65m units in 2012 (source: Eurovent).

There has been a trend towards **convergence in cooling and heating systems**, with integrated solutions becoming more common. Discussions with two air conditioning associations found that more diverse air conditioning solutions are needed.

A further key driver has been the transition towards the use of **more energy-efficient technologies and parts and components** in air conditioners and cooling systems. This has been driven globally by European legislation on Ecodesign implementing regulations to eliminate the worst-performing products.

Summary of applicable Union harmonisation legislation and standards

A mapping exercise was undertaken to identify applicable IM legislation and standards relevant to the air condition sector. The mapping of Union harmonisation legislation was based on desk research and discussions with individual manufacturers and the information has been verified by industry associations. The main applicable legislation, is in summary:

- Low Voltage Directive (LVD)
- Electromagnetic Compatibility Directive (EMC)

152 The data is based on sales to end-users irrespective of whether they are imported, manufactured within EU27 or assembled from imported components. Import and export is only reported from a national perspective so intra-EU and extra-EU figures cannot be determined from this derived data.

- Machinery Directive (2206/42/EC)
- Implementing Regulation on Ecodesign requirements, Regulation 206/2012 EC for air conditioning equipment below 12 kW.
- Regulation Ecodesign requirements for fans (327/2011 EC)
- Regulation Energy Labelling Air conditioners and comfort fans (626/2011 EC)
- Directive 2002/31/EC energy labelling of household air-conditioners
- Pressure equipment Directive 97/23/EC (PED)
- REACH Regulation (1907/2006 EC)
- RoHS Directive (2011/65/EC)
- Packaging and packaging waste (2004/12/EC)
- Regulation Ecodesign requirements electric motors (640/2009 EC)
- Regulation Ecodesign requirements glandless circulators (641/2009 EC)
- Regulation Ecodesign requirements water pumps (547/2012 EC)
- The Gas Appliances Directive (2009/142/EC) "GAD", which applies to gas-fired air-conditioning units

It should be noted that whereas for electrically-powered air conditioners, among the core applicable legislation is the LVD and the EMC, for gas-fired air-conditioning and/or heat pump appliances, the GAD may provide the main legal framework. The focus in this case however has not been on gas-fired air-conditioning. Since the HVAC sector is very large, we have sought to focus on other types of air–conditioning systems.

A more detailed mapping of the applicable legislation is provided as an annex to this case study. This provides a summary of the main issues addressed through the legislation (e.g. product safety, energy-efficiency), key administrative requirements for manufacturers and examples of relevant standards.

In addition, an overview of applicable environmental legislation affecting air conditioners and air conditioning systems has been mapped out and is provided in annex, since the interaction between Union harmonisation legislation and European environmental legislation has cumulative effects.

Analysis of costs of compliance with Union harmonisation legislation

10 interviews have been carried out as part of this case study, eight with firms, of which six firms provided sufficient quantitative data to be able to quantify the costs of compliance with IM legislation. Through the interviews, a good mix was achieved between firms of different size and market share. Two out of the top five global manufacturers were interviewed, as well as a large European manufacturer of air conditioners and an SME producing chillers. In addition, two interviews with industry associations have been carried out (see Section 8 –

information sources). Comments and data have also been provided by an international industry association (JRAIA - the Japan Refrigeration and Air conditioning Industry). In the following table, basic information about the firms interviewed is summarised:

Table 7-42: Basic information on the firms interviewed

Firm	Product category	Firm size	Annual turnover and sales from product in the EU	Main markets
A	Air conditioners & air conditioning systems	Large	Turnover £600m – 800,000 units	98% of sales in EU28
B	Air conditioners & air conditioning systems	Large	Turnover (UK) €100m >200 units	Europe, the Middle East and Africa
C	Air conditioners & air conditioning systems	Large	NA but production in EU numbers in millions of units	80% of sales in EU28
D	Industrial chillers	Small	100 units	Ca. 100% of sales in EU28
E	Air conditioners & air conditioning systems	Large	500,000 units	33% EU 66% outside EU
F	Air conditioners & air conditioning systems	Large	€520m – 300,000 units	50% sales EU28 50% outside EU (mainly Russia)
G	Air conditioners & air conditioning systems	Large	Turnover £42m - 2,500 precision aircon / 500 chillers	80% UK 20% RoW (EU and Middle East (10%))
H	Air conditioners & air conditioning systems	Large	Turnover €200m No. of units not available	Europe, Asia, USA – evenly split

It should be noted that sufficient data was obtained for SCM purposes from firms A, B, C, E, F and G. Firms D and H were not included in the SCM analysis. In the case of Firm D, this was because although data on human resources involved in compliance and testing was provided, this was an outlier as a % of staff costs compared with the total. In the case of Firm H, no data was available because they currently outsource manufacturing to ODM suppliers so do not have any information about compliance costs including testing.

In this section, a summary of how compliance with Union harmonisation regulations is managed in enterprises in the air conditioners and air conditioning systems sectors is provided. This sets out the main steps required in order to place an air conditioner or air conditioning system on the market and considers the internal business processes necessary. This provides important contextual information for interpreting the costs of complying with Union harmonisation legislation.

Overview as to how compliance is managed by air conditioning manufacturers

As mapped out in Section 3, a number of different pieces of Union harmonisation legislation are applicable to air conditioners. This includes longstanding New Approach directives such as the LVD-D and EMC-D (applicable to all electrical appliances) and more recent legislation adopted in the last decade, such as the Ecodesign requirements (implementing regulations for air conditioners and fan coolers), Energy Labelling requirements and requirements under RoHS and REACH relating to substances used in the manufacture of air conditioners. Additionally, air conditioners are subject to environmental legislation such as the F-Gas Regulation 842/EC/2006[153] and its different implementing regulations and the Energy Performance of Buildings Directive 2010/31/EU (EPBD).

Large firms and SMEs manage the process of ensuring regulatory compliance with Union harmonisation legislation in broadly similar ways. In large firms, there are commonly separate divisions dealing with different aspects of regulatory compliance: a regulatory compliance manager or department with overall responsibility for compliance (including following EU legislation-making and standardisation processes and familiarisation with the introduction of new and the revision of existing Union harmonisation regulations and the applicable administrative requirements), a division dealing with research and development and product design, and a division responsible for carrying out conformity assessment procedures through product testing within in-house R&D and/ or testing laboratories.

Large firms are in an advantageous position compared with SMEs however since they can devote staff to the earlier preparatory stages in the development and recasting of Union harmonisation regulations and in the development and revision of harmonised standards in order to anticipate and respond to regulatory developments. SMEs also try to follow and to anticipate regulatory developments.

SMEs also try to follow and to anticipate regulatory developments but they have less resources available to dedicate to this step. The European industry association pointed out that there is anecdotal evidence to suggest that smaller air-conditioning companies are leaving the market because of the complexity /cost of the regulation. It was difficult to verify this assertion since the smaller size segment of air conditioning companies were generally unwilling to take part in the case (although one small chillers firm did participate – and they were managing compliance with Union harmonisation legislation). Five main steps were identified in the process of achieving regulatory compliance for the study and these have been used in order to quantify the current costs of compliance. The steps are:

153 There is currently a proposal for a revised regulation on fluorinated greenhouse gases - COM(2012) 643

- Familiarisation with applicable/relevant obligations
- Introduction of processes or changes to product design and production processes to ensure compliance with substantive obligations
- Conformity assessment procedures and relevant documentation
- Declaration of conformity or other statement of compliance and CE marking
- Other activities related to obligations posed by authorities

Firms interviewed commented that while these five steps broadly reflect the processes involved in achieving regulatory compliance, for large firms, there is in addition a preparatory step that can involve significant time resources, that of "keeping track of EU legislation and standards".

Any differences between firms in their approach to managing compliance are commented on and the extent to which these differences are dependent on firm size and on the number of products/models being produced.

The companies interviewed were asked to assess the proportion of time FTEs spend on each of the five steps of the above process. Each firm provided slightly different information on this aspect as a result of their internal set-up considering factors such as the extent to which they relied on third party testing services, as opposed to carrying out conformity assessment tests in-house.

However, familiarisation with Union harmonisation legislation and the applicable administrative requirements was generally seen as quite time consuming (e.g. firm G mentioned that 30% of time was concentrated on this activity). The introduction of changes to product design and carrying out conformity assessment procedures were also seen as time-intensive (e.g. firm D invests 60% of time in total on these items). However, the production of a declaration of conformity and other activities stemming from regulatory obligations were generally seen as less time consuming (e.g. Firm A spends 20% of time in total in this regard). Staff specialising in regulatory compliance spend more time on familiarisation processes with Union harmonisation legislation and less on the other five steps, whereas for laboratory staff (engineers working in R&D and in testing) the majority of their time is spent on carrying out product testing and on conformity assessment.

Familiarisation with relevant legislation and purchase of standards

Preparatory steps – taking part in EU legislation-making and standardisation processes

Several of the larger air conditioning manufacturers interviewed stated that they invest resources in following EU legislation-making and standardisation processes. The aim is to enable them to shape and influence the development of new and the revision of existing Union harmonisation legislation.

This enables them to anticipate legislative changes so that new regulatory requirements or changes to existing requirements (and forthcoming updates to technical standards) can be incorporated from as early a stage in the product design process as possible. This enables

them to minimise substantive compliance costs by factoring in new requirements from as early a stage in the product design and R&D process as possible.

Large firms interviewed often have dedicated staff specialising in regulatory compliance. They are therefore able to actively contribute to EU legislation-making processes, for example by participating in the work of EU industry associations[154], responding to public consultations, attending workshops with industry representatives in order to establish a consensus industry position on new legislative proposals and taking part in EU standardisation processes.

Taking part in this preparatory step involves time and human resource costs. Several of the large firms interviewed have full-time regulatory compliance teams consisting of between two and four FTEs. A senior manager at a large European manufacturer estimated that *"Contributing to the policy debate regarding Eco-labelling and Ecodesign took several years from the start of the discussions until the adoption of these regulations. Given that both regulations potentially have a significant impact on the air conditioning industry, during the 2 year period leading up to their adoption was the most intensive, and the amount of time spent on these regulations alone amounted to 0.5 FTE".*

However, there are clear benefits for industry in actively following regulatory development and standards-making processes. This enables large firms to influence policy and legislative-making processes likely to affect them. Industry may not always be happy with the end result, but at least has the opportunity to influence the process. More generally, this facilitates regulatory compliance because large firms are then able to anticipate forthcoming legislative changes and updates to technical standards. This investment in participating directly in EU policy and legislative making processes gives large firms a competitive advantage over their smaller rivals, who typically follow regulatory developments but lack the resource to follow new developments closely.

Familiarisation with applicable legislation and administrative requirements

Familiarisation activities are required to ensure that air conditioning firms are aware of the applicable legislative and administrative requirements. At least in middle and larger sized firms, this step requires input from dedicated regulatory compliance staff who assume responsibility for keeping track of regulatory changes and updates to harmonised technical standards. They are then responsible for briefing different business divisions about new regulatory developments, such as product engineers, product managers and sales teams.

In large firms, such as firm F, there is a division of 2-3 people providing specialist in-house expertise on compliance matters. Another large company, Firm B, mentioned that they employ a full-time regulatory specialist and one of their main tasks is to update product managers, engineers and country sales teams on new legislative developments and how these will affect different product categories. They also provide guidance to colleagues on how new IM legislation and changes to existing regulations should be interpreted. Whist only a small number of full-time regulatory specialists are employed, familiarisation with legislation is an activity that cuts across a number of business functions (e.g. country sales teams and product engineers). Consequently, it was estimated that the total number of FTEs involved in

154 EU industry associations provide an opportunity for industry to feedback their views on the revision of existing EU regulations and on the proposed introduction of new legislation, for instance, through Commission working groups that have been set up on specific directives and regulations e.g. working group on Ecodesign.

familiarisation with the legislation is equivalent to 15 full time staff. However, Firm H tended to use product safety consultants to provide specialist advice and consultancy support to assist them in the familiarisation process with new legislation. It should however be noted that there is an intention to move this function in-house in the near future.

In SMEs, familiarisation requires a significant effort, but there are less dedicated resources available. Firm D, an Italian firm manufacturing chillers employs a full-time manager who specialises in regulatory compliance to keep track of regulatory developments. The person concerned estimated that approximately 50% of their time was spent on familiarisation activities. The owner of the company also spends about 20% of their time on compliance matters (of which about half on familiarisation).

Several interviewees commented that familiarisation with more Union harmonisation directives and regulations introduced in the past five years take up a lot more time than other pieces of legislation. Whereas the legal and administrative requirements for long-established Directives such as the LVD and EMC are well-known to manufacturers and have not changed fundamentally in years , a lot more time is required for compliance specialists to familiarise with the requirements set out in more recent legislation, especially legislation with either environmental, consumer protection or energy-efficiency objectives, such as RoHS and the Ecodesign implementing regulations.

Currently, Ecodesign requirements only apply to small air conditioners under 12 kW and comfort fans under 125W. There is a separate measure that applies to fans of between 125 W and up to 500 kW even if they are included as a component in larger equipment, as detailed in the following sub-section.

Introduction of changes to product design and production processes to ensure compliance with substantive obligations The introduction of new legislative requirements under Union harmonisation legislation may require changes to be made to products either during the R&D and design phase, during the production process and in the case of fans integrated into products, also to products that have already been placed on the market.

The costs of making such changes depend how far in advance air conditioning manufacturers are aware about forthcoming changes and on the length of the product life cycle. The research showed that it is much more costly for manufacturers to make design changes to existing product platforms than it is to incorporate new requirements into new product platforms or those at a very early stage in their development.

An Ecodesign preparatory study noted that the life cycle of air conditioning platforms is typically between 10 and 12 years. The life cycle of an individual air conditioning model is longer than for other types of industrial products[155]. Therefore, the introduction of substantive obligations has a more significant impact on air conditioners.

Since basic air conditioning platforms form the basis on which products are updated through the development of new models and variants, there can be major costs if design modifications have to be made or particular components are withdrawn. Eco-design requirements were regarded as the most administratively burdensome piece of Union harmonisation legislation.

155 In comparison, the lifecycle of a laptops platform in which different model variants are developed is in the region of 2 to 5 years. It is easier to integrate regulatory requirements into the development of new platforms rather than to invest in modifying platforms that have already been developed.

Implementing regulations setting out ecodesign requirements for air conditioners and comfort fans (Regulation EU 206/2012) applied from January 1st 2013 to units of <12KW. Since ecodesign targets the worst-performing products, redesign is necessary only for approximately 20% of existing models.

Even though large air conditioning units and systems have not yet been made subject to ecodesign legislation, the main implication has been that lower-performing fans integrated into larger air conditioning systems and units have had to be replaced or taken off the market for testing, adaptation or permanent removal.

A large European manufacturer of air conditioning systems, Firm G, commented that although they only produce large air conditioning systems over 12 12 kW, they have already been affected by the implementing regulations. *"Ecodesign requirements have meant that changes have had to be made to replace fans in older products. Sometimes, fans have had to be withdrawn by suppliers because they no longer meet the required performance threshold for energy efficiency"* . In such cases, the firm has then had to identify alternative energy-efficient fans to incorporate as components into larger products, such as air conditioners used for cooling purposes in data centres.

This in turn requires updating the corresponding technical documentation and DoCs and further testing has had to be carried out. Both Firm F and Firm G confirmed that are indirect impacts as a result of fan products used as components being withdrawn, such as a finished unit having to be retested under the EMC Directive, because the old fan originally included as a component when the product was placed on to the market is no longer compliant and a new type of fan has had to be installed. Firm F commented however that 'it is difficult to quantify such substantive compliance costs' since no data is kept on the total costs incurred across a number of different products due to the replacement of fans.

The comments made confirm the findings from an earlier evaluation of the Ecodesign Directive undertaken by CSES that there are some specific issues in respect of the compatibility of ecodesign requirements for fans when these are integrated into other types of products such as machinery and air conditioning systems and larger air conditioners.

Firm C suggested that since the core product safety directives applicable to air conditioners change infrequently that the introduction of new (and updating of existing) technical standards is a greater administrative burden than the legislation itself. Firms A and B had difficulties in determining the exact number of FTE involved in carrying out conformity assessment procedures under IM legislation internally since a significant proportion of manufacturing takes place in Asia. It was therefore difficult for them to know the exact number of engineers involved, especially since the engineers work on products designed for the global market, which will then be designed and tested to meet dual or multiple regulatory requirements.

There can be difficulties for manufacturers in meeting regulatory requirements, while at the same time addressing end-user and consumer needs. For instance, the aim of increasing energy-efficiency is not always compatible with that of reducing indoor and / or outdoor noise.

Conformity assessment procedures

The Supplier's Declaration of Conformity (SDoC) can be applied by manufacturers for most types of air conditioners. Most manufacturers therefore carry out the majority of product testing in internal laboratories, but may also use an external third-party (on a voluntary basis) to carry out some aspects of testing. The use of a third-party provides a useful external validation that helps to ensure an additional guarantee for the enterprise.

A European industry association indicated that although the SDoC procedure can be applied to the LVD, most manufacturers prefer to use a third party. In addition, some firms also make use of external product safety consultants in order to provide advice and to help project manage the testing and compliance process. For example, Firm H uses 2 consultants who work on a working part-time basis for the company for approximately 3 months a year advising on regulatory compliance linked to testing.

Firm D (an SME with 64 staff) employs 7 FTE that deal with regulatory compliance / conformity assessment, 2 of who deal with following regulatory compliance requirements and 4 of who work in the internal testing department. Whereas the EMC and the LVD were believed to be the least burdensome, Ecodesign, the MD and the PED were regarded as the most costly pieces of legislation. The firm has invested in accreditation for internal production control under the PED in relation to chillers which has limited its reliance on third parties.

Given the relatively low number of units manufactured by the SME, the costs of complying with IM legislation per unit are higher when compared with large companies. This message was reiterated by Eurovent, the air conditioning industry association that SMEs face much higher regulatory costs per unit. In comparison, large air conditioning manufacturers are able to spread the costs of compliance across a large number of units produced and sold in European markets.

In Firm E, 11 FTE are employed as regulatory and conformity assessment specialists, 5 staff work on internal testing and R&D for air conditioning and 4 staff perform similar activities but working for heaters. Firm E suggested that the initial set-up costs for establishing internal testing functions is expensive. This includes for safety tests (€30,000 to €40,000) and performance tests (€30,000 to €40,000) and room and equipment instrumentation (€200,000). Annual costs include calibration services for instrumentation (€20,000) and replacing instrumentation, estimated at between €30,000 and €50,000.

Firm F commented that Ecodesign particularly in relation to fans is the most costly piece of legislation, followed by the EMC and the LVD. The MD was viewed as being less costly. In total, part of the job description of 20 product engineers is to work on compliance-related matters and this equates to about 10-15% of their time e.g. 2-3 FTEs. The firm spends on average €1 million on external testing per annum and this includes carrying out testing in respect of the EMC-D and the LVD-D. In addition, there are one-off costs associated with the purchase of equipment (€50,000) and annual costs for calibrating equipment (this relates to €20,000 for IM regulations).

In the case of the LVD Directive, one of the oldest New Approach Directives, most testing is carried out by an in-house laboratory with a 3rd party technician being present. However, many SMEs do not have such a laboratory facility and therefore have to send samples to a 3rd party for testing. This means that testing costs can be significantly higher, both in absolute

terms and when spread across the total number of units sold. Perhaps surprisingly since the legislation is long-standing and well-embedded, Firm E suggested that the LVD was the most costly IM legislation[156] on the grounds that even if third party testing is not required, there is a need to validate internal test results and to use a notified body to test a random selection of products so as to provide additional reassurance that the product is safe.

In Firm G, conformity assessment procedures cut across the work of two specialised departments that have a combined annual budget of approximately €1.4 million. The development department is composed of 20 electrical and mechanical engineers and CAD designers. The test centre is composed of 6 engineers that evaluate designs and performance functionality. Overall, it is estimated that 3 FTE engineers spend 20 - 25% of their time ensuring that products are compliant. This includes the development of technical reports and product testing. With regard to salaries of staff working on compliance, one engineer has a salary of approximately €60,000 per annum; the costs of annual testing equipment were estimated in the region of €25,000.

Firm G commented that the Machinery Directive and Low Voltage Directives were less costly since the SDoC procedure can be applied. It was noted that some types of industrial air conditioning units must comply with the Pressure Equipment Directive (PED) . Here, complex tests need to be carried out by third parties, or if testing is carried out internally, there is a mandatory requirement that this must be carried out by a third party[157].

Declaration of conformity (DoC) or other statement of compliance and CE marking

Producing a DoC and CE marking was seen as less costly compared with the previous steps described. However, it was recognised that the minor administrative costs involved at the end of the compliance process are only possible once the preceding steps have been completed, which require investment by air conditioning firms.

Firm E stated that producing the DoC is neither problematic nor costly. Firm H stated that producing the DoC itself does not take up a lot of time, since the information contained in the DoC can typically be fitted on to one sheet of A4 paper. Rather, the conformity assessment procedures leading up to the DoC and the development of a technical file are the most time consuming aspect.

Other information obligations and administrative costs

Other administrative requirements under Union harmonisation legislation can however be costly. For instance, the requirement to translate instruction manuals into all EU languages was viewed as costly. Under the LVD Directive, an instruction manual must be supplied in the language where the product is sold. Some interviewees noted that instruction manuals are becoming bigger and more complex, with a requirement to "provide an ever-increasing number of safety warnings to consumers". Firm E suggested that industry would prefer to minimise the amount of text needed on products and to use pictorial symbols or warnings

156 The reason why the LVD can result in high costs is due to the duration of the testing process which can take up to one month in a third party laboratory, even after the manufacturer has carried out testing in-house. The main mechanism chosen by manufacturers to achieve presumption of conformity with the LVD is through harmonised standards. Two standards are applicable for air conditioners: (i) EN 60 335-1 (general standard applying to household and similar electrical appliances) and Part 2 specific additional requirements for each category of appliances standard for safety requirements in household appliances and (ii) EN 60 335-2-40: specific requirements for electrical heat pumps, air-conditioners and dehumidifiers.

157 This includes (PED) final observation of a pressure tests and (EMC) check for radiated and conductive emissions.

rather than written text that needs to be translated. This would help to reduce costs and reduce the length of compliance and other documentation that has to be provided with products.

Another point raised was that the administrative costs of producing energy labelling (as opposed to the testing of products to check their energy efficiency which is a substantive obligation and can be costly) have been kept to a minimum due to the use of pictograms rather than text. Pictograms were viewed as facilitating communication with consumers across the EU's multilingual market, without the need to spend money on translation or on producing lots of paper to accommodate translations into multiple languages.

Assessment of costs of Union harmonisation legislation for the whole sector

An assessment was undertaken of the compliance costs of Union harmonisation legislation for manufacturers in the air conditioners and air conditioning sector. As noted earlier, one chiller company was also included. Since the wider HVAC sector is very wide, not all categories of firm were interviewed (e.g. heating pumps firms). The aim was to have a narrower focus on air conditioning.

As noted in Section 4, the assessment was carried out on the basis of quantitative information provided by six manufacturers (from the eight interviewed in total). The costs are related to turnover. In the first column, we seek to distinguish between different types of costs. The distinction between one-off and recurrent costs has been taken into account in the analysis, and some costs, such as the costs of purchasing laboratory equipment have been annualised[158].

A summary of the estimated costs of compliance is provided below (it should be noted that the costs presented in the table represent the net costs after a deduction for "Business as Usual" costs has been taken into account).

Table 7-43: Summary of main costs of compliance for air conditioners manufacturing industry

	Unit of measurement	Average cost/ year (total)	Estimated no. of firms	Total costs (annualised)
Compliance with administrative requirements				**€ 17.198.600**
Familiarisation	Manufacturers	€ 64,617	100[159]	€ 6,461,700
Preparation of DoC and technical documentation	Manufacturers	€ 106,169	100	€ 10,616,900
Standards purchase	Manufacturers	€ 1,200	100	€ 120,000
Conformity assessment				**€ 23.524.975**

158 These costs were annualised in order to arrive at comparable annual costs, using a system similar to firms' accounting for depreciation. For some questions, we also asked questions in the SCM questionnaire about how much they spent on testing equipment over a 5 year period, which had to be annualised.

159 Although there is a lack of data on market size and structure at a sufficiently disaggregated level in Prodcom and SBS data, we estimate that there are approximately 20 major manufacturers active in Europe, and perhaps some 80 small and medium sized manufacturers. Even market studies do not provide reliable estimates in this regard so this is a "best estimate".

	Unit of measurement	Average cost/ year (total)	Estimated no. of firms	Total costs (annualised)
(internal)				
Product design	Manufacturers	€ 96,597	100	€ 9,659,650
Testing (internal)	Manufacturers	€ 53,653	100	€ 5.365.325
Testing equipment	Manufacturers	€ 85,000	100	€ 8,500,000
Conformity assessment (external)				**€ 9,360,000**
Consultancy/advisory services (product design)	Manufacturers	€ 18,720	100	€ 1,872,000
3rd party conformity assessment by notified bodies	Manufacturers	€ 74,880[160]	100	€ 7,488,000
Total				**€ 50.083.575**

The key assumptions made in order to arrive at the above annualised calculations are the following. The firms interviewed provided data on the level of human resources involved in compliance, for instance on familiarisation with the legislation and technical standards and on how much time and FTE staff are involved in the preparation and updating of DoCs and technical documentation. With regard to estimated salary costs for staff working on regulatory compliance, there were considerable differences between firms. As explained in Section 4, there were even major variations in staff costs *within* firms, depending which aspects of compliance were carried out in Europe and Asia. In order to provide a better basis for comparison between firms, we therefore sought information on human resources and applied a standard tariff using Eurostat data on average salaries. The figures used were €30 an hour, which equates to about €50000 year FTE.

Several firms were also able to provide data on the internal and external costs of testing. Where data was missing, imputations had to be made using data from those firms that did provide data. For instance, one of the top 5 global players provided data on their expenditure on third party conformity assessment, whereas the other was unable to, since testing and conformity assessment was carried out in Asia and the data was not available even internally. We therefore used data from those firms that were able to provide estimates and used this as the basis for assumptions about the level of expenditure for other firms (taking into account other data that was provided, such as the volume of sales units produced and sold in the European market, annual turnover and the number of product platforms manufactured annually).

Firms were asked to provide data on the costs of carrying out conformity assessment testing in-house, for instance their annual expenditure on conformity assessment procedures carried out internally(again taking into account the number of product platforms manufactured annually), and the one-off and recurrent costs linked to testing. This includes the one-off

160 There were considerable differences in the estimates of compliance costs for large, medium and small air conditioning manufacturers, reflecting significant differences in the volume of units sold annually in Europe. Standardised parameters were estimated based on the data obtained, taking into account differences between firms of different size thresholds.

purchase of laboratory equipment and the annual (recurrent) costs of calibrating testing equipment. Not all firms were able to provide this data, either because of commercial sensitivity considerations, or because the information was not shared internally by particular divisions carrying out the testing (especially for the larger Asian manufacturers). Nevertheless, sufficient data was obtained to be in a position to make assumptions about the level of costs in a typical firm, depending on its size, sales volume and the number of product platforms manufactured per year.

In quantifying the annualised costs of compliance, we attempted to take into account which compliance costs were one-off and which were recurring. It is important to note that the distinction is often blurred between the two in the case of compliance with Union harmonisation legislation. Examples of one-off costs are the purchase of laboratory and testing equipment, R&D costs, third party conformity assessment costs. Other costs are evidently recurrent, such as the recalibration of testing equipment. However, the picture is more nuanced for other types of compliance costs, which are both one-off and recurring. For example, the cost of the preparation of a DoC and technical documentation is mainly incurred prior to a product being placed on the market. However, in addition to these one-off costs, there are also recurring costs linked to the need to update and maintain a DoC for 10 years post-placement on the market. There is a need to update technical documentation, for instance, to reflect new spare parts and components that are introduced as replacements once a product is already on the market. As regards product design, the costs are mainly one-off, but there could also be recurrent costs if regulatory changes are made and modifications to product design are needed once the product is on the market.

"Business as Usual" (BAU) costs were also taken into account. A number of air conditioning manufacturers stated that a certain proportion (typically 20% to 30%) of product safety testing that they carry out can be considered as BAU since it forms part of internal quality assurance procedures. A number of firms stated that some testing would have been carried out anyway so as to minimise reputational risk even if there is no legal requirement to involve a third party in conformity assessment and the Supplier's Declaration of Conformity (SDoC) can be applied. It was common among manufacturers interviewed to involve a third party in testing for the Low Voltage Directive.

However, there was wide variance in estimates of BAU between firms. A number of firms suggested that approximately 50% of the human resources and cash costs of compliance were BAU, whereas other firms interviewed estimated the proportion to be lower, at 15-25%. An interesting finding was that several manufacturers noted a distinction in BAU depending on the objectives of different pieces of Union harmonisation legislation. A distinction can be drawn between safety requirements, which were seen as an integral part of BAU and those Union harmonisation regulations that related to environmental requirements, which were viewed as imposing additional compliance costs that would not occur in the absence of Union harmonisation regulations. The most commonly cited example in this regard were the eco-design requirements.

Although firms may consider some types of environmental requirements as part of BAU, for instance, as part of their marketing strategy to differentiate products from competitors, the % of BAU costs was much lower. Firm C pointed out that the business as usual case is hypothetical and that it was difficult to provide an accurate quantitative estimate given that without EU regulation, national legislation would apply for safety and environmental requirements. It was suggested that this would create a more complex and fragmented regulatory landscape than is currently the case.

Overall conclusions

This case study focused on air conditioners and air conditioning systems. Since the HVAC industry is very broad, it was not possible to include all categories of air conditioner.

There were difficulties in obtaining reliable data on the air conditioning sector in Europe since Prodcom data was only available at a high level of aggregation. However, global market data shows that the manufacturing of small air conditioners (<12 KwH) and comfort cooling systems is dominated by a small number of global manufacturers, especially from East Asia (the EU has only an estimated 7% share). According to data on the size of the world market for air conditioning in 2013, global production was 98m units in 2013, whereas the size of the European market was about 6.65m units sold in 2012. European manufacturers have a stronger market share in niche markets such as chillers and high-end data cooling systems.

IM legislation applicable to air conditioners and air conditioning systems includes some of the core product safety directives such as the Low Voltage Directive (LVD) and the Electromagnetic Compatibility Directive (EMC). In addition, IM legislation with an environmental focus is applicable, for instance the Ecodesign implementing regulations for small air conditioners and comfort fans <12kwH. From 2015, the extension of ecodesign requirements through Lot 3 Ecodesign Implementing Regulations for larger air conditioners is likely to result in extra administrative costs for industry. These future costs are expected to be quite high compared with well-established IM legislation.

On the basis of information provided by the eight companies interviewed, most of whom were able to provide quantitative information, the costs of compliance with Union harmonisation legislation were estimated at around €50.8 million, equivalent to c.a. 1% of annual turnover. Administrative compliance costs (familiarisation with the legislation and applicable administrative requirements, the preparation of a DoC and technical documentation) were estimated to be approximately €17.2 million. Substantive compliance costs, such as integrating Union harmonisation regulatory requirements into product design and carrying out testing as part of conformity assessment procedures (internally and externally) were estimated at € 23.5 million per year.

The interviews with firms were consistent in pointing to the Ecodesign Directive as one the main current cost drivers of compliance-related activities. It was acknowledged however that the costs of the introduction of new legislation, whilst high in the short-term tend to diminish over time as the legislation becomes better embedded. The need to replace fans integrated into larger air conditioning systems already in the development pipeline or about to be placed on the market was a particular industry concern, since many fans do not meet eco-design requirements.

Sources of information - interviews

References - Sources

- Preparatory study on the environmental performance of residential room conditioning appliances (airco and ventilation), Economic and Market analysis, July 2008.

- Market research data and Prodcom, Analysis presented in Sustainable Industrial Policy – Building on the Ecodesign Directive (DG ENTR).

- A comprehensive overview of applicable legislation in the area of Ecodesign, the Energy Performance of Buildings Directive and the Energy Labelling Directive was produced recently as part of an Ecodesign preparatory study for air conditioning equipment above 12 kW – see www.ecohvac.eu, task 1, page 128-160.

- JARN, the "Japan Air Conditioning, heating and refrigeration news" magazine, 25 May 2013 Prodcom data, 2010.

Interviews

- 1 with a national association in the UK (FITA), and 1 with an EU Industry association (Eurovent).

- 7 interviews with manufacturers of air conditioners, 1 interview with a manufacturer of chillers (6 of the 8 discussions yielded quantitative data.

Annex - Applicable Union harmonisation legislation and standards

This Annex provides information that supplements the summary overview of the applicable Union harmonisation legislation and standards in Section 3 of the case.

A mapping exercise was undertaken to identify applicable Union harmonisation legislation relevant to the air conditioning sector. An overview of relevant legislation and of relevant technical standards is now provided. This draws on desk research and has subsequently been verified by industry associations and enterprises. There are differences in the applicable legislation and technical standards depending on the size of the air conditioning system and its intended purpose (e.g. domestic, industrial, fixed installations vs. portable air conditioners). For example, Ecodesign implementing regulations have only so far been introduced for air conditioning systems <12 kW, although as will be shown in this case study, the withdrawal of non-compliant fan products can also affect manufacturers of larger air conditioning and precision engineering systems which integrate such fans into their products. The PED is only relevant to larger air conditioning systems for industrial use.

Table 7-44: Overview of Union harmonisation legislation and standards applicable to air conditioners and conditioning systems

Name of legislation	*Main issue addressed (safety, environment, other)*	*Administrative requirements for economic operators*	*Relevant standards*
Core legislation			
Low Voltage Directive (LVD)	Health & Safety (electrical)	Testing according to relevant safety standards Development of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations)	Two applicable standards to achieve presumption of conformity for portable and household air conditioning: Part 1 EN 60335-1 (general standard applying to household and similar electrical appliances) Part 2 EN 60335-2-40 Particular requirements for electrical heat pumps, air-conditioners and dehumidifiers EN 50564:2011 Ecodesign – stand by and off mode:
Electromagnetic Compatibility Directive (EMC)	Electromagnetic compatibility	Testing according to relevant technical standards Development of	

		technical file Declaration of conformity and CE marking	
Machinery Directive (2206/42/EC)	Safety	Development of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations)	Only applicable to air conditioning systems intended for industrial and/ or commercial use Requirements of the directive for cooling generators of ENTR Lot 6 are covered under the following standards: - EN 12693:2008 Refrigerating systems and heat pumps - Safety and environmental requirements - Positive displacement refrigerant compressors - EN 378-2:2008+A1:2009 Refrigerating systems and heat pumps - Safety and environmental requirements - Part 2: Design, construction, testing, marking and documentation
Gas Appliances Directive (GAD) 2009/142/EC	Specify the safety level required of appliances burning gaseous fuels by specifying design, operating characteristics and inspection procedures.		Two harmonised European standards have been cited in the OJEU under the GAD: (1) EN 12309-1:1999: Gas-fired absorption and adsorption air-conditioning and/or heat pump appliances with a net heat input not exceeding 70 kW - Part 1: Safety; and (2) EN 12309-2:2000: Gas-fired absorption and adsorption air-conditioning and/or heat pump appliances with a net heat input not exceeding 70 kW - Part 2: Rational use of energy[161]
RoHS Directive (2011/65/EC)	Use of hazardous chemicals	Collect compliance statement from suppliers (material	Note: since the 2011 recast Directive, there is an exclusion from RoHS for fixed installed cooling, air

161 It is of particular interest that the latter standard deals with the energy efficiency of gas-fired air-conditioning appliances (the energy efficiency aspect may be subject to one or several of the implementing measures under the EcoDesign Directive).

		declarations) Technical file with supplier declarations and own analysis tests Declaration of conformity to be kept for 10 years	conditioning and refrigerating systems and heating systems designed for non-residential use. CE marking has been applicable since the 2011 RoHS II recast.
Implementing Regulation on Ecodesign requirements[162]: Regulation 206/2012 EU for air conditioning equipment below 12 kW and comfort fans.	Energy consumption/ efficiency	Testing according to harmonised standard Technical file with results of studies and explanations of design choices made and the management system Development of product fiche Declaration of conformity and CE marking Installation instructions and manual	EN 14511:2011 Determination of Full load energy efficiency EN 14825 2011 Determination of part load energy efficiency EN 62301:2005 (CEN) Standby power consumption EN 12102:2008 Sound power level (CEN) Notes: Applies from 1st January 2013. A regulation on Ecodesign requirements for equipment above 12 kW is in preparation.
Regulation Ecodesign requirements for industrial fans (327/2011 EU)	Fan efficiency	Development of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations	
Regulation Energy Labelling Air conditioners and comfort fans (626/2011 EU)	Energy consumption/ efficiency	Technical file with results of studies and explanations of design choices made and the management system Development of	EN 14511:2011 Determination of Full load energy efficiency EN 14825 2011 Determination of part load

162 A comprehensive overview of applicable legislation in the area of Ecodesign, the Energy Performance of Buildings Directive and the Energy Labelling Directive was produced recently as part of an Ecodesign preparatory study for air conditioning equipment above 12 kW – see www.ecohvac.eu, task 1, page 128-160.

		product fiche Placing of energy label	energy efficiency EN 62301:2005 Standby power consumption (CEN) EN 12102:2008 Sound power level (CEN)
Other legislation			
Pressure equipment Directive 97/23/EC (PED)	Safety of pressurized systems	Development of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations)	EN 378: 2012 environmental & safety requirements Note: only applies to larger air conditioners
REACH Regulation (1907/2006 EC)	Use of chemicals	Collect statement from suppliers stating that product is in compliance with requirements REACH compliance statement	
Packaging and packaging waste (2004/12/EC)	Packaging	Declaration of Conformity	
Regulation Ecodesign requirements electric motors (640/2009 EC)	Motor efficiency	Development of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations	

Regulation Ecodesign requirements glandless circulators (641/2009 EC)	Circulator efficiency (chillers)	Declaration of Conformity CE marking	
Regulation Ecodesign requirements water pumps (547/2012 EU)	Circulator efficiency (chillers)	Declaration of Conformity CE marking	

The European Union's Ecolabel Regulation 66/2010 is a voluntary labelling scheme and can be awarded to products and services that have a lower environmental impact compared with other products in the same group. The label criteria were devised using scientific data on the whole of a product's life cycle, from product development to disposal. There is a link between the voluntary Ecolabel and compliance with Ecodesign regulations in that products bearing the Community eco-label are presumed to comply with the Ecodesign requirements stated in the applicable implementing measures.

Although EU environmental legislation is not formally within study scope, such legislation is particularly important in the air conditioning industry since it forms part of the overall body of EU legislation with which manufacturers must comply. A summary of the main environmental legislation that applies to air conditioners is summarised below:

Table 7-45: Overview of applicable environmental legislation affecting air conditioners and air conditioning systems

Name of legislation	*Main issue addressed (safety, environment, other)*	*Notes and references to relevant standards*
F-Gas Regulation (2006/842/EC)	Containment of greenhouse gases	F-gas regulation and its 10 supporting implementing regulations (leakage, certification personnel, labelling, etc.). Note: legislation under revision due to proposal to revise F-gas Regulation, COM(2012) 643 The aim is to reduce the emissions of fluorinates greenhouse gases covered by the Kyoto Protocol.

Implementing Regulations for the F-Gas Regulation Labelling F gas (1494/2007 EC)	Labelling Certification of technical personnel and companies Leakage	Personnel & company certification is mandatory and concerns personnel who install, maintain or service systems; leak check systems
Energy Performance of Buildings Directive 2010/31/EU (EPBD)	Energy Performance in buildings	Articles 15,16,17,18 deal with the inspection of air conditioning systems, but also the impact of national/ regional calculation methods e.g. SAP in UK, En EV in D, RT 2012 in F There are also a set of related standards developed under CEN TC 113 and CEN TC 228 Energy Performance of Buildings Directive. CEN Standard EN15251 (comfort conditions regarding temperature and humidity).
WEEE Directive (2012/19 EC)	Waste of electrical equipment	The scope is defined in the IA Annex of the WEEE directive (2002/96/EC). Air-conditioning products are dealt with in the IB Annex under 'Large household appliances', as 'Large cooling appliances', 'Air conditioner appliances', 'Other fanning, exhaust ventilation and conditioning equipment'.

3.10.8 Case study 8 – Integrated Circuits

Introduction

The product groups examined in this case study are integrated circuits. This covers a wide variety of products, sub-components and final applications as explained further in section 2, below.

The aim is to analyse the applicable Union harmonisation legislation, assess the costs associated with the implementation of the applicable Union harmonisation legislation, identify areas of overlaps and conflicts between the different parts of the legislation that may lead to problems and costs to industry. This case will also identify and assess the benefits of possible simplifications. The rationale for the selection of these product groups was that:

- Integrated circuits are a fully globalised product group, with important centres of European expertise integrated into the global value chain and which are directly impacted by European legislation

- Integrated Circuits are manufactured in stages, with a number of processes between the first step and the final application in a product. Costs are incurred at each stage of the production process

- Integrated Circuits are perhaps the single most prominent Key Enabling Technology, and are one of the key factors to realise the overall policy objectives of Europe 2020. As such, integrated circuits are the subject of a newly-released European strategy for micro- and nonelectrical components and systems

- Integrated circuits are a key input into a number of additional products and are used primarily by professional users.

This case study is based on desk research and qualitative interviews. In the first phase of the project, structured desk research was carried out in to establish an overview of the integrated circuit industry, identify relevant pieces of legislation and standards, and to identify companies within the industry. An interview with The European Semiconductor Industry Association (ESIA) was then carried out. Thirty-five companies were contacted for interviews. In the end, eight interviews with firms were carried out. The interviews covered one of the largest European-based manufacturers of integrated circuits, another large European manufacturer, one of the largest global manufacturers, based in Asia, and inputs from five smaller 'fabless' manufactures in a variety of applications. A number of companies declined to participate in the study, citing difficulty in assessing costs or, in many cases, confidentiality reasons.

Product definition and description of structure of the sector

According to the standardised language adopted by the International Electrotechnical Commission, a semiconductor is a device whose essential characteristics are due to the flow of charge carriers within a semi-conductor. According to IEC 521-10-03, this includes any *microcircuit in which all or some of the circuit elements are inseparably associated and electrically interconnected so that it is considered to be indivisible for the purpose of construction and commerce*. This includes a number of applications. The following PRODCOM categories have been used to outline the scope of the product group.

Products within scope
26112240 - Photosensitive semiconductor devices; solar cells, photo-diodes, photo-transistors, etc
26113003 - Multichip integrated circuits: processors and controllers, whether or not combined with memories, converters, logic circuits, amplifiers, clock and timing circuits, or other circuits
26113006 - Electronic integrated circuits (excluding multichip circuits): processors and controllers, whether or not combined with memories, converters, logic circuits, amplifiers, clock and timing circuits, or other circuits
26113023 -Multichip integrated circuits: memories
26113027 - Electronic integrated circuits (excluding multichip circuits): dynamic random–access memories (D RAMs)
26113034 - Electronic integrated circuits (excluding multichip circuits): static random–access memories (S–RAMs), including cache random–access memories (cache–RAMs)
26113054 - Electronic integrated circuits (excluding multichip circuits): UV erasable, programmable, read only memories (EPROMs)
26113065 - Electronic integrated circuits (excluding multichip circuits): electrically erasable, programmable, read only memories (E^2PROMs), including flash E^2PROMs
26113067 - Electronic integrated circuits (excluding multichip circuits): other memories
26113080 - Electronic integrated circuits: amplifiers

26113091 - Other multichip integrated circuits n.e.c.
26113094 - Other electronic integrated circuits n.e.c.

As is clear by the range of product types, the product category of integrated circuits contains a number of sub-types. In general, integrated circuits are the building blocks of a number of technologies that make up micro- and nano-electronic components and systems. This includes the semiconductors used in all types of digital application used in electronics, automotive, and medical devices. In addition, integrated circuits are moving into an additional range of applications that further complicate the sector. New technologies such as wearable applications are driving breadth of integrated circuits into new product types.

Market size and Industry Structure

The global turnover of the semiconductor sector has been estimated at €230 billion in 2012, while the value of products comprising micro- and nanoelectronic components represents around € 1,600 billion worldwide and has grown by 5% per year since 2000.[163]

The starting point for the size of the European market is the Eurostat PRODCOM database, supplemented by additional market studies. In the PRODCOM database the specific product are covered under the code 261130-XX. Based on data, turnover is in the range of EUR 56.8 billion. Other sources suggest a somewhat smaller industry, with European turnover in 2011 amounting to EUR 30,3 billion.[164] The most comprehensive report outlining the profile of the Integrated Circuits market is the EU Trade in Electronics Sector Fiche, which is cited by the Industry Association as an authoritative source of market information. The Sector Fiche indicates a market size of

Industry Structure

Semiconductor products are multinational composites, and the industry is highly decentralised and diverse. The process of manufacturing can be broken down into discrete steps, with up to 600 sequential operations for each circuit. Final products are based on wafer processing, testing, and assembly, which generally take place in different places, often in different regions across the globe. The value chain is very complex and long, with the industry moving into even greater levels of fragmentation.

Developing newer generations of chips, becoming smaller and more powerful at an exponential rate, requires a high degree of precision in the fabrication process and higher levels of investment. In the 1980s, a new business model emerged to help solve the need for constant investment, called the "foundry" model, comprised of different types of manufactures. Large foundries, called "fabs" are able to increase the volume of their production to a sufficient scope to allow them to update assembly and photolithography systems, and are more commonly located in the Asian Pacific region. The Taiwan Semiconductor Manufacturing Company (TSMC) is the world's largest dedicated independent semiconductor foundry, with its headquarters and main operations located Taiwan. As a corollary industry, the "fabless" semiconductor company model, is comprised of firms

163 European Commission. 2013.
164 Semiconductors: Global Industry Guide. 2012. MarketLine

focused on design, marketing, and sale of circuits while benefitting from lower capital costs while concentrating their research and development resources on the end market.

The industry continues to bifurcate into two types of integrated circuit producers:

- **Integrated Device Manufacturers** (IDM) that design, manufacture and sell their chips. This includes firms in the United States (e.g. Intel), Asia (e.g. Samsung), and in Europe (e.g. STMicroelectronics, NXP, Infineon).

- **Fabless manufacturers** that design components and provide integrated circuit products and services to customers but outsources manufacturing to foundry companies. Fabless manufacturers often source their products from multiple foundries to optimise their supply chain and secure constant access to materials.

- A hybrid '**fab-light**' model has also emerged, which is based on maintaining some high-value manufacturing in-house but outsourcing the rest to a foundry.

The continued migration of production to 'low cost' labour countries combined with the continued high rhythm of technological change has driven companies to focus on core competencies, meaning that European firms are increasingly specialised in one component of the value chain.[165] The emergence of a networked model has allowed for – and subsequently encouraged – a greater degree of specialisation and opportunity for new entrants in highly-innovative areas of design, logistics, services, and computer-supported manufacturing.

This globalisation of the industry has also created a very long and complex supply chain in which European firms increasingly focus on collaboration and industrial partnerships. It is common for companies to rely on supply chains for most subcomponents, with third party testing occurring at various stages along the production phase, depending on the product type, country of origin, and intended final application.

The European industry is driven by a high research-intensity, with the highest R&D intensity of any sector in Europe, at 14.8 percent.[166] Industry clusters are important in the integrated circuits sector, given the high R&D intensity and the need to specialise. The most significant European clusters are located around Grenoble (France), Eindhoven (Netherlands), Dresden (Germany) and Dublin (Ireland), but other European clusters such as Catania in Italy also have global presence. It also appears that the leading clusters will reinforce their position as technology transitions to a new platform based on 450 mm wafers.[167] To sustain these clusters, European-wide supply chains have developed, with additional high-tech clusters in increasingly specialised fields (such as Helsinki and Vienna). Table 7-46 outlines key descriptive data on the European market.

The largest manufacturer is located in Taiwan (TSMC). Within the top 20 producers in terms of worldwide sales, only three are located in Europe: STMicroelectronics, Infineon, and NXP. While European manufacturers do not command a large global share, some producers of integrated circuits have established sites in Europe, including sales, design, and research along with some production as well capacity. In 2011, European production represented less than 10 percent of global production, down from a high of 16 percent only a decade earlier.

165 http://ec.europa.eu/enterprise/newsroom/cf/_getdocument.cfm?doc_id=7382
166 The EU Industrial R&D Investment Scoreboard: http://iri.jrc.ec.europa.eu/scoreboard.html
167 European Strategy for Micro and Nanoelectronic Components and System

Nevertheless, in Europe, micro- and nanoelectronics is responsible for 200,000 direct and more than 1,000,000 indirect jobs. [168]

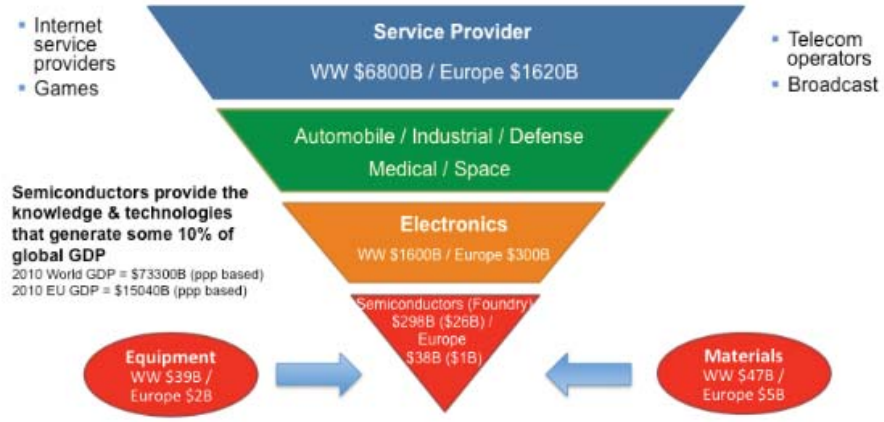
Table 7-46: Data on market size and industry structure

Parameter	Data
EU Market size	Market reports (2011) EUR 30.3 billion
Production volume/value in Europe	PRODCOM – Production Value (2010) – EUR 49.2 billion PRODCOM - Production Quantity: 11.415.218.521 units
Imports	PRODCOM - Value of Imports: 11.174.225.410 units
Exports	PRODCOM - EUR 8.8 billion
Number of enterprises	PRODCOM (2010) 6,984
Total Turnover	PRODCOM - EUR 56.8 billion
Number of employees	ESIA (2012) 200,000 direct employment PRODCOM (2010) 215,000

Source: Eurostat and market reports

The Final Report of the High-level Expert Group on Key Enabling Technologies[169] estimates that the European sector will enjoy a compound annual growth rate of 13 percent over the next years. But the industry data itself does not tell the complete story of the value of the integrated circuits sector to the overall European and global economy. Integrated circuits constitute a Key Enabling Technology (KET) and are valuable for the economic potential, their value-adding and enabling role, as well as their technology and capital intensity in terms of R&D and initiation investment costs.[170] The image below outlines the economic impact of the sector, both in terms of providing a market for suppliers of materials and equipment, moving up into direct employment and the subsequent industries enabled by the presence of software.

Figure 7-2: Value of Enabling Technology



Source: ESIA, 2010

168 http://ec.europa.eu/enterprise/sectors/ict/files/kets/hlg_report_final_en.pdf
169 High-Level Expert Group on Key Enabling Technologies. Final Report. http://ec.europa.eu/enterprise/sectors/ict/files/kets/hlg_report_final_en.pdf
170 High-Level Expert Group on Key Enabling Technologies. Final Report.

Analysis of applicable Union harmonisation legislation and standards

On the basis of desk research and input from firm interviews, we have identified the list of applicable pieces of Internal Market legislation, the basic administrative requirements and the relevant harmonised standards that can be used by manufacturers to meet the essential requirements.

In response to the internal market legislation, a number of **standards** have been developed, as outlined in table 7-47. Integrated circuits are highly technical and subject to broad international standardisation. Extensive standards exist. Given that the range of potential applications and sub-groups is limitless, only the major product-specific regulations have been reviewed. The table is meant to illustrate key standards that are aligned with specific requirements from internal market legislation, and is far from comprehensive.[171]

Standards vary according to the organisation issuing them. A number of standard-setting organisations exist, such as industry-led bodies (JEDEC), as well as the IEC and ISO/CEN. The IEC have been active in developing recent standards for the industry, as it focuses on the electronics industry.

Table 7-47: Summary of Union harmonisation legislation covering Integrated Circuits

Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
RoHS (2011/65/EC)	Use of hazardous chemicals	Collect compliance statement from suppliers (material declarations) Technical file with supplier declarations and own analysis tests Declaration of conformity to be kept for 10 years	EN 50581:2012 IEC62321

171 A search for 'integrated circuits' on the British Standards Institute database resulted in 685 individual standards. http://shop.bsigroup.com/en/SearchResults/?q=integrated%20circuits

Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
General product safety Directive	Health & Safety	Provide identification of the product by a product reference Carry out sample testing of products, keep a register of complaints and keeping distributors informed of such monitoring (voluntary) Inform authorities of dangerous products and actions taken to prevent risk Co-operate with the authorities upon request	CENELEC: EN 60950-1:2006/A12:2011
EMC	Electromagnetic compatibility, mostly in the downstream applications of some integrated circuits	Testing according to standards Development of technical file Declaration of conformity and CE marking	IEC 61000 IEC 61967 IEC 62132
Packaging and packaging waste (2004/12/EC)	Packaging	Declaration of Conformity	
REACH	Use of chemicals	Collect statement from suppliers stating that compliance with requirements REACH compliance statement	IEC 62474

The review of the various requirements and the discussions with manufacturers pointed to a few issues in relation to the implementation of the legal framework and the requirements:

- Of the regions that produce integrated circuits, Europe is the most highly-regulated region in the world and plays a key role in the development of global standards. Given the globalised nature of the industry, with highly developed supply chains, undue or particularly burdensome regulation can cause shifts in production location. The initial analysis suggests that most Directives place rather similar obligations on industry; namely, revise the design of some products and then subsequent requirements to test, document, and declare conformity to specific requirements.

- This uniformity in across the sector was pointed out in the interviews with firms as being a positive aspect of the current framework. The industry is in general agreement that the legislation and the surrounding legislative framework are fairly positive. However, specific instances of duplication and inconsistencies have been identified.

- The most specific piece of legislation relating to integrated circuits is the RoHS Directive, which has been in effect since 2006. It was recently updated, known as RoHS2 (2011/65/EU), to address some uncertainties raised by industry and to increase market surveillance. RoHS2 bans new electrical or electronic equipment containing lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl and polybrominated diphenyl ether flame-retardants above specified thresholds and places documentation requirements throughout the supply chain.

- The interviews with firms consistently pointed to the RoHS Directive as the main driver of compliance-related activities. However, the interviews also emphasised that the RoHS-related procedures are part of a larger change to the industry that is now so deeply integrated in to the supply chain that it could not be isolated, even hypothetically.

- RoHS applies to integrated circuits produced in Europe as well as those entering the EU that are manufactured abroad. Due to the global nature of the industry, RoHS has become a *de facto* global regulation. China recently adopted most of the provisions through 'China RoHS,' which applies to the bulk of manufactured products. The RoHS concept is thus deeply integrated into the global industry and provides a framework for much of the supply chain.

- RoHS provisions are also reinforced and complemented by REACH, Directive No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals. The General Product Safety Directive introduces mandatory requirements concerning the product identification, cooperation with authorities when requested and a voluntary conduct of tests of marketed products, and the keeping of a register of complaints.

Analysis of costs of compliance with Union harmonisation legislation

The information presented in this section is based on the in-depth interviews with eight producers of integrated circuits. The firms range in terms of size and production volume and a located at various points along the production chain.

Given that the integrated circuits industry is completely globalised, turnover has been estimated from the turnover from Europe or from the European subsidiary of global companies. Information has been taken from corporate reports. It should also be noted that

even though turnover is from Europe, the overall activity is fully global, such as R&D taking place in Europe with manufacturing happening in other regions, generally in Asia).

Firm	Product / Application	Firm Size	Annual turnover from product (global)	Share of EU market (% of total firm turnover)
A	Fabrication	Large (>1000 employees)	3,900,000,000	33
B	Fabrication	Large (>1000 employees)	17,100,000,000	10
C	Fabrication	Large (>1000 employees)	4,368,000,000	20
D	Fabless - telecommunications	Medium size (250-500)	388,000,000	32
E	Fabless – consumer electronics	Small (<250 employees)	2,400,000,000	10
F	Fabless –touchscreen components	Small (<250 employees)	3,000,000	100
G	Fabless - general	Small (<250 employees)	6,000,000	15
H	Fab-lite - general	Medium size (250-500)	1,800,000,000	66

On the basis of discussion with the integrated circuit producers, IM legislation generates impacts on the following stages of the production process:

- Familiarisation with legislation and the purchase of standards
- Development of alternative designs and the associated testing of materials
- Seeking authorizations and exemptions, if needed, from RoHS and REACH lists of restricted substances
- Documentation of c Documentation of compliance - Testing, technical file and certification
- Monitoring the suppliers in the supply chain for compliance and switching to avoid non-compliance
- Declaration of conformity, CE marking and instruction manual
- Response to market surveillance activities

A number of caveats are necessary.

- It should also be noted that while costs have been suggested at specific points along the path towards compliance with EU Internal Market legislation, specific data on the costs is not available for each step.

- The interviews have produced limited information on the specific impact. One key reason is that, as a result of the dominant use of the foundry model, much of the compliance costs are absorbed throughout the supply chain and not by an individual company. OEM suppliers in third countries are required to adhere to restrictions while also complying with design requirements set out by fabless producers.

- Compliance testing occurs very early in the supply chain and it is not possible to disaggregate compliance costs for the IC firms. In addition, firms have not been able to estimate the amount of resources involved in the design process linked directly to regulatory compliance versus design procedures relate to quality, reliability, or adherence to regulations and standards set out at an international level.

The general process followed by manufacturers to ensure compliance with the IM legislation includes the following closely interlinked steps, and any specific data on costs has been identified and noted.

Familiarisation with relevant legislation and purchase of standards

The introduction of new legislation places costs on firms, including the time and resources used to familiarise themselves with the legislation.

The purchase of standards is one approach to learning about the implications of specific relevant legislation, which generates financial costs. Interviews with firms suggest that no standard 'familiarisation period' can be feasibly created due to the differences in the requirements. Manufacturers, suppliers, distributors, and end producers of consumer products develop administrative systems or databases applicable requirements are organised. Databases are being developed to manage the complexity of keeping track with IM legislation, standards, and amendments.

However, the costs association with each of these features is dependent on the specifics of legislation, of the new provisions, the intended end use of the semiconductor, and of the product portfolio. Therefore, no general average can be derived, according to the interviews. Indeed, the interview respondents suggest that databases and tracking systems are a normal part of working in an industry with a long supply chain and diffuse set of suppliers.

The smaller fabless firm states that they rely on their suppliers as well as their customers to inform them of implications of the various pieces of legislation. Third party testing occurs, but it varies depending on the production chain. In terms of their suppliers, fabless manufacturers tend to create industry partnerships with 'fabs' that produce the raw inputs into the integrated circuits. In general, there are fewer and fewer producers and the fabs are highly involved in the discussions of standards and legislation. On the customer side, the main market for European producers includes some of the most highly-regulated industries, which are careful to conform to legislation. Therefore, according to the interview with a fabless manufacturer, the industry has knowledge of how to comply and this knowledge is shared up and down stream.

Under REACH, the substance of very high concern (SVHC) "candidate list" can be updated annually and functions as a "living list".[172] As soon as a SVHC appears on the "candidate list", suppliers of articles containing the SVHC must forward information on the listed SVHC contained in the article (above a concentration of 0.1%) to recipients. The list is updated every 6 months, and even the larger firms have a very difficult time managing the speed with which the list is updated, though the industry has not produced data to demonstrate the burden. The European Chemical Agency (ECHA) engages in a highly structured public consultation every year, with consultation period of 45 days.[173] However, the participation of industry representatives is highly context- and product-dependent; nevertheless, this period of consultation generates discussion in advance of the introduction of changes, which allows for some familiarisation with the legislation.

According to the interviewees, manufacturers rely on **standards** to meet the essential requirements. Standards vary according to the organisation issuing them. A number of standard-setting organisations exist, such as industry-led bodies (JEDEC), as well as the IEC and ISO. The IEC have been active in developing recent standards.

Two interviews with small fabless producers suggest that smaller companies rely on standards, but that often changes are generally clearly articulated by customers and additional standards are not always purchased. The firm indicated that standards are purchased as needed, with some periods of time requiring the purchase of standards, as well as significant variation depending on the product line. Moreover, industry standards are often translated into customer specifications. Even in the absence of specific standards, producers would need to comply with customer specifications.

New costs have been introduced since the industry has shifted from voluntary industry standards created by JEDEC, which were free, to the IEC standard EN 50581:2012 was made available in 2012 by CENELEC related to **"**Technical documentation for the evaluation of electrical and electronic products with respect to restriction of hazardous substances." This standard must be purchased. The current prices for the identified standards covering a majority of the sector include:

Relevant Standard	**Price (EUR)** [174]
EN 50581:2012	43
IEC62321	252
EN 60950-1:2006/A12:2011	277
IEC 61000	187
IEC 61967	122
IEC 62132	122
IEC 62474	204

172 An updated version of the "candidate list" can be found in the ECHA website: http://echa.europa.eu
173 http://echa.europa.eu/en/web/guest/view-article/-/journal_content/512b7526-9dd6-4872-934e-8c298c89ad99
174 The International Electrotechnical Committee is based in Switzerland and bases its prices on the Swiss Franc (CHF). Conversions use the following rate: CHF/EUR = 0.8147

Given that the range of potential applications and sub-groups is limitless, only the major product-specific regulations have been reviewed (see table above).

Development of alternative designs and the associated testing of materials

Internal market legislation generates two distinct costs on firms in terms of design choices. First, some manufacturers have had to redesign products to comply with restrictions on materials. Second, under the two most applicable internal market directives, RoHS and REACH, companies have an opportunity to petition for an exemption or authorisation from some of the limitation imposed by the legislation. Because two separate lists are created, with separate procedures for exemptions/ authorisation, there is a duplication of effort combined with a high degree of uncertainty about certain substances.

In terms of **redesign**, one important source of compliance costs has been the requirements of the **RoHS** Directive in relation to the use of lead, which is used in a number of components in the manufacture of integrated circuits. The industry is still in the process of phasing out lead. There were significant upfront costs for the conversion to lead-free packaging, and until recently the unique functionality of lead soldering was required for some components and packaging.

Exemptions have been obtained under RoHS to allow for the continued use of some lead in a limited number of applications. Thus, testing for compatibility and replacement programmes has been an ongoing activity for firms. A number of companies outlined a 'conversion roadmap' to demonstrate progress towards converting their product line towards compliance with RoHS.[175]

Large companies initiated compliance programmes in response to European regulations (especially RoHS) relatively early, while many smaller producers did not have the capacity or inclination to develop substitutes and only recently started to address this issue. RoHS compliance presents many product management and design decisions such as whether to bring products into compliance or to make them obsolete, or whether to make use of the currently granted exemptions.[176]

RoHS generated upfront costs of material substitution, given that many types of integrated circuits used lead soldering. While the interviews would not confirm the cost, some studies of the impact of RoHS suggest that the impact equals 1.9% of total turnover,[177] which is generated by the upfront costs of switching to lead-free components. This is roughly in line with a 2008 study which estimated that, generally, the average past and future one-off cost impact of RoHS lies between 1 and 2% of total turnover. However, these studies did not focus exclusively on integrated circuit manufacturers, nor did they document the precise source of costs.

Interviews with firms could not provide further information, though the interview with a large producer suggested that the RoHS compliance programmes are among the most pressing R&D and compliance issues for the industry, especially given the unique functions played by some substances, such as lead.

175 See, for example, the chart created by NXP: http://www.nxp.com/about/corporate-social-responsibility/environment/lead-free-halogen-free/matrix.html#complete

176 ESIA. 2009. Semiconductors: Enabling Sustainable Living in 21st Century Europe.

177 Cited in http://www.nema.org/Policy/Environmental-Stewardship/Documents/081203%20RoHS%20impact%20assessment%20summary.pdf

Seeking authorizations and exemptions

In terms of the authorization and exemption processes, some materials are critically important to the integrated circuits, both in terms of some harmful substances used in the production process while others are found in trace amounts in the final product due to their unique functionality in achieving performance goals for the product. The material development cycle in the semiconductor industry is typically 10-15 years, consisting of fundamental research, hazard and risk evaluation, demonstration and integration with manufacturing equipment (and sometimes the development of new manufacturing equipment or processes), and production. Where chemicals already used in manufacturing need to be replaced, ample time must be provided to develop substitutes for these chemical uses.

The large manufacturers stated in interviews that the requirements often serve as an impediment that is eventually overcome rather than a true barrier. No examples of specific instances could be presented where the use of a key substance could not be substituted or an exemption obtained. A review of company websites outlines the continued use of hazardous or dangerous materials in the production process, even though the substance does not end up in the finished product.

Nevertheless, the exemption and authorisation processes are very costly, according to the interviews, though no fixed amount is available. There are two aspects of the duplication that cause substantive costs. RoSH 2 and REACH apply to some of the same substances in the same products and processes, sometime resulting in duplication of administrative burdens. RoHS 2 provides rules on the restriction of certain hazardous substances in Electrical and Electronic Equipment (EEE), while REACH is a more general act regulating or restricting chemical substances. In terms of specific duplication, in a position paper from March 2013, Orgalime points out[178] that there is some overlap in the Directives. Four substances highlighted under RoHS2 for priority assessment, namely plasticisers BBP, DBP, DEHP and flame retardant HBCDD featured in the REACH Candidate list back in 2008 and are now also included in the list of substances subject to REACH authorisation in Annex XIV.

When seeking exemptions, there are two separate procedures that need to be followed and the two Directives do not recognise each other's lists of banned substances. In some cases, an exemption can be obtained in one list but not in another; in some of these cases, there could be a delay in obtaining the second exemption.

There appears to be inconsistency in the application of RoHS and REACH, especially in terms of valid procedures that are consistent for both Directives. The industry association, ESIA, points out that lists based around the REACH processes that target substances for *potential likely action* without any upfront risk review on whether or not the risk is managed in how the semiconductor sector uses the substance. This uncertainty creates barriers to product development without a full risk-based assessment taking place.

178 http://www.orgalime.org/sites/default/files/PP_Complementary_REACH_and_RoHS_Mar13.pdf

The overlap and inconsistency cause a duplication of effort and significant uncertainty for the industry, with the greatest effects in product development. So far, the interviews have produced limited information on the specific impact. One key reason is that, as a result of the dominant use of the foundry model, much of the compliance costs are absorbed throughout the supply chain and not by an individual company. OEM suppliers in third countries are required to adhere to restrictions while also complying with design requirements set out by fabless producers.

Compliance testing occurs very early in the supply chain and it is not possible to disaggregate compliance costs for the IC firms. In addition, firms have not been able to estimate the amount of resources involved in the design process linked directly to regulatory compliance versus design procedures relate to quality, reliability, or adherence to regulations and standards set out at an international level.

Documentation of compliance - Testing, technical file and certification

Testing has long been a normal procedure in the integrated circuits industry, either in-house or by specialised testing houses. With the emergence of RoHS and REACH, third party testing houses have emerged to fill the gap in internal capacity of some smaller fabless manufacturers. IDMs have in-house testing capabilities, and increasingly have started to offer testing services to their industry partners to help consolidate some of the processes within the supply chain.

Both RoHS and REACH require the development of a technical file following testing, most often following a specific standard created by the industry. RoHS2 introduces new requirements for companies to maintain technical files. This is a significant difference compared to the first version of the RoHS Directive, which did not prescribe any requirements for manufacturers to maintain compliance documentation.

Under the original RoHS, firms along the supply chain did not have this obligation; the final OEM manufacturer or importer who puts the finished branded equipment on the market in the EU incurred all the costs of managing the supply chain.[179]

As a result of major end users being required to monitor the supply chain, suppliers have long been encouraged through market pressure to maintain technical files, and this has long been a well-established practice in the integrated circuits industry.

However, the practice remained *ad hoc* and incomplete, according to the large manufacturer interviewed. RoHS2 now puts more of a structured framework in place. Standard EN 50581:2012 was made available in 2012 by CENELEC related to **"**Technical documentation for the evaluation of electrical and electronic products with respect to restriction of hazardous substances"[180] to meet the needs of technical documentation.

179 https://www.bomcheck.net/assets/docs/Guide%20to%20REACH%20Requirements%20for%20component%20suppliers%20and%20equipment%20manufacturers.pdf

180 This European Standard specifies the technical documentation that the manufacturer needs to compile in order to declare compliance with the applicable substance restrictions. The documentation of the manufacturer's management system is outside the scope of this European Standard. http://www.cenelec.eu/dyn/www/f?p=104:110:3448161281810912::::FSP_PROJECT,FSP_LANG_ID:23432,25

Information obligations add an additional administrative cost. An important source of administrative costs is with REACH Regulation. REACH places a legal obligation on all EU suppliers to provide substance declaration information when they supply their outputs (components and sub-assemblies) to the next manufacturer in the supply chain. This could extend to contract manufacturers when they supply equipment to OEM clients, drawing on information which component suppliers are required to disclose to the contract manufacturer. However, the costs vary depending on the unit type and the size of the order.

There are also certain synergies in the databases since many of the requirements are the same and industry standards are able to cover both Directives. A single technical file system can capture information pertaining to both RoHS and REACH. The General Product Safety Directive introduces mandatory requirements concerning the product identification, cooperation with authorities when requested and a voluntary conduct of tests of marketed products, and the keeping of a register of complaints.

Firms provided direct estimates of human resources dedicated to managing the technical files. The resources dedicated to managing these files vary significantly according to firm size and location in the production chain. For example, a small fabless producer (focusing on design and sales) with 25 employees reported that 1 FTE was required to address requests for documentation. A large global producer, with a staff of 24,000, stated that there are approximately 50 FTE dedicated specifically to compliance. In this latter case, approximately half of the staff time is normally dedicated specifically to RoHS. However, the total responsibility for maintaining the files is distributed across a number of additional staff resources, including sales staff, R&D, quality assurance, and management. Another large producer stated that the European-based team has a large legal team, with 42 people and one in-house council that focus on, among other domains, export compliance.

Monitoring the suppliers in the supply chain for compliance and switching to avoid non-compliance

Linked to the certification costs, firms in the downstream stages of the supply chain are required to verify the certification of their suppliers and then pass this information onto their clients. This places significant burdens throughout the supply chain. Although REACH and now ROHS2 place obligations on companies to pass on information, in practice it is the demands of customers that cause companies to collect stringent information, up to the standards of the eventual end-users.

A number of approaches have been adopted to monitor the supply chain. Downstream firms, especially larger firms operating with many suppliers, require relevant supplier to pre-register substances and preparations used in industrial (including engineering) processes and will monitor and support registration by suppliers.

As integrated circuits move from one producer to the subsequent stages of development, the common practice is to use a bill of materials (BOM) to document the materials and substances contained in the circuit. Ideally, suppliers will issue a Full Materials Declaration, which states all of the elements and substances that are contained in an integrated circuit. According to desk research and interviews, this is not consistently practiced. Confidentiality was raised as one potential barrier in obtaining all relevant information. In some cases, re-testing is required where there is a ‘break in the chain’ from one stage to the next. Confidentiality was also cited as one of the impediments to obtaining precise estimates; given that efficient management procedures are part of the value proposition of some companies, details were not forthcoming.

The main concern is the amount of detail that needs to be carried forward along the development process of integrated circuits. One difficulty that was mentioned by a large manufacturer was that there are potentially dozens of suppliers in any single component, and that it is often a problem if one of the intermediary suppliers has not kept adequate records. Often, the level of detail of a company's record system is actually a selling point in terms of the appeal of using a specific supplier.

Some companies are encouraging smaller suppliers to pre-register their Bills of Materials on private platforms that offer industry-wide databases to manage certification and declarations of compliance. BOMCheck is the most developed platform.[181] Under this system, suppliers can create a vendor account and the purchasers can apply for a subscription that allows for verification of records. For the BOMCheck system, the subscription fee for suppliers is an annual fee of EUR 300. [182] More than one million RoHS and REACH Materials Declarations from over 3,100 suppliers have been uploaded to the system, as of June 2013.[183]

Declaration of conformity, CE marking and instruction manual

Based on a review of the websites of a wide sample of the industry, it appears that the standard practice is to post Declarations of Conformity on the company webpage. This does not appear to be particularly burdensome, and the interviews suggest that this is a common practice that is recognised by firms in the sector. Indeed, the introduction of REACH and RoSH2 could potentially redistribute costs across the supply chain rather than place all costs on the single point at which the final product is placed on the market, meaning that costs are transferred rather than altered.

Manufacturers within the EU must obtain a declaration of ROHS compliance for all the parts, components, and materials that they are using, while importers need to obtain a declaration of compliance from their suppliers.

The set-up costs do, however, include the time to carry out the conformity assessment and check that standard documentation has been obtained. Some of the larger downstream companies facilitate this process on behalf of suppliers, and it ensures a smoother process for identifying required documentation. Based on the interviews with firms, the CE Marking is recognised as a normal cost of doing business and is not seen as unduly burdensome.

The industry has adopted Design for RoHS compliance guidelines, though this is internal for each company and differs based on the application. The large manufacturer uses this design guideline internally, while the small fabless manufacturer relies on the foundry to check for the compliance of its designs before shipment.

181 See the industry-led initiative, BOMCheck, developed by the European trade association COCIR and coordinated by the environmental consultancy ENVIRON, which sits on co-chairs the IPC 1752A materials declaration standard and serves as EMEA regional coordinator for the IEC 62474 materials declaration standard. https://www.bomcheck.net/

182 See press release: http://www.prnewswire.com/news-releases/bomcheck-celebrates-more-than-1-million-rohs-and-reach-materials-declarations-from-over-3100-suppliers-211932871.html

183 There is no limit to the number of part numbers that the supplier can load into the database or the number of customers that the supplier may have on BOMcheck.

Response to market surveillance activities

RoHS2 includes obligations for all EU Member States to perform systematic market surveillance including "*appropriate checks on product compliance on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples*". In contrast, RoHS1 did not prescribe any enforcement procedures that Member States were required to implement.

While the documentation requirements for compliance are burdensome, interviews did not yield specific instances of particular burdens with market surveillance beyond what would be expected under typical regulation. Under RoHS, firms have 28 days to provide sufficient documentation of conformity, and there is no suggestion in the available information that this is particularly burdensome.

Both the fabless and the IDM interviewed state that while there are some occasions that surveillance authorities request information, by far the largest burden is on supplying information to client downstream, such as manufactures of electronics, automotive, or other industries. The interview respondents state that given the highly-regulated nature of the end manufacturers (automotive, industrial processes, telecommunications industries), some of which are very tightly regulated in Europe and other countries, there is a high burden on the supply chain to maintain records.

Large firms maintain structured protocols for responding to surveillance requests while the smaller firm relies on an *ad hoc* approach, rarely exceeding the 1 FTE that has been allocated to maintaining the technical file, reacting when necessary to supply information. Details of the document management system were not shared, though the firm was clear in that a standard approach to managing supplier documentation is sufficient for responding to requests. It was also stressed that requests from clients are normally the key source of inquiries and far outweigh any burden from surveillance agencies.

Business as usual

Some of the costs indicated above should be considered as part of a business as usual scenario, especially those related to information sharing. While the interviews focused on the impact of RoHS and REACH, all interviews stated that quality management would still be part of internal procedures irrespective of the regulatory framework requirements, and the information requirement would remain just as burdensome. The large company stated that in some instances, the Directives and corresponding standards are helping to simplify the information as it moves through the supply chain as common standards are imposed for all companies. Product reliability tests are often conducted by established firms that want to ensure the quality of their products, so information will always need to be shared.

Furthermore, the presence of significant legislation in other countries (e.g. China and Japan) means that important part of the documentation required and the significant costs of maintaining sophisticated databases would likely have been incurred even in the absence of EU legislation.

<u>Estimation of Assessment of costs of Union harmonisation legislation for the whole sector</u>

Disentangling costs is limited, given the lack of information and the diffuse burdens across the supply chain. The complex and very long supply chain creates impacts for manufacturers

far upstream and downstream, though it is difficult to estimate the distribution of the burdens. Moreover, interviews suggest that the impacts of pieces of legislation are highly context-dependent, ultimately differing based on the product portfolio of a company (number and types of products), as well as the location with the supply chain.

On the basis of specific cost information from four of the interviews, we estimated the administrative costs for the main cost elements identified and, on the basis of certain assumptions, to extrapolate to the whole of the EU industry. The interviews did not provide sufficient data to present cost details. The following table presents some information. The average figures from the interviews were upscaled using turnover.

Type of Cost	Estimated annual costs for the whole sector
Internal	€ 7.6 million
Third parties	€ 26 thousand
Testing equipment	€ 10 thousand
Total	**€ 7.6 million**

As is evident, internal compliance costs represent the main cost element for the industry. The interviews suggest that internal processes and activities related to compliance were the highest share of the total costs. Compliance testing is linked to companies' R&D activities. Research and Development costs are inevitably high in the integrated circuits industry, which is a major factor explaining why integrated circuits are the most R&D intensive industry in Europe, according to the European Commission's R&D Scoreboard. Third party testing and testing equipment specifically for compliance with internal market legislation is marginal in terms of the overall R&D budgets. Again, a number of assumptions that have been made related to the costs need to be further examined and discussed with the relevant association.

Overall conclusions

This case study examined the role and costs of Union harmonisation legislation for integrated circuits, the building blocks of a number of technologies that make up micro and nano-electronic components and systems. According to PRODCOM data, the European market for integrated circuits has a total market size of €56.8 billion while other sources suggest that the industry is somewhat smaller industry, around €30 billion. European manufacturers do not command a large global share and European production represented less than 10 percent of total global production in 2011.

The applicable Union harmonisation legislation covers issues related to product safety only indirectly (through the General Product Safety Directive), electromagnetic compatibility (EMC) and focuses more on environmental impacts (REACH and RoHS Directives).

On the basis of information provided by some companies, the administrative costs for the sector were estimated at around €7.6 million. The interviews with firms consistently pointed to the RoHS Directive as being the main driver of compliance-related activities. However, the analysis also emphasised that RoHS-related procedures are part of broader changes within the industry that are now so deeply integrated into the supply chain that the compliance costs specifically linked to internal market legislation cannot be easily isolated.

Sources of information

- Eurostat Structural Business Statistics Database and PRODCOM
- Text of applicable IM legislation and relevant standards
- Policy and strategy documents published by the European Commission or relevant industry associations
- Industry Association: The *European Semiconductor Industry Association* (*ESIA*)
- Interviews with eight firms, varying in size, market share, and product applications.

ANNEX 8: FEEDBACK ON MARKET SURVEILLANCE IN THE EU [SWD(2014)23]

1. CHALLENGES FACING MARKET SURVEILLANCE AUTHORITIES

EQ17: What are the main challenges facing market surveillance authorities?

Market surveillance is a Member State responsibility, although the Commission has an important overall monitoring and coordination role. Effective market surveillance and regulatory enforcement is a crucial mechanism for ensuring the efficient and effective implementation of IM legislation for industrial products. It is vital for ensuring product safety and health and for promoting fair competition and a level playing field among economic operators. In order to strengthen the current approach to market surveillance, the EU adopted Regulation 765/2008 setting out common market surveillance rules and the Commission has proposed a Regulation on Market Surveillance as part of the wider Product Safety and Market Surveillance Package (PSMSP).

As noted earlier, market surveillance is inherently challenging and is considered by many stakeholders (e.g. 60.6% of NBs responding to our survey) to be the most problematic part of the IM regime for industrial products. Indeed, the impact assessment accompanying the PSMSP highlights a number of challenges, which have also been confirmed by the research undertaken for this evaluation.

A first challenge is the relatively **high levels of non-compliant products** entering the market, although instances of non-compliance often relate to minor administrative irregularities rather than to serious breaches of the essential requirements. There is evidently a balance to be struck between preventing non-compliant products from entering the market and avoiding the imposition of unreasonable requirements on responsible economic operators. It is also reported that there are relatively **few withdrawals of non-compliant products** from the market, although the RAPEX information system has helped to raise awareness of high-risk products (see section 4.82 below). However, the 2006 public consultation on the New Legislative Framework (NLF) found that 87% of operators considered there to be unfair competition due to the presence of non-compliant products on the internal market[184]. Evidence from a number of evaluations and impact assessments suggests that non-compliant products account for a sizeable share of the market in certain sectors. This is confirmed in data provided by market surveillance authorities[185].

For example, the impact assessment[186] on the proposed "Radio Equipment Directive" to replace the R&TTE Directive cited evidence from European Market Surveillance Authorities (MSAs) that presently between as little as an estim ated 28% and 56% of products were fully compliant with the essential requirements. Administrative compliance has been estimated at an even lower level by MSAs at about 20%. In the case of the Ecodesign Directive, non-compliance was estimated to be 10- 20%[187.] In other areas (e.g. Gas Appliances, Personal protective equipment) the existing studies indicate non-compliance levels of no more than 5-10%[188] and there are also cases – such as explosives – where, according to the relevant

184 EC (2012), Product Safety and Market Surveillance Package - COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT , http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=swd:2013:0033(51):FIN:EN:PDF

185 EC (2012), Commission Staff Working Document, Annexes to the Impact Assessment, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2013:0033(52):FIN:en:PDF

186 Proposal for a Directive of the European Parliament and of the Council on the harmonisation of laws of the Member States to the making available on the market of radio equipment

187 Evaluation of the Ecodesign Directive (2009/125/EC) - Final Report

188 Impact assessment study on the review of the Gas Appliances Directive 2009/142/EC

evaluation study[189], there are very few cases of non-compliance.

However, this is also a possible illustration of authorities giving a higher priority to products more directly linked to public safety issues. Estimates from market surveillance authorities and enterprises collected in 2006 also ranged from 1% for recreational craft to 30% for the Electrotechnical sector and even up to 50% for luminaires. Similar findings were obtained in three market surveillance campaigns carried out by the Administrative Cooperation group (ADCO) for the implementation of the Electro-magnetic Compatibility Directive focusing on Energy Saving Lamps, Power Tools and Consumer Entertainment Electronic Products. The level of technical non-compliance was 23% for the Energy Saving Lamps, 20% for the Power Tools and 50% for the Consumer Entertainment Electronic Products while according to the ADCO machinery NOMAD study around 80% of products do not comply with noise requirements.

A second challenge, related to the first, is the difficulty in **ensuring the traceability of products**, which was stressed by a number of interviewees, so that market surveillance authorities can obtain technical documentation not only at the point when products are placed on the market but for up to 10 years following their placement on the market. The limited traceability of products and of manufacturers strongly hinders market surveillance authorities in carrying out their work and improvements in this area would help to strengthen the efficiency and effectiveness of MSAs. However, it should be noted that economic operators were not generally favourable towards traceability requirements, and in particular, were against the introduction of requirements to register in databases. A major EU industry association stated that "the manufacturer is already legally responsible for ensuring regulatory compliance and for producing the DoC to achieve presumption of conformity. Traceability has become a religion and imposes unnecessary administrative burdens on economic operators, such as compulsory registration schemes and the requirement to put the address of the responsible economic operator on the label."

A market surveillance authority in the **UK** commented that concerns about the administrative burdens of registration schemes extend beyond industry to some public authorities. "The proposed new registration scheme under the new R&TTE is intended to improve the traceability of products. However, it risks causing a bigger divide between good and bad providers; by creating more hoops to jump through, it will discourage some economic operators from complying and could also give greater competitive advantage to non-compliant providers".

A Product Contact Point in **Sweden** pointed out that, although there has been a lot of discussion about traceability in the context of the Alignment Package, its value and importance depends on the type of product concerned, the directive or regulation in question and whether it is a professional or a consumer product. "When we refer to professional products where economic operators are known to one another, the extent to which there is really a need for traceability requirements should be reconsidered since this imposes unnecessary administrative requirements".

A third challenge is the **difference in approaches taken to market surveillance in different countries**, for example, how likely MSAs are to carry out testing themselves, as opposed to requesting technical information from economic operators. Such differences may undermine

189 Evaluation on dg enterprise and industry legislation – Cosmetics and Explosives Directives

the internal market since there could be variations for economic operators in their experiences, for instance, the type and frequency of requests for information from market surveillance authorities, the likelihood of having products tested, etc. Different approaches to market surveillance often reflect different levels of resources and technical expertise available to MSAs in each country; some stakeholders were of the view that the level of resources and expertise was insufficient in some countries.

One MSA in **Sweden** noted that "We test a broad selection of products ourselves and do not only ask manufactures to submit papers on the use of products. We also test a broad selection of products from different geographic origins both within and outside the EU. We do identify dangerous products and even where products are generally compliant, remarks are made for three-quarters of products tested". Another MSA in **Romania** noted that market surveillance needs to be "highly coordinated and capable of reacting rapidly. However, market surveillance has not kept pace with developments in the Union's regulatory framework, which could be overcome through the use of an "intelligent" model. This means that "random checking" will not be mathematically random, but will instead be focused on a risk-based approach and the identification of potential problem products and economic operators that have previously been non-compliant. Wholesalers, distributors etc. who are known by experience to comply with the rules may therefore expect a fewer inspection visits".

Encouragingly, stakeholders reported that market surveillance had improved and become more consistent across different Member States through the measures included in the NLF and, in particular the common rules on market surveillance set out in Regulation 765/2008. Some Member States (e.g. Greece, Ireland, Slovenia) had made significant changes to their market surveillance systems, such as the creation of national market surveillance authorities and the development of market surveillance programmes, as a direct response to the requirements of Regulation 765/2008.

Research Findings (RFs)

- (RF60) Market surveillance is considered to be the weakest part of the implementation system, partly due to the inherently difficult nature of the task and in part due to varying levels of resources and technical expertise available in different countries. (Stakeholder interviews; Survey of NBs)
- (RF61) There are high levels of non-compliance for some products, low levels of product withdrawals and a need to strengthen the traceability of products. However, there is the need for MSAs to differentiate between minor instances of non-compliance with administrative requirements and serious instances of non-compliance with essential safety requirements. (Data from previous studies; Stakeholder interviews)

2. CO-OPERATION AND INFORMATION SHARING BETWEEN MARKET SURVEILLANCE AUTHORITIES

EQ18: How effective is the co-operation between market surveillance authorities?

Through the evaluation, we also assessed the extent to which mechanisms and tools put in place to facilitate cooperation between market surveillance authorities and information sharing are working effectively, notably the Rapid Alert Information System (RAPEX) and the "ICSMS" tool (Information and Communication System for Market Surveillance.

Regulation 765/2008 includes a reference in the Regulation to the RAPEX system and has highlighted the importance of this exchange information mechanism for market surveillance in the Single Market. The report on the implementation of Regulation 765/2008 provides feedback on the added value of RAPEX. "Reference to the RAPEX system in the Regulation has extended the obligation to send RAPEX notifications to all goods falling within the scope of EU harmonisation legislation, including products for use in a professional context (e.g. industrial machinery) and products which may harm public interests other than health and safety (e.g. environment, security etc.). This has contributed to the protection of workers and the environment, although the total number of new notifications has been limited during the first two years of implementation".

However, a market surveillance authority in **Ireland** noted that "RAPEX has not led to many notifications for harmonised products for professional users and the ICSMS has been more useful in practice". Whereas RAPEX was viewed as being useful in informing market surveillance authorities and the Commission about high-risk products, and the database is useful for reporting purposes on products presenting serious risks, **ICSMS**[190], the general information support system for market surveillance also has an important contribution in ensuring that there are mechanisms in place for exchanging information between market surveillance authorities, joint working and for virtual communication and cooperation.

The tool provides a single portal containing information on specific products (product description, test results, in cases of non-compliance identified any remedial measures taken etc.). Two of the actions set out in the Multi-annual plan for market surveillance refer to ICSMS (Action 2: Maximise the benefits of ICSMS and Action 3: Create synergies between GRAS-RAPEX and ICSMS). A small number of stakeholders referred to ICSMS during the interview programme.

A market surveillance authority in **Germany** stressed the importance of the need for greater synergies between RAPEX and ICSMS. "ICSMS is a great operational tool to communicate with different market surveillance authorities in other EU Member States. Among the advantages of using the system are that it is available in all languages across EU28. Documents can be uploaded and although there is no automatic translation of all documents, most phrases are translated. This solves one of the practical difficulties in ensuring effective market surveillance - language problems can be a barrier to finding out about dangerous products and for avoiding duplication of effort between market surveillance authorities in different countries".

ICSMS was not seen as duplicating RAPEX but rather complementing it. It was pointed out that it is only available in EN and it does not provide a tool for communicating and collaborative working between market surveillance authorities, which ICSMS does.

The need to examine the scope to merge different databases on market surveillance that feed into Member State reporting requirements to the Commission was highlighted. For example, a market surveillance authority in **Belgium** noted that "Each year, Member States have to prepare a report on market surveillance carried out and set out the plan for the coming year. There are several databases that are useful, such as Circa, RAPEX, ICSMS. The Commission should investigate whether merging of databases is possible and should study

190 ICSMS provides an internet-based platform for the comprehensive exchange of information between all the market surveillance bodies. The tool has an internal area for the use of market surveillance authorities that can also be used by customs authorities and EU officials.

the value added of each database".

Research Findings (RFs)

- (RF62) RAPEX and ISCSMS are viewed as useful in informing market surveillance authorities. (Interviews of MSAs)
- (RF63) There is scope to increase the complementarity and synergy between RAPEX and ISCMS. (Interviews of MSAs)

3. RISK-BASED AND SYSTEMS-BASED AUTHORITIES

The proposed Market Surveillance Regulation is based on a risk-based approach to market surveillance (of both harmonised and non-harmonised products). One of the criticisms made by stakeholders is that there is no definition in the Regulation of what constitutes risk, and the criteria to assess it. A market surveillance authority in **Germany** commented that *"Market surveillance authorities should focus on checking non-conformity, since this is easier to perform against the regulatory requirements. If instances of product non-conformity are identified, and it is judged that these are likely to lead to a risk or to a serious risk, then these products should be alerted through the RAPEX system.* Although they were in favour of having common elements in Union harmonisation legislation built into a horizontal regulation, market surveillance should continue to be based on an assessment of product compliance with IM regulations.

However, the report on the implementation of Regulation (EC) No 765/2008 published in February 2013 as part of the PSMSP asserted that progress has already been made in the development of a **risk assessment methodology**. It was noted that the existing RAPEX Guidelines already provide for the risk assessment methodology for consumer goods, and are an important reference point for Member States. Moreover, in 2011, the Commission set up a Risk Assessment Task Force composed of Member States' experts whose role was to assess: (i) whether the existing methodology, whose main focus is on non-harmonised products, could suitably take into account the legal requirements of harmonised goods; (ii) how to address the need to assess risks to public interests other than health and safety, which are not taken on board by this methodology.

Through the research, we reviewed good practice in carrying out market surveillance (given the broad focus of our study, only selected examples are possible). In the **Netherlands**, a systems-based approach to market surveillance based on risk has been adopted. This was recognised by interviewees in other countries such as **Latvia,** as being an interesting, and potentially transferable example. An explanation as to how the system works is provided below:

Table 8-1: A systems-based and horizontal approach to market surveillance and regulatory enforcement[191]

In the Netherlands, the government adopted the "Vernieuwd Toezicht" (Renewed Surveillance Programme) in 2008. The aim is to strengthen the efficiency and effectiveness of market surveillance activities by fostering better relationships with economic operators and by raising

191 Source: Systeemtoezicht en Horizontaal Toezicht, conceptleidraad voor de Rijksinspecties, Begrippen en randvoorwaarden, December 2012 http://www.inspectieloket.nl/vernieuwing_toezicht/programma_systeemtoezicht/

awareness among enterprises about their legal obligations under product safety and environmental legislation.

A distinction is made between (i) horizontal enforcement and (ii) system-based enforcement. These two different types of enforcement are already being applied by some government inspections agencies. *Horizontal enforcement* involves combining regulatory enforcement with horizontal activities and support actions for enterprises.

Implementing a horizontal approach refers to the development of mutual cooperation between government and society. Horizontal enforcement is based on building mutual trust and a working relationship between government and economic operators based on the development and implementation of quality management systems to strengthen regulatory compliance. The agreements are set out in a covenant based on a partnership-based approach which is published on the inspection agency's website. The provision of relevant information, the exchange of knowledge, and if relevant the monitoring of business activities are sufficient to consolidate compliance.

S*ystem enforcement* focuses on the enforcement of quality and assurance systems and more specifically on the development of a strategy for companies to set up robust regulatory compliance procedures, documentation to measure the results achieved, interventions committed and the defects. Surveillance in general takes place on the basis of periodical (administrative) inspections. Surveillance is not aimed at checking whether individual regulations have been complied with. The confidentiality of the government in the enterprise is still based on inspection.

The application of horizontal and system-based approaches means that that one agency may apply the horizontal system and another may apply a system-based approach, while others adopt elements of both approaches. Through the application of a horizontal and system-based approach, the inspection can reduce the administrative burdens for enterprises/institutions which take their responsibility and do not injure the confidentiality received from the government. In addition the surveillance institutions are in the position to focus their capacity to enterprises performing not correctly.

An example of a surveillance authority that applies the system approach is the Food and Consumer Product Safety Authority (Voedsel en Warenautoriteit). The systems-based approach is targeted at larger manufactures and EU importers based on the following criteria: position in the value chain (manufacturer, EU importer or major distributor); they must have a relatively large share of the market;, regularly included on RAPEX or often having defects found during product inspections; their willingness to invest in strengthening business-processes aimed at ensuring the safety of products.

Research Findings (RFs)

- (RF64) There is a need for better definition and clarification of risk and how to assess it in the proposed Market Surveillance Regulation, building on the proposed risk assessment methodology in the PMSP. (Analysis of legal text; Interviews of MSAs)

- (RF65) There is a need for guidance on the relative merits of the alternative approaches to market surveillance and the circumstances under which each type of approach should be adopted. (Analysis of legal text; Interviews of MSAs)

ANNEX 9: REVIEW AND ASSESSMENT OF MARKET SURVEILLANCE ON NON-FOOD PRODUCTS IN THE EU

1. INTRODUCTION

In the framework of the implementation of Regulation (EC) No 765/2008 (also 'the Regulation') setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, Member States must periodically review and assess the functioning of their market surveillance activities. Article 18(6) of the Regulation requires such reviews to be carried out at least every four years and stipulates that the results are to be communicated to the other Member States and the Commission and made available to the public.

As Regulation (EC) No 765/2008 has been applicable since 1 January 2010, the first round of reviews and assessments communicated by the Member States relate to market surveillance activities carried out between 1 January 2010 and 31 December 2013.

In order to facilitate their compilation and transmission of the information, the Commission prepared – with the help of the members of the Internal Market for Products Expert Group, IMP-MSG – a template that Member States could use to structure the relevant information. Among other things, the template establishes a reference list of 29 sectors falling within the scope of the Regulation that should be included in the Member States' reviews and assessment (hereinafter 'the reference list of sectors').[192] Market surveillance carried out under Directive 2001/95/EC (General Product Safety Directive or GPSD) could be optionally included. At the same time, the template left Member States free to determine the relevant criteria for the assessment of the different (general/sectoral) market surveillance activities.

The reviews and assessments prepared by each Member states are available on the following page (under the section "List of national reviews and assessments of the functioning of market surveillance activities"): http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm. The reports have also been published by Member States[193].

This annex gives a combined overview of the Member States' own reviews and the assessments of market surveillance activities, and attempts to present main findings on the implementation of the EU requirements for market surveillance.

In particular, the remainder of the document is structured as follows:

(a) A snapshot of the information provided by each Member State by explaining the approach taken when collecting and assessing the functioning of market surveillance activities, the general organisation of market surveillance and the resources available to it, the sectors covered by the national report and the conclusions drawn.

(b) The main findings on the implementation of the Regulation at national level in the 2010-2013 period and points to challenges faced. Finally it contains some considerations on the results of this first application of Article 18(6) of the Regulation.

192 The template also clarifies that market surveillance activities conducted under REACH and CLP Regulations fall within the scope of Regulation 765/2008. However, since they are already the subject matter of specific reports available to the public, they could be excluded from the reviews and assessment carried out pursuant to Article 18(6) of the Regulation.

193 However at the time of writing the Commission is still awaiting for confirmation of publication by one Member State.

(c) A more detailed analysis of information provided by Member States for a specific sector (Toys).

2. OVERVIEW AND ASSESSMENT

All Member States, have communicated to the Commission their review and assessments of market surveillance activities during the 2010-2013 period. The majority of Member States chose to follow the common template prepared by the Commission, while Germany, Croatia, Lithuania, the Netherlands and the UK chose a different format for their report.

Overall, most Member States provided a considerable amount of data and other information on their activities. This section summarises the information provided by each Member State by organising it according to the following scheme:

General market surveillance activities

- General organisation: this part sums up the way market surveillance responsibilities are distributed among different authorities and the main tools for cooperation and coordination between them, as well as with customs in a given Member State. The information contained in Member States' reports according to Article 18(6) of the Regulation should be integrated with the information already provided in national market surveillance programmes[194] and in the Report on the implementation of Regulation (EC) No 765/2008[195].

- Resources: this part indicates the overall resources made available to market surveillance, if mentioned in Member States' reports.

- Own assessment: this part contains each Member State's own assessment of the distribution of responsibilities, cooperation and coordination between national authorities, as well as of the total resources available to them.

Market surveillance in specific sectors

- Coverage: this part explains how many of the 29 sectors (plus 1 optional sector) that the Commission recommended to include in the national reviews and assessments are covered in each Member State's report.

- Distribution of resources: this section indicates those sectors in which a given Member State concentrates most of the available resources and those where resources are lacking according to the national report.

- Own assessment: this part summarises each Member State's own assessment of the functioning of market surveillance sectoral activities in the 2010-2013.

194 See the section "National market surveillance programmes " on the following page: http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm

195 COM(2013)77.

2.1 Belgium

General market surveillance activities

General organisation: Belgium refers to the information on the general organisation of market surveillance provided in the national programmes. Market Surveillance pursuant to Regulation (EC) No 765/2008 is handled at national level (with voluntary contributions from individual regions) and is carried out by several federal government departments, agencies and institutes. The majority of products covered by the harmonised European legislation fall under the responsibility of the Federal Public Service (FPS) for Economy, SMEs, Self-employed and Energy.

Table 9-1: Distribution Market Surveillance Responsibility in Belgium

FPS for Economy, SMEs, Self-employed and Energy	Toys Machinery Cableway installations Personal protective equipment Lifts Equipment for use in explosive atmospheres Pressure equipment Pressure receptacles Household appliances measuring energy consumption Central-heating boilers Gas appliances Low voltage electrical equipment Electromagnetic compatibility Non-automatic weighing instruments Explosives for civil use Pyrotechnic articles Construction products Pre-packaged products

FPS Health, Food Chain Safety and the Environment	Chemical products Cosmetic products Electrical and electronic equipment Noise emissions of equipment used outdoors
Scientific Institute for Public Health	In vitro diagnostic medical devices
FPS Finance	Customs activities
Federal Agency for Medicines and Health Products	Pharmaceutical products Medical devices Active implantable medical devices
FPS Mobility and Transport	Motorised vehicles Transportable pressure equipment Recreational craft Railway systems Marine equipment
Federal Agency for the safety of the Food Chain	Fertilisers
Belgian Institute for Postal services and Telecommunications	Radio equipment and telecommunications terminal equipment Electromagnetic compatibility Eco-design and energy labelling
Federal Agency for Nuclear Control	Medical devices and similar products Radiopharmaceuticals Dosimeters

In cases where several authorities have responsibility for a particular area, the area is assigned to the authority with primary responsibility.

There is no national body to coordinate market surveillance activities but for the purpose of Article 18(5) (national programmes) and Article 22 (RAPEX) of the Regulation, a coordinator role has been assigned to the Interministerial Economic Commission (IEC) within the Federal Public Service for Economy for the exchange of information.

Overall resources: Belgium does not provide this resource information.

Own assessment: The report does not provide an assessment of the effectiveness or efficiency of the general market surveillance organisation.

Market surveillance in specific sectors

Coverage: The Belgian report covers most sectors indicated in the reference list (including non-harmonised consumer products falling under the GPSD) with the exception of medical devices, cosmetics, transportable pressure equipment, cableways, pyrotechnics, explosives for civil uses, recreational crafts and marine equipment.

Distribution of resources: Belgium provides information on resources for the period 2010-2013 on market surveillance for some of the various federal government departments and product sectors.

Resources for market surveillance for the FPS Economy decreased from 1.1 million EUR in 2010 to 0.8 million EUR in 2013, coupled with a decline in the number of inspectors from 11 to 7.5 full-time equivalent unit (FTEs) staff.

The FPS Public Health, Food Chain Safety and Environment is responsible for enforcing the national Products Standards Act of 21 December 1998, checking a wide range of consumer products for the possible presence of dangerous substances. A yearly budget of 425 000 EUR (not including staff members) has been allocated for market surveillance, with 16 FTEs' staff availability of which 13 inspectors.

The information on the amount of resources dedicated to market surveillance by the FPS Mobility shows an increase in the period 2010-2013 from around 133 000 EUR to 206 000 EUR, with an increase in FTE availability from 1 to 2.5 (1.5 FTEs for inspectors).

The report stipulates allocation of resources on market surveillance on electrical appliances and equipment falling under the low voltage directive (0.7-0.5 mln EUR; 0.6-0.4 staff), appliances burning gaseous fuels (102 000-217 000 EUR; 1.0 staff) and eco-design and energy labelling with a budget of 73 000 EUR over 2013 and 1 FTE for staff available.

Other indicated sectors are electrical equipment with a budget of 40 000 EUR over 2013 and 0.7 FTEs, electrical equipment falling under the Electromagnetic Compatibility Directive (48 000-40 000 EUR; 0.7 staff) and efficiency requirements for hot-water boilers (26 500 EUR-28 600 EUR; 0.2 staff). Coverage also extends to the construction products sector where 1.5 FTEs are allocated to market surveillance activities

Own assessment: The Belgian report provides information on enforcement and communication activities carried out in most sectors. The results of some inspection campaigns can be found on the responsible authorities' websites. In general the report does not provide for an assessment of the effectiveness or efficiency of these sector-specific activities.

2.2 Bulgaria

General market surveillance activities

General organisation: Market surveillance authorities within the meaning of Regulation (EC) No 765/2008 are the following institutions:

– the State Agency for Metrological and Technical Supervision (DAMTN), which carries out market surveillance activities for products covered by the New Approach directives (except Medical Devices), for eco-design requirements, for energy-related products, on

waste from electrical and electronic equipment and restriction of hazardous substances;

– the Consumer Protection Commission (KZP), which is the specialized state authority in Bulgaria dealing with the problems of consumer protection. It is also one of the main internal market surveillance authorities. Its main activities relate to the surveillance of the safety of general products and services on the Bulgarian market, the protection of the main consumer rights, trade practices and methods of sale, etc. In addition KZP is the Bulgarian contact point for the RAPEX system;

– the Executive Agency for Medicines (IAL) to which are assigned the market surveillance activities for medical devices;

– the Regional Health Inspectorates (RZI) responsible for cosmetics and chemicals;

– the Bulgarian Food Safety Agency (BABH), responsible for fertilisers;

– the Technical Control Inspectorate (KTI) responsible for agricultural and forestry machinery and

– the Regional Inspectorates for the Environment and Water (RIOSV) responsible for surveillance of fluorinated greenhouse gases and ozone depleting substances.

The market surveillance authorities function according to the distribution of competences between four ministries, namely the Ministry of the Economy and Energy, the Ministry of Health, the Ministry of Agriculture and Food and the Ministry of the Environment and Water.

Coordination and exchange of information between market surveillance authorities in Bulgaria takes place by means of a Council established by a governmental act in 2005.

Overall resources: Bulgaria provides information on the resources of the two major market surveillance authorities. From the total budget of DAMNT between 2010 and 2013, about 2.3 million EUR were dedicated each year to market surveillance related to the New Approach directives[196] (except for Medical Devices), eco-design and waste of electrical and electronic equipment . Furthermore, the authority employed each year 275 full-time equivalent unit (FTE) staff (out of which about 150 inspectors). During the same period, the market surveillance budget of KZP decreased from 1 to 0.7 million per year[197] and the authority employed about 130 FTEs for staff (of which about 110 inspectors).

Own assessment: Bulgaria assesses the functioning of the main market surveillance authorities (see section below). No specific assessment of general organisation (e.g. cooperation and coordination) is provided.

Market surveillance in specific sectors

Coverage: The Bulgarian report covers all sectors in the reference list, except cosmetics, efficiency requirements for hot-water boilers and marine equipment, as well as non-harmonised consumer goods. It also includes, leather labelling, crystal glass, food-imitating products, packaging, liquid fuels and wheeled tractors.

196 The budget also covers inspections of industrial equipment during use, as well as quality control of liquid fuels.
197 Correspondingly, the share of KZP's resources dedicated to market surveillance went down from 62% to 40%.

Distribution of resources: One third of DAMNT financial resources were dedicated to market surveillance of products put into operation (industrial use) such as pressure equipment, transportable pressure equipment, machinery, lifts, and cableways; about 25% was allocated to market surveillance of products placed on the market like toys, personal protective equipment, construction products, noise emissions, ATEX, pyrotechnics, civil explosives, radio equipment and telecommunications terminal equipment, restriction of hazardous substances and waste from electrical and electronic equipment, eco-design; about 13% to market surveillance of measuring instruments.

More than two-thirds of the resources available for market surveillance to KZP were dedicated to the enforcement of the Packaging Directive[198] (0.3-0.4 million EUR per year) and the safety of non-harmonised consumer products (0.2-0.3 million EUR per EUR), followed by leather, textile and energy labelling (respectively up to 80 000, 70 000 and 60 000 EUR/year during the reporting period).

Own assessment: according to the Bulgarian report in the period 2010-2013 DAMTN succeeded in achieving the general objectives laid down in the sectoral programmes by applying the requirements of Regulation (EC) No 765/2008. On the other hand, difficulties experienced in market surveillance relate in particular to the lack of information in tracing products back along the distribution chain to the producer or the responsible economic operator, lack of cooperation by certain economic operators, e-commerce challenges, high cost of tests in some sectors, unavailability of expert staff to carry out assessment of compliance in certain sectors (e.g. personal protective equipment).

KZP is also considered to have achieved good results, despite an insufficient number of staff having to deal with an increasing volume of activities. The same inspectors carry out market surveillance activities in all sectors falling within the competence of the KZP. A lack of material and financial resources hampers work relating to the outsourcing of laboratory analyses establishing product compliance with safety requirements or the conformity and reliability of information provided by economic operators in labels or advertising messages.

The Bulgarian report contains information on the way the other authorities work in their respective areas. A specific assessment of their activities is not systematically provided.

2.3 Czech Republic

General market surveillance activities

General organisation: market surveillance in the Czech Republic is carried out by various central government bodies – authorities subordinated to specific ministries with specific powers. Coordination among authorities and with customs is ensured by bilateral agreements.

The report from the Czech Republic does not provide an overview of the general organisation of market surveillance at national level. On the other hand, it refers to the detailed annual reports prepared by some of these authorities, notably by the Trade Inspectorate Authority (CTIA), which assumes overall responsibility for the vast majority of the product areas mentioned in the reference list of sectors (medical devices, toys, protective equipment, aerosol, machinery, lifts, noise emissions, equipment for use in potentially explosive atmospheres, gas appliances, electromagnetic compatibility, low voltage electrical products

198 Directive 94/62/EC.

and appliances, radio equipment and telecommunications terminal equipment, measuring instruments, recreational crafts, as well as timber, batteries and novelty lighters.

Overall resources: the total national resources for market surveillance cannot be estimated because the budget of the relevant authorities does not distinguish between funds earmarked for market surveillance and other tasks. The same can be said for staff. However as CTIA carries out almost exclusively market surveillance its total budget[199] (on average around 9.5 million EUR per year between 2010 and 2013) provides a good indication of resources for market surveillance for most sectors.

The total number full-time equivalent units (FTE) for staff employed in market surveillance was between 940 and 1090 per year[200], out of which between 415 and 445 inspectors. Resources decreased over the 2010-2013 period.

Own assessment: According to the national report the functioning of market surveillance in the Czech Republic can generally be considered effective. The level of cooperation between surveillance authorities is very good. In areas where the powers of certain supervisory authorities overlap, rules are in place to ensure effective coordination of the surveillance.

Individual surveillance authorities carry out specifically-focused inspections, the results of which are then used both to set priorities for further surveillance activities and to enhance the efficiency of surveillance authorities' activities. Various surveillance authorities keep their own databases of monitored products, and this undoubtedly has a positive impact on the overall success of surveillance activities.

The representatives of the various market surveillance authorities regularly attend European and international meetings; relevant market surveillance information is then shared with other surveillance authorities.

The main problems encountered by surveillance authorities relate to:

- The persistent problem lack of funds and material resources to ensure the truly effective implementation of surveillance activities.

- The lack of an accident and injury database (IDB) to determine surveillance priorities.

- Frequent difficulties in tracking and tracing products/manufacturers throughout the supply chain (particularly from third countries), which is naturally reflected in the overall efficiency and effectiveness of market surveillance. The sale of products via e-shops further contributes to this.

- The proportion of poor-quality, high-risk products from third countries that reach the market via informal supply channels (e.g. marketplaces), where the efficiency of surveillance remains questionable.

199 The figure excludes the wages of personnel not directly involved in markets surveillance.

200 Between 415 and 460 staff was employed by CTIA, 414-479 for the Environmental Inspectorate (chemicals and consumer products under the GPSD), 50-60 people worked for the Energy Inspectorate (competent for the area of ecodesign and energy labelling), 47 for the Health Ministry (cosmetics, products for children up to three years and food contact materials), 35 for the Rail Authority (interoperability, simple pressure vessels, transportable pressure equipment and cableways),5 for the Arms and Ammunition Authority (pyrotechnics, firearms and ammunitions) and 0.5 or the Mining Authority (civil explosives and mining machinery.

Market surveillance in specific sectors

Coverage: the Czech report includes all sectors in the reference list, plus timber products, mining machinery, batteries, blasting technology resources and food contact materials.

Distribution of resources: There is no information on the distribution of financial resources. As to the staff figures reported in the section above on overall resources, it is noted that about 75% of total inspectors were employed by CTIA, slightly less than 10% by the Energy Inspectorate competent for eco-design and energy labelling and a further 5% by the Environmental Inspectorate competent for chemicals.

Own assessment: the Czech Republic provides extensive information on enforcement and communication activities carried out in most sectors and points to challenges faced; furthermore, additional information can be found in some of the annual reports produced by Czech authorities[201]. On the other hand, the report does not provide for a more general assessment of the effectiveness or efficiency of these sector specific activities.

2.4 Denmark

General market surveillance activities

General organisation: Denmark refers to the information on the general organisation of markets surveillance provided in the national programmes. Due to the decentralised organisation of market surveillance in Denmark, the Market Surveillance Committee established in 2010 has the task of contributing to the exchange of information about initiatives and strategic projects, to disseminate best practices (e.g. to ensure that the authorities make the best possible use of the tools available for exchanging information) and to help to clarify the boundaries between authorities and create opportunities for collaboration in overlapping areas. The Committee is chaired by the Danish Business Authority. The latter authority and the Danish Safety Technology Authority serve jointly as the Secretariat. Compliance with the Regulation's requirement largely depends on the active commitment of the authorities to the work of the Market Surveillance Committee.

Overall resources: Between 2010 and 2013**,** Denmark devoted between 8.2 and 8.6 million EUR per year to market surveillance. Overall staff available to market surveillance can be estimated at around 72-78 full-time equivalent units (FTE) (among which between 30 and 35 inspectors[202]). Data show that the budget and staff for the market surveillance authorities remained fairly constant over the 2010-2013 period. The figures are largely based on estimates and therefore have some uncertainty associated with them.

Own assessment: According to the Danish report, market surveillance in Denmark is working well overall, and collaboration between the relevant authorities is satisfactory. Danish authorities also participate actively in relevant European fora, including the ADCO groups (administrative collaboration). None of the authorities have reported any problems in relation to collaboration with the notified bodies.

201 For instance the latest CTIA annual report indicates that in 2013, the Czech Trade Inspection Authority carried out a total of 37,299 inspections, which was 23% less than in the previous years. However, the rate of inspections with findings increased from 28.6% in 2012 to 35.5% in 2013.

202 The proportion of staff who are inspectors may be slightly greater, since some authorities have not classified their staff in more detail.

The following challenges are identified:

- The need to always prioritise initiatives and optimise the use of resources in order to implement comprehensive, effective market surveillance.

- The ineffectiveness of surveillance and penalties in respect of e-commerce businesses that sell to Danish consumers, but are situated in third countries or merely act as intermediaries.

- Businesses' lack of knowledge and guidance concerning the legislation.

- Examples of cases where authorities in the Member States take contradictory decisions despite harmonised legislation.

Market surveillance in specific sectors

Coverage: The Danish report covers almost all sectors indicated in the reference list (including non-harmonised consumer products), the only exception being explosives for civil uses and efficiency requirements for hot-water boilers. It also includes food contact materials and some national legislation.

Distribution of resources: The sectors to which the greatest part of resources was allocated are medical devices (1.5-2 mln EUR; 9-11 staff), machinery (1.3-1 mln EUR; 11.3-8.8 staff), electrical appliances and equipment falling under the low voltage directive (1-1.2 mln EUR; 10.7-12.3 staff).

The report notes that no ad hoc resources were allocated to market surveillance in the areas of noise emissions and recreational craft.

Own assessment: Demark provides extensive information on enforcement and communication activities carried out in most sectors and points to challenges faced. In general the Danish report does not provide an assessment of the effectiveness or efficiency of these sector specific activities.

2.5 Germany

General market surveillance activities

General organisation: Information on the general organisation of market surveillance in Germany can be found in the national programme for 2014. In Germany the responsibility for market surveillance falls within the remit of the Länder. Since 2000, the coordination of activities of the individual Länder is ensured by the Working Committee on Market Surveillance (AAMÜ). AAMÜ also decides on inter-regional focus initiatives in Germany as part of proactive market surveillance. This Committee also includes representatives from customs authorities and other sectors, e.g. the Federal Network Agency (electromagnetic compatibility and R&TTE directives) and the German Institute for Construction Technology (construction products).

From 1 January 2013 the coordination tasks of the Länder market surveillance authorities, as in Article 18(5) (national programmes), Article 22 (RAPEX) and Article 23 (ICSMS) of Regulation (EC) No 765/2008, were transferred to the Central Authority of the Länder for

Safety (ZLS). In certain cases ZLS also has the power of enforcement in relation to a specific product. The new set up has improved coordination.

Overall resources: Germany has omitted information on financial resources and staff as it believes that it would not contribute towards any conclusion on the effectiveness or efficiency of market surveillance activities.

Own assessment: The national report does not provide an assessment of the general organisation of market surveillance in Germany.

Market surveillance in specific sectors

Germany's report under Article 18(6) of the Regulation follows a different approach from that proposed in the common template. Germany summarises the results of the market surveillance actions included in the four-year programme established in 2010. Exceptions are made for the Electrical products under electromagnetic compatibility and the radio equipment and telecommunications terminal equipment sectors for which more specific information has been provided (see below).

Coverage: In general, the German report concerns the sectors covered by the national Product Safety Act which transposed the General Product Safety Directive and 12[203] other directives among the 29 included in the reference list of products. In addition the Product Safety Act covers non-harmonised non-consumer products.

The report focuses on the 11 target areas for proactive market surveillance mentioned in the programme for sectors covered by the Product Safety Act. Some of these areas are based on hazard presented by products, while others are of a more horizontal nature. The majority of these action areas cannot be linked directly to specific product sectors. The table below shows the number of market surveillance campaigns[204] implemented under each area.

Table 9-2: Action areas and corresponding market surveillance campaigns

Action area	Number of market surveillance campaigns
Area 1: Optimisation of target group-specific information	94
Area 2: Uniform application of revised RAPEX guidelines	4
Area 3: Cooperation with customs authorities	166
Area 4: Electronic sales channels	247
Area 5: Safety through standardisation	33
Area 6: Hot surfaces	95

203 Aerosol dispensers (75/324/EEC), Simple pressure vessels (2009/105/EC), Personal protective equipment (89/686/EEC), Appliances burning gaseous fuels (2009/142/EC), Equipment and protective systems intended for use in potentially explosive atmospheres (94/9/EC), Recreational craft (94/25/EC), Lifts (95/16/EC), Pressure equipment (97/23/EC), Machinery (2006/42/EC), Low voltage (2006/95/EC) , Toys (2009/48/EC), Noise emission in the environment by equipment for use outdoors (2000/14/EC).

204 This may either consists in sampling and testing, or also encompass activities such as collecting, processing and editing of information (e.g. on categories of potential users).

Area 7: Electrical fire hazards	127
Area 8: Closing forces	5
Area 9: Market surveillance and operational safety	408
Area 10: Safety of products for children	158
Area 11: Cheap products from non-EU countries	631

Furthermore, Germany reports the following information on specific sampling and testing activities conducted under the Product Safety Act:

Overall the market surveillance authorities of the Länder performed approx. 78 000 checks in total from 2010 to 2013, in which around 138 000 products were inspected with regard to their conformity;. 4 761 products were tested in laboratories.

It was found that 47 % (65299) of the products inspected did not comply with requirements205. By contrast, the proportion of those products that presents a serious risk is only 0.7 % (1032 cases).

About 15% (2930) of the overall measures (17969) were taken by market surveillance authorities, while the rest was taken voluntarily by companies.

Following those measures, 562 products were withdrawn from the market, 100 products were recalled from consumers, 8863 products were destroyed and 206 sanctions were imposed.

Distribution of resources: The report mentions resource allocation to Electrical products under electromagnetic compatibility and the radio equipment and telecommunications terminal equipment sectors. In total and between 2010 and 2013 € 12.1 million to € 11.6 million were available to the market surveillance authorities with a staff allocation of a consistent 85 full-time equivalent units (FTE).

Own assessment: Germany considers that setting priorities in the form of action areas proved useful in a context of limited resources, although experience suggests that certain action areas should be adjusted or discontinued and new action areas added (e.g. market surveillance at trade fairs, involvement in standardisation). No assessment of the effectiveness or efficiency of market surveillance activities in specific sectors is provided. Improvements in market surveillance are needed to address the challenge of on-line sales where the relevant economic operator is often outside the EU and border controls are performed by customs, for which product specific-specialist knowledge must be available.

2.6 Estonia

General market surveillance activities

General organisation: Market surveillance is carried out by seven authorities: the Consumer Protection Board, the Health Board, the Technical Surveillance Authority, the Labour

205 The percentage of rejected products does not indicate a representative value for the entire market; it is due to the fact that official investigations are initiated primarily in those cases where it can be assumed there is a high probability that non-compliant products are being placed on the market

Inspectorate, the Maritime Administration, the Environmental Inspectorate and the Agricultural Board.

To facilitate cooperation and exchange of information between the authorities, a market surveillance council has been set up at the Ministry of Economic Affairs and Communications, made up of representatives from all market surveillance authorities, including the Tax and Customs Board, and from the ministries under whose jurisdiction they operate. Exchange of information between market surveillance authorities also takes place bilaterally.

Overall resources: Estonia states that it is not possible to indicate financial resources that are dedicated solely to market surveillance, since this is only a part of the responsible authorities' activities. It is possible to indicate the operating expenses of the authorities as a share of the total national budget. This translates into 29.7 million EUR in 2010 (0.53% of 5.6 billion EUR) and increasing to 35.4 million EUR in 2013 (0.46% of 7.7 billion EUR).

Further, the number of staff available to market surveillance authorities ranged from 1354 full-time equivalent units (FTE) in 2010 to 1360 FTEs in 2013, of which 43 to 41 were dedicated to inspectors.

Own assessment: The report indicates that the results of Estonia's market surveillance activities are good and the functioning of the country's organisation and infrastructure is qualified as efficient. The taking part in international cooperation projects by some market surveillance authorities has provided a good overview of practices in other countries. In the same way the exchanges of officials programme financed by the European Commission has also been assessed as useful.

The main challenges for market surveillance authorities derive from:

- The plurality of sectors and responsibilities coupled with limited human resources, training and in-service training opportunities. The lack of resources pushes Estonia towards a more risk- and project-based surveillance, but awareness of regulations among economic operators is described as poor, meaning that there is additional pressure on resources for starting awareness-raising campaigns.

- Increase of e-commerce and catalogue sales that make it difficult for the authorities to perform checks.

- Non-existence of test laboratories and notified bodies making the assessment of conformity in major technical sectors very difficult.

- Carrying out market surveillance and the harmonisation of customs procedures. Problems have been noted in cases where an economic operator wants to import a product with no CE marking and bring it into conformity with the requirements at a later stage. In these types of situations Estonia mentions that surveillance authorities have difficulties reconciling the concepts of "placing on the market" and "release for free circulation" as defined in Regulation (EC) No 765/2008. It has not always been possible to carry out these operations in the customs zone.

- Perceived shortcomings in national legislation. Estonia's market surveillance authorities

report that the wording of legal acts is often perceived as ambiguous for economic operators. Further, cooperation between authorities has on occasion been suspended since it was not clear how they should divide the responsibility for surveillance on certain products. Estonia found a solution to this through mutual agreements and amendments to legal acts.

Market surveillance in specific sectors

Coverage: The Estonian report covers most sectors indicated in the reference list (including non-harmonised consumer products falling under the GPSD such as lighters and children's clothing) with the exception of eco-design and energy labelling, efficiency requirements for hot-water boilers fired with liquid or gaseous fuels and non-road mobile machinery.

Distribution of resources: No information on the distribution of resources is provided.

Own assessment: Estonia provides extensive information on enforcement and communication activities carried out in most sectors, and points to the challenges faced. The report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

2.7 Ireland

General market surveillance activities

General organisation: Market surveillance is dispersed across various Government Departments and State Agencies and responsibility for Community harmonisation legislation is allocated according to competence. The responsibilities of market surveillance authorities are conferred through primary legislation in the case of chemicals and secondary legislation implementing Community harmonisation legislation for the other sectors.

There is no national body to coordinate market surveillance activities nor does a single piece of overarching market surveillance legislation exist. Under Regulation (EC) No 765/2008 the Department of Jobs, Enterprise and Innovation coordinates Ireland's notifications.

Overall resources: Ireland does not provide specific resource information and states that there is no specific budget to fund market surveillance authorities since they are part of larger organisations. It is estimated that approximately 4.8 million EUR is available to authorities for market surveillance activities. The number of staff available to market surveillance authorities remained somewhat stable from 41.7 full-time equivalent units (FTE) in 2010 to 41.6 FTEs in 2013 in total.

Own assessment: The Irish report identifies the following issues in the functioning of market surveillance:

- The resources of the HSA have been reduced in recent years which impact negatively the ability to engage in market surveillance. Further the absence of independent test laboratories renders assessing of conformity very difficult and costly. Problems also arise on the reporting and recording of accidents that occur outside the workplace since there is no state supported system in place.

- The NCA has been operating with 7 to 8 FTEs in the Product Safety Unit. The report mentions significant budgetary and staffing constraints.

Market surveillance in specific sectors

Coverage: Ireland reports on most of the sectors from the reference list (including non-harmonised consumer products falling under the GPSD) with the exception of construction products, aerosol dispensers, cableways, noise emissions for outdoor equipment, radio and telecom equipment under electromagnetic compatibility and radio equipment and telecommunications terminal equipment, efficiency requirements for hot-water boilers, recreational crafts, marine equipment and non-road mobile machinery.

Distribution of resources: Information on the distribution of resources is provided for the medical devices sector with a stable budget of 1.4 million EUR for 2010-2013 and a full-time equivalent unit (FTE) availability of 15.8 to 17.3, with 1.5 FTEs for inspectors. Eco-design and labelling had a budget of 150 000 EUR allocated with 1 FTE available in 2013 and 4 FTEs for inspectors.

The electrical and electronic equipment sector under restriction of hazardous substances, waste from electrical and electronic equipment and batteries directives had a budget allocated of approximately 37 000 EUR with a spike of 64 500 EUR in 2012 (between 0.25 and 0.20 FTEs staff available). The chemicals sector had a budget available from around 44 300 EUR in 2010 to 25 500 EUR in 2013, with 0.14 to 0.05 FTE staff availability in the same period.

No financial budget is indicated for the cosmetics sector but between 6.25 and 7.25 FTEs was available for market surveillance activities between 2010 and 2013 (5.25 FTEs for inspectors). For fertilisers these were 2 FTEs available for market surveillance activities between 2010 and 2013 (1.5 FTEs for inspectors).

Own assessment: In the area of medical devices, the HPRA does not have any legislative powers over distribution or distributors apart from the provisions set out in the New Approach legislation. Concern is particularly on the device management, storage and traceability throughout the distribution chain. Legislative powers are being sought to request distributors to conduct appropriate follow-up and be required to request an audit of their quality systems.

Further, on the specific sector of medical devices and cosmetics, Ireland's report on its market surveillance activities notes that enforcing compliance on medical devices and cosmetics sold through online web shops is challenging due to issues around traceability. Concerning medical devices the HPRA is actively involved in developing the framework for implementing a unique device identifiers (UDI) system. Applying a harmonised market surveillance approach and action effectively is seen as problematic when different Member States take varying positions in the qualification and classification of products as medical devices.

Issuing alerts on hazards is required under the EU legislation, but not specifically addressed under national legislation which is seen as problematic. Furthermore, in the event a serious issue arises and action is taken under the medical device legislation, the penalties are deemed as minor when the potentially serious nature of the offence is considered.

2.8 Greece

General market surveillance activities

General organisation: Market surveillance pursuant to Regulation (EC) No 765/2008 is handled at national level. Greece reports that in 2012 a new legal framework was developed,

with the General Secretariat for Industry of the Ministry of Development and Competitiveness as the country's National Market Surveillance Authority. The body is responsible for coordinating the other market surveillance authorities already in place, and for streamlining communication. The report mentions that an audit methodology has been developed for each product, at manufacturers' premises and at product operating, distribution and storage sites. An electronic national information exchange system has been put in place that should back the market surveillance procedure.

Overall resources: Greece does not provide general resource information per market surveillance authority since they have not been identified separately. An amount of 50 000 EUR (excluding wage costs) is estimated for the General Secretariat for Industry.

Own assessment: The report does not provide an assessment of the effectiveness or efficiency of the general market surveillance organisation. It identifies the lack of financial resources as a challenge, particularly with regard to the costs of laboratory tests and the transportation of inspectors. Other challenges mentioned are:

- The lack of traceability of information during laboratory tests in some sectors.
- The lack of having specialised inspectors in place for certain sectors (e.g. lifts).
- The lack of consistency in imposing sanctions.
- The difficulty of locating the responsible person in the supply chain.
- The overlap of responsibilities in certain sectors (e.g. noise emissions).

Market surveillance in specific sectors

Coverage: The Greek report covers most sectors indicated in the reference list (including non-harmonised consumer products falling under the GPSD) with the exception of medical devices, cosmetics, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, marine equipment, motor vehicles and tyres and non-road mobile machinery.

Distribution of resources: No information on the distribution of financial resources per sector has been provided, with the exception of the radio equipment and telecommunications terminal equipment sector with a budget of around 33 000 EUR allocated in 2010 and 8 500 EUR in 2013. 5 full-time equivalent units (FTE) have been attributed in this period (from 2 to 4 FTEs for inspectors). In general 0.2 to 2.5 FTEs of staff are allocated to most sectors with chemicals being the exception counting 90 FTEs of staff of which 65 FTEs of inspectors available to market surveillance authorities.

Own assessment: Greece provides extensive information on enforcement and communication activities carried out in most sectors and points to challenges faced that reflect those mentioned previously. In general the report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

2.9 Spain

General market surveillance activities

General organisation: Market surveillance is coordinated at national level by the Spanish Consumer Affairs, Food Safety and Nutrition Agency (which acts on rare occasions as a surveillance authority) and is carried out by various authorities who are organised on either a national or regional level. Only in very special cases involving imports or products controlled by the customs authorities does it act as a market surveillance authority.

The customs authorities are part of the Tax Agency but border controls also involve another body called SOIVRE (the Official Service of Surveillance, Certification and Technical Assistance of Foreign Trade). It monitors a series of products before they reach the customs offices. It conducts surveillance activities with regard to documents, inspections and testing. For the sectors of products, toys, textiles, shoes, some personal protective equipment, some electrical products and wood products and their derivatives, a safety certificate must be obtained in advance from SOIVRE so that customs can release them for free circulation. The Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) acts as a market surveillance authority only in cases where the customs authorities ask for support on the basis of Articles 27-29 of Regulation (EC) No 765/2008 (The report mentions it carries out 80 exercises each year). It is also the contact point for RAPEX.

Furthermore, the Ministry of Industry, Energy and Tourism examines the extent of legislative compliance of the industrial products placed on the markets (1349 industrial products were inspected in 2013). The main lines of action that are described in the report focus on the inspection of distribution centres (through reactive and proactive compliance assessment) and the testing on products in accordance with the legislation in force.

Overall resources: No general resource information per market surveillance authority is specified but the combined estimated budget of the consumer affairs authorities is mentioned. Approximately 26.7 million EUR was available to authorities in 2010 to 20.7 million EUR in 2013, which is approx. 0.025% of the national budget. The number of staff available to market surveillance authorities counted 312 full-time equivalent units (FTE) in 2010 and dropped to 208 FTEs in 2013 in total. Between 212 and 125 FTEs were available for inspectors.

Own assessment: The report does not provide an assessment of the effectiveness or efficiency of the general market surveillance organisation but points to challenges faced. In particular, the shortage of resources is a main cause of lack of monitoring of imports and problems with traceability of products. It also mentions that penalties laid down in national law might not be a sufficient deterrent for larger companies trying to market non-compliant products. The country aims to increase the use of ICSMS.

Market surveillance in specific sectors

Coverage: The Spanish report provides some information on enforcement activities (i.e. number inspections, tests performed, finding of non-compliance and restrictive measures taken) on the sectors that fall under the responsibility of the Subdirectorate-General for Quality and Industrial Safety of the Ministry of Industry, Energy and Tourism only i.e. list, electrical appliances and equipment under the low voltage directive, radio and telecoms equipment under electromagnetic compatibility directive, machinery, pressure equipment,

construction products, chemicals and lifts.

Distribution of resources: No information on the distribution of financial resources per sector has been reported.

Own assessment: In general the report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

2.10 France

General market surveillance activities

General organisation: France refers to the information on the general organisation of markets surveillance provided in the national programmes. In France, market surveillance is mainly performed by officials of the Directorate-General for Competition, Consumer Affairs and Fraud Repression (DGCCRF) and, for products imported from countries outside the European Union, the Directorate-General for Customs and Indirect Taxation (DGDDI) which is a surveillance authority for the entire market so that customs officials may collect samples of products, have them tested by a laboratory and, depending on the test results, decide on any action to be taken. The DGCCRF and DGDDI have a territorial network at their disposal. For laboratory tests they can use the Joint Laboratory Service (SCL) and can also call upon private laboratories.

Other services also contribute to market surveillance[206], either by carrying out checks themselves or with the help of services on the ground.

The Ministry of Economy, Directorate-General for Competitiveness, Industry and Services (DGCIS) DGCIS, ensures coordination of the application of Regulation (EC) No 765/2008

Overall resources: In the 2010-2013 period between 2.5 and 2.9 million EUR per year were dedicated to testing of toys, cosmetics and professional products, while around a further 1.5 million EUR per year were dedicated to testing of equipment for use in potentially explosive atmospheres, pyrotechnical articles, radio equipment and telecommunications terminal equipment and, to a lesser extent, to pressure equipment, gas appliances and civil explosives. [207] In addition to these figures, the report mentions about 13.5 million EUR (excluding testing activities) allocated to market surveillance authorities in a number of (mainly consumer product) sectors.[208] In various sectors resources declined over the 2010-2013 period. No specific details on resources for market surveillance are given for medical devices, professional machinery, lifts, cableways, noise emissions and products falling under restriction of hazardous substances, waste from electrical and electronic equipment and batteries legislation. Overall over 260 full-time equivalent units (FTE) are reported for all the sectors mentioned above for both testing and other activities. These figures do not include

206 They include the: Direction Générale de la Compétitivité, de L'industrie et des Services (DGCIS), for measuring instruments; Direction Générale de la Prévention des Risques (DGPR) for gas appliances, pressure equipment, chemical products, explosives and materials for use in potentially explosive atmospheres; Direction des Affaires Maritimes (DAM) for recreational craft and marine equipment; Direction Générale du Travail (DGT) for machinery and equipment, and personal protective equipment; Service Technique des Remontées Mécaniques et des Transports Guidés (STRMTG) for cableway installations used to transport persons; Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM) for medical devices and cosmetics; Agence Nationale des Fréquences (ANFR) for radio equipment.

207 Budget including both tests carried out by State laboratory and tests subcontracted to private laboratories.

208 Toys, cosmetics, consumer machinery, non harmonised consumer goods, construction products, electromagnetic compatibility, radio and telecommunications, low voltage electrical products, chemicals, energy labelling, recreational craft, motor vehicles, fertilisers.

customs budget and staff for market surveillance.

Own assessment: The French report does not contain an assessment of the general organisation of market surveillance.

Market surveillance in specific sectors

Coverage: The French report covers all sectors in the reference list (including non-harmonised consumer products), except eco-design, efficiency requirements for boilers and non-road mobile machinery.

Distribution of resources: By looking at the overall resources mentioned in the above sections, between 2010 and 2013 the biggest share of resources (about 25%) was allocated to non-harmonised consumer goods, about 10% each respectively to toys, cosmetics and radio equipment and telecommunications terminal equipment, 5% respectively to low voltage electrical products and energy labelling[209].

Own assessment: According to the French report overall market surveillance activities functioned satisfactorily in France, and products covered by harmonised European regulations were subject to appropriate inspection. Apart from a few exceptions, such as cosmetics products, a more specific assessment of the activities carried out in a given sector is not provided.

In some sectors (i.e. equipment for use in potentially explosive atmospheres, pyrotechnical articles, civil explosives and gas appliances), insufficient cross-border cooperation is mentioned as a difficulty to tackle when relevant economic operators are located abroad. In others (radio equipment and telecommunications terminal equipment) it is noted that control procedures are not adequate to handle products sold on line.

2.11 Croatia

General market surveillance activities

General organisation: The report covers the period 1 July 2013 to 31 December 2013 and mentions that the overall responsibility for market surveillance was with the State Inspectorate until the end of that year. Upon becoming a Member State of the European Union a contact point was set up in the Inspectorate for the exchange of official notifications on measures and actions (through RAPEX). The Inspectorate conducted inspections with the Customs Administration of the Ministry of Finance implementing Articles 27 to 29 of Regulation (EC) No 765/2008. A Commission that was set up in 2009, and that had ceased its activities by the end of 2013, coordinated and communicated between inspectorates responsible for controls of products placed on and/or made available to the market.

As of 1 January 2014 the Ministry of the Economy took over the tasks of the State Inspectorate, namely the protection of consumers, product safety and pressure equipment and the tasks of the mining and electricity inspectorate.

Other authorities are the State Office for Metrology (measuring instruments, non-automatic weighing instruments and pre-packaged products), the Ministry of the Interior (pyrotechnical

209 The percentage mentioned here are very rough and purely indicative estimates.

articles), the Croatian Regulatory Authority for Network Industries (radio equipment and telecommunications terminal equipment), the Ministry of Agriculture (fertilisers) and the Ministry of Health (cosmetic products, toys and chemical products)

Overall resources: No further general resource information is specified.

Own assessment: The report does not provide an assessment of the effectiveness or efficiency of the overall market surveillance organisation.

Market surveillance in specific sectors

Coverage: For the period indicated above, the Croatian report covers: (i) the sectors under the responsibility of the State Inspectorate, i.e. personal protective equipment, construction products, machinery, electrical appliances and equipment under the low voltage directive, other consumer products under GPSD (lighters and children's clothing with drawstrings) and textile products and footwear in accordance with Regulation (EC) No 1007/2011 and Directive No 94/11/EC; (ii) other sectors covered by the State Office for Metrology (measuring instruments, non-automatic weighing instruments and pre-packaged products), the Ministry of the Interior (pyrotechnical articles), the Croatian Regulatory Authority for Network Industries (radio equipment and telecommunications terminal equipment), the Ministry of Agriculture (fertilisers) and the Ministry of Health (cosmetic products, toys and chemical products);

Distribution of resources: No information on the distribution of financial resources per sector has been reported.

Own assessment: In general the report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

2.12 Italy

General market surveillance activities

General organisation: Italy refers to the information on the general organisation of markets surveillance provided in the national programmes for the 2010-2013 periods. It also recalls that a least 7 Ministries are responsible for market surveillance activities under the scope of the report, in addition to Guardia di Finanza, which carries out product safety controls in the national territory, and the Customs Agency, responsible for product checks at the border.

Overall resources: In the section on overall resources, Italy mentions about 1.5 mln EUR per year; however this budget actually coincides almost entirely with the budget of the Ministry of Economic Development which is responsible for many - but not all, and not exclusively[210] - of the product areas falling under the scope of the Regulation (i.e. personal protective equipment, electromagnetic compatibility, low voltage electrical products and appliances, radio equipment and telecommunications terminal equipment, measuring instruments, eco-design and energy labelling legislation, labelling of textiles and footwear), as well as for general product safety.

210 E.g. the Health Ministry, the Carabinieri's specialised territorial cells called NAS and the regional offices share responsibility for conducting inspections in the area of some consumer products, including toys. Furthermore, Guardia di Finanza verifies the execution of restrictive measures issued by the Ministry of Economic Development. The resources of these other entities involved in market surveillance are not included.

The section also mentions about 1 100 full-time equivalent units for staff (FTE) (of which 100 customs staff, about 100 staff units of various ministries[211]that carry out documentary checks, and more than 900 inspectors[212]that carry out field work) for market surveillance in the areas of responsibility of the Ministry of Economic Development (see above), the Ministry of Health (toys, consumer goods, medical devices and cosmetics), the Employment Ministry (machinery) and the Environment Ministry (noise emissions).

Own assessment: According to the national report, the entry into force of the Regulation helped the development of market surveillance in Italy. The practice of national programmes has helped to focus controls on products intended for vulnerable consumers (children and elderly), and has brought about several restrictive measures of both a voluntary and mandatory nature. Italy's report considers that market surveillance conducted between 2010 and 2013 has been effective overall, in particular due to the importance given to the training of inspectors. The lack of resources however limits the ability to ensure continuity in training, as well as to increase the number of (proactive) inspections and laboratory checks.

Market surveillance in specific sectors

Coverage: Italy's report covers 15 of the 29 sectors indicated in the reference list. Excluded from the report are, in particular, construction products, pressure equipment, lifts, gas appliances, electrical equipment falling under the electromagnetic compatibility directive, certain chemicals, motor vehicles, recreational craft, equipment for use in potentially explosive atmospheres and non-road mobile machinery. On the other hand, Italy's report includes non-harmonised consumer products, tobacco products and the labelling of footwear.

Distribution of resources: Italy's report does not contain information on the overall amount of resources dedicated to market surveillance and its distribution across sectors. The figure of 1.5 million EUR is provided for market surveillance carried out by the Ministry of Economic Development notably in relation to a range of consumer goods and to eco-design/energy labelling legislation.

The report notes that no ad hoc financial resources are attributed to market surveillance in the areas of maritime equipment, pyrotechnics and civil explosives, where only some limited reactive surveillance activity is carried out[213].

The figures on staff are covered in the previous section on overall resources.

Own assessment: Italy provides quite extensive information on enforcement and communication activities carried out in several sectors, and points to challenges faced (notably the lack of resources); however in general the Italian report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities. The report points to the best practice established in the sector of medical devices where market surveillance relies on the use of an extensive database covering more than 500 000 products and allowing information-sharing with healthcare agencies and businesses.

211 63 people from the Ministry of Economic Development, around 25-30 from the Ministry of Health dealing with certain aspects of toys, consumer goods; medical devices and cosmetics and a few units from the Employment and Environment Ministries dealing respectively with machinery and noise emission legislation.

212 This figure includes 500 FTEs from Guardia di Finanza, 275 from Chambers of Commerce, 100 Carabinieri NAS.

213 However pyrotechnics and civil explosives also come under the responsibility of the police.

2.13 Cyprus

General market surveillance activities

General organisation: Cyprus refers to information reported in the 2014 national market surveillance programme.

Overall resources: Cyprus does not report overall resources available, however the report mentions between 200 and 290 000 EUR per year and slightly less than 5 full-time equivalent units for staff (FTE) for low voltage electrical products, 150 000 EUR per year and 8 FTEs for construction products. Lower resources are reported for eco-design and energy labelling (increasing from 4 500 up to 39 000 EUR per year during the period), civil explosives (33 000 EUR per year), electronic magnetic compatibility (between 20 and 30 000 EUR per year), pyrotechnical articles (22 000 EUR per year), aerosol dispensers (5-15 000 EUR per year) and gas appliances (10 000 EUR per year). No resources were attributed for market surveillance of radio and telecommunications equipment.

Own assessment: No specific assessment of the general organisation (e.g. cooperation and coordination) is provided.

Market surveillance in specific sectors

Coverage: the Cyprus report covers about two-thirds of the products in the reference list. Sectors excluded are: cosmetics, noise emissions for outdoor equipment, measuring instruments, electronic and electronic equipment under restriction of hazardous substances, waste from electrical and electronic equipment and batteries, chemicals, efficiency requirements for hot-water boilers, recreational craft, marine equipment, non-road mobile machinery, motor vehicles and fertilisers.

Distribution of resources: See section on resources above.

Own assessment: the Cyprus report contains an assessment of market surveillance carried out by the Department of Labour Inspection of the Ministry of Labour in the sectors of personal protective equipment, pressure equipment, machinery, lifts and equipment for use in potentially explosive atmospheres, for which checks performed on products imported from third countries are considered satisfactory. At the same time the these sectors are said to face difficulties due to lack of traceability, mismatch between the customs product classification and the nomenclature used by market surveillance authorities, a lack of financial resources to conduct checks, and time-consuming procedures for imposing penalties.

Furthermore, market surveillance of radio and telecommunications equipment is considered as inadequate due to underfinancing and understaffing of the Department of Electronic Communications of the Ministry of Communications.

2.14 Latvia

General market surveillance activities

General organisation: Market surveillance in Latvia is handled by 11 different authorities[214] subordinated to 7 different ministries. To facilitate cooperation and exchange of information between the authorities, a Market Surveillance Council was set up in 2000 at the Ministry of Economics, and it meets twice a year. It is made up of representatives from all market surveillance authorities and from the ministries under whose jurisdiction they operate.

Overall resources: The report provides estimates since it is not possible to indicate financial resources dedicated to market surveillance because this is only a part of the responsible authorities' activities. It is estimated that approximately 1.6 million EUR was available to authorities in 2010 to 2.2 million EUR in 2013, which is a stable 0.03% of the national budget. The number of full-time equivalent units for staff (FTE) available to market surveillance authorities counted 101.3 FTEs in 2010 to 117.8 FTEs in 2013 in total. Between 74.5 and 83 FTEs were available for inspectors.

Own assessment: The Latvian report identifies the following challenges:

- A lack of coordination of activities among Member States surveillance authorities with respect to the release of goods for free circulation leading to situations where goods that were not released onto the market in one Member State enter the market through another one.

- Insufficient cooperation with the Member States market surveillance authorities in cases where the compliance of goods is being assessed or where irregularities have been identified.

- In practice there is not always cooperation between the market surveillance authorities and the notified bodies.

- A lack of resources to fully implement the EU's legal acts governing non-food goods.

- A large number of importers are not aware of the requirements for imported goods.

- The requirements are not differentiated for EU-manufactured or imported goods, leading to situations where it is simpler to manufacture goods outside the EU as the amount of checks that the surveillance authorities can perform on imported goods is small.

- Restricted resources lead to insufficient laboratory controls.

- Inspectors find it challenging to ensure the fulfilment of the registration requirements of chemical substances as stipulated in the REACH Regulation.

Market surveillance in specific sectors

Coverage: The Latvian report covers all sectors in the reference list (including non-harmonised consumer products).

214 The Consumer Rights Protection Centre (CRPC), State Labour Inspectorate, Health Inspectorate, State Agency for Technical Surveillance, State Plant Protection Service, State Environment Service, Excise Goods Department of the State Revenue Service, Customs Board of the State Revenue Service, Assay Office of Latvia, State Police, the Food and Veterinary Service (FVS).

Distribution of resources: In general no information on the distribution of financial resources per sector has been provided, with the exception of the chemical substances sector with a budget of around 300 000 EUR and a staff availability of 12 full-time equivalent units (FTE) in 2010 and 9.5 in 2013. The number of inspectors in the period has been fairly consistent of around 8 FTEs with a drop in 2013 to 5.5 FTEs. The medical devices sector is mentioned with a budget of approx. 37 000 EUR allocated in 2010 and 21 000 EUR in 2013. 2.5 FTEs have been attributed in this period which went down to 1.5 in 2013. A consistent 1.5 FTEs to inspectors has been available. Lastly the sector of electrical and electronic goods subject to the low voltage directive is mentioned with figures ranging from 30 000 EUR to 31 000 EUR for the years 2011 to 2013, with a consistent staff availability of 2 FTEs.

Own assessment: The report provides information on enforcement and communication activities carried out in several sectors, and points to challenges faced. It does not provide for an assessment of the effectiveness or efficiency of these sector specific-activities.

2.15 Lithuania

General market surveillance activities

Lithuania's report under Article 18(6) of the Regulation follows a different approach than the one proposed by the Commission, as an extensive study to evaluate the national legal framework was already launched in 2013.

General organisation: the Lithuanian report focuses on the legal framework for market surveillance. This is characterised by the existence of: (ii) the Product Safety Law that acts as a general 'umbrella' legal instrument regulating, among other aspects, market surveillance for both (non-food[215]) products and services; (ii) special law regulating market surveillance for certain product areas (e.g. metrology, pharmaceuticals) or certain specific aspects (e.g. accidents at work, electronic communications, implementation of RAPEX system); (iii) by-laws regulating in detail specific matters (e.g. rules on the application of restrictions on marketing of products).

Overall resources: The Lithuanian study does not cover this information.

Own assessment: The purpose of Lithuania's study is to evaluate whether national law has properly implemented the provisions of the Regulation. The study concludes that certain aspects of the national legal framework should be improved. In particular, it notes that:

– as the Product Safety Law only applies to consumer products, certain non-consumer products may fall outside the scope of control powers. Furthermore, the legal technique of resorting to by-laws to regulate powers to apply restrictive measures and sanctions are not efficient: although the provisions of the EU Regulation apply directly, they are not referred to in Lithuanian market surveillance legislation.

– the legislation does not contain an approved and exhaustive list of market surveillance authorities. In practice, the fact that the State Non-Food Product Inspectorate under the Ministry of Economy is treated (except for products regulated by special laws) as an 'umbrella' market surveillance authority should help avoiding "grey areas" (i.e. cases where the safety of consumer products is not controlled by any authority). However,

215 According to the Lithuanian study that the scope of the Product Safety Law in respect of foodstuff is unclear.

this responsibility of the Non-Food Product Inspectorate should be regulated by law. Furthermore, there is no similar 'umbrella' authority in the area of non-consumer goods.

– the legal framework regulating the function of coordination among authorities is defective and could be improved by clearly clarifying and aligning the responsibilities of both the ministries involved in the process and the market surveillance authorities, and at the same time by establishing a model for cooperation (activity coordination).

– the lack of clarity of the EU framework also create confusion. More detailed legislation would be needed to clarify and regulate specific functions (e.g. authorities' obligation to cooperate, accumulate scientific knowledge, monitor accidents) of the market surveillance systems established by the EU Regulation.

Market surveillance in specific sectors

The Lithuanian study does not include information on enforcement and communication activities carried out in specific sectors.

2.16 Luxembourg

General market surveillance activities

General organisation: In Luxembourg there are eight market surveillance authorities[216]. The "Institut Luxembourgeois de la Normalisation, de l'Accréditation, de la Sécurité et qualité des produits et services", ILNAS, is, since 2008, the market surveillance authority responsible for the bulk of consumer products (i.e. toys, other consumer products falling under the GPSD, low voltage electrical appliances, electromagnetic compatibility, radio and telecommunication equipment eco-design and energy labelling) and for equipment for use in potentially explosive atmospheres. On the other hand, the "Inspection du Travail et Mines", ITM, has, between 2010 and 2013, been the market surveillance authority responsible for personal protective equipment, civil explosives, pyrotechnic articles, cableways, machinery, lifts, pressure equipment, aerosols, gas appliances and construction equipment.[217] The responsibilities of ILNAS and ITM cover about two-thirds of the sectors mentioned in the reference list.

ILNAS coordinates market surveillance at national level with the help of a national committee.

Overall resources: Luxembourg reports that the complexity of the budgets of the different administrations involved does not allow an estimation of the total amount of resources dedicated to market surveillance. During the 2010-2013 period ILNAS' annual budget for market surveillance (excluding the technical laboratory) ranged between 50 000 and 75 000 EUR. The budget declined over time. Total staff amounted to 6-7 full equivalent units (FTE). The figure on ITM's market surveillance budget is not available. ITM's total staff amounted to 0.65-1.15 FTEs.

Own assessment: the Luxembourg report focuses on ILNAS achievements in the areas of cooperation with customs (notably the agreement signed in 1998 and updated in 2012), the

216 ILNAS, Métrologie légale, Commissariat aux Affaires Maritimes, Direction du marché intérieur et de la consommation, Direction de la Santé, ITM, Administration de l'Environnement, Département des transports

217 On 1 August 2014 the responsibility for market surveillance authority in these areas were transferred to ILNAS

exchange of data via a common Intranet (EC.SDM) and regular training on product safety and legal requirements.

Market surveillance in specific sectors

Coverage: The Luxembourg report covers about two-thirds (19) of the sectors in the reference list (29), as well as non-harmonised consumer products.

Distribution of resources: no information is available in addition to the data mentioned above for ILNAS and ITM.

Own assessment: Luxembourg provides quite detailed information on ILNAS' market surveillance activities and more succinct information on ITM's market surveillance activities; however it does not contain a specific assessment of those activities. Resources available to ILNAS are said to be insufficient to ensure effective market surveillance. The number of inspectors went up by 8 units in 2014, together with a substantial increase in the responsibilities of ILNAS.

2.17 Hungary

General market surveillance activities

General organisation: The report does not supply information on the general organisation of market surveillance at national level but focuses on the activities of each of the authorities separately. Surveillance is dispersed across various bodies, and responsibility for Community harmonisation legislation is allocated according to jurisdiction. There are 14 market surveillance authorities.

Overall resources: The overall resources are stipulated for 8 authorities running in the 2010-2013 period to an annual global amount of 1.8 to 6.6 million EUR. This strong increase is mostly due to a lack of information on the amount of resources in 2010. A similar calculation gave 902 full-time equivalent units (FTE) in 2010 to 1496 FTEs in 2013 in total as the number of staff available to market surveillance authorities. Between 274 and 568 FTEs were available for inspectors.

Own assessment: No specific assessment of the general organisation (e.g. cooperation and coordination) is provided.

Market surveillance in specific sectors

Coverage: Hungary’s report covers the sectors from the reference list (including non-harmonised consumer products falling under the GPSD).

Distribution of resources: The report covers the distribution of resources per authority, subdivided over most sectors (no calculation method is given). Budget allocated to most sectors range between 1000 and 30 000 EUR per year covering a three-year time span and a staff and inspector availability of between 1 and 4 FTEs. Next to toys (see section below) the biggest sectors mentioned in terms of resource availability are the sector of electrical and electronic goods subject to the low voltage directive with figures ranging from around 633 000 EUR to 672 000 EUR for the years 2010 to 2013, with a staff availability between 36 and 39 FTEs of which 30 and 32 FTEs for inspectors respectively. For the machinery sector a budget of between 74 000 EUR and 169 000 EUR was available with a staff availability of 7

FTEs in 2010 and 9 in 2013. The number of inspectors in the period has been fairly consistent, between 4 and 6 FTEs. For construction products the budget ranged between 64 000 EUR and 92 000 EUR, with 6 to 7 FTEs staff availability of which 4 FTEs for inspectors. Further for personal protective equipment a budget between 38 000 EUR and 55 000 EUR is reported with staff availability between 3 and 4 FTEs of which a consistent inspector availability of 2 FTEs.

Own assessment: The report provides information on enforcement activities carried out by the various market surveillance authorities. It does not provide for an assessment of the effectiveness or efficiency of sector-specific activities.

2.18 Malta

General market surveillance activities

General organisation: Market surveillance tasks in Malta are carried out by the Market Surveillance Directorate within the Technical Regulations Division of the Malta Competition and Consumers Affairs Authority (MCCAA). The report does not provide additional information on the organisation of market surveillance at national level.

Overall resources: in the 2010-2013 period the annual global resources for market surveillance ranged between 0.15 and 0.18 million EUR. The staff dedicated to market surveillance amounted to 5 full time equivalent units (FTE).

Own assessment: Malta does not provide a specific assessment of the general organisation of market surveillance, although it notes that enforcement measures have been hindered by inadequate testing facilities. The difficulty should be mitigated in future as the MCCAA is asking for basic Market Surveillance screening equipment for toys, child care articles as well as to a lesser extent other directives. Other challenges encountered concern:

– the lack of traceability of products brought to Malta via EU intermediate economic operators who import them from third countries. This also gives rise to the problem of lack of documentation such as the Declarations of Conformity, owing to a breakdown in communication between the operator in Malta and the manufacturer.

– the lack of clarity of certain standards which give presumption of conformity to the applicable EU Directives. This leaves room for different interpretations which are not easily enforceable.

Market surveillance in specific sectors

Coverage: The report covers all sectors in the reference list.

Distribution of resources: Overall resources are allocated according to priorities that depend on the use of the product groups as well as the vulnerability of consumers. Hence, toys, plant protection products and electrical appliances are given the highest priority due to the widespread distribution of all three kinds of products, coupled with the vulnerability of children and/or untrained consumers as well as the fact that plant protection products are consumed in foods. Other product categories falling under the GPSD or the New Approach Directives are given a secondary level of priority with less emphasis on proactive enforcement. Lack of resources is mentioned as the reason for no or limited market surveillance in sectors such as equipment for use in explosive atmospheres, civil explosives,

gas appliances, medical devices, transportable pressure equipment and construction products.

Own assessment: Malta provides detailed information on enforcement activities carried out in most sectors; however in general the report does not provide for an assessment of the effectiveness or efficiency of these sector-specific activities.

2.19 Netherlands

General market surveillance activities

General organisation: Market surveillance of products is organised between six national market surveillance authorities[218], each with their own sector of responsibility. Political responsibility for the authorities lies with the Ministries of Economic Affairs (which also coordinates and monitors the implementation of Regulation (EC) No 765/2008), Social Affairs and Employment, Infrastructure and the Environment, and Health, Welfare and Sport respectively.

Proactive inspections are carried out based on risk assessments (including compliance risk) while reactive inspections are executed on the basis of RAPEX notifications, alerts from other sources and complaints from businesses and consumers. Product examinations are executed by the authorities' own laboratories as much as possible and tend to focus on manufacturers and EU importers, taking into account (past) compliance behaviour of companies. All authorities are also connected to ICSMS, with one national administrator.

Products are checked by the relevant market surveillance authority before they are released for free circulation, and activities are coordinated with customs four to five times a year through a national forum that was set up in 2008 (the Alliance Working Group on Product Market Surveillance and External Border Controls) and which is chaired by the Netherlands Food and Consumer Product Safety Authority (NVWA).

Overall resources: Overall, in the 2010-2013 periods, the total national budget for market surveillance was estimated to be 20 million EUR. The staff dedicated to market surveillance involves 175 full-time equivalent units (FTE) (the report does not provide further details). Further resource information is provided for the Dutch Food and Consumer Product Safety Authority, stating that the agency has a workforce of 110 FTEs in total, divided over 45 inspectors, 45 laboratory workers and 20 development and strategy employees. An annual budget of around 11 million EUR is provided by the Health, Welfare and Sport ministry. The Netherlands Radiocommunications Agency has a yearly budget of 1.6 million EUR per year, with around 10 FTEs involved in market surveillance activities (of which roughly 6 for inspectors). For the Social Affairs and Employment Inspectorate a staff count of 5.5 FTEs in 2010 is reported with an increase to 12 FTEs in 2013. The Inspectorate for Environmental Affairs and Transport mentions 65 FTEs for market surveillance on a number of sectors of EU product legislation. Verispect mentions a budget of 0.2 million EUR for market surveillance of measure instruments and a number of FTEs increasing from 0.3 in 2010 to 1.5 in 2013.

Own assessment: The report states that with Regulation (EC) No 765/2008 the market

218 Social Affairs and Employment Inspectortae (I-SZW), Human Environment and Transport Inspectorate (ILT), the Netherlands Radiocommunications Agency (AT), Verispect B.V., Health Care Inspectorate (IGZ), Netherlands Food and Consumer Product Safety Authority (NVWA).

surveillance of products has improved with better sharing and improvement of surveillance methods between authorities, and better cooperation between national and international agencies, while challenges still remain such as in E-Commerce where the Regulation is deemed to be unclear on the legal grounds necessary to execute border controls on consumer products for personal use in a third country.

Market surveillance in specific sectors

Coverage: the report covers the majority of sectors included in the reference list. The sectors excluded are transportable pressure equipment, cableways, noise emissions for outdoor equipment, pyrotechnics, efficiency requirements for hot-water boilers fired with liquid or gaseous fuels, marine equipment, non-road mobile machinery and fertilisers.

Distribution of resources: the report does not provide this information.

Own assessment: The Netherlands provides an overview of the enforcement activities carried out in a number of sectors, although it does not provides the details about inspections requested in the Commission template. Furthermore, the report does not provide for an assessment of the effectiveness or efficiency of the sector-specific activities but it does so for the authority Netherlands Radiocommunications Agency where its market surveillance is assessed as adequate and has improved over time.

Information-led and risk-oriented surveillance has been integrated into the operations and the agency is held publicly to account for the work performed. More information is warranted according to the agency to make further improvements and internet surveillance could be improved and better deployed in market surveillance. Challenges lie with the private imports of non-conforming equipment for personal use by consumers and the execution of the new regulatory framework for both the electromagnetic compatibility directive and the revised radio equipment directive will require the necessary capacity.

2.20 Austria

General market surveillance activities

General organisation: Depending on the legal provisions that apply to a given product, market surveillance is exercised either by federal or by provincial authorities. The responsibilities of the Federal Government are dealt with by default in the form of indirect federal administration[219] (i.e. the executive powers of the Federal Government are exercised in the provinces by the provincial governor and the provincial departments), except if the Federal Constitution attributes them explicitly to federal authorities. Therefore depending on the sectors, market surveillance in Austria is carried out by provincial authorities either exercising their own powers or through indirect administration, or by federal authorities.

The Federal Ministry for Science, Research and Economy coordinates the Austrian market surveillance authorities pursuant to Regulation (EC) No. 765/2008. This Decision, however, is without prejudice to the responsibility of the relevant department or province for the content of each part of the programme. A permanent Market Surveillance Coordination Body composed of representatives of federal and provincial market surveillance authorities and customs acts as a communication and coordination forum.

219 This concerns around 100 district administration authorities across the nine federal provinces.

Overall resources: Austria considers that examining the amount of resources used is not a particularly helpful way to assess market surveillance, as it focuses on expenditure rather than results. Furthermore, in the case of indirect federal administration it is impossible to determine the specific budget allocated to market surveillance as the same staff performs a wide range of tasks. Nevertheless in the area of measuring instruments for which the responsible authority is the Federal Ministry of Science, Research and Economy, Austria mentions an annual budget of between 0.8 and 0.9 million EUR and a staff of 15 full-time equivalent units (FTE) during the 2010-2013 period.

Own assessment: Austrian assessment focuses on the effectiveness of sectoral market surveillance (see below). No specific assessment of the general organisation (e.g. cooperation and coordination) is provided.

Market surveillance in specific sectors

Coverage: the Austrian report covers the large majority (about four-fifths) of sectors included in the reference list. The sectors excluded are transportable pressure equipment, cableways, energy labelling, non-road mobile machinery, equipment for use in potentially explosive atmospheres, electrical and electronic equipment under restriction of hazardous substances, waste from electrical and electronic equipment and batteries directives.

Distribution of resources: the Austrian report does not include this information.

Own assessment: Austria considers that according to Article 19 of Regulation (EC) No. 765/2008, the extent of market surveillance activities must follow the principle of risk assessment, that is it should depend on the potential of a certain type of product to endanger public interests in a case of non-compliance. Since this potential varies considerably from sector to sector, the level of market surveillance activities must also vary.

Against this background the Austrian report considers that market surveillance functions well in the country and resources are being employed effectively. For the directives whose focus is on user safety, the effectiveness of market surveillance would be substantiated by the extremely low number of accidents caused by defective products recorded in the IDB (Injury Database). For the other directives, whose purpose is not the safety of individuals, but for example measurement accuracy, environmental protection, or an effective use of the radio spectrum, this would be proven by the low number of serious complaints. The fact that a relatively high proportion of non-compliant products was nevertheless found during inspections testifies to the expert knowledge and motivation of the inspectors, and is not a direct reflection of the market situation.

2.21 Poland

General market surveillance activities

General organisation: Poland refers to the information on the general organisation of markets surveillance provided in the national programmes. In Poland, the Office of Competition and Consumer Protection (OCCP) carries out, monitors and coordinates market surveillance

activities. It further cooperates with customs and 9 other market surveillance authorities[220].

The Market Surveillance Steering Committee is in place to develop cooperation between the authorities involved in the national product control system, share experiences and information, and increase the national system's effectiveness through the harmonisation of procedures applied by the authorities. Representatives of all the authorities participate in the yearly Committee meetings, as does the Ministry of Finance (representing customs) and the Ministry of Economy (responsible for legislative matters).

Overall resources: It is estimated that approximately 8.8 million EUR was available to authorities in 2010 to 10.2 million EUR in 2013, which is a somewhat stable 0.0013% of the national budget. The number of staff available to market surveillance authorities counted 2424 full-time equivalent units (FTE) in 2010 to 2477 FTEs in 2013 in total. Between 1549 of which 1389 FTEs were available for inspectors.

Own assessment: The report mentions that with restricted resources (financial and staffing), market surveillance authorities establish control priorities on the basis of risk analysis. Given these constraints however, the current system is approved of and further systematic cooperation of authorities with customs has contributed to an increase in the effectiveness of the general market surveillance organisation as well.

Market surveillance in specific sectors

Coverage: The Polish report covers all sectors in the reference list, except efficiency requirements for hot-water boilers, motor vehicles and tyres and non-road mobile machinery.

Distribution of resources: the report does not include this information.

Own assessment: Poland provides extensive information on enforcement and communication activities carried out in most sectors and points to challenges faced. In general the report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

2.22 Portugal

General market surveillance activities

General organisation: Pursuant to Regulation (EC) No 765/2008, market surveillance is handled by 8 authorities[221] each with their own sector(s) of responsibility. The report further mentions that external border control is assigned to the Tax and Customs Authority which is not considered a market surveillance authority.

Overall resources: This information is not included in the report but the resources for some of the market surveillance authorities are given. On the basis of the information supplied, ASEA is the biggest authority in budgetary terms. Its budget ranged from approximately 25 million

220 National Labour Inspectorate (PIP), Office of Electronic Communications (UKE), Inspection for Environmental Protection (IOS), Rail Transport Inspection (UTK), Construction Audit Authority (ONB),State Mining Authority (WUG), Independent Maritime Offices (UM), Road Transport Inspection (ITD), Office for Registration of Medical Products, Medical Devices and Biocidal Products (URPL).

221 Authority for Food and Economic Safety (ASEA), National Authority for Medicines and Health Products (INFARMED), National Communications Authority (ICP-ANACOM), Mobility and Land Transport Institute I.P. (IMT), Directorate-General for Natural Resources, Safety and Maritime Services (DGRM), National Directorate for the Public Security Police (DNPSP), Regional Inspectorates for Economic Activities – Azores and Madeira respectively (IRAE).

EUR in 2010 to almost 21 million EUR in 2013. Staff available to market surveillance authorities ran up to 526 full-time equivalent units (FTE) in 2010 to 500 FTEs in 2013. Between 277 and 249 FTEs were available for inspectors. ICP-ANACOM's budget ranged from 1.3 million EUR in 2010 to 1.6 million EUR in 2013 with 9 to 10 FTEs for staff (6 to 7 FTEs for inspectors). For INFARMED a budget of 1.6 million EUR to 1.1 million EUR is mentioned, with 23.5 to 22 FTEs for staff of which 22.5 to 19.5 FTEs for inspectors.

Own assessment: The report does not provide an assessment of the effectiveness or efficiency of the general market surveillance organisation.

Market surveillance in specific sectors

Coverage: the report covers the majority of sectors included in the reference list. The sectors excluded are transportable pressure equipment, lifts, cableways, equipment for use in potentially explosive atmospheres, chemicals, eco-design and energy labelling, efficiency requirements for hot-water boilers and motor vehicles and tyres,

Distribution of resources: the Portuguese report does not include this information.

Own assessment: The report provides extensive information on enforcement and communication activities carried out in most sectors and points to challenges faced. In general the report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

2.23 Romania

General market surveillance activities

General organisation: Market surveillance in Romania is handled by 14 different market surveillance authorities. Coordination and exchange of information between the authorities is facilitated by the Ministry of Economy, Trade and Business Environment which has set up a Coordinating Committee consisting of representatives of market surveillance authorities, customs authority and the national standardisation body.

Overall resources: This information is not included in the report but the resources for some of the market surveillance authorities are given. The State Inspectorate for Construction (the market surveillance authority for construction products except for fixed fire-fighting systems – fixed systems for fire alarm/detection, for fire-fighting, for fire and smoke control and for explosion protection) had a budget allocation of approximately 681 000 EUR in 2010 that was more halved to 300 000 EUR in 2013. Personnel availability in 2010 was 50 full-time equivalent units (FTE), decreasing to 18 FTEs in 2013.

The Ministry of Agriculture and Rural Development's budget for market surveillance activities (responsible for surveillance in the area of fertilizers) ranged from 289 000 EUR in 2010 to 327 000 EUR in 2013 with 53 to 48 FTEs for staff (53 to 48 FTEs for inspectors). For the Labour Inspection (responsible for issues relating to occupational health and safety and to work relations) a budget of approximately 205 000 EUR is reported for 2010 rising to 280 000 EUR in 2013. Staff allocation is at a stable 22 FTEs. Further, for the National Authority for Management and Regulation in Communications (ANCOM), focussing on electromagnetic compatibility and radio equipment and telecommunications terminal equipment, a budget for 2010 and 2013 of 75 000 EUR is reported, with a stable FTE count of 5 for staff, of which 4 for inspectors.

Own assessment: The report does not provide an assessment of the effectiveness or efficiency of the general market surveillance organisation.

Market surveillance in specific sectors

Coverage: The report covers all sectors in the reference list except for medical devices.

Distribution of resources: Figures are provided for a few sectors. Budget allocated to recreational craft and marine equipment was approximately 128 000 EUR and dropped to 63 000 EUR from 2010 to 2013 with the staff and inspector availability following from 5 to 3 FTEs. For electromagnetic compatibility and radio equipment and telecommunications terminal equipment, the budget remained relatively stable between 2010 and 2013 with 75 000 EUR, with 5 FTEs for staff (of which 4 FTEs for inspectors). Fertilizers had a budget available from approximately 290 000 EUR in 2010 to 327 000 EUR in 2013. Staff availability (including that for inspectors) ranged from 53 FTEs in 2010 to 48 FTEs in 2013. The biggest sector mentioned is that of construction products with a budget available of 680 917 EUR in 2010 and falling to 299 320 EUR in 2013,with staff availability following that trend from 50 in 2010 and 18 FTEs in 2013 (of which 49 and 18 FTEs for inspectors).

Own assessment: The report provides extensive information on enforcement and communication activities carried out in most sectors. In general the report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities. The lack of certified laboratory in certain fields is mentioned as a challenge for market surveillance. In the sector of fertilisers the authorities noted the limits represented by the lack of transport means and resources to pay laboratory tests.

2.24 Slovenia

General market surveillance activities

General organisation: Market surveillance in Slovenia is handled by 9 different market surveillance authorities[222] subordinated to 6 different ministries. Political responsibility for the authorities lies with the Ministries of Health, Labour, Interior, Agriculture Forestry and Food, Infrastructure and Spatial Planning and the Ministry of Economic Development and Technology respectively.

The latter Ministry is responsible for the implementation of Regulation (EC) No 765/2008 and coordinates the work of the inspectorates and oversees the exchange of information within a Working Group that is made up of representatives of all market surveillance authorities and representatives of the Customs Administration. It meets twice a year or as necessary.

The report further mentions that the Customs Administration has, on the basis of EU Guidelines for import controls in the field of product safety and conformity, drawn up a catalogue of measures (e.g. on the release of the free circulation of goods) that supports cooperation between customs authorities and the responsible surveillance authorities.

Overall resources: This information is not included in the report.

222 Market Inspectorate of the Republic of Slovenia (TIRS), Metrology Inspectorate, Health Inspectorate, Chemicals Office, Public Agency for Medicinal Products and Medical Devices (JAZMP), Labour Inspectorate, Internal Affairs Inspectorate (IRSNZ), Agriculture and Environment Inspectorate, Transport, Energy and Environment Inspectorate.

Own assessment: The Slovenian report mentions that, between 2010 and 2013, improvement has been made in the knowledge of the requirements of Regulation (EC) No 765/2008 and cooperation in accordance with these requirements. The cooperation between the inspection services for surveillance of products in use and the inspection service responsible for surveillance for products on the market has been reinforced. Further, cooperation between the customs authorities and the inspectorates has been strengthened.

The report also mentions that progress has been made on building a stronger knowledge base on RAPEX and ICSMS where TIRS is the contact point for RAPEX, and the ICSMS falls under the responsibility of the Ministry of Economic Development and Technology. The relevant supervisory authorities exchange information with authorities from other Member States through various available fora and working groups such as PROSAFE and ADCO groups.

The report mentions that there is a lack of resources for the implementation of surveillance activities, in particular the testing of products, in combination with a lack of human resources, creating a strain on participation in working groups and in general creating an incomplete picture of the state of affairs in surveying products on the market.

Market surveillance in specific sectors

Coverage: The report covers all sectors in the reference list except for efficiency requirements for hot-water boilers.

Distribution of resources: Figures are provided for some sectors. Budget allocated to most sectors range between approximately 3000 and 60 000 EUR per year in the period 2010-2013 and a staff and inspector availability between 0.5 and 7 full-time equivalent units (FTE).

Own assessment: The report provides information on enforcement and communication activities carried out in most sectors. It does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

2.25 Slovakia

General market surveillance activities

General organisation: Slovakia provides extensive information on the general organisation of market surveillance. Market surveillance activities pursuant to Regulation (EC) No 765/2008 rest with several ministries. The organisation of market surveillance in Slovakia can be split into two large groups: consumer products and products used by businesses. As a result there are often two surveillance authorities responsible for the enforcement of a given piece of harmonisation legislation (e.g.; personal protective equipment, machinery). However certain products such as medical devices and cosmetics fall under the responsibility of a single surveillance authority, regardless of whether they are consumer or professional products.

The Slovak Trade Inspectorate, which acts under the control of the Ministry of Economy[223], is

223 The Ministry's responsibility also encompasses the Main Mining Office, which carries out the state surveillance of the explosives market.

the market surveillance authority for most non-food consumer products.[224]

The National Labour Inspectorate (under the control of the Ministry of Labour, Social Affairs and Family) is, together with 8 regional labour inspectorates, the market surveillance authority for most professional products.

The State Institute for Drug Control and the Public Health Authority[225] (both under the control of the Ministry of Ministry of Health) are the surveillance authority for medical devices and cosmetics respectively.

The Regulatory Authority for Electronic Communications and Postal Services and other authorities under the control of the Ministry of Transport, Construction and Regional Development are the surveillance authority for radio and telecommunications equipment and electromagnetic compatibility, motor vehicles, cableways, marine equipment and other products.

The Slovak Metrological Inspectorate (under the control of the Slovak Office of Standards, Metrology and Testing) is the surveillance authority for measuring instruments and pre-packaging.

The Slovak report describes the way each of these authorities works.

The authorities cooperate in the organisation and performance of inspections and exchange information on the basis of bilateral agreements. Intra-sector vertical coordination is ensured by individual authorities, which provide guidelines and training to inspectors, and direct their activities.

Overall resources: According to the Slovak report it is not possible to distinguish within the budget of each authority the share of resources allocated to market surveillance from other tasks. The same can be said for staff.

In the 2010-013 period the total annual budget and staff of the Trade Inspectorate amounted to 4.6 million EUR and 252 full-time equivalent units (FTE).

The National Inspectorate employed overall between 109 and 150 staff per year, and estimates that among them about 18[226] FTEs carried out market surveillance. As expenditure per employee (including wages, goods and services) was approximately 18 800 EUR, it is understood that resources for market surveillance in the area of professional products could possibly be estimated around 0.3 million EUR[227].

The Public Health Authority and the regional authorities estimate that, out of an overall annual budget of between 30 and 33 million EUR, about 0.2-0.35 million EUR were dedicated to market surveillance in the cosmetics area; furthermore, they employed more than 2000 staff, about 150 of which provided market surveillance for cosmetics, alongside other activities, such as official inspections of foodstuffs.

224 The Trade Inspectorate is the sole surveillance authority only in relation to toys, pyrotechnics, construction products, electrical appliances and equipment under the low voltage directive, gas appliances, and the labelling of products and recreational craft.
225 Together with 36 regional public health authorities.
226 16 inspectors from regional labour inspectorates and 2 employees of the National Inspectorate.
227 This figure is not explicitly provided by the Slovak report, but corresponds to the value of the multiplication of estimated full-equivalent units of staff for market surveillance and expenditure per employee.

The State Institute for Drug Control had a total budget between 3.7 and 4.2 million EUR and overall FTE count between 165 and 196 per year.

Own assessment: Slovakia rates positively the functioning of its market surveillance activities. During the reporting period there were no serious threats to the health and safety of the public or other public interests.

The financial resources allocated by ministries to surveillance authorities for their activities were limited and central government budget rules do not permit an increase in financial resources for market surveillance authorities. Lack of funds particularly affects laboratory testing. Therefore, the market surveillance authorities, in cooperation with the relevant ministries, jointly assessed the market situation in Slovakia and adapted their activities to topical issues.

Slovakia makes use of all possibilities of cooperation with other EU Member States. The situation would be eased if EU legislation were simplified and streamlined in the field of market surveillance concerning harmonised legislation.

Cooperation between authorities, including vertical intra-sector cooperation, is considered effective. So far, there has been no acute need to establish a nationwide coordinating body for market surveillance. This option will be considered after the new EU market surveillance regulation has been adopted.

Cooperation between market surveillance authorities and customs authorities has improved considerably at the end of the reporting period. This can be attributed in part to an initiative of the Commission (DG TAXUD), which produced manuals for customs officers and promoted cooperation between customs authorities and market surveillance authorities. Individual surveillance authorities have signed cooperation agreements with customs authorities. They exchange information on dangerous products, work together on inspections and organise joint training for their employees.

Market surveillance in specific sectors

Coverage: The Slovak report covers half of the sectors in the reference list. Sectors excluded are pressure equipment, aerosols, machinery, lifts, equipment for use in potentially explosive atmospheres, electromagnetic compatibility, radio and telecommunications equipment, electrical equipment under restriction of hazardous substances, waste from electrical and electronic equipment and batteries, efficiency requirement for hot-water boilers, marine equipment, motor vehicles, non-road machinery and non-harmonised consumer goods (optional).

Distribution of resources: As mentioned in the section on overall resources, according to Slovakia the resources available to market surveillance cannot be easily distinguished from those related to other tasks. A comparison of resources allocated to market surveillance in different sectors cannot be done, however estimates of staff carrying out market surveillance (alongside other activities) in different sectors are given. Excluding medical devices and cosmetics for which no specific estimates are provided, the biggest number of employees work in the sectors of toys, personal protective equipment and low voltage products, together with eco-design/energy labelling.

Own assessment: Slovakia considers that in the reporting period, there were no serious

deficiencies in the operation and functioning of market surveillance authorities or situations threatening the health and safety of consumers, professional users and other public interests, and therefore rates positively the overall functioning of market surveillance. Apart from a few exceptions, such as for cosmetics products, a more specific assessment of the activities carried out in a given sector is not provided.

The biggest problem in the area of consumer products falling within the scope of Regulation (EC) No 765/2008 concerns the traceability of individual businesses in the distribution chain. As Slovakia has few manufacturers of consumer products, inspections must focus on distributors and retailers. Most consumer products were manufactured in third countries and entered the Slovak market from other Member States. It was virtually impossible to identify the importers and, sometimes, distributors of such products. Slovakia also notes that the application of Article 21(1) and (2) of Regulation (EC) No 765/2008 tends to be abused by economic operators, and this hampers market surveillance.

In some sectors (low voltage electrical products) the insufficient definition of product ranges by Custom Tariff codes has prevented the ability to draw risk profiles to be used for checks by customs.

2.26 Finland

General market surveillance activities

General organisation: Finland refers to information provided in the general national programmes. There are nine market surveillance authorities in Finland (i.e. seven sectoral authorities, the National Police Board and Customs). Over the 2010-2013 period it appears that some of the tasks previously conducted by other authorities were transferred to the Finnish Safety and Chemical Agency (Tukes).

The Ministry of Employment and Economy carries out coordinative tasks related to market surveillance and is responsible for the coordination of the national implementation of Regulation (EC) 765/2008. The Ministry is supported by the Advisory Board of Conformity Assessment Affairs that brings together the different authorities as well as stakeholders.

Market surveillance is mostly conducted at central authority level, although there are exceptions to this (e.g. market surveillance of certain professional products is conducted by the Department for Occupational Safety and Health at the Ministry of Social Affairs and Health, as well as Regional State Administrative Agencies' occupational health and safety).

Overall resources: Between 2010 and 2013**,** Finland devoted between 7.2 and 7.7 million EUR per year to market surveillance. Overall staff available to market surveillance can be estimated at around 90-93 full-time equivalent units (FTE), including customs officials. Despite some fluctuations the annual budget for the market surveillance authorities remained fairly constant over the 2010-2013 period. Staff figures diminished very slightly.

Own assessment: Finland considers that cooperation between different market surveillance authorities through the different discussion forums was efficient. Also cooperation with customs worked well.

Finnish authorities used the RAPEX and ICSMS systems actively (for instance 222 RAPEX notifications were made in 2013).

The report mentions the challenge provided by on-line sales by economic operators located outside the EU. It also mentions that in some sectors formal requirements such as technical documentation and CE marking are disregarded by businesses, possibly due to a lack of knowledge or understanding of those requirements.

Market surveillance in specific sectors

Coverage: The Finnish report covers all sectors indicated in the reference list (including non-harmonised consumer product), with the sole exception of non-road mobile machinery.

Distribution of resources: The sector to which the greatest part by far of resources was allocated is low voltage electrical appliances and equipment (between 1.1-1.4 million EUR per year and 7-8 FTEs). This was followed by toys (0.78 million EUR and 13 FTEs) and other consumer products falling under the General Product Safety Directive (0.7 million EUR and 11.5 FTEs), construction products (0.6-0.7 million EUR and 5.5 FTEs), eco-design and energy labelling[228] (0.3-0.5 million EUR and 3 FTEs), radio and telecommunications equipment (0.5-0.17 million EUR and 4-1.5 FTEs), recreational craft (0.3-0.4 million EUR and 4 FTEs) and pressure equipment (0.3 million EUR and 2.2-3.2 FTEs).

Own assessment: Finland provides extensive information on enforcement and communication activities carried out in most sectors. It reports that market surveillance activities have been carried out according to market surveillance programmes. Depending on the sectors, market surveillance is either carried out proactively or exclusively in response to complaints. In different sectors it is also noted that the level of market surveillance is regarded as sufficient, although the report does not detail the specific criteria used for the assessment (e.g. market sizes, estimate of potential non-compliance). Efficient surveillance was carried out in some areas such as toys (38 recalls and 20 withdrawals in 2010-2013), personal protective equipment (26 recalls and 32 withdrawals), non-harmonised consumer products (70 recalls and 40 withdrawals), machinery (22 recalls and 23 withdrawals), despite the relatively limited amount of resources. Very efficient surveillance was also carried out regarding electrical appliances and equipment under LVD (224 recalls and 437 withdrawals). Due to lack of resources in some sectors markets surveillance was very selective in comparison to market size (medical devices, motor vehicles, eco-design and energy labelling restriction of hazardous substances, waste from electrical and electronic equipment and batteries). The absence of an administrative cooperation group (ADCO) complicates the possibility of cross-border cooperation in the sectors of marine equipment and motor vehicles.

2.27 Sweden

General market surveillance activities

General organisation: Sweden refers to the information on the general organisation of market surveillance provided in the national programmes. Market surveillance is carried out by 16 public authorities and 290 municipalities. The Swedish Board for Accreditation and Conformity Assessment (Swedac) is responsible for coordination, including presiding over the Market Surveillance Council that consists of the 16 authorities as well as the Swedish Customs and the Swedish National Board of Trade. It also functions as the national administrator for ICSMS, whereas the Swedish Consumer Agency is the contact point for

228 Including checks for hot-water boilers efficiency requirements.

RAPEX.

Overall resources: Between 2010 and 2013**,** Sweden allocated between 10.4 and 14.3 million EUR per year to market surveillance. Overall staff available to market surveillance almost doubled and is estimated at approximately 43.5 in to 2010 to 91.5 full-time equivalent units (FTE) in 2013. There is no distinction made for inspectors since at most Swedish market surveillance authorities no particular distribution of occupational categories exists.

Own assessment: The report mentions that, even though there is room for improvement, cooperation between market surveillance authorities works well. Given that various authorities are responsible for various aspects of the same product, close cooperation is deemed important by Sweden to achieve effective market surveillance.

Many authorities are actively engaged in disseminating information to economic actors, and their cooperation is functioning well and voluntary corrective actions are common. Further, cooperation between authorities and the Swedish Customs has shown a steady improvement over the years.

Cooperation on a European level works well but the administration that is involved in joint projects is seen as burdensome making, it difficult for authorities to prioritise this cooperation in their activities.

Drawing definitive conclusions on how market surveillance is functioning is challenging but a conclusion that may be drawn is that formal non-compliance is common in most sectors while deficiencies in compliance with basic product requirement vary from one sector to another.

A challenge that is mentioned is that authorities find it cumbersome to report via different information exchange systems and a single integrated system would be welcomed. Also the report mentions on-line sales by economic operators located outside the EU is a challenge.

Market surveillance in specific sectors

Coverage: The Swedish report covers all sectors indicated in the reference list (including non-harmonised consumer products).

Distribution of resources: The biggest sector of resource allocation that is mentioned in the report is medical devices with a budget ranging from 3 million EUR in 2010 to 4 million EUR in 2014 and a staff allocation of approximately 25 FTEs. The cosmetic products sector is mentioned with around 1.1 million for the years 2012 and 2013 with a staff allocation of 8.75 FTEs and 7.5 FTEs, of which for inspectors 5.75 and 4.5 FTEs in 2012 and 2013 respectively. The construction products sector shows a drop in budget from 1.7 million EU in 2010 to 715 000 EUR in 2013 but an increase in staff from 2 to 4.5 FTEs. Other sectors mentioned are radio and telecommunications (approx. 0.7 million EUR and 1.5 FTEs), low-voltage equipment (approx. 0.6 million EUR – 0.7 million EUR and 5.7 FTEs), electrical equipment (approx. 0.1 million EUR and 1.1 FTEs), measuring instruments (approx. 0.4 million EUR – 0.95 million EUR and 4-6.5 FTEs) and other consumer products falling under the General Product Safety Directive (approx. 0.25 million EUR per year and 1.5 FTEs).

Own assessment: The report provides information on enforcement and communication activities carried out in most sectors. It qualifies the market surveillance activities in some other sectors as working well or satisfactorily. The report does not detail the specific criteria used for the assessment. However, for the medical devices sector for example it is stated that

market checks and penalties have contributed positively to compliance with regulations.

2.28 United Kingdom

General market surveillance activities

General organisation: Information on the general organisation of market surveillance in the UK can be found in the national programme. Exercised within a framework of local autonomy, market surveillance generally has been divided between the Health and Safety Executive (HSE) which is responsible for products in the workplace (functions as the national administrator for ICSMS as well) and the UK's Local Authorities' Trading Standards Departments, responsible for consumer product safety. The Medical Devices Regulations and related legislation are enforced by the Department for Health's (DH) specialist Medicines and Healthcare products Regulatory Agency (MHRA). Automotive-related products are the responsibility of the Department for Transport's Vehicle and Operator Services Agency (VOSA). Non-safety legislation is enforced through a number of sector-specialist bodies.

The UK's National Market Surveillance Coordination Committee is responsible for coordination and has set up an MSCC Stakeholders Group to create dialogue between the members of the MSCC, business and other interested parties. The UK Customs authorities work closely with the MSA to identify products that are likely to present a risk, through a targeted border controls approach.

Overall resources: The report states that because all of the UK MSAs are autonomous enforcement bodies and the market surveillance network is diverse, it is not feasible to provide data about the overall resources.

Own assessment: The report does not provide an assessment of the effectiveness or efficiency of the general market surveillance organisation.

Market surveillance in specific sectors

Coverage: The report contains statistics on enforcement activities carried out by the UK Trading Standards local authorities in the areas of toys, electrical appliances, cosmetics and childcare articles for 2011 (approximately 60% of Trading Standards responded) and 2012 (approximately 93% of Trading Standards responded).

Distribution of resources: The report does not include this information.

Own assessment: The report provides information on enforcement and communication activities carried out in some sectors. The report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

3. MAIN FINDINGS

All **Member States fulfilled the obligation** to submit reports in accordance with Article 18(6) of Regulation (EC) 765/2008 and most **Member States were able to provide a significant amount of information**, despite the understandable difficulties of the exercise (notably, the relatively short time available to discuss the common indicators and to collect information).

The information provided is **valuable as it provides better and useful insights into the**

practical enforcement of product legislation in the EU for the first time.

The examination of the reports submitted in this first round of national reviews and assessments shows that the **level of detail of information provided varies from Member State to Member State**. Critical factors in this respect have proven to be the sector-specific focus and the range of sectors covered. The reports, which followed the sector-focused approach proposed by the Commission cover a wider range of sectors and contain in general more accurate and complete information on the enforcement activities carried out.

The following main findings are based on the results of the exercise and the efforts needed to pursue the correct implementation of the Regulation. They are not recommendations or conclusions. Rather this section is to be seen as a synthetic overview of all the information gathered and possible follow up that can be derived thereof.

3.1 Main findings on sector coverage

As the scope of Regulation (EC) 765/2008 extends to all EU harmonisation legislation, Member States were requested to include all product areas or sectors falling within this scope. To this end the template prepared by the Commission provided a reference list of 29 sectors which Member States were free to expand, and also covering market surveillance activities carried out in relation to non-harmonised consumer products falling within the scope of the General Product Safety Directive. On the other hand, the Commission indicated that the inclusion of market surveillance activities in relation to chemical products within the scope of Reach and Classification and Labelling Regulations was not considered necessary because of the detailed reporting and assessment already carried out and made public according to the specific provisions of this legislation.

Against this background most Member States have provided detailed information on enforcement activities carried out in the majority of sectors. Even though the actual coverage of national reports varies between Member States, the following snapshot can be made for the ones that followed the common template established by the Commission:

- **All or almost all sectors** were covered by Latvia, Finland, Sweden, Slovenia, Denmark, France, Malta, Bulgaria, Poland, Czech Republic, Romania, and Hungary.

- **More than two thirds of sectors** were covered by Austria, Greece, Estonia, Belgium, Ireland, Portugal and Cyprus.

- **About half of the sectors** were covered by Slovakia, Italy and Luxembourg.

- **Less than half of the sectors** were covered by Spain. The report however includes only aggregate information on activities carried out for two macro areas encompassing respectively products for consumers and professional users.

The products/legislation areas most often left out of national reports are:

- **Non-road mobile machinery** (Directive 97/68/EC) and the efficiency requirements for hot-water boilers fired with liquid or gaseous fuels pursuant to Directive 1992/42/EEC, which are covered only by 7-8 Member States.

- **Transportable pressure equipment** (Directive 2010/35/EU), Noise emissions for outdoor equipment (Directive 2000/14/EC), **Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres** (Directive 1994/9/EC), which are covered only by 15-16 Member States.

A complete overview of the sectors covered by each national report is given in Annex 2.

As regards to some **countries that chose not to use the common template**, it is noted that, **in general they provided less detailed information on enforcement activities carried out specific sectors**. In particular:

- The report from Croatia covers activities concerning 12 of the 29 sectors included in the reference list and provides some basic statistics on inspections and checks carried out.

- The report from Germany in principle covers activities concerning 12 of the 29 sectors included in the reference list (see detailed country overview); however, because those activities are not presented on a sector-by-sector basis it is not possible to know whether the information reported actually refers to all relevant product areas or only some of them.

- The report from the Netherlands in principle covers activities concerning 21 of the 29 sectors included in the reference list. However factual he information on activities carried is provided only for a smaller set of sectors and is mostly of qualitative nature.

- The report from the United Kingdom in general does not provide information on inspections in specific sectors in the 2010-2013 period, except for toys, electrical appliances, cosmetics and childcare articles.

- The report from Lithuania provides an assessment of national legal framework and therefore does not contain information on inspections carried in specific sectors.

Based on these findings it would be useful to understand from Member States the reasons why a certain number of sectors were left out of the national reports. In some cases this may be due to the fact that certain products may not be relevant in all countries (e.g. cableways, marine equipment) or that Member States may not have intuitively considered certain pieces of legislation as product harmonisation (e.g. Directive 1992/42/EEC on efficiency requirements for hot-water boilers fired with liquid or gaseous fuels).

Apart from these special cases however the exclusion of a sector might be due either to a **lack of structured market surveillance in the sector** (i.e. authorities make no interventions or those interventions are sporadic and not recorded) or to **coordination problems within a Member State** (i.e. the central authority responsible for the coordination of market surveillance could not obtain the necessary input from the sector-specific authority).

In addition to the sectors included in the reference list, a number of the national reports also included additional product areas (see detailed country-by-country overviews in section 3). This suggests that it could be useful to **discuss with Member States the opportunity to include additional sectors in the reference list of sectors for future exercises**.

3.2 Main findings on the overall resources available to market surveillance

With regard to the template drawn up by the Commission, some of the Member States have indicated that the information on levels of resources could not be easily obtained. This is because in many cases authorities responsible for market surveillance have at the same time to carry out tasks of another nature, and the budget of those authorities does not earmark funds for market surveillance.

The problem also affects the figures on staff, who are often asked to carry out different types of tasks next to market surveillance in sectors falling within the scope of Regulation (EC) 765/2008.

Against this background, it is noted that:

- The information on resources for market surveillance activities is **available** in Denmark, Finland, the Netherlands, Poland and Sweden. It also available to a large extent in France, albeit in a different format (distinction is made between budget and staff dedicated to testing of products and other market surveillance activities).

- The information is **partially available** for Italy (budget available only for the Minister of Economic Development, staff available also for some additional Ministries), the Czech Republic (budget available only for CTIA; staff available also for other authorities although difficult to distinguish between market surveillance and other tasks), Luxembourg (budget available only for ILNAS, staff available also for ITM), Estonia, Ireland, Latvia, Malta and Slovakia (an estimation of total budget and staff for some but difficulty to distinguish between market surveillance and other tasks), Bulgaria (budget and staff available for DAMTN and KZP), Cyprus (details on resources available for about 10 sectors), Spain (estimation of the combined budget of the consumer affairs authorities) and Portugal, Romania and Hungary (budgets available for 4, 5 and 8 authorities respectively),

- The information is **not available** for Austria and Belgium (impossible to determine the budget allocated to market surveillance tasks carried out under indirect federal administration), the United Kingdom (impossible to provide data on the overall resources because all of the UK MSAs are autonomous enforcement bodies and the market surveillance network is diverse), Germany (according to whom information on the level of resources for market surveillance is not relevant to assess its effectiveness and efficiency), Croatia and Slovenia (no specific reason specified).

- In the case of Lithuania, it is not possible to say if resources for market surveillance are known or not, since the report follows a different approach and therefore does not cover this aspect.

This brief overview suggests that in a number of cases the availability of information on resources for market surveillance could be improved by increasing transparency of resources allocation within national authorities' budgets and by working out methods to estimate which share of certain resources (e.g. staff) can be attributed to different activities. The difficulty of estimating resources when market surveillance tasks are delegated to local authorities is less clear and requires more in-depth investigation.

Information provided by Member States on the level of resources **should be interpreted**

carefully due to the significant gaps in information in some of the countries. In some, for instance, resources mentioned concern only the central administration but do not take into account local administrations or other police officers involved in inspections. Furthermore, it is not clear if all budget figures provided include remuneration of staff as suggested in the Commission's template. For these reasons the information provided can only be subject to cross-country comparisons to a very limited extent.

Despite these limitations however, the information available provides interesting insights into the importance attributed to the enforcement of product legislation by a given Member State and represents a solid starting point for further enquiries. It also allows **for some insight into whether authorities have in practice the means to accomplish the tasks attributed to them**.

Many Member States note that **resources for market surveillance are limited and lacking**. For instance, a lack of resources is claimed by Spain, Poland, Slovenia, Estonia, Denmark, Italy, Czech Republic, Malta, Luxembourg, Slovakia, Bulgaria (budget for testing, expert staff in certain sectors) and Cyprus. It would then appear useful for Member States to try and **estimate the amount of resources necessary** to increase the amount of enforcement to a more satisfactory level and to take **initiatives to fill the resource gap**.

3.3 Main findings on the assessment of market surveillance carried out by Member States – discussion of evaluation criteria

According to Article 18(6) of Regulation (EC) 765/2008 the assessment of the functioning of national market surveillance should be carried out by Member States.

The template prepared by the Commission was meant to help Member States to structure the information in a manner that could facilitate its evaluation. The idea behind the template was that reporting information on the general organisation of market surveillance (infrastructures, distribution of competences, resources available) and sector-specific activities (information and communication activities, number, type and outcomes of inspections) could help present all the basic 'facts' to be assessed.

On the other hand the template left **Member States free to determine the relevant criteria for the assessment** of their (general/sectoral) national market surveillance activities.

It is then interesting to observe that a number of Member States have actually interpreted the requirement of Article 18(6) of the Regulation as for the most part a mere reporting obligation, and have used the Commission template more as a questionnaire on possible 'indicators' of activities rather than as an aid for their own analysis and evaluation. As a result of this, in many cases the reports provide sector-by-sector information but do not actually *evaluate* the amount and type of activities carried out.

However, the following few examples of assessments of market surveillance activities by specific Member States are noted:

- Austria considers that the overall level of market surveillance can be regarded as sufficient in the light of the **low number of complaints** lodged with market surveillance authorities and the **low number of accidents** recorded in the Injury Database.

- Slovakia rates the functioning of market surveillance as generally positive since it considers that in the reporting period there were **no serious deficiencies in the**

operations of market surveillance authorities or situations threatening the health and safety of consumers, professional users and other public interests.

- The Netherlands, Sweden, Denmark, Poland, Estonia, Slovenia and the Czech Republic consider the market surveillance activities to be effective or satisfactory since **the cooperation and coordination between authorities** is of such a level (or has improved) that it has a positive impact on the overall success of surveillance activities.

- Germany, Bulgaria and Finland consider market surveillance activities satisfactory as they were carried out **according to market surveillance programmes**.

- Finland also points to the efficiency of market surveillance by comparing the number of product recalls and withdrawals achieved in 2010-2013 with the relatively small level of resources available during the same period.

- Furthermore, specific attention should be devoted to the approach of Lithuania's evaluation study. Interestingly, it had the objective to **assess whether national law has properly implemented the EU requirements** for market surveillance laid down in Regulation (EC) 765/2008 and makes suggestions on how to further improve the national regulatory framework.

In light of the above, it would appear useful to discuss with Member States the advantages and disadvantages of the different approaches to the assessment of market surveillance and to build a common understanding on the relevant **evaluation criteria.**

In this regard, the assessment of the market surveillance carried out in a given sector is also expected to be connected to the **specific market context** in which the market surveillance activities took place. For this reason figures on the number and type of inspections should be analysed against the backdrop of the relevant estimates of the size of the national market for the products concerned, the number of manufacturers/importer/wholesale or retail distributors based in the Member States and, the volume of imports from other Member States or third countries, and so on. This information seems among those necessary to assess the scale and the reach of market surveillance activities.

The Commission also notes that the Lithuanian approach to evaluation introduces an additional and interesting dimension to the discussion on the assessment of the functioning of market surveillance.

3.4 Main findings on challenges faced by market surveillance authorities

Many national reports comment on major difficulties identified in the course of market surveillance activities. One of them is certainly the lack of sufficient resources. Additional common challenges appear to be the following:

- Various reports (e.g. Denmark, France, Germany, the Netherlands, Czech Republic, Finland, Bulgaria) note that current control procedures are not apt to handle **products sold on line**. In this connection, for instance, Germany suggests that it is worth considering whether, for internet commerce, there should be further accountable parties beyond the economic operators defined in Regulation (EC) No 765/2008, for example commercial platforms that do not fall within the current definitions of a distributor or importer. Moreover, for effective market surveillance of products sold on the internet and that are offered from outside the EU, collaboration with customs authorities is of

crucial importance.

- Some reports stress the need to reinforce **customs controls.** In this respect Germany notes that product-specific specialist knowledge must be available to a greater extent locally at import control sites: risk profiles based on the findings of market surveillance authorities have proven worthwhile, but an improvement would be possible, for example, by conducting special training for customs officials or by posting market surveillance specialists at customs offices for direct, joint customs clearance. Furthermore, to make it harder for non-European manufacturers, whose non-compliant products have been rejected by a customs authority, to switch to other customs clearance locations, improved cooperation between the customs authorities of the EU Member States also seems necessary). Slovakia and Cyprus point to the existing mismatch between the customs product classification and the nomenclature used by market surveillance authorities, which hamper cooperation in some areas (e.g. electrical low voltage equipment, personal protective equipment, pressure equipment, equipment for use in potentially explosive atmospheres, lifts and machinery).

- France mentions insufficient **cross-border cooperation** in some sectors (i.e. equipment for use in potentially explosive atmospheres, pyrotechnic articles, civil explosives and gas appliances), as a difficulty to tackle when relevant economic operators are located abroad. Finland mentions complications due to the lack of ADCOs for marine equipment and motor vehicles.

- Spain, the Czech Republic, Malta, Slovakia, Bulgaria and Cyprus note the lack of **traceability** information especially, when products are imported into the EU by intermediaries located in other Member States

- The Czech Republic notes the difficulty of dealing with products from third countries sold via **informal channels** (marketplaces), and the ineffectiveness of market surveillance techniques in this case.

- Spain and Ireland note **that penalties** laid down in national law **might not be a sufficient deterrent,** in particular in the case of larger companies trying to market non-compliant products;

- Estonia and Ireland note that **the non-existence of test laboratories** makes conformity assessment difficult and costly.

- Many reports mention **economic operators' lack of knowledge** about applicable product rules. Finland for instance mentions that in some sectors formal requirements such as technical documentation and CE marking are disregarded by businesses, possibly due to lack of knowledge or understanding of those requirements. France suggests a simplification of product legislation and the need to provide summaries of legislation applicable to categories of products to be made available to businesses.

- Bulgaria notes the **lack of cooperation by certain economic operators**; Slovakia refers to businesses' abuses of the legal principles on the notification of restrictive measure contained in Article 21 (1) and (2) of Regulation (EC) 765/2008.

- France mentions the need to reduce the **administrative burden** for market surveillance authorities (i.e. simplify current safeguard clause procedures for serious risk products by

using the Rapex system). Sweden notes that there is a demand for a single integrated system since reporting in different information exchange systems is deemed cumbersome and not always suitable.

The reflections of the market surveillance authorities should guide current and future policy initiatives in the on-going implementation of Regulation (EC) 765/2008.

3.5 Main findings on possible issues with current practice by market surveillance authorities

The analysis of the specific information provided by Member States for the toys sector that is conducted in the following section sheds light on some aspects of market surveillance activities in practice. The Commission suggests a number of possible concrete follow-up actions that could improve national enforcement of legislation in relation to potential gaps identified. These actions could also be easily applied to other product areas. They have been grouped by relevant area and can be summarised as follows:

- **Focus of market surveillance activities**: authorities to discuss and compare methodologies for selecting proactive inspections and to screen information provided by stakeholders; draw up a set of best practices; enquire into the accessibility and visibility of national stakeholders' complaint procedures.

- **Follow-up to discovery of non-compliance**: enquire into reasons why a significant number of inspections where non-compliance is found appear to be left without follow up; enquire about criteria used by Member States to choose whether to apply sanctions in addition to compulsory corrective action or not.

- **Cooperation with customs**: identify and overcome obstacles to cooperation between customs and market surveillance authorities; discuss possibility to recognise customs as markets surveillance authorities.

- **Cross-border cooperation**: enquire into obstacles to cross-border cooperation; inform sector authorities of the mutual assistance principles of Regulation (EC) 765/2008; make those principles operational by building up a common procedure.

4. CASE STUDY OF A SPECIFIC SECTOR: TOYS

This section showcases a more in-depth analysis of the information provided by Member States in relation to market surveillance activities carried out during the 2010-2013 period in the toys sector.

The reason why a single sector has been chosen is to demonstrate that with the correct use of the template that was provided by the Commission, more insight into the difference and commonalities of market surveillance activities by Member States on a sectoral level can be discerned since the results of the analysis offer indications of the size and the type of enforcement activities carried out in each country[229]. The objective is to shed a brighter light on some aspects of market surveillance activities in practice.

229 Naturally differences between countries can partly be attributed to different levels/styles of enforcement activities and partly to diverging interpretations of the indicators.

4.1 On the number of product-related accidents, user and industry complaints

Information on the number of product-related accidents, user and industry complaints is provided by 17 Member States out of the 28 that submitted a report according to Article 18(6) of Regulation (EC) 765/2008. In half of them (Bulgaria, Ireland, France, Hungary, Malta, Portugal, Finland and Sweden) the average number of product-related accidents and complaints per year is between 14 and 31; in four cases the average number is much higher (215 for Poland, 212 for Italy[230], 120 for Czech Republic and 90 for Slovakia); in four other cases very few complaints are reported (4 for Denmark, 1 respectively for Greece and Luxembourg, 0 for Romania and Cyprus)

The number and the importance of product-related accidents, user and industry complaints provides indications to market surveillance authorities of the presence of possible non-compliant products available on the market. These figures should be viewed in relation to the population of each country and to the number of products made available in national markets. The fact that a certain number of the Member States do not provide any information on product-related accidents, user and industry complaints may however suggest that accidents and complaints are not systematically recorded. It also raises the question about the accessibility and visibility of national complaint procedures.

4.2 On the number of inspections

The average yearly number of inspections[231] reported for the period between 2010 and 2013 changes significantly from Member State to Member State (from 4 in Ireland to more than 2 800 in France). The following outlook is provided for groups of countries of broadly similar number of inhabitants[232]:

- Germany (81 million inhabitants): no information on toy inspections provided.

- France, Italy and the UK (60-66 million inhabitants): France reports an average of 2 834 inspections per year[233]; Italy reports 1 115 inspections including however both toys and other non-harmonised consumer products; the UK reports 1 482 per year.

- Spain and Poland (38-46 million inhabitants): Poland reports 754 inspections per year on average; no information on toys inspections is provided by Spain.

- Romania and the Netherlands (16-20 million inhabitants): Romania reports 1 496 inspections per year; the Netherlands notes that between 2012 and 2013 135 manufacturers and importers of toys were inspected and that some of the companies were trading in different product groups.

- Belgium, Greece, Czech Republic, Portugal, Hungary, Sweden, Austria and Bulgaria

230 Also includes those concerning non-harmonised consumer goods.

231 According to the common template prepared by the Commission, inspections are regular or ad hoc visits, controls (including checks on the internet) or other forms of contacts (mail, telephone) undertaken by an inspector, with an enforcement focus (excluding pure information-exchange) and aimed at verification of product safety and compliance. Where several products/models/regulations are checked during the same exercise, this should be counted as one inspection. In order to be considered an inspection, there must be an official report prepared following the action.

232 The number of inhabitants is taken here as a very simple (although admittedly very rough) estimate of national market sizes.

233 The figure does not include checks carried out by customs that in France are market surveillance authorities.

(7-11 million inhabitants): Belgium reports 1 270[234] inspections per year on average; Greece reports 28 inspections[235], however the yearly activity went down over the period from 38 to 8 inspections; the Czech Republic reports 1 631 inspections; Portugal reports 235 inspections with a big increase in 2012 and 2013 (respectively 453 and 405 inspections) by comparison with 2010 and 2011 (50 and 30 inspections each); Hungary reports 1 180 inspections; Sweden reports 84 inspections; Austria reports 584 inspections with a big increase in 2012 and 2013 (respectively 117 and 130 inspections) by comparison with 2010 and 2011 (52 and 37 inspections each); Bulgaria reports 1 739 inspections.

- Denmark, Finland, Slovakia, Ireland and Croatia (4-6 million inhabitants): Denmark reports 113 average inspections per year, with a drop in the number of inspections carried out in 2012 and 2013 (90 per year) compared to those carried out in 2010 and 2011 (respectively 138 and 133); Finland reports 1 351 inspections with big drop in 2013 (808 inspection) compared to the previous year (1 739 inspections); Ireland reports 4 inspections[236]; Croatia reports 384 inspections for the last semester of 2013.

- Lithuania, Slovenia and Latvia (2-3 million inhabitants): no information is available for Lithuania; Slovenia reports 1 757 average inspections per year (including those in kindergartens); Latvia reports 116 inspections.

- Estonia (1.3 million inhabitants) reports 402 average inspections per year

- Cyprus, Malta and Luxembourg (less than a million inhabitants): Cyprus reports 960 average inspections per year, with a peak of activity in 2010 (1 257 inspections) compared to the other years; Malta reports 149 inspections; Luxembourg reports 51 inspections including visual inspections of labelling.

The figures reported in this section should be interpreted carefully as it cannot be excluded that the figures collected by different Member States do not entirely correspond. For instance it is likely that certain checks at the border[237] are included by some Member States and excluded by others depending on the way responsibilities are shared.

The overview above reports the figures provided by the Member States. It does not constitute an assessment of the amount of effort made by market surveillance authorities and whether enforcement activities carried out were to an appropriate scale. Assessing the scale of the checks would presuppose among others information about the number and type of economic operators making products available in a given country, as well as the number of products involved in a given inspection (e.g. an inspection addressing the principal or exclusive national importer of a product made available throughout the whole national market is expected to involve a larger number of products than inspections carried out in a single retail outlet).

234 For 2010 and 2011 Belgium reports respectively 110 and 639 investigations to which the follow-up to Rapex notifications concerning toys should be added. The inclusion of toys Rapex notifications for years 2012 and 2013 brings the number of inspections respectively up to 2251 and 2078.

235 The Greek report notes these were carried out "at virtually zero cost".

236 Not limited to toys.

237 For instance sample checks, if any, conducted by customs without prior coordination with market surveillance authority and which did not give rise to subsequent in-depth investigations.

4.3 On the nature of inspections

Proactive vs reactive inspections: When looking at the share of proactive (including inspections prompted by customs) versus reactive inspections, it appears that about 60 % of the inspections reported by Member States[238] for the period 2010-2013 were proactive inspections. However the situation changes from country to country (see Table 9-3 below). At the high end of the spectrum are France, Romania, Luxembourg and Latvia whose reported inspections are virtually entirely self-initiated, followed by Poland and Greece (83%), Slovenia (77%), Bulgaria, Hungary, Croatia and Sweden (65-60%), Denmark, Malta and Portugal (55-50%) and then Slovakia (38%). At the low end of the spectrum are Belgium (12%)[239] - recorded a high number of reactions to Rapex notifications - and Ireland (0%).

Table 9-3: Share of self-initiated inspections out of total inspections (percentages)

BE	12
BG	65
CZ	n.a.
DK	55
DE	n.a.
EE	n.a.
IE	0
EL	83
ES	n.a.
FR	99
HR	61
IT	n.a.
CY	n.a.
LV	98
LT	n.a.
LU	99
HU	62
MT	54

238 This average is based on data provided by 17 Member States. In particular it excludes Germany, Spain, Lithuania and the Netherlands for which no information on investigations in the toys sectors is provided. It also excludes Estonia, Italy, Czech Republic, Cyprus, Austria, Finland and the UK whose data are incomplete or contained inconsistencies so that the share of self-initiated investigations could not be calculated.

239 As regards Belgium the share is calculated on the figures provided for 2013 only.

NL	n.a.
AT	n.a.
PL	83
PT	50
RO	99
SI	77
SK	38
FI	n.a.
SE	60
UK	n.a.

Types of checks: The share of physical and laboratory checks as opposed to merely administrative checks is about 100% for Bulgaria, Denmark, Cyprus, Latvia and Slovakia, close to 90% for Czech Republic, around 75-80% for Luxembourg and Slovenia, and 57-58% for Finland and Sweden. Lower shares are given for Portugal (27%) and Croatia (18%).

Unfortunately the relevant share cannot be calculated for some countries due to different interpretations of the information requested. It appears nevertheless that a very high total number of physical and laboratory tests were carried out by France, the UK, Hungary and Poland.

In most cases the share of laboratory tests cannot be singled out due to the different approaches used in collecting the data.

4.4 On the share of inspections prompted by customs

The average share of inspections prompted by customs is about 20% [240], but varies between a country such as Ireland, where all inspections concerning toys in the 2010-2013 period were initiated by customs, and countries such as Greece, Romania, Slovenia, Portugal, Malta, Hungary and Slovakia where virtually none or only 1% of the inspections were prompted by border control authorities. The share is 7-11% for the UK, Sweden and Denmark, 19-20% for Poland, Latvia and Cyprus, 25-26% for Luxembourg and Bulgaria, 38% for Croatia, 54% for Finland.

Table 9-4: Share of inspections prompted by customs (percentages)

BE	n.a.
BG	26

240 This average is based on data provided by 18 Member States. Notably, it excludes Germany, Spain, Lithuania and the Netherlands, for which no information on investigations in the toys sectors is provided. It also excludes Estonia, Italy, Czech Republic, Cyprus and Austria whose data are incomplete or contained inconsistencies so that the share of self-initiated investigations could not be calculated. It excludes France where customs are market surveillance authorities and carry out checks for themselves.

CZ	n.a.
DK	10
DE	n.a.
EE	n.a.
IE	100
EL	0
ES	n.a.
HR	38
IT	n.a.
CY	n.a.
LV	19
LT	n.a.
LU	25
HU	1
MT	0
NL	n.a.
AT	n.a.
PL	19
PT	0
RO	0.
SI	0
SK	1
FI	54
SE	7
UK	11

The relatively low involvement of customs in some countries appears at odds with the fact that many of the toys on national markets are imported from third countries. This might be explained by possible cooperation issues between customs and market surveillance authorities. It might possibly also be due to the fact that, traditionally being used to a different 'core business', customs may not feel fully committed to the more recent goal of product safety and compliance. As a matter of fact countries like France and Finland, where customs

are directly involved in market surveillance, the percentage of inspections prompted by them is remarkably higher.

4.5 On the outcomes of inspections: Finding of non-compliance

The share of inspections reported by Member States giving rise to a finding of non-compliance was on average 44% in the EU[241]. Again however there are significant differences between Member States: the share is 83% for Sweden, 81% for Romania, 73% for Malta, 54% for Poland, 45% for Latvia and Greece, 39-40% for Slovakia and Bulgaria, 32-34% for Hungary and Luxembourg, 26% for Denmark, 12-15% for Portugal, France, Croatia and Slovenia.

The level of non-compliance rates found by toys market surveillance authorities on the one hand represents an indication of the existence of non-compliance in the sector, while on the other hand it says something about the authorities' ability to spot it. For instance, it is assumed that the rate should be lower overall for proactive inspections involving random sample checks (like, apparently, for France, Slovenia and Luxembourg), while it should be higher for targeted proactive inspections and reactive inspections pursuant to concrete indications (e.g. by complainants, Rapex notifications) that point to the non-compliance of certain products. However, the quality, respectively, of the prioritisation work leading to random sample checks and the screening/assessment of the complaints also has an impact on the probability of spotting non-compliance.

4.6 On the outcomes of inspections: Measures and penalties

Follow up to inspections where non-compliance was found: The comparison of the number of inspections where non-compliance was found, with the sum of (voluntary or compulsory) measures taken by market surveillance authorities and/or the total number of sanctions/penalties applied, provides an indication of the follow-up given by market surveillance authorities. On the basis of the data provided, it appears that on average the EU authorities were able to provide a follow-up in two-thirds of cases at most.[242]

Table 9-5 shows that, among Member States with percentages higher than the EU average, Estonia and Hungary indicate the application of measures and/or sanctions for all inspections reported for the 2010-2013 period; Latvia, Portugal and Luxembourg indicate a follow up respectively for 86%, 75% and 71% of the inspections; Finland and Denmark for 68-69% of inspections. Among Member States indicating percentages lower than the EU average, Malta and Greece report 52%, Cyprus 46%, Czech Republic, Bulgaria and Sweden 36-37%, France 29%, Slovakia 14%.

Table 9-5: Follow up to inspections: percentage of cases of non-compliance where measures and/or penalties were applied

241 This is the simple average of national percentages based on data provided by 16 Member States, while the weighted average is 32%. Those averages exclude Germany, Spain, Lithuania and the Netherlands for which no information on investigations in the toys sectors is provided. They also excludes Belgium, Estonia, Italy, Czech Republic, Cyprus, Austria, Finland and the UK whose data are incomplete or contained inconsistencies so that the share of self-initiated investigations could not be calculated.

242 This average is based on data provided by 17 Member States. Notably, it excludes Germany, Spain, Lithuania and the Netherlands for which no information on investigations in the toys sectors is provided. It also excludes the UK, Belgium, Poland, Slovenia, Croatia, Italy and Austria whose data are incomplete or contained inconsistencies so that the share of self-initiated investigations could not be calculated. The average probably overestimates the number of inspections with a follow-up, as in some case both corrective action and sanctions were imposed in a given inspection, so the figures worked out by the Commission involve some double counting.

BE	n.a.
BG	37
CZ	37
DK	68
DE	n.a.
EE	100
IE	100
EL	52
ES	n.a.
FR	29
HR	n.a.
IT	n.a.
CY	46
LV	86
LT	n.a.
LU	71
HU	98
MT	52
NL	n.a.
AT	n.a.
PL	n.a.
PT	75
RO	100
SI	n.a.
SK	14
FI	69
SE	36
UK	n.a.

Corrective action vs sanctions: On average corrective action was taken in the EU for 50% of

the inspections that found non-compliance, while sanctions were applied for about 20% of those inspections. It appears that countries like Sweden, Finland, Malta, Luxembourg, Cyprus, Estonia and Denmark have given a net preference to corrective measures, others like Czech Republic, Portugal, and Slovakia have mainly applied sanctions/penalties, while the remaining have used an evenly-balanced mix of both.

Voluntary vs compulsory corrective action: The respective roles of voluntary and compulsory corrective action can be estimated only for eleven Member States and shows that Estonia, Greece, Cyprus, Latvia, Luxembourg, Croatia, Hungary and Finland resorted to a large extent to compulsory measures while Bulgaria, Sweden and, to a lesser extent, Denmark resorted mostly to voluntary measures.

The fact that corrective action and/or sanctions are reported only for a subset of inspections where non-compliance is found raises the question of what happens for the remaining inspections that have spotted non-compliance: is this due to lack of traceability/identification of the economic operators, or difficulties to reach him/her abroad, or the fact that the product is no longer on the market. One Member State observed that a small proportion of producers are based in the national territory and that the possibility of imposing measures in relation to the responsibilities of distributors is rather limited. On the other hand the fact that many market surveillance authorities focus their inspections on distributors and importers is expected to influence only the type and not the number of follow-ups provided.

It also appears that sanctions do not systematically accompany the imposition of compulsory corrective action.

4.7 On cross-border cooperation

Among the twelve Member States providing information on this point, only the Czech Republic and Denmark reported cases of inspections - 18 and 1 respectively - in which other Member States were invited to collaborate during the 2010-2013 period.

The indicator suggests that cross-border cooperation is extremely low. This is particularly problematic in a sector like toys where products are very often imported from third countries and from other EU countries.

4.8 On budget and staff

Only 10 Member States indicated budget[243] and/or staff available for market surveillance activities in the toys area between 2010 and 2013. These were on average as follows:

- Bulgaria: 640 320 €, 75 overall staff dedicated to market surveillance of both toys and the other 'new Approach' products, of which 30 inspectors;

- Denmark: 233 300 €, 2 overall staff of which 1 inspector;

243 According to the indication contained in the common template, the budget figure should cover all financial resources which are assigned by public authorities to market surveillance and enforcement activities as well as to projects and measures aimed at ensuring compliance of economic operators with product legislation. These measures range from communication activities (consumer/business information and education) to pure enforcement and market surveillance activities. They include the remuneration of staff, direct costs of inspections, laboratory tests, training and office equipment costs. Enforcement activities at regional/local level should also be reported. Other activities undertaken by these authorities not related to the enforcement of product legislation laws should be excluded from the calculation.

- France: 1 560 000 € excluding budget for testing products, 23 overall staff of which 20 inspectors;

- Hungary: 441 579 €, 33 overall staff of which 21 inspectors;

- Finland: 780 000 €, 13 overall staff of which 12 inspectors;

- Sweden: 178 641 €, 2.5 overall staff of which 0.5 inspectors;

- Greece: 13 overall staff of which 10 inspectors;

While the budget of Bulgaria and Finland remained stable overall between 2010 and 2013, the budgets of Denmark and France were reduced and those of Hungary and Sweden increased.

In addition Ireland and Slovenia report the figures of 5.875.000 € and 5.633.460 € respectively, which amount to the total budget of the authorities responsible, amongst others, for toys market surveillance. Ireland indicates that 7 authorised officers work in the product safety unit and that additional officers are available to assist if required. Slovenia reports that the total number of the authority's employees is 133, while the total number of inspectors is 110. They are engaged in the official control of all areas of Inspectorates' field of operation. There is no specialisation by area.

It is surprising that only a few Member States could quantify the resources available for market surveillance of toys. Information on the availability of information on resources appears important to identify major resource gaps to be addressed.

In relation to data provided, it is not clear if all the figures consistently include the remuneration of staff and other possible common costs (overheads), in addition to specific market surveillance costs (e.g. sampling and testing costs).

4.9 On the assessment provided by Member States

Most Member States completed the information reported in the previous sections with useful additional descriptions of the activities carried out, the type of non-compliances found or the working methods used. Many consider that enforcement and information actions must be continued. Lack of knowledge about legal requirements applicable to toys and economic operators' responsibilities are very often reported.

Only a few Member States (notably Cyprus and Sweden, as well as in a much less detailed manner Bulgaria, Austria, Slovakia) were able to report information on the number and type of economic operators, value of market, value and import flows, which as noted in the section on the number of inspections, appears as an important piece of information to assess the scale of market surveillance checks. Not surprisingly, therefore, no Member State conducted an explicit assessment of market surveillance along those lines. Nevertheless Bulgaria mentions that a consistent and comprehensive monitoring of the market took place. On the other hand, Finland comments on the efficiency of enforcement efforts which lead to a certain number of products recalls and withdrawals despite relatively small resources. Among the challenges faced, toys market surveillance authorities mention 'Asian marketplaces' and fairs selling cheap toys where low rates of non-compliance are found and where products found to be unsafe are often put back on the market, sometimes after rebranding. Also, Denmark mentions the need to clarify the legal position of agents, and the responsibility of distributors when a manufacturer declares bankruptcy.

5. AVERAGE EU STATISTICS PER SECTOR DERIVED FROM THE 2010-2013 REVIEW AND ASSESSMENT REPORTS

The statistics in the next pages are calculated on the basis of data made available by Member States. Statistics should be interpreted with due care due to fact that some inconsistencies in the interpretation of the different definitions given by some respondents. It is also noted that not all Member States provided information on all items. For instance the following table shows the number of Member States reported concrete information on inspections carried out in a given sector.

Table 9-6: Member States reporting data on the number of inspections per sector

Sector	No of MS reporting data
Medical devices	13
Cosmetics	14
Personal protective equipment	17
Construction products	16
Aerosol dispensers	4
Simple pressure vessels and pressure equipment	12
Transportable pressure equipment	10
Machinery	19
Lifts	5
Cableways	7
Noise emissions for outdoor equipment	6
Equipment and protective systems intended for use in potentially explosive atmospheres	8
Pyrotechnics	17
Explosives for civil uses	12
Appliances burning gaseous fuels	14
Measuring instruments, non-automatic weighting instruments and pre-packed products	16
Electrical equipment under EMC	13
Electrical appliances and equipment under LVD	20
Electrical and electronic equipment under ROHS, WEEE and batteries	9
Chemicals	16

Sector	No of MS reporting data
Eco-design & energy efficiency	15
Recreational craft	7
Marine equipment	3
Motor vehicles and tyres	4
Non-road mobile machinery	4
Fertilisers	13
Other consumer products under GPSD (optional)	13
Biocides	2
Textile & footwear labelling	5
Crystal glass	1

Source: National reports

Table 9-7: Statistics on inspections carried out in the 2010-2013 period by all national authorities having provided data

Information below is only indicative information as data are not always fully comparable.

		SECTOR 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)		SECTOR 2 - Cosmetics		SECTOR 3 - Toys		SECTOR 4 - Personal Protective Equipment		SECTOR 5 - Construction Products	
Member State	**Population (million)**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**
BE	11.29					1,269.50	112.49				
BG	7.20	121.00	16.80			1,738.75	241.42	610.25	84.73	805.50	111.84
CZ	10.54	167.00	15.85	1215.25	115.32	1,631.25	154.79	395.75	37.55	349.00	33.12
DK	5.66	16.50	2.92	91.00	16.08	113.00	19.97	32.25	5.70	51.67	9.13
DE	81.20										
EE	1.31	111.00	84.52	485.50	369.69	401.50	305.73	360.75	274.70	24.50	18.66
IE	4.63	47.50	10.27	104.25	22.54	4.33	0.94	29.00	6.27		
EL	10.81					28.25	2.61	24.25	2.24	80.75	7.47
ES	46.44										
FR	66.99			1589.50	23.73	2,833.75	42.30	594.00	8.87	923.75	13.79
HR	4.23					768.00	181.76				
IT	60.80	125.00	2.06	1385.25	22.79			35.25	0.58		
CY	0.85	20.75	24.50			959.50	1132.81	20.75	24.50		
LV	1.99	25.75	12.97	412	207.44	116.00	58.41	78.00	39.27	105.25	52.99
LT	2.92										
LU	0.56					51.00	90.59				
HU	9.85	39.50	4.01	12351.75	1254.11	1,180.25	119.83	181.75	18.45	509	51.68
MT	0.43	111.00	258.53	83.75	195.07	149.25	347.62	57.50	133.93		
NL	16.90										
AT	8.58	14.25	1.66	1946.75	226.76	583.50	67.97	52.25	6.09	57	6.64
PL	38.01	33.00	0.87	203.75	5.36	754.00	19.84	562.75	14.81	1573.25	41.40
PT	10.37	2913.75	280.85	1293.5	124.68	234.50	22.60	52.50	5.06	75.5	7.28
RO	19.86					1,495.75	75.31	294.75	14.84	1595.5	80.33
SL	2.06	16.50	8.00	1921.5[244]	931.47	1,756.50[245]	851.48	157.00	76.11	322.75	156.46
SK	5.42	2.25	0.42	10472.5	1931.71	1,517.00	279.82	382.75	70.60	579.75	106.94
FI	5.47	13.25	2.42	382.25	69.86	1,351.25	246.95	182.75	33.40	322.5	58.94

[244] Figures include also all beauty care services inspections.

[245] Figures include also inspetions in kindergartens.

SE	9.75	30.25	3.10	125	12.82	84.00	8.62	71.50	7.34	59.75	6.13
UK	64.88			1327.50	20.46	1,482.00	22.84				

		SECTOR 6 - Aerosol dispensers		**SECTOR 7 - Simple pressure vessels and Pressure Equipment**		**SECTOR 8 - Transportable pressure equipment**		**SECTOR 9 - Machinery**		**SECTOR 10 - Lifts**	
Member State	**Population (million)**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**
BE	11.29							93.25	8.26	6.75	0.60
BG	7.20	236.50	32.84	650.25	90.28	168.25	23.36	951.00	132.04	184.67	25.64
CZ	10.54	1759.00	166.92	118.25	11.22	10.50	1.00	434.00	41.18	31.00	2.94
DK	5.66	0.50	0.09	29.25	5.17	1.50	0.27	152.25	26.90	0.25	0.04
DE	81.20										
EE	1.31			3.75	2.86			75.75	57.68		
IE	4.63			1.00	0.22			52.25	11.30	57.00	12.32
EL	10.81	9.50	0.88	7.00	0.65	2.50	0.23	41.75	3.86	2.00	0.18
ES	46.44										
FR	66.99			3,300.00	49.26	2.00	0.03	1,027.25	15.33		
HR	4.23										
IT	60.80							102.75	1.69		
CY	0.85	65.75	77.63	191.50	226.09	17.75	20.96	70.75	83.53	43.75	51.65
LV	1.99			8.00	4.03	66.75	33.61	21.75	10.95	0.25	0.13
LT	2.92										
LU	0.56										
HU	9.85			26.75	2.72	128.25	13.02	569.50	57.82	97.00	9.85
MT	0.43	97.25	226.51	97.25	226.51			17.00	39.60	104.00	242.23
NL	16.90										
AT	8.58	3.50	0.41	3.50	0.41	3.50	0.41	51.50	6.00	12.50	1.46
PL	38.01	0.75	0.02	125.00	3.29	230.75	6.07	884.00	23.26	2.25	0.06
PT	10.37	20.50	1.98	74.25	7.16			51.50	4.96		
RO	19.86	60.00	3.02	81.25	4.09	7.25	0.37	558.50	28.12	7.00	0.35
SL	2.06	4.00	1.94	241.25	116.95	98.00	47.51	178.25	86.41	44.75	21.69
SK	5.42										
FI	5.47	1.00	0.18	22.00	4.02			248.25	45.37	0.25	0.05
SE	9.75	1.00	0.10	3.75	0.38	3.00	0.31	1,903.50	195.28	1.00	0.10
UK	64.88										

		SECTOR 11 - Cableways		SECTOR 12 - Noise emissions for outdoor equipment		SECTOR 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres		SECTOR 14 - Pyrotechnics		SECTOR 15 - Explosives for civil uses	
Member State	**Population (million)**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**
BE	11.29			68.33	6.06						
BG	7.20	1.33	0.19	183.33	25.46	5.00	0.69	742.25	103.06	26.50	3.68
CZ	10.54	6.75	0.64	119.75	11.36	33.50	3.18	235.50	22.35	3.50	0.33
DK	5.66			2.00	0.35	5.00	0.88	71.50	12.63		
DE	81.20										
EE	1.31							33.25	25.32	14.00	10.66
IE	4.63					2.00	0.43	443.50	95.87	443.50	95.87
EL	10.81							7.50	0.69	1.00	0.09
ES	46.44										
FR	66.99	45.50	0.68			22.50	0.34	85.25	1.27	10.00	0.15
HR	4.23							2.00	0.47		
IT	60.80			134.67	2.22			16.25	0.27	13.25	0.22
CY	0.85					0.25	0.30	32.75	38.67	55.50	65.52
LV	1.99	0.25	0.13	21.75	10.95			380.25	191.46	380.25	191.46
LT	2.92										
LU	0.56										
HU	9.85			49.25	5.00	10.00	1.02			84.75	8.60
MT	0.43							1.50	3.49		
NL	16.90										
AT	8.58	6,080.00	708.22					1225.50	142.75		
PL	38.01	5.50	0.14	386.75	10.18	39.50	1.04	110.50	2.91	4.00	0.11
PT	10.37	4.50	0.43	37.25	3.59			3747.75	361.24	5935.50	572.11
RO	19.86	0.25	0.01	307.25	15.47	21.00	1.06	58.00	2.92	15.50	0.78
SL	2.06	117.50	56.96	69.50	33.69			27.00	13.09	1.25	0.61
SK	5.42	16.75	3.09					244.75	45.15	87.25	16.09
FI	5.47			16.25	2.97	82.00	14.99	36.25	6.62	2.00	0.37
SE	9.75			8.00	0.82	1.50	0.15	3.50	0.36		
UK	64.88										

		SECTOR 16 - Appliances burning gaseous fuels		SECTOR 17 - Measuring instruments, Non-automatic weighing instruments (NAWI) and Pre-packaged products		SECTOR 18 - Electrical equipment under EMC		SECTOR 19 - Radio and telecom equipment under RTTE		SECTOR 20 - Electrical appliances and equipment under LVD	
Member State	**Population (million)**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**
BE	11.29	22.00	1.95					578.00	51.22	788.50	69.87
BG	7.20	466.75	64.81	1339.75	186.02	831.33	115.43	242.25	33.64	1774.75	246.42
CZ	10.54	58.50	5.55	491.50	46.64	840.00	79.71	241.00	22.87	1306.50	123.98
DK	5.66	30.75	5.43	115.25	20.36	112.50	19.88	112.50	19.88	456.00	80.57
DE	81.20					6.53	0.08	6.53	0.08		
EE	1.31	21.25	16.18	6.75	5.14	185.50	141.25	1,865.75	1420.69	193.00	146.96
IE	4.63			14149.50	3058.77					4.33	0.94
EL	10.81			12872.50	1190.52	4.50	0.42	136.50	12.62	103.75	9.60
ES	46.44										
FR	66.99	10.00	0.15	897.00	13.39	525.00	7.84	745.50	11.13	2076.50	31.00
HR	4.23			1106.00	261.76			18.00	4.26		
IT	60.80			103.75	1.71			350.75	5.77	104.25	1.71
CY	0.85	9.33	11.02			117.75	139.02	16.00	18.89	121.25	143.15
LV	1.99	8.75	4.41	25.25	12.71	141.00	70.99	9.00	4.53	461.00	232.11
LT	2.92										
LU	0.56	51.25	91.04	717.50	1274.52	441.00	783.36	190.50	338.39	275.75	489.82
HU	9.85	23.00	2.34	214.25	21.75	104.75	10.64	170.00	17.26	2065.25	209.69
MT	0.43	6.00	13.97			24.00	55.90	24.00	55.90	163.25	380.23
NL	16.90			8 NAWI examined	0.47	150	8.88	150	8.88		
AT	8.58			4699.75	547.44	55.50	6.46	276.25	32.18	55.50	6.46
PL	38.01	28.75	0.76	20.75	0.55	560.50	14.75	285.25	7.51	1105.50	29.09
PT	10.37	26.00	2.51	221.25	21.33	16.00	1.54	321.75	31.01	149.25	14.39
RO	19.86	101.50	5.11	1723.25	86.76	390.75	19.67	765.00	38.52	1092.50	55.01
SL	2.06	41.00	19.88			8.75	4.24	180.25	87.38	312.50	151.49
SK	5.42	34.00	6.27	206.00	38.00					1318.25	243.16
FI	5.47	3.75	0.69			272.25	49.76	164.75	30.11	2031.25	371.22
SE	9.75	6.50	0.67	3.67	0.38	54.25	5.57	44.25	4.54	373.75	38.34
UK	64.88										

		SECTOR 21 - Electrical and electronic equipment under RoHS, WEEE and batteries		SECTOR 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)		SECTOR 23 - Ecodesign and Energy labelling		SECTOR 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels		SECTOR 25 - Recreational craft	
Member State	**Population (million)**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**
BE	11.29	18.00	1.59			57.25	5.07	3.25	0.29		
BG	7.20	252.75	35.09	589.25	81.82	717.50	99.62			24.00	3.33
CZ	10.54	57.00	5.41	17.25	1.64	146.25	13.88	10.00	0.95	146.00	13.85
DK	5.66	16.50	2.92	50.25	8.88	194.50	34.37			0.25	0.04
DE	81.20										
EE	1.31	193.00	146.96	673.75	513.03						
IE	4.63	38.75	8.38	85.50	18.48			16.25	3.51		
EL	10.81	130.00	12.02	395.00	36.53	103.75	9.60	4.67	0.43	3.50	0.32
ES	46.44										
FR	66.99			711.00	10.61	262.25	3.91			51.50	0.77
HR	4.23										
IT	60.80					26.00	0.43				
CY	0.85					215.75	254.72				
LV	1.99	141.00	70.99	402.00	202.41	141.00	70.99			3.25	1.64
LT	2.92										
LU	0.56					19.50	34.64				
HU	9.85	24.00	2.44	3693.50	375.01	45.25	4.59	6.75	0.69		
MT	0.43	163.25	380.23	95.00	221.27	32.00	74.53			11.75	27.37
NL	16.90										
AT	8.58			64.25	7.48	56.67	6.60			3.25	0.38
PL	38.01	134.00	3.53	128.75	3.39	254.25	6.69			52.50	1.38
PT	10.37	120.75	11.64								
RO	19.86	473.75	23.85			136.50	6.87	3.75	0.19	22.00	1.11
SL	2.06	276.75	134.16	44.25	21.45	60.75	29.45			22.50	10.91
SK	5.42			103.50	19.09	120.75	22.27			14.00	2.58
FI	5.47	326.50	59.67	7.75	1.42	616.50	112.67			96.25	17.59
SE	9.75	190.25	19.52	23.50	2.41	94.75	9.72			6.00	0.62
UK	64.88										

		SECTOR 26 - Marine Equipment		SECTOR 27 - Motor vehicles and tyres		SECTOR 28 - Non-road mobile machinery		SECTOR 29 - Fertilisers		SECTOR 30 - Other consumer products under GPSD	
Member State	**Population (million)**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**	**Number of inspections**	**Inspections per 100000 inhabitants**
BE	11.29			256.25	22.71						
BG	7.20			566.25	78.62	68.00	9.44	497.75	69.11	7,643.50	1061.27
CZ	10.54							205.25	19.48	146.00	13.85
DK	5.66			1689.25	298.47			250.00	44.17		
DE	81.20										
EE	1.31			66.50	50.64			216.25	164.67	774.75	
IE	4.63							116.50	25.18	2.33	0.50
EL	10.81										
ES	46.44										
FR	66.99			272.00	4.06			74.50	1.11	1,485.00	22.17
HR	4.23							220.00	52.07		
IT	60.80	1.25	0.02							23.25	0.38
CY	0.85			22.00	25.97						
LV	1.99			21.50	10.83	63.50	31.97	232.5	117.06	66.50	33.48
LT	2.92										
LU	0.56									40.25	71.50
HU	9.85			15.50	1.57	2.50	0.25	210.75	21.40	2,281.25	231.62
MT	0.43	0.25	0.58	25.00	58.23			0.25	0.58		
NL	16.90							2.50	0.15		
AT	8.58									1,964.00	228.77
PL	38.01	16.00	0.42					103.25	2.72		
PT	10.37	13.50	1.30	2.25	0.22			41.25	3.98	292.00	28.15
RO	19.86	9.00	0.45	934.00	47.03	140.00	7.05	1752.5	88.24	6.50	0.33
SL	2.06			28.00	13.57	42.00	20.36	335.5	162.64		
SK	5.42			0.50	0.09			139.75	25.78		
FI	5.47			362.75	66.30			283.5	51.81	931.75	170.28
SE	9.75	1.25	0.13	249.50	25.60	6.00	0.62			264.50	27.14
UK	64.88										

Table 9-8: Statistics on inspections based on tests performed in laboratories carried out in the 2010-2013 period by all national authorities having provided data
Information below is only indicative information as data are not always fully comparable.

		SECTOR 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)		SECTOR 2 - Cosmetics		SECTOR 3 - Toys		SECTOR 4 - Personal Protective Equipment		SECTOR 5 - Construction Products	
Member State	**Population (million)**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**
BE	11.29							32.00	2.84		
BG	7.20					13.50	1.87			2.00	0.28
CZ	10.54			165.75	15.73						
DK	5.66			40.00	7.07	33.00	5.83	0.00	0.00	0.00	0.00
DE	81.20										
EE	1.31										
IE	4.63	0.00	0.00	21.00	4.54						
EL	10.81					63.00	5.83	1.00	0.09	4.00	0.37
ES	46.44										
FR	66.99			608.75	9.09	827.00	12.34	92.00	1.37	37.50	0.56
HR	4.23					60.00	14.20				
IT	60.80							4.50	0.07		
CY	0.85	0.25	0.30			61.25	72.31			261.00	308.14
LV	1.99			20.50	10.32	29.50	14.85	11.75	5.92	5.75	2.90
LT	2.92										
LU	0.56					7.50	13.32				
HU	9.85	0.25	0.03	191.50	19.44	70.75	7.18	1.75	0.18	4.00	0.41
MT	0.43										
NL	16.90										
AT	8.58	0.00						0.50	0.06	24.00	2.80
PL	38.01	10.50	0.28	35.25	0.93	498.25	13.11	9.25	0.24	30.00	0.79
PT	10.37	96.75	9.33	142.50	13.74	14.75	1.42	1.50	0.14	0.00	0.00
RO	19.86					3.25	0.16	0.00	0.00	1.50	0.08
SL	2.06	0.00	0.00	15.00	7.27	44.25	21.45	10.25	4.97	5.75	2.79
SK	5.42	0.00	0.00			159.25	29.37	22.50	4.15	16.25	3.00
FI	5.47	0.00	0.00	125.75	22.98	731.75	133.73	37.25	6.81	0.50	0.09
SE	9.75			47.50	4.87	3.75	0.38	26.75	2.74		
UK	64.88					633.00	9.76				

		SECTOR 6 - Aerosol dispensers		SECTOR 7 - Simple pressure vessels and Pressure Equipment		SECTOR 8 - Transportable pressure equipment		SECTOR 9 - Machinery		SECTOR 10 - Lifts	
Member State	**Population (million)**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**
BE	11.29										
BG	7.20	0.00	0.00					2.00	0.28		
CZ	10.54										
DK	5.66	0.00	0.00	0.00	0.00	0.00	0.00	8.00	1.41	0.00	0.00
DE	81.20										
EE	1.31										
IE	4.63							0.00	0.00		
EL	10.81										
ES	46.44										
FR	66.99			8.00	0.12	2.00	0.03	315.75	4.71		
HR	4.23										
IT	60.80										
CY	0.85										
LV	1.99			0.00	0.00			3.25	1.64	0.00	0.00
LT	2.92										
LU	0.56										
HU	9.85			0.75		0.00	0.00	8.00	0.81	0.00	0.00
MT	0.43										
NL	16.90										
AT	8.58	1.75	0.20	1.75	0.20	1.75	0.20			0.00	0.00
PL	38.01	0.25	0.01	1.25	0.03	0.00	0.00	2.25	0.06	0.00	0.00
PT	10.37	0.00	0.00	0.00	0.00			0.75	0.07		
RO	19.86							0.00	0.00		
SL	2.06			0.00	0.00	0.00	0.00	13.25	6.42		
SK	5.42										
FI	5.47	0.00	0.00	1.25	0.23	0.00	0.00	9.25	1.69	0.00	0.00
SE	9.75										
UK	64.88										

		SECTOR 11 - Cableways		SECTOR 12 - Noise emissions for outdoor equipment		SECTOR 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres		SECTOR 14 - Pyrotechnics		SECTOR 15 - Explosives for civil uses	
Member State	**Population (million)**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**
BE	11.29										
BG	7.20							8.00	1.11		
CZ	10.54									1.00	0.09
DK	5.66	0.00	0.00	0.00	0.00	0.00	0.00	25.50	4.51		
DE	81.20										
EE	1.31										
IE	4.63							0.00	0.00	0.00	0.00
EL	10.81										
ES	46.44										
FR	66.99	0.00	0.00			21.75	0.32	85.25	1.27	10.00	
HR	4.23										
IT	60.80							0.00	0.00	0.00	0.00
CY	0.85							0.00	0.00	0.00	0.00
LV	1.99	0.00	0.00	3.25	1.64						
LT	2.92										
LU	0.56										
HU	9.85			0.50	0.05	0.00	0.00	0.00	0.00	0.00	0.00
MT	0.43	0.00	0.00								
NL	16.90										
AT	8.58	0.00	0.00	0.00	0.00						
PL	38.01	0.00	0.00	0.00	0.00	1.00	0.03	6.00	0.16	0.00	0.00
PT	10.37	0.00	0.00	0.75	0.07			2.50	0.24	2.50	0.24
RO	19.86			0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
SL	2.06	0.00	0.00	0.00	0.00						
SK	5.42										
FI	5.47	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
SE	9.75										
UK	64.88										

		SECTOR 16 - Appliances burning gaseous fuels		SECTOR 17 - Measuring instruments, Non-automatic weighing instruments and Pre-packaged products		SECTOR 18 - Electrical equipment under EMC		SECTOR 19 - Radio and telecom equipment under RTTE		SECTOR 20 - Electrical appliances and equipment under LVD	
Member State	**Population (million)**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**
BE	11.29	16.50	1.46			29.00	2.57	0.00	0.00	137.75	12.21
BG	7.20	8.00	1.11	0.00	0.00	5.00	0.69			15.00	2.08
CZ	10.54										
DK	5.66	18.00	3.18			0.00	0.00	0.00	0.00	59.50	10.51
DE	81.20					1.11	0.01	1.11	0.01		
EE	1.31			0.00	0.00						
IE	4.63	1.25	0.27	0.00	0.00						
EL	10.81			0.00	0.00			6.50	0.60	7.50	0.69
ES	46.44										
FR	66.99	10.00	0.15	78.75	1.18	48.75	0.73	181.50	2.71	316.25	4.72
HR	4.23										
IT	60.80			1.75	0.03			120.50	1.98	28.25	0.46
CY	0.85					4.00	4.72	0.00	0.00	32.75	38.67
LV	1.99	0.00	0.00	13.25	6.67	38.00	19.13	0.00	0.00	66.33	33.40
LT	2.92										
LU	0.56	1.25	2.22	716.25	1,272.30	10.50	18.65	5.75	10.21	18.50	32.86
HU	9.85	0.00	0.00	34.75	3.53	80.50	8.17	168.25	17.08	163.50	16.60
MT	0.43										
NL	16.90			8	0.47	5	0.30	5	0.30		
AT	8.58	0.00	0.00	2,611.50	304.20	0.00	0.00	0.00	0.00	0.25	0.03
PL	38.01	0.00	0.00	0.00	0.00	119.50	3.14	51.75	1.36	35.25	0.93
PT	10.37	0.00	0.00	1.00	0.10	2.25	0.22	131.25	12.65	1.50	0.14
RO	19.86			2,551.75	128.48	5.33	0.27	1.33	0.07	0.00	0.00
SL	2.06	5.00	2.42	4.25	2.06	8.75	4.24	8.75	4.24	46.50	22.54
SK	5.42	9.50	1.75	0.00	0.00						
FI	5.47	2.25	0.41	0.00	0.00	66.50	12.15	18.00	3.29	728.50	133.14
SE	9.75	6.00	0.62					43.25	4.44		
UK	64.88										

		SECTOR 21 - Electrical and electronic equipment under RoHS, WEEE and batteries		SECTOR 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)		SECTOR 23 - Ecodesign and Energy labelling		SECTOR 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels		SECTOR 25 - Recreational craft	
Member State	**Population (million)**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**
BE	11.29	8.00	0.71			43.00	3.81	3.25	0.29		
BG	7.20			1.50	0.21	3.00	0.42				
CZ	10.54			1.00	0.09						
DK	5.66	33.00	5.83	12.75	2.25	60.50	10.69			0.00	0.00
DE	81.20										
EE	1.31										
IE	4.63	38.50	8.32	14.75	3.19	0.00	0.00	0.00	0.00		
EL	10.81	6.00	0.55	227.75	21.06	7.50	0.69	4.00	0.37		
ES	46.44										
FR	66.99			60.75	0.91	0.00	0.00			0.00	0.00
HR	4.23										
IT	60.80					2.00	0.03				
CY	0.85					0.00	0.00				
LV	1.99	38.00	19.13	17.25	8.69	38.00	19.13			0.00	0.00
LT	2.92										
LU	0.56					0.00	0.00				
HU	9.85	0.00	0.00	46.25	4.70	0.00	0.00	0.00	0.00		
MT	0.43										
NL	16.90										
AT	8.58			23.75	2.77	0.00	0.00			0.00	0.00
PL	38.01	66.00	1.74	41.33	1.09	30.75	0.81			0.00	0.00
PT	10.37	0.00	0.00								
RO	19.86	19.25	0.97			0.00	0.00				
SL	2.06	0.00	0.00	17.50	8.48	7.50	3.64			0.00	
SK	5.42			0.00	0.00	0.00	0.00				
FI	5.47	73.25	13.39	2.00	0.37	9.75	1.78	0.00	0.00	0.00	0.00
SE	9.75	61.50	6.31	8.00	0.82	100.00	10.26				
UK	64.88										

		SECTOR 26 - Marine Equipment		SECTOR 27 - Motor vehicles and tyres		SECTOR 28 - Non-road mobile machinery		SECTOR 29 - Fertilisers		SECTOR 30 - Other consumer products under GPSD	
Member State	**Population (million)**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**	**Number of inspections based on tests performed in laboratories**	**Inspections based on tests performed in laboratories per 100000 inhabitants**
BE	11.29							55.33	4.90	3.25	0.29
BG	7.20			80.50	11.18			176.00	24.44	1,479.50	205.42
CZ	10.54							66.00	6.26		
DK	5.66	0.00	0.00	0.00	0.00			250.00	44.17		
DE	81.20							4,224.25	52.02		
EE	1.31										
IE	4.63							116.50	25.18	1.00	0.22
EL	10.81							329.00	30.43	46.00	4.25
ES	46.44										
FR	66.99	0.00	0.00	5.00	0.07			41.00	0.61	67.75	1.01
HR	4.23							25.00	5.92		
IT	60.80	0.00	0.00							3.25	0.05
CY	0.85										
LV	1.99					1.00	0.50	80.25	40.41	2.75	1.38
LT	2.92										
LU	0.56									6.25	11.10
HU	9.85			0.00	0.00	0.00	0.00	108.75	11.04	94.25	9.57
MT	0.43										
NL	16.90										
AT	8.58	0.00	0.00	0.00	0.00						
PL	38.01	0.00	0.00					14.25	0.37		
PT	10.37	0.00	0.00	0.00	0.00			0.00	0.00	3.00	0.29
RO	19.86					0.00	0.00	127.75	6.43	0.00	0.00
SL	2.06					0.00	0.00	16.50	8.00		
SK	5.42			0.00	0.00						
FI	5.47	0.00	0.00	0.50	0.09			283.50	51.81	826.50	151.05
SE	9.75			70.00	7.18	2.00	0.21			13.33	1.37
UK	64.88										

Table 9-9: Statistics on enforcement activities carried out in the 2010-2013 period by national authorities having provided data (averages per Member State and per year)

Information below is only indicative information as data are not always fully comparable.

Information on enforcement activities carried out in the 2010-2013 period	SECTOR 1 - Medical devices	SECTOR 2 - Cosmetics	SECTOR 3 - Toys	SECTOR 4 - Personal Protective Equipment	SECTOR 5 - Construction Products
1. Number of product related accidents / user complaints	542	36	31	8	18
2. Number of substantiated complaints by industry concerning unfair competition	3	10	10	3	35
3. Number of inspections (total number)	267	2082	891	209	465
3.1 number of reactive inspections	196	840	425	42	46
3.2 number of self-initiated inspections	59	869	487	142	397
3.3 number of inspections prompted by the customs	12	72	211	17	28
4. Number of inspections based on:					
4.1 tests performed in laboratories	12	129	191	17	28
4.2 physical checks of products	1497	2378	1709	251	584
5. Number of inspections resulting in:					
5.1 finding of non-compliance	114	784	283	78	218
5.2 corrective actions taken by economic operators (“voluntary measures”)	109	36	97	42	88
5.3 restrictive measures taken by market surveillance authorities	4	69	103	12	46
5.4 application of sanctions/penalties	8	21	124	25	33
6. Number of inspections where other Member States were invited to collaborate	6	4	1	1	1

Information on enforcement activities carried out in the 2010-2013 period	SECTOR 6 - Aerosol dispensers	SECTOR 7 - Simple pressure vessels and Pressure Equipment	SECTOR 8 - Transportable pressure equipment	SECTOR 9 - Machinery	SECTOR 10 - Lifts
1. Number of product related accidents / user complaints	1	8	3	23	1
2. Number of substantiated complaints by industry concerning unfair competition	0	0	0	38	0
3. Number of inspections (total number)	161	277	57	374	147
3.1 number of reactive inspections	21	17	4	70	10
3.2 number of self-initiated inspections	139	273	46	303	144
3.3 number of inspections prompted by the customs	0	13	21	36	0
4. Number of inspections based on:					
4.1 tests performed in laboratories	0	1	1	33	0
4.2 physical checks of products	186	76	47	434	74
5. Number of inspections resulting in:					
5.1 finding of non-compliance	59	17	8	105	15
5.2 corrective actions taken by economic operators (“voluntary measures”)	5	12	3	169	4
5.3 restrictive measures taken by market surveillance authorities	1	3	1	14	2
5.4 application of sanctions/penalties	49	2	3	12	1
6. Number of inspections where other Member States were invited to collaborate	0	0	0	2	0

Information on enforcement activities carried out in the 2010-2013 period	SECTOR 11 - Cableways	SECTOR 12 - Noise emissions for outdoor equipment	SECTOR 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	SECTOR 14 - Pyrotechnics	SECTOR 15 - Explosives for civil uses
1. Number of product related accidents / user complaints	0	1	1	22	1
2. Number of substantiated complaints by industry concerning unfair competition	0	0	0	3	0
3. Number of inspections (total number)	483	108	20	375	442
3.1 number of reactive inspections	0	2	2	4	5
3.2 number of self-initiated inspections	14	69	16	343	346
3.3 number of inspections prompted by the customs	0	5	1	66	0
4. Number of inspections based on:					
4.1 tests performed in laboratories	0	1	4	12	1
4.2 physical checks of products	268	100	25	157	19
5. Number of inspections resulting in:					
5.1 finding of non-compliance	1	26	7	224	426
5.2 corrective actions taken by economic operators (“voluntary measures”)	0	20	4	25	2
5.3 restrictive measures taken by market surveillance authorities	0	4	1	212	258
5.4 application of sanctions/penalties	1	5	1	8	0
6. Number of inspections where other Member States were invited to collaborate	0	0	0	2	0

Information on enforcement activities carried out in the 2010-2013 period	SECTOR 16 - Appliances burning gaseous fuels	SECTOR 17 - Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	SECTOR 18 - Electrical equipment under EMC	SECTOR 19 - Radio and telecom equipment under RTTE	SECTOR 20 - Electrical appliances and equipment under LVD
1. Number of product related accidents / user complaints	5	6	7	25	54
2. Number of substantiated complaints by industry concerning unfair competition	3	1	7	5	30
3. Number of inspections (total number)	53	1946	247	307	742
3.1 number of reactive inspections	8	175	13	28	113
3.2 number of self-initiated inspections	35	1303	189	224	580
3.3 number of inspections prompted by the customs	9	0	103	116	107
4. Number of inspections based on:					
4.1 tests performed in laboratories	5	354	27	41	104
4.2 physical checks of products	54	1410	213	253	743
5. Number of inspections resulting in:					
5.1 finding of non-compliance	24	110	144	213	255
5.2 corrective actions taken by economic operators (“voluntary measures”)	10	16	53	62	74
5.3 restrictive measures taken by market surveillance authorities	6	15	15	78	95
5.4 application of sanctions/penalties	5	29	51	59	89
6. Number of inspections where other Member States were invited to collaborate	1	0	3	7	2

Information on enforcement activities carried out in the 2010-2013 period	SECTOR 21 - Electrical and electronic equipment under RoHS, WEEE and batteries	SECTOR 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)	SECTOR 23 - Ecodesign and Energy labelling	SECTOR 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	SECTOR 25 - Recreational craft
1. Number of product related accidents / user complaints	5	6	5	1	249
2. Number of substantiated complaints by industry concerning unfair competition	1	5	0	1	0
3. Number of inspections (total number)	160	443	174	6	33
3.1 number of reactive inspections	14	11	6	0	16
3.2 number of self-initiated inspections	138	392	125	6	17
3.3 number of inspections prompted by the customs	8	2	5	0	10
4. Number of inspections based on:					
4.1 tests performed in laboratories	29	34	17	1	0
4.2 physical checks of products	107	512	823	7	127
5. Number of inspections resulting in:					
5.1 finding of non-compliance	40	101	49	4	13
5.2 corrective actions taken by economic operators (“voluntary measures”)	12	9	30	3	13
5.3 restrictive measures taken by market surveillance authorities	11	30	8	0	2
5.4 application of sanctions/penalties	7	11	14	1	1
6. Number of inspections where other Member States were invited to collaborate	0	0	0	0	0

Information on enforcement activities carried out in the 2010-2013 period	SECTOR 26 - Marine Equipment	SECTOR 27 - Motor vehicles and tyres	SECTOR 28 - Non-road mobile machinery	SECTOR 29 - Fertilisers	SECTOR 30 - Other consumer products under GPSD
1. Number of product related accidents / user complaints	1	25	2	4	38
2. Number of substantiated complaints by industry concerning unfair competition	0	2	1	1	5
3. Number of inspections (total number)	5	282	54	260	382
3.1 number of reactive inspections	1	64	1	3	74
3.2 number of self-initiated inspections	5	242	53	232	248
3.3 number of inspections prompted by the customs	3	5	2	0	29
4. Number of inspections based on:					
4.1 tests performed in laboratories	0	17	1	370	50
4.2 physical checks of products	10	179	210	488	449
5. Number of inspections resulting in:					
5.1 finding of non-compliance	1	73	7	155	123
5.2 corrective actions taken by economic operators (“voluntary measures”)	0	46	5	11	33
5.3 restrictive measures taken by market surveillance authorities	1	38	3	42	37
5.4 application of sanctions/penalties	0	59	4	5	22
6. Number of inspections where other Member States were invited to collaborate	0	1	0	0	1

Information on resources (subject to availability)	SECTOR 1 - Medical devices	SECTOR 2 - Cosmetics	SECTOR 3 - Toys	SECTOR 4 - Personal Protective Equipment	SECTOR 5 - Construction Products
7.1 Budget available to market surveillance authorities in nominal terms (€)	€ 1,391,889.47	€ 4,993,717.97	€ 1,917,787.47	€ 270,913.43	€ 425,273.22
7.2 Budget available to market surveillance authorities in relative terms (%age of total national budget)	29.43254%	1.36390%	1.52086%	0.01616%	0.80222%
8. Staff available to market surveillance authorities (full-time equivalent units)	59	256	32	12	18
9. Number of inspectors available to market surveillance authorities (full-time equivalent units)	48	59	24	10	13
Share of inspections resulting in finding of non-compliance out of total inspections	**42.54%**	**37.68%**	**31.77%**	**37.56%**	**46.91%**
Share of self-initiated inspections out of total inspections	**22.20%**	**41.76%**	**54.67%**	**68.12%**	**85.48%**
Share of corrective actions taken by economic operators out of finding of non-compliance	**96.12%**	**4.55%**	**34.12%**	**54.10%**	**40.22%**
Share of restrictive measures out of finding of non-compliance	**3.88%**	**8.86%**	**36.29%**	**15.78%**	**21.29%**
Share of application of sanctions / penalties out of finding of non-compliance	**6.98%**	**2.69%**	**43.75%**	**32.37%**	**15.22%**
Share of inspectors out of staff available to market surveillance authorities	**82.16%**	**23.05%**	**73.51%**	**78.13%**	**74.96%**

Information on resources (subject to availability)	SECTOR 6 - Aerosol dispensers	SECTOR 7 - Simple pressure vessels and Pressure Equipment	SECTOR 8 - Transportable pressure equipment	SECTOR 9 - Machinery	SECTOR 10 - Lifts
7.1 Budget available to market surveillance authorities in nominal terms (€)	€ 9,634.69	€ 355,539.54	€ 274,911.67	€ 564,027.54	€ 425,111.19
7.2 Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.15992%	0.02177%	3.25103%	0.02428%	0.01378%
8. Staff available to market surveillance authorities (full-time equivalent units)	22	23	23	72	23
9. Number of inspectors available to market surveillance authorities (full-time equivalent units)	18	7	6	51	5
Share of inspections resulting in finding of non-compliance out of total inspections	**36.48%**	**6.20%**	**13.80%**	**27.98%**	**10.15%**
Share of self-initiated inspections out of total inspections	**85.84%**	**98.48%**	**81.37%**	**80.87%**	**98.24%**
Share of corrective actions taken by economic operators out of finding of non-compliance	**8.64%**	**71.27%**	**34.51%**	**161.74%**	**29.53%**
Share of restrictive measures out of finding of non-compliance	**0.85%**	**16.86%**	**12.07%**	**13.32%**	**14.60%**
Share of application of sanctions / penalties out of finding of non-compliance	**83.98%**	**9.67%**	**41.75%**	**11.56%**	**5.40%**
Share of inspectors out of staff available to market surveillance authorities	**84.35%**	**30.26%**	**26.52%**	**71.67%**	**20.52%**

Information on resources (subject to availability)	SECTOR 11 - Cableways	SECTOR 12 - Noise emissions for outdoor equipment	SECTOR 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	SECTOR 14 - Pyrotechnics	SECTOR 15 - Explosives for civil uses
7.1 Budget available to market surveillance authorities in nominal terms (€)	€ 741,722.38	€ 169,646.69	€ 210,451.04	€ 336,074.13	€ 196,517.44
7.2 Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.00001%	0.00394%	0.00336%	0.01025%	0.00333%
8. Staff available to market surveillance authorities (full-time equivalent units)	18	14	12	10	10
9. Number of inspectors available to market surveillance authorities (full-time equivalent units)	3	3	1	5	1
Share of inspections resulting in finding of non-compliance out of total inspections	**0.29%**	**24.07%**	**34.65%**	**59.77%**	**96.21%**
Share of self-initiated inspections out of total inspections	**2.96%**	**63.47%**	**77.49%**	**91.28%**	**78.33%**
Share of corrective actions taken by economic operators out of finding of non-compliance	**25.81%**	**77.16%**	**60.37%**	**11.30%**	**0.35%**
Share of restrictive measures out of finding of non-compliance	**1.61%**	**14.13%**	**15.31%**	**94.60%**	**60.63%**
Share of application of sanctions / penalties out of finding of non-compliance	**82.26%**	**19.23%**	**12.50%**	**3.54%**	**0.08%**
Share of inspectors out of staff available to market surveillance authorities	**16.98%**	**24.32%**	**8.68%**	**50.80%**	**15.31%**

Information on resources (subject to availability)	SECTOR 16 - Appliances burning gaseous fuels	SECTOR 17 - Measuring instruments. Non-automatic weighing instruments and Pre-packaged products	SECTOR 18 - Electrical equipment under EMC	SECTOR 19 - Radio and telecom equipment under RTTE	SECTOR 20 - Electrical appliances and equipment under LVD
7.1 Budget available to market surveillance authorities in nominal terms (€)	€ 186,410.22	€ 316,776.94	€ 1,213,246.73	€ 1,630,900.55	€ 663,663.40
7.2 Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.01062%	0.07485%	0.01320%	0.02428%	0.12735%
8. Staff available to market surveillance authorities (full-time equivalent units)	10	10	17	18	17
9. Number of inspectors available to market surveillance authorities (full-time equivalent units)	5	9	5	12	13
Share of inspections resulting in finding of non-compliance out of total inspections	**45.51%**	**5.64%**	**58.30%**	**69.43%**	**34.39%**
Share of self-initiated inspections out of total inspections	**65.60%**	**66.96%**	**76.51%**	**72.99%**	**78.16%**
Share of corrective actions taken by economic operators out of finding of non-compliance	**42.15%**	**14.32%**	**37.07%**	**28.94%**	**29.17%**
Share of restrictive measures out of finding of non-compliance	**24.54%**	**13.51%**	**10.70%**	**36.62%**	**37.31%**
Share of application of sanctions / penalties out of finding of non-compliance	**21.18%**	**26.58%**	**35.46%**	**27.91%**	**34.75%**
Share of inspectors out of staff available to market surveillance authorities	**46.37%**	**90.47%**	**30.37%**	**63.11%**	**75.56%**

Information on resources (subject to availability)	SECTOR 21 - Electrical and electronic equipment under RoHS. WEEE and batteries	SECTOR 22 - Chemicals (Detergents. Paints. Persistent organic pollutants)	SECTOR 23 - Ecodesign and Energy labelling	SECTOR 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	SECTOR 25 - Recreational craft
7.1 Budget available to market surveillance authorities in nominal terms (€)	€ 191,120.50	€ 145,000.46	€ 215,344.26	€ 120,923.50	€ 284,263.69
7.2 Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.01399%	69.55812%	0.03023%	0.00000%	0.07500%
8. Staff available to market surveillance authorities (full-time equivalent units)	14	64	15	9	12
9. Number of inspectors available to market surveillance authorities (full-time equivalent units)	5	38	11	9	5
Share of inspections resulting in finding of non-compliance out of total inspections	**25.32%**	**22.86%**	**28.48%**	**61.00%**	**39.77%**
Share of self-initiated inspections out of total inspections	**86.10%**	**88.46%**	**71.90%**	**98.50%**	**51.53%**
Share of corrective actions taken by economic operators out of finding of non-compliance	**30.28%**	**8.85%**	**60.65%**	**82.42%**	**99.48%**
Share of restrictive measures out of finding of non-compliance	**26.12%**	**29.73%**	**16.85%**	**5.14%**	**17.86%**
Share of application of sanctions / penalties out of finding of non-compliance	**17.03%**	**10.85%**	**28.49%**	**12.84%**	**6.42%**
Share of inspectors out of staff available to market surveillance authorities	**35.20%**	**58.46%**	**77.42%**	**97.88%**	**36.75%**

Information on resources (subject to availability)	SECTOR 26 - Marine Equipment	SECTOR 27 - Motor vehicles and tyres	SECTOR 28 - Non-road mobile machinery	SECTOR 29 - Fertilisers	SECTOR 30 - Other consumer products under GPSD
7.1 Budget available to market surveillance authorities in nominal terms (€)	€ 75,853.75	€ 456,843.17	€ 14,324.38	€ 135,640.69	€ 618,900.94
7.2 Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.00005%	0.39436%	0.00334%	0.29036%	3.69804%
8. Staff available to market surveillance authorities (full-time equivalent units)	2	17	0	9	28
9. Number of inspectors available to market surveillance authorities (full-time equivalent units)	1	15	0	7	13
Share of inspections resulting in finding of non-compliance out of total inspections	**17.63%**	**25.95%**	**13.39%**	**59.40%**	**32.12%**
Share of self-initiated inspections out of total inspections	**88.35%**	**85.96%**	**99.38%**	**89.27%**	**64.93%**
Share of corrective actions taken by economic operators out of finding of non-compliance	**21.39%**	**62.66%**	**68.41%**	**7.19%**	**27.05%**
Share of restrictive measures out of finding of non-compliance	**55.00%**	**51.29%**	**47.83%**	**27.31%**	**30.25%**
Share of application of sanctions / penalties out of finding of non-compliance	**15.28%**	**80.83%**	**49.57%**	**3.55%**	**17.70%**
Share of inspectors out of staff available to market surveillance authorities	**86.08%**	**85.32%**	**100.00%**	**77.13%**	**47.55%**

Table 9-10: Application of penalties by market surveillance authorities in the 2010-2013 period

Sectors	Number of Member States providing penalties information	Average number of penalties applied per Member State and per year (simple average)
Sector 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	11	7.93
Sector 2 - Cosmetics	10	21.10
Sector 3 - Toys	19	123.89
Sector 4 - Personal Protective Equipment	15	25.38
Sector 5 - Construction Products	16	33.17
Sector 6 - Aerosol dispensers	12	49.44
Sector 7 - Simple pressure vessels and Pressure Equipment	11	1.66
Sector 8 - Transportable pressure equipment	11	3.28
Sector 9 - Machinery	15	12.10
Sector 10 - Lifts	9	0.81
Sector 11 - Cableways	11	1.16
Sector 12 - Noise emissions for outdoor equipment	10	5.00
Sector 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	8	0.88
Sector 14 - Pyrotechnics	13	7.95
Sector 15 - Explosives for civil uses	10	0.34
Sector 16 - Appliances burning gaseous fuels	15	5.08
Sector 17 - Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	18	29.18
Sector 18 - Electrical equipment under EMC	15	51.04
Sector 19 - Radio and telecom equipment under RTTE	18	59.40
Sector 20 - Electrical appliances and equipment under LVD	15	88.73
Sector 21 - Electrical and electronic equipment under RoHS, WEEE and batteries	9	6.89
Sector 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)	11	10.98
Sector 23 - Ecodesign and Energy labelling	16	14.10
Sector 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	5	0.50
Sector 25 - Recreational craft	11	0.83
Sector 26 - Marine Equipment	9	0.14
Sector 27 - Motor vehicles and tyres	10	59.13
Sector 28 - Non-road mobile machinery	4	3.56
Sector 29 - Fertilisers	14	5.48
Sector 30 - Other consumer products under GPSD	11	86.13

6. TEMPLATE FOR THE 2010-2013 REVIEW AND ASSESSMENTS

[Template for the] review and assessment of the functioning of market surveillance activities pursuant to Article 18(6) of Regulation (EC) No 765/2008 - 2010-2013

[Member State]

Explanations for using this template

The template foresees a review and assessment of the functioning of market surveillance at different levels:

- an aggregate level ("Overview of general market surveillance activities) that allows a snapshot of overall organisation and resources of market surveillance in Member States.

- a sector specific level.

For each of these levels the template organises the information in two sections.

Section A is meant to include some basic 'facts' on the infrastructure in place or activities carried out, which can be used as basis for the evaluation of the functioning of market surveillance. This information is expected to complement - avoiding duplication - information already provided in the National Market Surveillance Programmes for the 2010-2013 period. Please take note of a few important remarks:

- The information indicated in section A can and should be accompanied by any **additional (quantitative or qualitative) explanations** that allows the meaning of the figures provided to be fully appreciated and to prevent their possible misinterpretation

- If the **information indicated in the template is not available but can be estimated**, Member States are invited to provide estimates (but are asked to specify that this is the case).

- If the **information indicated in the template is not available and cannot be estimated**, yet Member States collect analogous information in a different format, they are invited to indicate 'n.a.' (=not available) and to add the information they possess, together with the explanations needed for its correct interpretation.

- The information indicated in the template is meant to be a '**common minimum denominator' that can be complemented with additional information** that a Member State may wish to include to provide the appropriate picture on the activities carried out, such as qualitative information on how MSAs have carried out their activities, any trends or key issues that are worth highlighting, legislative initiatives undertaken etc ,

Section B contains a Member State's exclusive assessment of its own activities. For this reason, the template does not suggest a specific format. However the assessment should be based on the information provided in Section A, as well on information provided in the National Market Surveillance Programmes for the 2010-2013 period.

1

Contents

Scope of the report

[Member States' review and assessments pursuant to Article 18(6) should cover market surveillance activities for all products falling under Union harmonisation legislation. For convenience, Member States *may* extend the scope of the report also to market surveillance activities carried out in the area of consumer non harmonised products.

A non-exhaustive list of sectors concerned is annexed to this template. Member States are invited to indicate: 1) whether certain sectors mentioned in list are expressly excluded from the review and assessment, and, 2) whether additional sectors are included. It is suggested they do so by filling in the last column of the annex]

3

Overview of general market surveillance activities

A. Review of general market surveillance activities

Information on the general market surveillance organisation and infrastructures in place for the 2010-2013 period2013

[This section should provide an overview of the relevant market surveillance organisation and horizontal infrastructures in place for the 2010-2013 period according to Regulation 765/2008 (competence of market surveillance authorities, mechanisms of coordination and exchange of information, cooperation with customs, etc.)]. To avoid duplication when the information has already been provided in the National Market Surveillance Programmes, this section could contain a simple reference to the latest update of the programmes and the relevant link to the websites of the relevant national and European website where the programme is available.

[free text]

Information on total resources available for market surveillance activities (subject to availability)

[This section should contain information on total resources allocated to market surveillance authorities by a Member State for all necessary activities (enforcement, communications) at either general or sectoral level.]

		2010	2011	2012	2013
1.1	Budget available to market surveillance authorities in nominal terms[1] (€)				
1.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)				
2	Staff available to market surveillance authorities (full-time equivalent units)				
3	Number of inspectors available to market				

[1] The budget figure should cover all financial resources which are assigned by public authorities to market surveillance and enforcement activities (including related infrastructures) as well as to projects and measures aimed at ensuring compliance of economic operators with product legislation.

These measures range from communication activities (consumer/business information and education) to pure enforcement and market surveillance activities. They include the remuneration of staff, direct costs of inspections, laboratory tests, training and office equipment cost. Enforcement activities at regional/local level should also be reported. Other activities undertaken by these authorities not related to the enforcement of product legislation should be excluded from the calculation.

	surveillance authorities (full-time equivalent units)				

B. Assessment of the functioning of market surveillance activities

[This section contains a Member State's exclusive assessment of the information provided in Section A. It could point, among others things, to horizontal difficulties, if any, encountered by authorities in carrying out their activities (e.g. lack of traceability information, problems with distribution of competences, lack of resources, insufficient deterrence of penalties, etc.)].

[free text]

5

Market surveillance activities in specific sectors

Sector [Number and Name from Annex, e.g. Sector 1 Medical Devices]

[Market surveillance authorities are requested to provide information for all relevant sectors where they conducted market surveillance in the 2010-2013 period. A list of reference sectors is annexed to this template. National authorities are also of course free to provide information at a more detailed level than the one proposed in the reference list of sectors (e.g. breaking down information on pressure equipment inspections according to the complexity of the equipment dealt with), if this is appropriate in view of the characteristics of a specific sector]

1.A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints				
2.	Number of substantiated complaints by industry concerning unfair competition				
3.	Number of inspections[2] (total number)				
3.1	number of reactive inspections[3]				
3.2	number of self-initiated inspections[4]				
3.3	number of inspections prompted by the customs[5]				

[2] Inspections are regular or ad hoc visits, controls (including checks on the internet) or other forms of contacts (mail, telephone) undertaken by an inspector, with an enforcement focus (excluding pure information exchange) and aimed at verification of product safety and compliance. Where several products/models/regulations are checked during the same exercise, this should be counted as one inspection. In order to be considered an inspection, there must be an official report prepared following the action.

[3] Inspections prompted by specific complaints (from consumers/users, notified bodies, competing businesses, trade-unions, etc.), accidents or incidents, information from other Member State authorities (e.g. via RAPEX notifications), etc.

[4] This concerns 'proactive' inspection s explicitly planned to target product categories/economic operator that may be found to be non-compliant on the basis of knowledge built and priorities set by authorities.

[5] These are inspections either initiated following customs' suspension of the release of products for free circulation or carried out directly by market surveillance authorities when they are responsible for the control of products at the border pursuant to Articles 27-29 of Regulation 765/2008.

4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products[6]				
5	Number of inspections resulting in:				
5.1	finding of non-compliance[7]				
5.2	corrective actions taken by economic operators ("voluntary measures")[8]				
5.3	restrictive measures[9] taken by market surveillance authorities .				
5.4	application of sanctions/penalties				
6	Number of inspections where other Member States were invited to collaborate				

Information on communication activities carried out in the 2010-2013 period (optional)

[This section should contain information on guidance, training courses and other initiatives carried out by market surveillance authorities for businesses, consumers, users or other stakeholders, namely with the objective of enhancing businesses' understanding of product rules and facilitate compliance, enhancing consumers/users' awareness of product hazards and rules, meaning of markings, prevention of accidents, etc.]

[free text]

[6] This refers to visual examination of the product in order to verify the existence of markings, warnings and information and determining obvious technical shortcomings product according to the requirements of the applicable Union legislation.

[7] This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

[8] Voluntary measures are defined as corrective action taken manufacturers, importers or distributors either to bring the product into compliance or to limit its availability on the market (e.g. stopping of sales, informing consumers/users, withdrawals from the market, recall from consumers/users) on the business' own initiative, possibly in consultation with the authority but without the measure being imposed by the latter.

[9] Compulsory measures to prohibit or restrict the product being made available on the national market, to withdraw it or to recall it. These measures are those taken when the economic operators did not follow up on previous request of market surveillance authorities to take corrective action or where authorities have to intervene urgently.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms [10] (€)				
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)				
8	Staff available to market surveillance authorities (full-time equivalent units)				
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)				

1.B. Assessment of the functioning of market surveillance activities in the sector

[This section contains a Member State's exclusive assessment of its own activities. It is expected to be based on information provided in section A, as well on information provided in the sectoral National Market Surveillance Programmes for the 2010-2013 period.

When conducting their evaluation Member States are invited to refer to the specific market context in which surveillance has been carried out (e.g. estimates of size of the national market for the products concerned, number of manufacturers/importer/ wholesale or retail distributors based in the Member state, volume of imports from other Member States or third countries, etc.)]

[free text]

[10] The budget figure should cover all financial resources which are assigned by public authorities to market surveillance and enforcement activities as well as to projects and measures aimed at ensuring compliance of economic operators with product legislation. These measures range from communication activities (consumer/business information and education) to pure enforcement and market surveillance activities. They include the remuneration of staff, direct costs of inspections, laboratory tests, training and office equipment cost. Enforcement activities at regional/local level should also be reported. Other activities undertaken by these authorities not related to the enforcement of product legislation laws should be excluded from the calculation.

Sector [Number and Name from Annex, e.g. Sector 2 Cosmetics]

2.A. Review of market surveillance activities in the sector

[...]

2.B. Assessment of the functioning of market surveillance activities in the sector

[...]

Sector [Number and Name from Annex, e.g. 3 Toys]

[....]

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Annex 1: Reference list of sectors

Product sectors	Relevant legislation[11] [12]	Included in this report? (Y/N)
1. Medical devices (including In vitro diagnostic medical devices and Active implantable medical devices)	Directives 93/42/EEC, 98/79/EC and 90/385/EEC	
2. Cosmetics	Regulation 1223/2009	
3. Toys	Directive 2009/48/EC	
4. Personal protective equipment	Directive 89/686/EEC	
5. Construction products	Regulation 305/2011	
6. Aerosol dispensers,	Directive 75/324/EEC,	
7. Simple pressure vessels and Pressure equipment	Directives 2009/105/EC and 97/23/EC	
8. Transportable pressure equipment	Directive 2010/35/EU	
9. Machinery	Directive 2006/42/EC	
10. Lifts	Directive 1995/16/EC	
11. Cableways	Directive 2000/9/CE	
12. Noise emissions for outdoor equipment	Directive 2000/14/EC	
13. Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	Directive 1994/9/EC	
14. Pyrotechnics	Directive 2007/23/EC	
15. Explosives for civil uses	Directive 93/15/EEC	
16. Appliances burning gaseous fuels	Directive 2009/142/EC	
17. Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	Directives 2004/22/EC, 2009/23/EC and 2007/45/EC	
18. Electrical equipment under EMC	Directive 2004/108/EC	
19. Radio and telecom equipment under RTTE	Directive 1999/5/EC	
20. Electrical appliances and equipment under LVD	Directive 2006/95/EC	
21. Electrical and electronic equipment under RoHS, WEEE and batteries	Directives 2011/65/EU, 2002/96/EC and 2006/66/EC	
22. Chemicals (Detergents, Paints, Persistent organic pollutants)[13]	Regulation 648/2004 Directive 2004/42/EC	

[11] For ease of reference this table indicates established EU legislation. New legislation having replaced or amended that listed in the table should be also taken into account for the relevant period in which it is applicable.

[12] For ease of reference in some cases (e. g. eco-design, energy labelling), this table only indicates EU framework legislation, but is intended to cover also product specific EU legislative acts.

[13] This section focuses on chemicals other than those falling under REACH and CLP Regulations. Market surveillance activities conducted under REACH and CLP Regulations fall within the scope of Regulation 765/2008, however, since they are already the subject matter of specific reports available to the public, they may be excluded from the current report. It is nevertheless asked to Member states to include in this section a link to the REACH and CLP reports for the relevant period.

	Regulation 850/2004	
23. Ecodesign and Energy labelling	Directives 2009/125/EC and 2010/30/EU	
24. Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	Directive 1992/42/EEC	
25. Recreational craft	Directive 1994/25/EC	
26. Marine equipment	Directive 96/98/EC	
27. Motor vehicles and tyres	Directives 2002/24/EC and 2007/46/EC, and Regulation (EC) No 1222/2009	
28. Non-road mobile machinery	Directive 97/68/EC	
29. Fertilisers	Regulation 2003/2003	
30. Other consumer products under GPSD (optional)	Directive 2001/95/EC	
31. .... (Additional sectors – please specify)		

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7. SECTORS COVERED BY MEMBER STATES REPORTS

Product sectors	Relevant legislation	Included in the report? (Y/N)																											
		BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SI	SK	FI	SE	UK
1. Medical devices (including In vitro diagnostic medical devices and Active implantable medical devices)	Directives 93/42/EEC, 98/79/EC and 90/385/EEC	N	Y	Y	Y	-	Y	Y	N	N	Y	N	Y	Y	Y	-	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
2. Cosmetics	Regulation 1223/2009	N	N	Y	Y	-	Y	Y	N	N	Y	Y	Y	N	Y	-	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y
3. Toys	Directive 2009/48/EC	Y	Y	Y	Y	-	Y	Y	Y	N	Y	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
4. Personal protective equipment	Directive 89/686/EEC	Y	Y	Y	Y	-	Y	Y	Y	N	Y	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
5. Construction products	Regulation 305/2011	Y	Y	Y	Y	-	Y	N	Y	N	Y	Y	N	Y	Y	-	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
6. Aerosol dispensers	Directive 75/324/EEC	Y	Y	Y	Y	-	N	N	Y	N	Y	N	N	Y	Y	-	Y	N	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
7. Simple pressure vessels and Pressure equipment	Directives 2009/105/EC and 97/23/EC	Y	Y	Y	Y	-	Y	Y	Y	N	Y	N	N	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
8. Transportable pressure equipment	Directive 2010/35/EU	N	Y	Y	Y	-	Y	Y	Y	N	Y	N	N	Y	Y	-	N	Y	Y	Y	N	Y	N	Y	Y	N	Y	Y	Y

Product sectors	Relevant legislation	Included in the report? (Y/N)																											
		BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SI	SK	FI	SE	UK
9. Machinery	Directive 2006/42/EC	Y	Y	Y	Y	-	Y	Y	Y	N	Y	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
10. Lifts	Directive 1995/16/EC	Y	Y	Y	Y	-	Y	Y	Y	N	Y	N	N	Y	Y	-	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	Y
11. Cableways	Directive 2000/9/CE	N	Y	Y	Y	-	Y	N	Y	N	Y	N	N	Y	Y	-	Y	N	Y	N	Y	Y	N	Y	Y	Y	Y	Y	N
12. Noise emissions for outdoor equipment	Directive 2000/14/EC	Y	Y	Y	Y	-	N	N	N	N	Y	N	Y	N	Y	-	N	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y
13. Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	Directive 1994/9/EC	Y	Y	Y	Y	-	N	Y	N	N	Y	N	N	Y	Y	-	Y	Y	Y	N	N	Y	N	Y	Y	N	Y	Y	Y
14. Pyrotechnics	Directive 2007/23/EC	Y	Y	Y	Y	-	Y	Y	Y	N	Y	Y	Y	Y	Y	-	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
15. Explosives for civil uses	Directive 93/15/EEC	N	Y	Y	N	-	Y	Y	Y	N	Y	N	Y	Y	Y	-	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
16. Appliances burning gaseous fuels	Directive 2009/142/EC	Y	Y	Y	Y	-	Y	Y	Y	N	Y	N	N	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

Product sectors	Relevant legislation	Included in the report? (Y/N)																											
		BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SI	SK	FI	SE	UK
17. Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	Directives 2004/22/EC, 2009/23/EC and 2007/45/EC	N	Y	Y	Y	-	Y	Y	Y	N	Y	Y	Y	N	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
18. Electrical equipment under electromagnetic compatibility	Directive 2004/108/EC	Y	Y	Y	Y	Y	N	N	Y	Y	Y	N	N	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
19. Radio equipment and telecommunications terminal equipment	Directive 1999/5/EC	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
20. Electrical appliances and equipment under the low voltage directive	Directive 2006/95/EC	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
21. Electrical and electronic equipment under restriction of hazardous substances, waste from electrical and electronic equipment and batteries	Directives 2011/65/EU, 2002/96/EC and 2006/66/EC	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	N	N	N	Y	-	N	Y	Y	Y	N	Y	Y	Y	Y	N	Y	Y	Y
22. Chemicals (Detergents, Paints, Persistent organic pollutants)	Regulation 648/2004 Directive 2004/42/EC Regulation 850/2004	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	N	N	Y	-	N	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	
23. Ecodesign and Energy labelling	Directives 2009/125/EC and 2010/30/EU	Y	Y	Y	Y	-	N	Y	Y	N	Y	N	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y

Product sectors	Relevant legislation	Included in the report? (Y/N)																											
		BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SI	SK	FI	SE	UK
24. Efficiency requirements for hot-water boilers fired with liquid or gaseous fuels	Directive 1992/42/EEC	Y	N	Y	N	-	N	Y	Y	N	N	N	N	N	Y	-	N	Y	N	N	N	N	N	Y	N	N	Y	Y	N
25. Recreational craft	Directive 1994/25/EC	N	Y	Y	Y	-	Y	N	Y	N	Y	N	N	N	Y	-	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
26. Marine equipment	Directive 96/98/EC	N	N	N	Y	-	Y	N	N	N	Y	N	Y	N	Y	-	N	N	Y	N	Y	Y	Y	Y	Y	N	Y	Y	N
27. Motor vehicles and tyres	Directives 2002/24/EC and 2007/46/EC, and Regulation (EC) No 1222/2009	Y	Y	N	Y	-	Y	Y	N	Y	Y	N	N	Y	Y	-	N	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y
28. Non-road mobile machinery	Directive 97/68/EC	Y	Y	N	Y	-	N	N	N	N	N	N	N	N	Y	-	N	Y	N	N	N	N	N	Y	Y	N	N	Y	Y
29. Fertilisers	Regulation 2003/2003	Y	Y	N	Y	-	Y	Y	Y	N	Y	Y	N	N	Y	-	N	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Y	N
30. Other consumer products under GPSD (optional)	Directive 2001/95/EC	Y	Y	Y	N	-	Y	Y	Y	Y	Y	Y	Y	N	Y	-	Y	Y	N	Y	Y	N	Y	Y	N	N	Y	Y	N

8. OVERVIEW OF INFORMATION PROVIDED FOR THE TOYS SECTOR

Belgium

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints				
2.	Number of substantiated complaints by industry concerning unfair competition				
3.	Number of inspections (total number)	110 (not including 2660 Rapex inspection not divisible by sector)	639 (not including 4786 Rapex inspection not divisible by sector)	2251	2078
3.1	number of reactive inspections	n.a.	n.a.	2213	1837
3.2	number of self-initiated inspections	n.a.	n.a.	38	241
3.3	number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products				
5	Number of inspections resulting in:				
5.1	finding of non-compliance				
5.2	corrective actions taken by economic operators ("voluntary measures")				
5.3	restrictive measures taken by market surveillance authorities			11	97
5.4	application of sanctions/penalties				
6	Number of inspections where other Member States were invited to collaborate				

Information on communication activities carried out in the 2010-2013 period (optional)

No information

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

No information

Bulgaria

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	20	15	19	13
2.	Number of substantiated complaints by industry concerning unfair competition				
3.	Number of inspections (total number)	1106	1939	2296	1614
3.1	number of reactive inspections	830	820	503	282
3.2	number of self-initiated inspections	276	1119	1793	1332
3.3	number of inspections prompted by the customs	476	393	266	659
4	Number of inspections based on:				
4.1	tests performed in laboratories	17	17	16	4
4.2	physical checks of products	1106	1939	2296	1614
5	Number of inspections resulting in:				
5.1	finding of non-compliance	474	820	1224	282
5.2	corrective actions taken by economic operators (“voluntary measures”)	76	105	431	80
5.3	restrictive measures taken by market surveillance authorities	8	3	47	19
5.4	application of sanctions/penalties	60	52	85	60
6	Number of inspections where other Member States were invited to collaborate				

Information on communication activities carried out in the 2010-2013 period (optional)

Six seminars with Bulgarian producers and importers of toys were organised in connection to the implementation of Directive 2009/48/EC (from 20 July 2011) - one in 2011 and one in 2012, while four seminars were organised in 2013 in connection with the implementation of the new chemical requirements (from 20 July 2013). Organisers of the seminars were the Bulgarian Institute for Standardisation and the Bulgarian association of producers and importers of toys.

At the initiative and with the support of the European Commission, a seminar was organised in 2012 by the Bulgarian association of producers and importers of toys.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)	653072	649252	650465	608490
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)				
8	Staff available to market surveillance authorities (full-time equivalent units)	75	75	75	75
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	30	30	30	30

B. Assessment of the functioning of market surveillance activities in the sector

The number of toys produced in Bulgaria is small – accounting for no more than 10 % of the market. These are mainly toys made of wood, plastic, soft stuffed toys and sand drawing sets. The bulk of toys placed on the Bulgarian market is imported from third countries and in particular from China.

Given the great variety of products, despite the consistent and comprehensive monitoring of the market, there are still cases of toys marketed with the wrong age restrictions for use by the manufacturer; missing compulsory warnings on the toy as required in Directive 2009/48/EC or imprecise specific warnings; Bulgarian instructions for use which do not match the size and content of the manufacturer's instructions.

Czech Republic

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	44	71	79	139
2.	Number of substantiated complaints by industry concerning unfair competition	Not recorded	29	23	59
3.	Number of inspections (total number)	1801	1682	1440	1602
3.1	number of reactive inspections	4574	5435	2108	1316
3.2	number of self-initiated inspections	1	4	4	3
3.3	number of inspections prompted by the customs	Not recorded	9	37	68
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products	1634	1550	1286	1314
5	Number of inspections resulting in:				
5.1	finding of non-compliance	1053	925	911	1346
5.2	corrective actions taken by economic operators ("voluntary measures")	1		1	
5.3	restrictive measures taken by market surveillance authorities	1			2
5.4	application of sanctions/penalties	390	49	549	548
6	Number of inspections where other Member States were invited to collaborate			9	27

Information on communication activities carried out in the 2010-2013 period (optional)

A market surveillance authority (specifically the Czech Trade Inspection Authority) works with the audit authority to hold public seminars approximately twice a year at toy exhibitions and trade fairs. In addition, the Czech Trade Inspection Authority staff answers all written and telephone enquiries made by the general public. In general, public health authorities under the Ministry of Health organise various training events or participate in those held by various institutions or professional associations. There is regular cooperation, for example, with PROKOS (the association of cosmetics manufacturers) and ČSZV (the Czech Association for Branded Products), whose training events are routinely attended by public health authorities

delivering contributions on legislation and the results of surveillance activities. The situation is much the same with associations of packaging material manufacturers, with which there is also intensive communication. In addition, public health authorities regularly organise various seminars and workshops with professionals as a means to exchange experiences. The most extensive series of seminars was held in 2013 with the aim of familiarising the public with new legislation on cosmetics, particularly in relation to the EU's Cosmetic Products Notification Portal (CPNP).

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

The Czech Trade Inspection Authority's activities in this sector have sought to guarantee the same level of consumer protection and consumers' legitimate interests (i.e. life, health, property and the natural environment) within the EU internal market. Consumer product inspections concentrated primarily on third-country products, which were assessed in cooperation with customs authorities before they were released into free circulation in accordance with European TAXUD methodology.

The Czech Trade Inspection Authority is involved in international surveillance actions which are concerned, entirely or marginally, with the Toy Safety Directive and which are financially supported by the European Commission.

Since 2012, it has participated in a joint international surveillance project, co-financed by the European Commission and organised by Prosafe JA China 1 and JA China 2, which has yet to be completed.

The project seeks to establish a platform for cooperation with Chinese customs and surveillance authorities on the one hand and with EU customs and surveillance authorities on the other. The cooperation established should engender confidence in the safety of imported products and facilitate trade between China and the EU. In this context, another pilot project will be launched this year for the mutual assessment and recognition of the conformity of products covered by the Toy Safety Directive.

State health surveillance under the responsibility of the Ministry of Health draws on annual national and regional inspection plans based on methodology and compiled centrally by the Ministry of Health. The preparation of these plans is rooted in the market situation and an analysis of past results of state health surveillance, an analysis of legislative requirements and an assessment of the risk posed by products to consumers. Every year, targeted tasks of the Chief Health Officer are announced, which focus on nationwide problems that have been singled out. Regionally, targeted tasks – aimed at addressing problems typical for the region – are also carried out. In 2013, the focus was on dolls containing soft plastic parts, based on RAPEX notifications and internally conducted market research. This corroborated the presence of high concentrations of such toys, especially in 'Asian marketplaces'. This surveillance was carried out to confirm the high content of phthalates in soft plastic parts to a level that exceeded the limit established by the REACH Regulation and could threaten the health of the youngest members of the population, for whom these toys are intended.

In 2013, there were 408 toy inspections encompassing 1 550 products. A total of 258 product samples were taken for laboratory analysis; 142 of these products were classified as substandard. Customs administration authorities cooperated in the inspections of toys (dolls) with soft plastic parts – this product type was inspected upon entry into the Czech Republic and also directly on the market. In all, 87 products were declared unsafe, and a relatively large number of substandard products were seized by the customs authorities at the border and subsequently destroyed. Market inspections reveal problems with the sale of this type of product at markets, in particular 'Asian marketplaces', as the product origin cannot be traced because, in most cases, only the name of the vendor is known. Documents intended to prove the origin of a product, such as invoices, are false, if they exist at all. In some cases, non-existent barcodes, or companies that do not trade in the given type of product, are reported. Furthermore, it was found that, after a certain period of time had passed, products previously declared unsafe were placed back on sale, sometimes rebranded.

Denmark

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints[246]	4	3	5	5
2.	Number of substantiated complaints by industry concerning unfair competition	1	1		
3.	Number of inspections (total number)[247]	138	133	91	90
3.1	number of reactive inspections[248]	66	43	47	46
3.2	number of self-initiated inspections	72	90	44	43
3.3	number of inspections prompted by the customs		11		
4	Number of inspections based on:				
4.1	tests performed in laboratories	25	71	15	21
4.2	physical checks of products[249]	133	81	81	81
5	Number of inspections resulting in:				

246 Data available from the Environmental Protection Agency only.
247 The table covers the number of products and not the number of inspections. The number is based on an average.
248 A significant proportion took place as the result of complaints from consumers, possibly as the result of accidents.
249 All product inspections within the jurisdiction of the Danish Safety Technology Authority include a physical check. Figures reflect the number of products and not the number of inspections. They cover both the Danish Safety Technology Authority and the Danish Environmental Protection Agency.

		2010	2011	2012	2013
5.1	finding of non-compliance	30	20	44	24
5.2	corrective actions taken by economic operators ("voluntary measures")	8	16	13	11
5.3	restrictive measures taken by market surveillance authorities[250]	10	8	4	4
5.4	application of sanctions/penalties	2	3	0	1
6	Number of inspections where other Member States were invited to collaborate	0	0	1	2

Information on communication activities carried out in the 2010-2013 period (optional)

The Environmental Protection Agency holds two dialogue meetings a year with the toy sector. At these meetings, both the Environmental Protection Agency and the sector provide information about what has happened since the last meeting, and they discuss anything that needs to be clarified in relation to both regulation and case handling. In addition to this, the Environmental Protection Agency also published a folder in collaboration with the Danish Safety Technology Authority in 2010, containing ten good tips for the procurement and handling of toys, aimed at buyers in local authorities and day-care institutions: http://www.sik.dk/Global/Publikationer/Foldere/10-gode-raadtil-haandtering-og-indkoeb-af-legetoej

In order to help toy distributors gain an overview of their obligations, the Danish Safety Technology Authority produced a folder in 2012, for distribution during visits to shops. The folder is also available on the website:

http://www.sik.dk/content/download/23244/300319/version/1/file/Til_distributoerer_af_legetoej_rev_+maj_2014.pdf.

The Danish Safety Technology Authority is happy to make contributions concerning rules, etc. on toys, in order to give the sector the best basis for complying with the rules and only producing and dealing in safe toys. This is primarily done through dialogue meetings every six months, but also for example at the Nordic and Baltic Information Seminar on Toy Safety, which was held in Malmö on 20 September 2012.

The Danish Safety Technology Authority has taken part in the Commission's employee exchange. One colleague involved in toys (as well as one colleague involved in electrical products) was therefore on exchange at the NVWA in the Netherlands in January 2013. In 2013, the Danish Safety Technology Authority undertook a strategic fact-finding initiative on consumer behaviour with a view to producing information materials about the proper use of products. The investigation found that Danish consumers do not perceive toys as risky. They therefore do not read instructions for use or warning labels, and they make up their own rules. Some 16 % of consumers therefore said that they have never refrained from buying a toy

250 For infringements that do not have any significance for safety, the Danish Safety Technology Authority provides guidance/recommendations to the person responsible. Such infringements are not included in the figures.

purely because it has a warning symbol indicating that it is 'not suitable for children aged 0-3'.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)	381800	213300	168400	169700
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.00056%	0.00031%	0.00024%	0.00024%
8	Staff available to market surveillance authorities (full-time equivalent units)	2.08	1.46	1.62	1.67
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	0.58	1.06	1.23	1.27

B. Assessment of the functioning of market surveillance activities in the sector

Environmental Protection Agency:

Access to market surveillance in this sector is risk-based. Initiatives in the form of information, guidance and controls are organised and carried out on the basis of risk assessments, based on knowledge from scientific work and news in a broad sense, the age of the rules and the scope of consolidated guidance, the number of reported cases, including via Rapex, and the number of infringements detected during controls. The prioritisation of this product area therefore varies. Information, guidance and controls in collaboration with the Danish Safety Technology Authority have been given a high priority in 2014, particularly information and guidance, as part of a special initiative on the safe use of products for children.

Danish Safety Technology Authority:

The Authority's experience is that it is appropriate to keep the sector informed of the focus that the forthcoming proactive initiatives on toys will have. The potential shop types are thus prepared for the possibility of controls, and they can therefore instruct their employees how to react when the authorities pay a visit. A broader, earlier effect is thus achieved in the form of self-discipline. In order to measure the impact that a market surveillance initiative has had, including follow-up activities (usually concluding communication with the sector or consumers), the Authority has repeated some initiatives at intervals of a few years. The Danish Safety Technology Authority has compared the results of the magnetic toy initiative from 2012 with the previous initiative, which ran from 2007 to 2010. There has been an improvement, since 36 % of the toys that were selected posed a danger to consumers, compared to 60 % previously. We published the following article:

http://www.sik.dk/Global/Publikationer/Artikler/OEvrige-artikler/2012/Sikkerheden-vedmagnetlegetoej-kan-stadig-forbedres

Application of the Market Surveillance Regulation to the toy sector poses some challenges, including the following:

- Agents: The legal position for agents must be clarified, i.e. whether an agent may be treated as part of the distribution chain and have the associated responsibilities. The Danish Safety Technology Authority will therefore work to clarify this with the Commission.

- What should be done if the manufacturer responsible has been declared bankrupt or has otherwise ceased to exist? Can the product continue to be sold, and what liability do the other players in the distribution chain have with regard to procuring technical documentation for product safety?

- Manufacturers (and test laboratories) are not particularly aware of the fact that a standard must be harmonised in order for them to assume compliance with the safety requirements contained in the Toy Directive when the standard is complied with.

Germany

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

No information

Information on communication activities carried out in the 2010-2013 period (optional)

No information

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

No information

Estonia

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

Surveillance activities in numbers	2010	2011	2012	2013
Total number of inspections	427	396	382	401
Number of notices sent by the Tax and Customs Board	12	9	18	11

Total number of products inspected[251]	847	584	442	369
Number of products tested	56	73	58	73

Results of surveillance activities	2010	2011	2012	2013
Number of non-compliant products[252]	49	57	47	15
Number of products presenting a serious risk	10	13	13	17

Measures applied[253]	2010	2011	2012	2013
Number of memos	27	28	39	48
Number of orders	38	34	1	0
Number of penalty payments and total amount	0	0	0	0
Number of substitutive enforcements	0	0	0	0
Number of misdemeanour procedures	0	0	0	0
Fines imposed as part of a misdemeanour procedure	0	0	0	0

Products withdrawn from the market	2010	2011	2012	2013
Total number of products withdrawn from the market[254]	21	10	6	7
Number of products recalled from consumers[255]	2	19	Data not available	Data not available
Number of voluntary measures taken by economic operators[256]	6	8	6	7

251 The total number of products inspected by only one authority, the Health Board, has been given here. The total number of products inspected by the Consumer Protection Board is not available. With the current information system, it is only possible to return the number of inspection visits. At the same time it is known that the total number of products inspected by the Consumer Protection Board in 2011 was approximately 1 670.

252 For the Consumer Protection Board, it is only possible to give the number of non-compliant products out of the products tested. The percentage of infringements detected during the inspection visits was as follows: 2010 – 40.1%; 2011 – 34.4%; 2012 - 33%; 2013 – 63.5%.

253 For the Consumer Protection Board, only the number of memos is available.

254 The data for 2010–2011 consist of data from both of the authorities; there are no data available about the Consumer Protection Board for 2012–2013. Number of product articles.

255 The data from 2010–2011 consist of data of the Consumer Protection Board. The Health Board has no data available.

256 Only data from 2010 are available for the Consumer Protection Board. The data from 2011–2013 consist only of the data for the Health Board.

Information on communication activities carried out in the 2010-2013 period (optional)

As far as toys are concerned, the Health Board has inspected whether the requirements laid down in Directive 2009/48/EC and 2001/95/EC of the European Parliament and of the Council and in the REACH regulation have been implemented. Special attention has been paid to the mechanical and physical properties of toys meant for children below three years of age since such toys may cause choking and injuries to the most vulnerable target group. The Health Board has also studied the phthalate content of rubber toys and childcare products, as phthalates are reproductive toxicants and may cause fertility problems in the long term.

Every year the Health Board carried out the ad hoc study "Inspection of possible phthalate content in childcare products and soft toys". The aim of the ad hoc study was to find out whether the childcare products (toys, childcare articles, etc.) on the Estonian market are in conformity with the requirements of point 51 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH).

During the ad hoc inspection, a total of 60 products per four years were inspected, of which 10 products (16%) were not in conformity with the requirements. In 2010 and in 2011 the Consumer Protection Board along with 14 market surveillance authorities took part in a project on toys financed by the European Commission and managed by the PROSAFE cooperation network. The aim of the project was to ensure that only safe toys were on the EU market; the project was aimed at inspecting magnetic toys, the content of small parts in toys and the content of heavy metals in toys. The project resulted in the preparation of several instructions and reference materials for the organisation of surveillance over toys.

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

No information

Ireland

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period[257]

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	36	36	36	17
2.	Number of substantiated complaints by industry concerning unfair competition				
3.	Number of inspections (total number)		1	3	9

257 The Agency is unable to provide detailed statistical information in relation to enforcement activities as detailed in this section as the data relating to complaints, investigations and inspections is not recorded by the Agency in a comparable format and the Agency is not in a position to devote resources to detailed statistical analysis of this data at this time.

		2010	2011	2012	2013
3.1	number of reactive inspections		0	3 (not limited to toys)	9 (not limited to toys)
3.2	number of self-initiated inspections		0		
3.3	number of inspections prompted by the customs		1	3 (not limited to toys)	9 (not limited to toys)
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products	0		258	
5	Number of inspections resulting in:				
5.1	finding of non-compliance	n.a.	1	3	9
5.2	corrective actions taken by economic operators ("voluntary measures")	259			
5.3	restrictive measures taken by market surveillance authorities	n.a.	1	3	9
5.4	application of sanctions/penalties	n.a.	n.a.	n.a.	n.a.
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

The National Consumer Agency hosts and operates 2 websites as follows ;

1. Agency corporate-focused website – http://corporate.nca.ie/eng/. This website provided information and guidance relating to business and corporate product safety issues including information on the role of the Agency as Ireland's market surveillance authority for safety of products covered by the EU Directives, product safety guidelines and responsibilities for businesses, and related 'Frequently Asked Questions' (FAQs), links to specific sectoral information including toy safety and magnetic toys, RAPEX weekly summary reports, product safety recalls, press releases, business zones guides including a Toy Safety page, Guide to Toy Safety, Toy Safety Tips and links to the relevant Irish legislation containing the transposed legislation.

2. 2. General consumer-focused website at http://www.consumerhelp.ie/ with information on the role of the Agency as Ireland's market surveillance authority for safety of products covered by the EU Directives, enforcement of product safety legislation,

258 Representative items from customs consignments were visually and physically checked.
259 The Agency achieved voluntary corrective actions (where necessary) in majority of cases.

investigation of complaints about unsafe products, alerting consumers about unsafe products by posting product recalls and RAPEX notifications detailing all product recalls that have taken place in the European Union, and general information for consumers on Toys and Play Equipment .

October 2010 - The National Consumer Agency hosted the 'Seminar on new EU Toy Safety Directive' an information seminar on the requirements of the new EU Toy Safety Directive for industry.

2012 – NCA participated in a training event hosted by the Chambers of Commerce and TIE to raise awareness about the new EU Toy Safety Directive and related standards.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)[260]	7200000	6300000	5200000	4800000
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	n.a.	n.a.	n.a.	n.a.
8	Staff available to market surveillance authorities (full-time equivalent units)[261]	7	7	8	8
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)[262]	7	7	8	8

B. Assessment of the functioning of market surveillance activities in the sector

The National Consumer Agency (NCA) is the statutory body established by the Irish Government to enforce consumer law and promote consumer rights with responsibility for market surveillance in respect of the safety of a wide range of non-food consumer products. Our role in relation to product safety includes enforcing product safety legislation, investigating complaints about unsafe products, carrying out surveillance activities, alerting consumers about unsafe products, advising manufacturers, suppliers, retailers and their representative bodies about their responsibilities, and managing Ireland's input to the EU product safety rapid alert system, RAPEX

The National Consumer Agency has also contributed to the National Sector Specific Market Surveillance Programmes 2010 -2011 and 2012 – 2013.

260 The Budget across is the total NCA budget for all activities (excluding financial awareness and education). It is not possible to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

261 Number of authorised officers in Product Safety Unit with additional authorised Officers available to assist on specific projects if required.

262 Number of authorised officers in Product Safety Unit with additional authorised Officers available to assist on specific projects if required.

Greece

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	0	0	1	0
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	4	0
3.	Number of inspections (total number)	30	43	32	8
3.1	number of reactive inspections	3	4	4	7
3.2	number of self-initiated inspections	27	38	28	1
3.3	number of inspections prompted by the customs	0	1	0	0
4	Number of inspections based on:				
4.1	tests performed in laboratories	63	68	23	98
4.2	physical checks of products	0	34	9	3
5	Number of inspections resulting in:				
5.1	finding of non-compliance	12	19	6	13
5.2	corrective actions taken by economic operators ("voluntary measures")	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities[263]	10	6	6	4
5.4	application of sanctions/penalties[264]	10	6	6	4
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

No information

263 For the year 2012, the three prohibitions/withdrawals relating to samples with an abnormal phthalate content were issued by the General Chemical State Laboratory (Directorate for the Environment). For the year 2013, the prohibition/withdrawal relating to a sample with an abnormal phthalate content was issued by the General Chemical State Laboratory (Directorate for the Environment).

264 Fines as well as mandatory measures (withdrawals) were imposed on economic operators.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)[265]				
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)[266]				
8	Staff available to market surveillance authorities (full-time equivalent units)	3	3	3	3
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	10	10	10	10

B. Assessment of the functioning of market surveillance activities in the sector

From 2010-2013, the market surveillance authority for toys carried out 113 inspections, involving the inspection of 261 outlets for toys throughout Greece (importers, distributors and manufacturers) and 900 types of toy were given mainly visual inspections. All this was carried out at virtually zero financial cost. Fines totalling EUR 111 611.60 were established and collected.

Spain

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

No information

Information on communication activities carried out in the 2010-2013 period (optional)

No information

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

No information

265 The annual budget for resources and training related to the General Secretariat for Industry's entire market surveillance operation (for this purpose rows 7.1 and 7.2 have not been completed, which relate exclusively to toys).

266 The annual budget for resources and training related to the General Secretariat for Industry's entire market surveillance operation (for this purpose rows 7.1 and 7.2 have not been completed, which relate exclusively to toys).

France

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	22
2.	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	4
3.	Number of inspections (total number)	3773	2694	2224	2644
3.1	number of reactive inspections	15	24	20	15
3.2	number of self-initiated inspections	3758	2674	2204	2639
4	Number of inspections based on:				
4.1	tests performed in laboratories	868	773	877	790
4.2	physical checks of products	18500	15000	19000	17000
5	Number of inspections resulting in:				
5.1	finding of non-compliance	380	341	401	326
5.2	corrective actions taken by economic operators ("voluntary measures")	n.a.	n.a.	n.a.	n.a.
5.3	restrictive measures taken by market surveillance authorities	72	54	50	74
5.4	application of sanctions/penalties	52	40	39	42
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

Information on communication activities carried out in the 2010-2013 period (optional)

No information

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)[267]	2000000	1620000	1300000	1320000

267 Doesn't include the budget for product testing.

		2010	2011	2012	2013
8	Staff available to market surveillance authorities (full-time equivalent units)	26.5	20.5	21.5	21.5
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	24	18	19	19

B. Assessment of the functioning of market surveillance activities in the sector

No information

Croatia[268]

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints				
2.	Number of substantiated complaints by industry concerning unfair competition				
3.	Number of inspections (total number)				384
3.1	number of reactive inspections				150
3.2	number of self-initiated inspections				90
3.3	number of inspections prompted by the customs				144
4	Number of inspections based on:				
4.1	tests performed in laboratories				30
4.2	physical checks of products				40
5	Number of inspections resulting in:				
5.1	finding of non-compliance				50
5.2	corrective actions taken by economic operators ("voluntary measures")				2

268 Data only between 1 July 2013 – 31 December 2013

		2010	2011	2012	2013
5.3	restrictive measures taken by market surveillance authorities				60
5.4	application of sanctions/penalties				40
6	Number of inspections where other Member States were invited to collaborate				

Information on communication activities carried out in the 2010-2013 period (optional)

No information

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

No information

Italy

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

No distinguishable information provided: combination of sector 3 and 30

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	205 (A) 13 (C)	229 (A) 13 (C)	96 (A) 11 (C)	275 (A) 7 (C)
2.	Number of substantiated complaints by industry concerning unfair competition				
3.	Number of inspections (total number)	1168	1305	547	1567
3.1	number of reactive inspections	218	450	259	372
3.2	number of self-initiated inspections				
3.3	number of inspections prompted by the customs				
4	Number of inspections based on:				

		2010	2011	2012	2013
4.1	tests performed in laboratories		415		
4.2	physical checks of products				
5	Number of inspections resulting in:				
5.1	finding of non-compliance		228		
5.2	corrective actions taken by economic operators ("voluntary measures")				
5.3	restrictive measures taken by market surveillance authorities		185		
5.4	application of sanctions/penalties				
6	Number of inspections where other Member States were invited to collaborate				

Information on communication activities carried out in the 2010-2013 period (optional)

No information

Information on resources (subject to availability)

No distinguishable information provided: combination of sector 3 and 30

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)	n.a	n.a.	n.a.	n.a.
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	n.a	n.a.	n.a.	n.a.
8	Staff available to market surveillance authorities (full-time equivalent units)	7	7	11	10
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	100 (NAS)	n.a.	n.a.	n.a.

B. Assessment of the functioning of market surveillance activities in the sector

Following the RAPEX alerts on microbiological or chemical issues relating to consumer products (toys and other), under the responsibility of the Ministry of Health, NAS (the Health Protection Unit of the Carabinieri) launched a review of the national market. The main issues reported include a lack of detailed information as to the distribution network, imports via unofficial channels and the lack of documentation and invoices showing the origin of the products. The lack of resources significantly restricts the ability to perform control tests.

Cyprus

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	0	0	0	0
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	1257	962	834	785
3.1	number of reactive inspections	9	8	4	3
3.2	number of self-initiated inspections	n.a.	n.a.	21	8
3.3	number of inspections prompted by the customs	0	11	0	5
4	Number of inspections based on:				
4.1	tests performed in laboratories	74	69	59	43
4.2	physical checks of products	1183	893	775	742
5	Number of inspections resulting in:				
5.1	finding of non-compliance	n.a.	27	52	85
5.2	corrective actions taken by economic operators ("voluntary measures")	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities	33	19	17	27
5.4	application of sanctions/penalties	0	2	0	2
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

Information sheets are sent to toy importers, informing them of their obligations and giving them advice and instructions. Furthermore, regular visits are paid to distributors and importers, during which they are given oral information and submitted to inspection. In addition, information material on the implementation of the Toy Safety Directive has been printed (30 000 copies) and will be distributed to importers, distributors and consumer organisations. Moreover, all the communications from the department relating to toys are notified to consumer organisations and associations of economic operators.

A seminary-workshop was held on 22 September 2011 as part of the pan-European campaign for the CE marking. The seminar was intended primarily for economic operators, as well as consumers. The new Toy Safety Directive was presented as part of that seminar. The department also took part in the Christmas pan-European Toy Safety Campaign (December 2011).

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

Market surveillance activities in relation to toys are being carried out almost on a daily basis, throughout the territory of Cyprus. In particular, inspectors carry out inspections on the basis of the RAPEX weekly report (which includes toys), and at the same time they conduct visual and physical inspections of toys.

In addition, samples of toys are taken and examined twice a year. Usually, the first sampling (2nd quarter of the year) includes 30 toy samples, the physical and mechanical properties (EN71-1) of which are examined, and the second sampling (4th quarter of the year) includes 30 toy samples which are tested for the migration of heavy metals (EN71-3). All laboratory tests are performed by the State General Laboratory. The exact sampling schedule is established in an agreement between the two parties at the beginning of each year. Other laboratory tests may be conducted in the context of our participation in EU programmes, e.g. PROSAFE.

Finally, inspection campaigns are being carried out with respect to specific toy categories (e.g. inflatable toys, skates, projectile toys) or in specific sales premises of toys (e.g. open-air markets).

Inspection methodology:

Conducting visual and physical inspection of toys. These inspections are usually performed on own initiative and/or on the basis of the RAPEX notification. In some cases, these inspections are performed following consumer complaints.

The actions/procedures followed are:

- checking the CE marking;
- checking the warnings that should be affixed on toys;
- assessing the compliance of toys with the basic safety requirements of the applicable national legislation;
- physical inspection of toys for children under the age of 3 for detachable small parts, sharp points, laces, liquids, etc.;
- if there are doubts about any toy, all relevant information and documentation in relation to the product are requested from the economic operator;
- conducting sample checks on products and carrying out laboratory tests on them;

- taking measures when it is found that toys do not comply with the safety requirements of the applicable national legislation.

The specific market framework on which the surveillance scheme is carried out:

- Assumptions as to the size of the national market: n.a.
- Number of manufacturers: 1
- Number of importers: 68
- Number of distributors: 397
- Import volume (third countries): EUR 16 459 997.00

Latvia

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	n.a.
2.	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.
3.	Number of inspections (total number)	153	57	145	109
3.1	number of reactive inspections	2	0	5	3
3.2	number of self-initiated inspections	151	51	93	69
3.3	number of inspections prompted by the customs	0	6	47	37
4	Number of inspections based on:				
4.1	tests performed in laboratories	36	12	31	39
4.2	physical checks of products	153	57	145	109
5	Number of inspections resulting in:				
5.1	finding of non-compliance	60	23	61	63
5.2	corrective actions taken by economic operators (“voluntary measures”)	59	16	43	41

		2010	2011	2012	2013
5.3	restrictive measures taken by market surveillance authorities	1	7	18	22
5.4	application of sanctions/penalties	15	34	60	22
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

Information on communication activities carried out in the 2010-2013 period (optional)

No information

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

No information

Lithuania

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

No information

Information on communication activities carried out in the 2010-2013 period (optional)

No information

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

No information

Luxembourg

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	0	0	1	0
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	78	80	22	24
3.1	number of reactive inspections	1	0	2	0
3.2	number of self-initiated inspections	64	49	18	19
3.3	number of inspections prompted by the customs	13	31	2	5
4	Number of inspections based on:				
4.1	tests performed in laboratories	8	2	12	8
4.2	physical checks of products	40	49	14	19
5	Number of inspections resulting in:				
5.1	finding of non-compliance	22	27	13	7
5.2	corrective actions taken by economic operators ("voluntary measures")	1	5	2	1
5.3	restrictive measures taken by market surveillance authorities	10	22	11	6
5.4	application of sanctions/penalties	0	0	0	0
6	Number of inspections where other Member States were invited to collaborate	1	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

Surveillance was carried out sporadically in retail outlets. These inspections comprised visual inspections of labelling and the documentation provided. Systematic verification was carried out together with officials of the Administration des Douanes et Accises at import.

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

No information

Hungary

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	21	25	25	31
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	1153	1510	1015	1043
3.1	number of reactive inspections	465	571	352	393
3.2	number of self-initiated inspections	683	926	656	641
3.3	number of inspections prompted by the customs	5	13	7	9
4	Number of inspections based on:				
4.1	tests performed in laboratories	76	55	62	90
4.2	physical checks of products	1422	2695	2476	2094
5	Number of inspections resulting in:				
5.1	finding of non-compliance	207	305	479	512
5.2	corrective actions taken by economic operators ("voluntary measures")	4	3	2	1
5.3	restrictive measures taken by market surveillance authorities	161	237	223	230
5.4	application of sanctions/penalties	130	197	153	137
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

In its communication activities, the NFH gives priority to communicating product safety information to consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual

product groups, as well as dangerous products prohibited by the Authority, on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)	317192	522807	465263	461052
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.000637	0.00105	0.000837	0.0008
8	Staff available to market surveillance authorities (full-time equivalent units)	32	35	30	34
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	21	23	19	22

B. Assessment of the functioning of market surveillance activities in the sector

The consumer protection authority examined the following types of toys between 2010 and 2013:

- Dolls/doll kits: according to experience, 90 % of the products analysed have a high phthalic ester-type softener content in the heads of dolls. Instead of the heads of dolls, the softener is mostly located in the bodies of dolls and other accessories. 18 % of the labelling is incomplete, 4 % of the products do not have conformity documentation. The complaint ratios were nearly equal in all three years.

- Projectile toys: their most typical defect is the separation of the suction disc and the higher than permitted phthalic ester-type softener content of the suction disc. This product group was also inspected as part of sample testing/individually every year; the Authority increasingly often encountered phthalic-free products in 2013 and this year. Projectiles are already made of different materials, thus they do not contain any softener and the design of projectiles has been changed: they consist of a piece cast in one mould, thus they have no small part that can get separated. In terms of labelling, 25 % of them are inadequate, and 3 % do not have conformity documentation.

- Toys for children under the age of three: Of the baby toys tested in 2012, 112 types or 388 toys (20.9 %) were complained about due to inadequate markings, labels and warnings. During the inspections, samples were taken from 14 toys presumed to be suspicious from a safety point of view. On the basis of the results of laboratory tests, two baby toys proved to be dangerous. One baby chew toy represents a serious risk to small children from the point of view of choking hazard, while a pram rattle poses a

high risk in terms of eye injuries. In 2013, the product group was examined as part of laboratory tests, where dangerous softeners were also found in a small proportion. In the case of this product group, manufacturers pay greater attention to hazards posed by small parts and pull cords. The documentation was correct in the case of 85.7 % of the toys.

- Bubble blowers/replenishers: In the case of this product group, microbiological analyses were carried out on several occasions. In 25 % of the cases, microbiological infections were found, in one case due to a specific defect of the product.

- Tricycles and scooters: The majority of the products did not meet the requirements set for load-bearing capacity, brakes, stability, burr and sticking. With regard to labelling, product-specific warning notices were incomplete or completely missing.

- Textile puppets (2013) and textile doll clothes (2012): The Authority analysed these products for their azo-dye content (in specific analyses); in two analyses, one product did not meet the requirements.

- Expanding toys: A very small group of toys belongs to the group of expanding toys: In 20 % of these products, they expand too much (several fold in size). The Authority checked these products, too, in its own laboratory tests and sampling tests every year.

- Make-up kits: They were not subjected to independent thematic reviews, but about 10 of them were tested (randomly and through consumer complaints) every year. In terms of microbiological and heavy metal content, the products meet the requirements.

- Toy books: During the inspection of children's books, a total of 20 products were sampled, of which deficiencies relating to the conditions of distribution were established in the case of 12 (60 %), and non-conformity affecting product safety, which represents a medium risk, was established in the case of one (5 %). It can be stated from the experience gained that the manufacturers and importers are not aware of the fact that they have to meet not only the requirements set for books, but also those set for children's toys. They do not know the boundary between books and toys. In many cases, therefore, conformity markings were not shown either.

- Toy mobile phones: The Authority inspected these product groups as part of independent thematic reviews in 2011 and 2012. On both occasions, the Authority established that the volume emitted was too high in nearly 82 % of the products, 30 % did not conform to the structural specifications, and 17 % were malfunctioning.

On the basis of experience of the past period, it can be stated that it is a frequent problem in the case of toys that the documentation certifying the conformity of the product is incomplete or inadequate. In the case of EC declarations of conformity, the most frequent errors are the name and ID number of the registered organisation. The inspection of a significant part of the products is carried out by an (unregistered) Chinese subsidiary of a registered organisation. Another error is the ambiguous identifiability (lack/quality of photograph, difference in identification markings). It is an error that occurs less frequently, but so much the more significant, that the product is examined in accordance with inappropriate standards or conformity with the required regulations is not examined, thus not all hazards arising during normal use are taken into account by the manufacturer.

Malta

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	4	3	5	3
2.	Number of substantiated complaints by industry concerning unfair competition	18	13	6	5
3.	Number of inspections (total number)	149	127	159	162
3.1	number of reactive inspections	25	20	75	94
3.2	number of self-initiated inspections	101	91	73	60
3.3	number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products				
5	Number of inspections resulting in:				
5.1	finding of non-compliance	89	84	108	112
5.2	corrective actions taken by economic operators ("voluntary measures")	33	37	44	43
5.3	restrictive measures taken by market surveillance authorities	27	6	7	7
5.4	application of sanctions/penalties				
6	Number of inspections where other Member States were invited to collaborate				

Information on communication activities carried out in the 2010-2013 period (optional)

No information

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

Toys are one of the priority product groups for the Market Surveillance Authority in Malta. Hence, these products feature prominently in the national market surveillance's annual programme. After an initial period of around 3 years in which economic operators were not fully aware of the operations of the market surveillance authority in Malta, and which resulted in a lack of action from the part of the operators to respond to findings by the surveillance authority, an increase in voluntary measures was encountered as awareness increased.

Netherlands

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

No information

Information on communication activities carried out in the 2010-2013 period (optional)

No information

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

In 2012 and 2013, 135 manufacturers and importers of toys were inspected, though it should be noted that some of these companies were trading in many different product groups. Much emphasis was placed on the contents of technical files. Many of the technical files were found to be still missing or incomplete.

From 2011 to 2014, 630 toy samples were examined in terms of their physical and mechanical safety. The focus is on toys for children under 3 years old and especially on combating the risk of choking.

In addition, various groups of toys (wooden and plastic toys, balloons, finger paints, fancy dress costumes, playhouses/tents and cuddly toys) were examined in terms of their chemical safety. Depending on the type of material, they were tested for plasticisers, heavy metals, AZO dyes, preservatives and nitrosamines. Fire safety was also inspected. To this end, tests were conducted to verify compliance with the requirements of Annex XVII to the REACH regulation and those of the GPSD. A general compliance level of 90 % was found. An inspection of the microbiological safety of cuddly toys did not reveal any deviations.

Austria

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	n.a.
2.	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.
3.	Number of inspections (total number)	592	461	702	579
3.1	number of reactive inspections	n.a.	n.a.	n.a.	n.a.
3.2	number of self-initiated inspections	n.a.	n.a.	n.a.	n.a.
3.3	number of inspections prompted by the customs	n.a.	n.a.	n.a.	n.a.
4	Number of inspections based on:	202	114	229	109
4.1	tests performed in laboratories	n.a.	n.a.	n.a.	n.a.
4.2	physical checks of products	n.a.	n.a.	n.a.	n.a.
5	Number of inspections resulting in:	Sampling and reviews together			
5.1	finding of non-compliance	n.a.	n.a.	n.a.	n.a.
5.2	corrective actions taken by economic operators ("voluntary measures")	n.a.	n.a.	n.a.	n.a.
5.3	restrictive measures taken by market surveillance authorities	n.a.	n.a.	n.a.	n.a.
5.4	application of sanctions/penalties	n.a.	n.a.	n.a.	n.a.
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

Information on communication activities carried out in the 2010-2013 period (optional)

Information on websites, booklets: Toy booklet produced by the Federal Ministry of Health as of 2009; second booklet produced in association with the Austrian Federal Economic Chamber (WKO) in 2011, both available on the homepage:

http://bmg.gv.at/home/Schwerpunkte/VerbraucherInnengesundheit/Spielzeug/Ratgeber_zur_Spielzeugwahl

Educational, informational and training events, particularly during 2010 and 2011 prior to the coming into force of the new Toy Safety Directive 2009/48/EC.

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

Market surveillance for goods subject to the Austrian Food Safety and Consumer Protection Act (LMSVG) – i.e. food, drinking water, food-contact materials (materials intended to come into contact with food), toys, and cosmetics – follows the indirect federal administration structure. The system of controls is described in the Food Safety Report (LMSB), which is produced annually.

Link:
https://www.verbrauchergesundheit.gv.at/lebensmittel/lebensmittelkontrolle/LMSicherheit.html

The Federal Ministry of Health coordinates the control and surveillance activities by producing an annual Inspection Plan (Sampling and Review Plan), which has to be adhered to by the relevant supervisory authorities in the federal provinces. The extent to which these requirements are met is set out in a comparison of target versus actual performance.

To ensure consistent surveillance and a risk-oriented approach, specially developed procedures are adhered to during the surveillance activities. Internal audits are also held at regular intervals to ensure compliance with the quality assurance system. In addition, in July 2014 a report was submitted to the responsible department of the Directorate-General for Enterprise and Industry, in accordance with Article 48 of the Toy Safety Directive 2009/48/EC.

The sector in Austria features many small and medium-sized businesses, predominantly retail companies. A large percentage of the products come to Austria from other Member States.

The LMSVG stipulates that products on the market must be inspected, as well as the businesses themselves; the number of breaches determined refers to the total of both types of inspections. The most common defect was incorrect labelling. The large degree of fluctuation results from there being a different focus of inspection each year (for example, cheap toys sold at fairs).

Poland

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	n.a.	249	188	209

		2010	2011	2012	2013
2.	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.
3.	Number of inspections (total number)	925	727	662	702
3.1	number of reactive inspections	n.a.	132	111	123
3.2	number of self-initiated inspections	n.a.	478	475	493
3.3	number of inspections prompted by the customs[269]	95	113	129	243
4	Number of inspections based on: [270]				
4.1	tests performed in laboratories	477	456	544	516
4.2	physical checks of products	925	727	662	702
5	Number of inspections resulting in:				
5.1	finding of non-compliance	512	364	369	383
5.2	corrective actions taken by economic operators ("voluntary measures")[271]	486	1082	1047	1016
5.3	restrictive measures taken by market surveillance authorities[272]	77	80	70	45
5.4	application of sanctions/penalties[273]	24	34	17	23
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

No information

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

Controls of toys were carried out by the Trade Inspectorate continually. In the years 2010 – 2013 controls covered 14670 products, challenging 5003 of them. Controls covered, among other things: soft stuffed toys, dolls, baby toys for watching, catching and/ or squeezing; art and handicraft materials and similar articles, books used in playing, costumes, fancy dress and

269 The number of opinions issued at the request of the customs authorities is given.
270 Estimate data. In case of some authorities the number of products is given.
271 The number of operations is given.
272 The number of measures applied is given.
273 The number of administrative decisions is given.

masks, toys for developing skills, toys found in foodstuffs, toys for playing in sand and in water, toys for playing in water, toys - equipment for sports games and balls, toys into which a child can enter, audiovisual equipment, construction toys and puzzles, sets for experimenting, functional toys, game sets, and mechanically and/or electrically propelled vehicles.

For the last few years there has been a noticeable trend on the Polish market of a similar proportion of toys queried in relation to toys which were in compliance with the requirements. Approximately one third of toys checked during a given calendar year are challenged.

Polish operators continue to have problems with correct age classification of toys. As a result, they put incorrect markings on toys, or do not even place any warnings essential for children's carers buying toys.

However, it should be stressed that instructions and warnings are easy to correct and operators have no problems with voluntarily following the recommendations of inspectors.

Another frequent irregularity is an indication of "adult supervision" being necessary. It should be noted that such supervision is necessary only in respect of toys whose use can be dangerous, e.g. functional toys, toys for keeping a child afloat, or chemical toys. Such a warning can mislead a parent making a purchase by suggesting dangers which do not actually arise.

The most frequent danger which has a direct impact on children's safety is the presence of small particles (whether they separate automatically or appear as a result of using a little force). In addition, tests performed every year indicate the presence of other serious risks which have a negative impact on children's' health. They include, for example, exceeding the admissible acoustic pressure level in toys emitting sounds (this creates a risk of damage, or even loss, of hearing), the presence of sharp and jagged edges (risk of injury or wounds), or the presence of chemical substances which have a negative impact on reproductive and hormonal systems (phthalates - in 2013, in every third sample tested the acceptable concentration level of these substances was exceeded).

There may be many reasons for these non-compliances. However, the most probable is the absence on the part of operators placing toys on the market, of sufficient knowledge of applicable provisions regarding the assessment of compliance. Regular checks by the Trade Inspectorate regarding correct assessment of compliance of toys with essential requirements raise the awareness of operators, in particular importers, indicating how important it is to check and confirm that goods placed on the market meet the relevant requirements.

Portugal

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	10	60	15	24
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	50	30	453	405
3.1	number of reactive inspections	43	30	133	261
3.2	number of self-initiated inspections	7	0	320	144
3.3	number of inspections prompted by the customs	0	0	0	0
4	Number of inspections based on:	0	0	0	0
4.1	tests performed in laboratories	0	0	59	0
4.2	physical checks of products	14	0	32	144
5	Number of inspections resulting in:	0	0	0	0
5.1	finding of non-compliance	7	0	75	34
5.2	corrective actions taken by economic operators ("voluntary measures")	n.a.	n.a.	n.a.	n.a.
5.3	restrictive measures[274] taken by market surveillance authorities	0	0	0	2
5.4	application of sanctions/penalties	0	0	59	26
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

[ASAE] With the publication of Directive 2009/48/EC, internal training activities were held for its inspectors, in which they were made aware of changes to the legislation on toy safety. Documentary inspection procedures, checklists and sample collection procedures were drawn up, so as to cover various types of toys, with the aim of creating an operating methodology for all cases covered by legislation.

274 Compulsory measures to prohibit or restrict the product being made available on the national market, to withdraw it or to recall it. These measures are taken when the economic operators did not follow up on a previous request from market-surveillance authorities to take corrective action, or where authorities have to intervene urgently.

The ASAE held an information session for secondary school pupils in February 2011. The session covered toys typical of the carnival season, with specific focus on their labelling and general principles of the CE marking and its meaning.

Following an invitation from Toy Industries of Europe (TIE), the ASAE participated as a speaker in the Seminar on Toy Safety held in Madrid in October 2012. This event, funded by the European Commission, was organised by TIE in collaboration with the Spanish Association of Toy Manufacturers (AEFJ). It was mainly aimed at Portuguese and Spanish economic operators representing various parts of the supply chain (manufacturers, importers and distributors) and testing laboratories.

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

[ASAE] The ASAE participated in a joint action called Joint Action 2010 'Children's Fancy Dress Project' organised by PROSAFE (Product Safety Forum of Europe) and supported by the European Commission. During this action, it collected 59 samples of Halloween and Carnival costumes. The greatest difficulty encountered related directly to the transitional period provided for in the legislation. The main difficulty regarded not impeding the making available on the market of toys which are in accordance with Directive 88/378/EEC and which were placed on the market before 20 July 2011. However, in Portugal, there are virtually no toy manufacturers and the number of importers is not significant, and so inspection actions related to distributors and retailers. The infringements detected related to the lack of labelling in Portuguese, the absence of a CE marking, noncompliance with distributor's duties, violation of the requirements relating to the EC declaration, violation of the rules and conditions on affixing the CE marking and the refusal of economic operators to submit documentation or information requested by the market-surveillance authority.

Romania

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	0	0	0	0
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	1207	1352	1592	1832
3.1	number of reactive inspections	0	1	5	8
3.2	number of self-initiated inspections	1205	1349	1583	1821

		2010	2011	2012	2013
3.3	number of inspections prompted by the customs	2	2	4	3
4	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	13	0
4.2	physical checks of products	1205	1349	1583	1821
5	Number of inspections resulting in:				
5.1	finding of non-compliance	954	1092	1256	1545
5.2	corrective actions taken by economic operators ("voluntary measures")	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities	670	817	891	898
5.4	application of sanctions/penalties	1058	1286	1433	1647
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

No information

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

No information

Slovenia

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	n.a.
2.	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.

		2010	2011	2012	2013
3.	Number of inspections (total number)	1905	1866	1715	1540
3.1	number of reactive inspections	505	468	281	227
3.2	number of self-initiated inspections	1345	1374	1396	1279
3.3	number of inspections prompted by the customs	n.a.	n.a.	n.a.	n.a.
4	Number of inspections based on:				
4.1	tests performed in laboratories	62	76	14	25
4.2	physical checks of products	1345	1374	1396	1279
5	Number of inspections resulting in:				
5.1	finding of non-compliance	303	204	275	231
5.2 5.3 [275]	corrective actions taken by economic operators ("voluntary measures") restrictive measures taken by market surveillance authorities	278	177	264	260
5.4	application of sanctions/penalties	79	31	99	99
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

Information on communication activities carried out in the 2010-2013 period (optional)

To facilitate the understanding and uniform application of the Directive by manufacturers, importers and distributors, at the end of 2010 the Slovenian Chamber of Commerce (TZS), in cooperation with the Ministry of Health, Health Inspectorate and the Institute of Public Health Maribor, organized an all-day conference "Presentation of innovations in the field Toy Safety Directive 2009/48/EC and, consequently, the Slovenian legislation". During the presentation there was also a general discussion with the participants of the conference. In order to facilitate the monitoring of the changes introduced by the Directive, as part of the obligations relating to economic operators that operate toys, such as in the field of security requirements, the Health Inspectorate collected all relevant information on web pages concerning the safety of toys, and prepared summaries of the most important content relating to the requirements of the Directive.

275 As the information system does not provide separate information on the number of inspections that result in corrective and restrictive measures based on the number of administrative (listed in pt. 5.2 and 5.3) and violation of measures (5.4) imposed, the number of checks which result in corrective and restrictive measures can only be inferred. On the basis of these it can be concluded that the trader takes the corrective measures identified in the majority of cases of non-compliance before the inspection procedure is completed, and determining whether further restrictive measures are necessary. The number of inspections that result in non-compliance being identified (5.1) does not include the identified inconsistencies in sampling activities. Also included in the number of measures are measures for non-compliant samples.

The meetings were organized by the Regional Chamber of Craft; we introduced legislation on the safety of toys.

As a result of the European information seminar on the safety of toys in 2012, the Inspectorate in the field of toys published a translation of frequently asked questions on the website:

http://www.zi.gov.si/si/storitve/gospodarski_subjekti/varnost_igrac/pogosto_zastavljena_vprasanja

The website of the Inspectorate includes publicly available information on topical issues (eg. Used toys, toys sold online, puzzle, amber necklaces ...). The Health Inspectorate's website http://www.zi.gov.si/si/delovna_podrocja/varnost_igrac (and links) contains all the information on the safety of toys aimed at economic operators and consumers.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)[276]	6565372	5813788	5171789	4982892
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.066	0.060	0.057	0.051
8	Staff available to market surveillance authorities (full-time equivalent units)[277]	135	133	134	129
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)[278]	112	110	110	109

B. Assessment of the functioning of market surveillance activities in the sector

Inspections on the safety of toys take place in the context of regular and special inspections. Further monitoring is carried out by sampling. The frequency of periodic audits is determined on the basis of a risk assessment that takes into account the nature and scope of activities or facilities that are checked, in relation to the requirements, and changes in regulations and topical issues, taking into account as well the available resources of the inspectorate. A special form of emergency controls are those that are carried out where non-compliance has been identified.

Monitoring also takes place in the context of the various actions which focus on changes each year depending on the results of the checks in previous years, changes to regulations in the field of potential new risks and the latest knowledge of the profession. In addition, health inspectors carry out surveillance in kindergartens.

276 Overall authority budget.
277 Number of employees instead of full-time equivalent units
278 Total number of inspector instead of full-time equivalent units

Control of toys that, prior to the enactment of the new Directive were mainly based on the control of the product, has passed to the control of management of the quality assurance system of production of toys, and the monitoring of their safety on the market all the way to the consumer. This approach enables the efficient functioning of market surveillance authorities.

Slovenia has only a small proportion of producers and importers of toys, and therefore the imposition of the measures in relation to the responsibilities of distributors rather limited. In the case of unsafe products information on the RAPEX system is provided, but no feedback on the results of the control of the manufacturers / importers in countries where these companies have their headquarters.

Slovak Republic

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	4	19	18	13
2.	Number of substantiated complaints by industry concerning unfair competition	37	82	107	76
3.	Number of inspections (total number)	1937	1736	1351	1044
3.1	number of reactive inspections	996	1084	923	720
3.2	number of self-initiated inspections	941	652	399	312
3.3	number of inspections prompted by the customs	n.a.	n.a.	29	12
4	Number of inspections based on:				
4.1	tests performed in laboratories	255	113	140	129
4.2	physical checks of products	1682	1623	1211	915
5	Number of inspections resulting in:				
5.1	finding of non-compliance	909	547	846	33
5.2	corrective actions taken by economic operators ("voluntary measures")	n.a.	n.a.	n.a.	n.a.
5.3	restrictive measures taken by market surveillance authorities	n.a.	n.a.	n.a.	n.a.
5.4	application of sanctions/penalties	80	80	80	80

		2010	2011	2012	2013
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

Information on communication activities carried out in the 2010-2013 period (optional)

Trade Inspectorate activities in the field of information and other communication activities are described in the report on the evaluation of the application of Directive 2009/48/EC on toy safety, prepared and sent, on request, to the European Commission in July 2014.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)	n.a.	n.a.	n.a.	n.a.
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	n.a.	n.a.	n.a.	n.a.
8	Staff available to market surveillance authorities (full-time equivalent units)	n.a.	n.a.	n.a.	n.a.
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	25	25	25	25

B. Assessment of the functioning of market surveillance activities in the sector

The Trade Inspectorate is Slovakia's only surveillance authority for toys. Inspections are conducted to a high standard. The Trade Inspectorate systematically and annually organises nationwide inspection actions and periodic sampling to verify safety. As there are only a few small toy manufacturers (wooden and fabric toys) in Slovakia, inspections focus mainly on distributors and importers from third countries. Inspections mainly centre on economic operators of Chinese origin established in Slovakia. Particulars concerning inspections (set out in more detail), and related surveillance problems faced by the Trade Inspectorate, are described in the report on the evaluation of the application of Directive 2009/48/EC on toy safety, prepared and sent, on request, to the European Commission.

Finland

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	28	14	31	25
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	1507 792 (T) 715 (C)	1351 698 (T) 653 (C)	1739 906 (T) 833 (C)	808 81 (T) 727 (C)
3.1	number of reactive inspections	43 (T)	19 (T)	43 (T)	49 (T)
3.2	number of self-initiated inspections	34 (T)	26 (T)	30 (T)	41 (T)
3.3	number of inspections prompted by the customs	0	0	0	0
4	Number of inspections based on:				
4.1	tests performed in laboratories	706 26 (T) 680 (C)	636 29 (T) 607 (C)	777 28 (T) 749 (C)	808 41 (T) 672 (C)
4.2	physical checks of products	36 1 (T) 35 (C)	47 1 (T) 46 (C)	 84 (C)	60 5 (T) 55 (C)
5	Number of inspections resulting in:				
5.1	finding of non-compliance	229 29 (T) 200 (C)	190 10 (T) 180 (C)	203 26 (T) 177 (C)	189 25 (T) 164 (C)
5.2	corrective actions taken by economic operators (“voluntary measures”)	28 (T)	8 (T)	25 (T)	18 (T)

		2010	2011	2012	2013
5.3	restrictive measures taken by market surveillance authorities	160 1 (T) 159 (C)	138 2 (T) 136 (C)	73 1 (T) 72 (C)	109 7 (T) 102 (C)
5.4	application of sanctions/penalties	0	0	0	0
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

Tukes gives press releases and publishes the results of market surveillance activities and other remarks it has made while carrying out market surveillance. During 2010-2013, a total of 9 press releases (1-3 each year) were published based on the Toy Safety Directive.

Tukes also informs consumers, businesses and other stakeholders about changes in legislation or safety requirements. When necessary, training and lectures are provided for associations, schools and other stakeholders.

Tukes also gives guidance to consumers, businesses, and other stakeholders by answering their questions via phone and email. Tukes is also active in the social media and uses its channels to spread information on dangerous products, risks, project results and other issues. Tukes constantly looks for new ways to inform the public and the stakeholders about safety issues.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)	780000 230000 (T) 550000 (C)	780000 230000 (T) 550000 (C)	780000 230000 (T) 550000 (C)	780000 230000 (T) 550000 (C)
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.002	0.002	0.001	0.001
8	Staff available to market surveillance authorities (full-time equivalent units)	13 3 (T) 10 (C)	13 3 (T) 10 (C)	13 3 (T) 10 (C)	13 3 (T) 10 (C)
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	12 2 (T) 10 (C)	12 2 (T) 10 (C)	12 2 (T) 10 (C)	12 2 (T) 10 (C)

B. Assessment of the functioning of market surveillance activities in the sector

Market surveillance programs have been carried out as planned. Programs include 1-3 current projects (topics vary yearly). Despite the relatively small resources Tukes has been effective, and 38 recalls and 20 withdrawals have been done during 2010-2013.

Sweden

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	32	13	21	35
2.	Number of substantiated complaints by industry concerning unfair competition				
3.	Number of inspections (total number)	52	37	117	130
3.1	number of reactive inspections	39	19	35	43
3.2	number of self-initiated inspections	10	14	77	77
3.3	number of inspections prompted by the customs	3	4	5	10
4	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	15	0
4.2	physical checks of products	18	10	61	88
5	Number of inspections resulting in:				
5.1	finding of non-compliance	19	23	113	124
5.2	corrective actions taken by economic operators (“voluntary measures”)	13	13	21	35
5.3	restrictive measures taken by market surveillance authorities	0	2	12	3
5.4	application of sanctions/penalties	0	0	0	1
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

In 2012 and 2013, the three market surveillance authorities in Sweden, the Swedish Consumer Agency, Kemikalieinspektionen [the Swedish Chemicals Agency] and the National Electrical Safety Board cooperated on a joint project. In the joint authority project in 2012-2013, contacts were built up with the Swedish trade associations, Barn och baby [Children and Baby], PUFF (Företagare-Föreningen för grossister och tillverkare inom present-, interiör- och designbranschen) [Company Owners-Association of wholesalers and manufacturers of gift, interior and design products) and Svensk dagligvaruhandel [the Association of Swedish Grocery Retailers]. The Swedish Consumer Agency has an established collaboration with Leksaksbranschen [the Swedish Toy Association]. These industry associations have helped to disseminate information on training courses, market surveillance and other information that the authorities wished to issue. During the joint authority project, there has also been closer cooperation with the Swedish Toy Association, since they have acted as a sounding board for the development of information material.

Through the training courses held within the framework of the joint authority project, an e-mail list was built up with over 100 recipients wishing to have information on toy safety from the authorities. The authorities did not obtain all these recipients via the industry associations. Other interested parties have also taken part in the training sessions for the industry such as SIS [the Swedish Standards Institute], Swerea IVF, the IKEM [Innovation and Chemical Industries in Sweden] industry association (formerly the Swedish Plastics and Chemicals Federation), Leksaksbranschen [the Swedish Toy Association], Naturvårdsverket [the Swedish Environmental Protection Agency] and Läkemedelsverket [the Swedish Medical Products Agency].

The Swedish Consumer Agency has deliberately prioritised work on information for economic operators for the 2011-2014 period, and for that reason no general information campaign aimed at consumers has been conducted. Nevertheless, a training course on the dangers of magnets in toys was carried out for consumer guidance in 2012. This took place in advance of market surveillance of magnets in toys and other products.

The Swedish Consumer Agency and the Swedish Chemicals Agency presented a paper, along with other authorities, at a European Commission information campaign organised by TIE and the Swedish Toy Association in Malmö in 2012.

In 2012 and 2013, the three market surveillance authorities in Sweden cooperated on a joint project.

The joint authority project in the 2012-2013 period included a sub-project on proactive work. In this sub-project, the three authorities reviewed their information on each authority's website. The Swedish Chemicals Agency has developed a new website that deals with legislation relating to toys in various ways. The Swedish Consumer Agency has also produced new pages on its website in order to clarify the information on the new legislation. The National Electrical Safety Board also has a site describing its procedures on toy supervision. These three websites link to one another in the hope that this will make it easier for companies to search for information on toy safety regulations. During the course of the project, the Swedish Consumer Agency's website on toy safety was visited 6887 times (unique page views).

Printed information material aimed at companies has also been produced. This material clarifies companies' responsibilities as regards toy safety according to their role in the supply chain. The material is entitled "Ansvarsroller för leksakers säkerhet" [Roles and responsibilities for toy safety] and consists of a playing card and three leaflets. The card is intended to help determine a company's roles and responsibilities according to the circumstances for each toy. The card contains a question on one side, for example: "What is my role if I buy toys from a company in Sweden or another EU country?" The other side of the card contains the answer: "Distributor". When the company's role for the toy in question has been determined using the guide on the playing card, more information on the responsibilities deriving from that role can be obtained from one of the three leaflets. The three brochures provide information on the responsibilities of manufacturers, importers and distributors and summarise the requirements established for each role. The information material is available in printed format from the three authorities, but can also be downloaded from the Swedish Consumer Agency's website.

During the work on the project, companies requested more information from the authorities, including a checklist of the rules applying to a toy. On the basis of those requests, the authorities produced joint information material entitled "Är leksaken säker?" [Is the toy safe?] The material is largely based on a "mind-map" and highlights the different regulations with which a toy must comply. The information material is available for download from the Swedish Consumer Agency's website.

During year two of the project, what was, for the authorities, a new way of working with information was used. The three authorities produced a joint information letter about the new rules on toy safety. The letter contained some basic information on requirements for toys and market surveillance, as well as information on market surveillance to be carried out in 2013. The information letter was sent to approximately 300 companies identified as toy dealers using the authorities' own records and import statistics on toys from Swedish Customs. The letter was distributed to members of five industry associations: the Swedish Toy Association, Children and Baby, the Association of Swedish Grocery Retailers, the Swedish Trade Federation and PUFF (Company Owners-Association of wholesalers and manufacturers of gift, interior and design products).

Two training sessions for companies and other operators in the toy industry were organised in the project in collaboration with the industry association the Swedish Toy Association. One occasion in autumn 2012, when the training course had a duration of three days, and one occasion in spring 2013, when the training course had a duration of one and a half days. After the end of the project (May 2014) a further training session of one and a half days was arranged jointly by the authorities and the Swedish Toy Association. Training consisted of presentations on the new rules on toy safety and market surveillance carried out by the three market surveillance authorities for toys. The Swedish Medical Products Agency, the Swedish Environmental Protection Agency, SIS (the Swedish Standards Institute), Swerea IVF, the IKEM [Innovation and Chemical Industries in Sweden] industry association (formerly the Swedish Plastics and Chemicals Federation) also took part. The industry also participated with presenters describing how to work with the requirements in practice. Time at the training sessions was also set aside for questions. The companies were able to give notice of questions in advance. The training materials entitled "Roles and responsibilities for toy safety" and "Is the toy safe?" were distributed to the companies along with additional information material on the EC declaration of conformity and labelling of toys, the requirements regarding chemicals and the Commission's brochure on the Toy Safety Directive. Participation in the training sessions was high, with 80-100 persons per session on the seven training days. The feedback

received from the participating companies showed that they considered the training sessions to be good and they requested [...] In order to compile information from the training sessions for the companies taking part and to enable information from the training sessions to be distributed to more companies, special websites were created after the various training sessions where presentations from the training session, as well as questions and answers from the question and answer session, were published.

Links to the training session websites were also posted on the Swedish Consumer Agency website.

The addresses for these websites are:

http://www.eko.kov.se/Leksakerssakerhet/,

http://www.eko.kov.se/Leksakerssakerhet2013/ and

http://www.leksaksbranschen.se/index.php/om-leksaksbranchen/utbildning-i-leksakerssakerhet-14-15-maj-2014.Since the Swedish law on toy safety also covers public activities in Sweden, a letter on the new rules on toy safety was sent to SKL (Sveriges Kommuner och Landsting – the Swedish Association of Local Authorities and Regions). SKL then produced information for its members, with the support of the Swedish Consumer Agency.

That information was also submitted to the Commission, within the framework of supervision of the Directive, in a separate report on the application of the Toy Safety Directive.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)	176800	154300	170365	213100
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	n.a.	n.a.	n.a.	n.a.
8	Staff available to market surveillance authorities (full-time equivalent units)	2.4	2.0	2.2	2.8
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	0.3	0.3	0.3	0.3

B. Assessment of the functioning of market surveillance activities in the sector

There are toys on the Swedish market that do not comply with the applicable safety requirements for toys. Continued market surveillance of toy safety is therefore necessary, both to remove dangerous toys from the market and to disseminate information to companies.

The total value of toys supplied to the Swedish market each year is around 4 billion Swedish kronor. It is estimated that 300 companies import toys to Sweden. It is estimated that there are 200 manufacturers. The number of operators other than manufacturers can be roughly

estimated at over 400. It is difficult to estimate the number of outlets for toys on the market, but there are probably more than 10 000. In addition, there are on-line operators that are not registered in Sweden.

Most toys are manufactured in Asia. During visits to companies it was found that a common way to buy toys is via trading houses or "traders", who in turn have contacts with various factories. Therefore, those purchasing through a trading house or a trader often do not come into direct contact with the manufacturer. This can make the establishment of requirements and communication between the customer and the manufacturer more difficult.

Purchasing via a trading house should not constitute an obstacle to supplying only safe toys. The economic operators have a great responsibility for checking the toys delivered to them and to require that the toys should comply with applicable requirements. It was revealed during visits to companies that several companies have a poor knowledge of the rules on toys, and this naturally makes it more difficult for them to impose requirements on the suppliers.

Nor were many companies aware of their responsibilities according to whether they have manufactured, imported or purchased the toy on the internal market. They were aware that there are differences in terms of responsibility and they considered that the manufacturer should have the greatest responsibility. Having greater knowledge of their own and other operators' responsibility in the supply chain should make it easier for requirements to be imposed between operators.

Toys are heavily regulated products. With the large number of rules applying to toys, there should be a system at each company for imposing requirements on and communicating with suppliers. Many companies lack such a system.

United Kingdom

A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of inspections		1665	1299	
2.	Number of inspections concerning products sold over the internet		92	62	
3.	Number of products inspected		45517	8806	
4.	Number of products tested in labs		696	570	
5.	Number of non-compliant products found on the market		2195	955	
6.	Number of dangerous products posing a serious risk		353	149	
7.	Number of administrative decisions taken		561	36	

		2010	2011	2012	2013
8.	Number of products withdrawn from the market		690	67	
9.	Number of products recalled from the market		8	33	
10.	Number of decisions taken by authorities in charge of external border controls to suspend products at the border			160	
11.	Number of decisions to reject products at the border				
12.	Number of products destroyed		827	451	
13.	Number of voluntary measures taken by companies		347	76	
14.	Number of voluntary withdrawals		135	34	
15.	Number of voluntary recalls		32	28	
16.	Number of sanctions imposed		18	37	
17.	Number of total pieces of advice offered to all in supply chain			335	

Information on communication activities carried out in the 2010-2013 period (optional)

No information

Information on resources (subject to availability)

No information

B. Assessment of the functioning of market surveillance activities in the sector

Trading Standards are part of Local Authorities, of which there are over 200 in the UK. Each local authority acted independently setting its own priorities. The "Home Authority" principle operates among local authorities.

The Home/Lead Authority Partnerships helped councils to work together effectively and avoid duplication of effort when regulating businesses who trade across local council boundaries, and support them by providing contact points for advice and guidance in order to maintain high standards of public protection and develop a consistent approach to enforcement. Further details of Trading Standards market surveillance activities have been described in this document.

In relation to the Toy Safety Directives, the UK provided two reports to the European Commission in 2014 which gave accounts of how they applied the Directives. The two reports were the Questionnaire on the Application of Article 51 of the Directive and on its application.

BIS are encouraging authorities to look at more ambitious strategic projects and projects which involve authorities working in partnership to deliver the outputs. Project proposals should be for products which have been placed on the market i.e. not products intercepted at ports. As before, there is separate funding for testing products at ports via the National Trading Standards Board (NTSB). BIS requires in return a report covering the activities and the analysis of the outcomes. BIS will expect the outputs from successful projects to be made available for all UK Trading Standards Departments via the NTSB Information Hub and other interested bodies.

BIS is also continuously reviewing the UK market surveillance structure with its relevant stakeholders and MSAs. From a workshop organised by BIS earlier in 2014 with these bodies, BIS asked representatives of UK MSAs for their views such as improving enforcement, more effective communication, funding and training. The workshop informed a follow-up exercise where a questionnaire, based on break-out session outcomes, was sent to those who attended. The outputs from these activities have now been summarised by BIS with priority actions identified on how BIS will work together with UK MSAs to improve how the UK's market surveillance regime operates. In late 2014, BIS commenced an independent review of the UK's consumer product recall system and will expect a report to be with BIS Ministers in autumn 2015.

ANNEX 10: ORGANISATION OF MARKET SURVEILLANCE OUTSIDE THE EU

1. AUSTRALIA

Principal website: www.productsafety.gov.au

Legislative framework

The legislative framework in Australia is established in the *Competition and Consumer Act 2010* (CCA), which incorporates the Australian Consumer Law (ACL) at Schedule 2. This legislation gives the Commonwealth Minister the power to set standards, impose interim and permanent bans and order compulsory recalls. It also establishes two notification requirements (for recalls and serious injuries, illnesses and deaths), a consumer guarantees regime which includes a requirement that goods be of acceptable quality including being safe; and a product liability regime (giving consumers a right of action for losses where goods are not safe). State and territory ministers have the power to create short interim bans and compel suppliers to recall goods. The CCA is administered by the Australian Competition and Consumer Commission (ACCC), jointly with state and territory consumer agencies.

Web reference: www.austlii.edu.au/au/legis/cth/consol_act/caca2010265

How are the rules for product requirements set?

Where there are safety concerns about consumer goods a mandatory standard can be imposed. Mandatory standards are regulations made by the Commonwealth Minister who is advised by the ACCC. Mandatory standards often draw on Australian voluntary standards or may draw from international standards. Australian Standards are not legal requirements in Australia unless they are 'called up' through regulations. In addition some Australian bans prohibit goods that do not meet certain requirements (rather than prohibiting sale completely)—see below.

Web reference: www.productsafety.gov.au/mandatorystandards

How are goods prohibited from sale for safety reasons?

Unsafe goods can be prohibited from sale in Australia through the imposition of a ban. Bans can be interim (lasting 60–120 days) or permanent. Permanent bans are imposed by the Commonwealth Minister on advice from the ACCC. Commonwealth, state and territory ministers are able to impose interim bans.

Web reference: www.productsafety.gov.au/bans

Are there notification requirements?

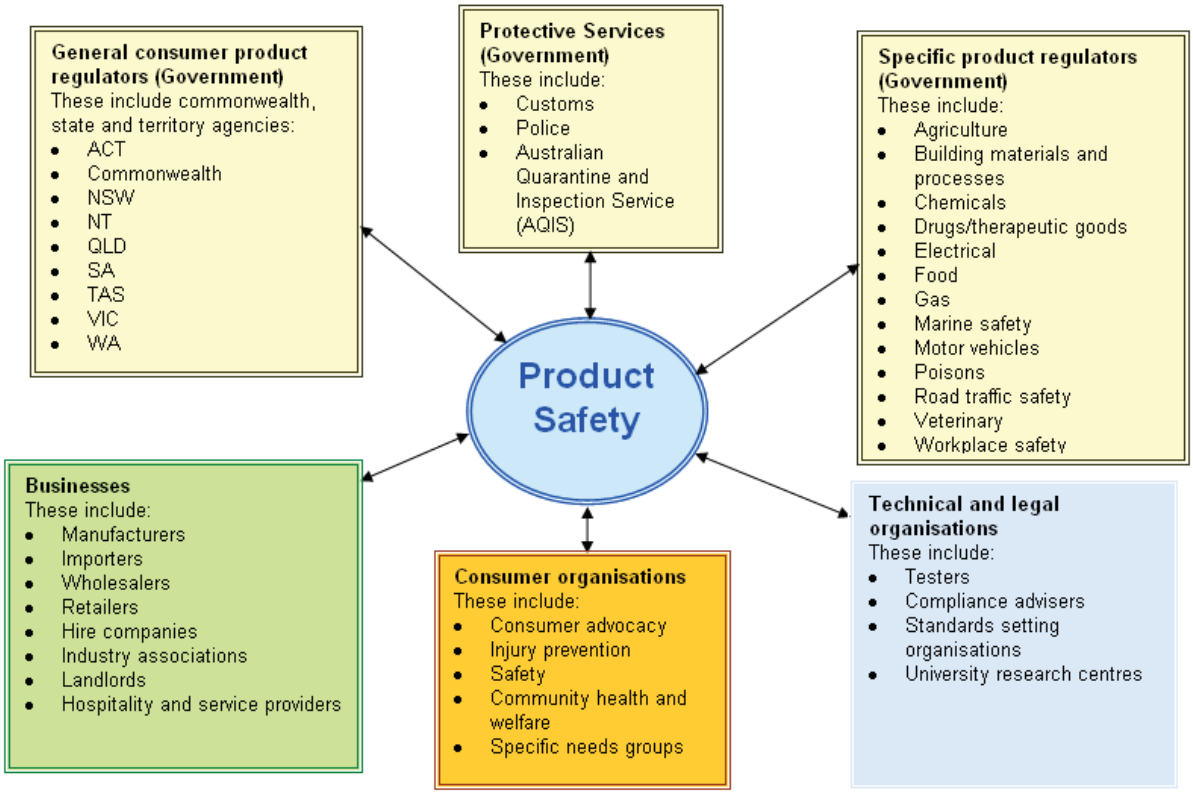
There are two mandatory notification requirements in Australia. Suppliers are required to notify the Commonwealth Minister of a recall within two days of initiating the recall. Suppliers are also required to notify the Commonwealth Minister within two days of becoming aware of a serious illness, injury or death caused by the use of a product they sell. Both notifications can be made via online forms on ACCC websites.

Web references: www.productsafety.gov.au/recalls; www.recalls.gov.au

Are there likely to be any changes to regulatory arrangements?

The ACL will be reviewed by 2018. Regulations are frequently developed and reviewed. Information on changes is available on the Product Safety Australia website.

Organisation chart



2. CANADA

Legislative framework

The legislative framework in Canada is established in the *Canada Consumer Product Safety Act* (CCPSA). The Act sets out general requirements and powers, and contains a provision to make regulations. There are currently over 30 regulations under the CCPSA that outline more specific requirements for certain consumer products and/or hazards. In addition, the Act contains a schedule of prohibited consumer products (Schedule 2).

The CCPSA is administered by Health Canada, specifically the Consumer Product Safety Program. Note that cosmetics, which are subject to the *Cosmetic Regulations under the Food and Drugs Act*, are also administered by the Program.

Web reference:

http://laws-lois.justice.gc.ca/eng/acts/C-1.68/index.html

http://laws-lois.justice.gc.ca/eng/acts/F-27/index.html

How are the rules for product requirements set?

The CCPSA modernised Canada's product safety system and introduced new tools to prevent or address dangers to human health or safety posed by consumer products. These include powers to order corrective measures or mandatory product recalls, and an administrative

monetary penalties scheme with fines up to CDN$25,000 per day for non-compliance with an order.

The CCPSA contains a general prohibition against the manufacture, import, advertisement or sale of consumer products that are a danger to human health or safety.

It also includes other prohibitions against the manufacture, import, advertisement or sale of consumer products that are prohibited or that do not meet regulatory requirements.

For some consumer products, specific product requirements are set out in regulations. Such regulations may outline specifications or make reference to an existing standard. Standards that are incorporated by reference in regulations are considered to be 'mandatory standards'. In the case where there are no regulations set out for a specific product, suppliers may look to an available health and/or safety standard as part of their due diligence. Suppliers may also look to published guidelines from Health Canada or another relevant organization (e.g. regulators in other jurisdictions, industry associations, etc.).

How are goods prohibited from sale for safety reasons?

Orders for mandatory recall can be made for consumer products where the Minister believes on reasonable grounds that they pose a danger to human health and safety.

This determination of whether a consumer product poses a danger to human health or safety is informed by risk assessments, through inspections, product testing or lab reports, and/or professional judgement from the Consumer Product Safety Program, among other considerations.

While there are a number of enforcement powers in the CCPSA to address dangers to human health and safety (including product specific regulations), the Program usually takes a step-wise approach to enforcement where appropriate, first considering voluntary measures.

Are there notification requirements?

A person who manufactures imports or sells a consumer product for commercial purposes must report incidents to Health Canada. Incidents are defined as any occurrence, defect, characteristic, or incorrect or insufficient labelling that resulted or may reasonably have been expected to result in death, serious injury or serious adverse health effects. Incidents also include recalls or other measures initiated by another jurisdiction for health and safety reasons.

Such incidents must be reported to Health Canada and the manufacturer within two days. A manufacturer (or if the manufacturer carries on business outside Canada, an importer) of a product that is involved with a reportable incident in Canada is also required to submit to Health Canada a more detailed written report. This report must be submitted within ten days after the day on which they became aware of an incident unless Health Canada specifies a different timeframe

Health Canada's website: http://www.hc-sc.gc.ca/cps-spc/legislation/acts-lois/ccpsa-lcspc/indust/guide-reporting-declaration/index-eng.php

Are there likely to be any changes to regulatory arrangements?

Federal government departments and agencies are required to make their forward regulatory plans publicly available on their websites annually; Health Canada's Forward Regulatory Plan provides information on planned and potential regulatory initiatives that Health Canada expects to bring forward over the next two years. It is intended to give consumers, business, other stakeholders and trading partners greater opportunity to inform the development of regulations and to plan for the future. This Plan will be adjusted and updated over time as Health Canada's operating environment also changes over time. A list of Government-wide forward regulatory plans is also available on the Treasury Board of Canada Secretariat's website.

Web reference:

Treasury Board of Canada Secretariat's website: http://www.tbs-sct.gc.ca/rtrap-parfa/plan-eng.asp

Health Canada's website: http://www.hc-sc.gc.ca/ahc-asc/legislation/acts-reg-lois/frp-ppr/2016-2018/index-eng.php

3. JAPAN

Legislative framework

In Japan, Consumer Product Safety Act which is administrated by Ministry of Economy, Trade and Industry (METI) and Consumer Affairs Agency (CAA) gives a framework for collecting and publishing information of product accidents.

METI designates products which are considered to have higher possibilities of causing hazards respectively as positive lists and sets technical requirements on them under Consumer Product Safety Act and other regulation acts including Electrical Appliances and Materials Safety Act, Gas Business Act and Act on the Securing of Safety and the Optimization of Transaction of Liquefied Petroleum Gas (hereafter referred to as "LP Gas Act").

Web references:

Consumer Product Safety Act (Collection and Publication of Product Accident Reports, only in Japanese): http://www.meti.go.jp/product_safety/producer/point/04-1.html

Consumer Product Safety Act (Technical Requirements on Designated Products, only in Japanese):
http://www.meti.go.jp/policy/consumer/seian/shouan/index.htm?PHPSESSID=e7aa1

Electrical Appliances and Materials Safety Act:

http://www.meti.go.jp/english/policy/economy/consumer/pse/index.html

Gas Business Act(Only in Japanese): http://www.meti.go.jp/policy/consumer/seian/gasji/

LP Gas Act(Only in Japanese): http://www.meti.go.jp/policy/consumer/seian/ekiseki/

How are the rules for product requirements set?

Under Consumer Product Safety Act, Electrical Appliances and Materials Safety Act, Gas Business Act and LP Gas Act, METI designates products which are considered to have higher possibilities of causing hazards as positive lists and sets technical requirements respectively on them.

Manufacturers and importers are obliged to confirm their products to be conformable to the technical requirements (as well as to conduct self-inspections) and affix prescribed labels (PS marks) on them as well as certifications of their conformity.

As for "Specified Products" which are considered to have especially higher risks, manufacturers and importers are obliged to undergo conformity assessment tests conducted by conformity assessment bodies registered with the government.

In 2014, as for electrical appliances and materials, METI revised the technical requirements from "specification-based" descriptions where the government defines detailed specifications of dimensions, shapes and materials etc. of every item to "performance-based" descriptions where the government only defines essential safety performances.

The similar revisions will be conducted for City Gas and LP Gas equipment and appliances in early 2016.

How are goods prohibited from sale for safety reasons?

As for Consumer Product Safety Act, under certain conditions including cases where serious product accidents have occurred due to defects in the consumer products or where serious danger has occurred to the lives or bodies of consumers or the occurrence of such danger is considered to be imminent, the competent minister may order manufacturers and importers to recall the consumer products and to otherwise take measures necessary to prevent the occurrence and increase of serious danger to the lives or bodies of consumers.

Additionally, as for Consumer Product Safety Act, Electrical Appliances and Materials Safety Act, Gas Business Act and LP Gas Act, the Minister of Economy, Trade and Industry may order manufacturers and importers to collect the consumer products or to take any other necessary measures to prevent the spreading of the hazards or interference caused by the products. Also, under certain conditions where manufacturers and importers violate technical requirements or other necessary regulations to be preserved, the Minister of Economy, Trade and Industry may prohibit manufacturers and importers from affixing labels (PS marks) to their products, which substantively represents prohibition of sales.

Web reference:

http://www.meti.go.jp/product_safety/producer/system/06.html (only in Japanese)

Are there notification requirements?

Manufacturers and importers of designated products under Consumer product Safety Act, Electrical Appliances and Materials Safety Act, Gas Business Act and LP Gas Act shall notify the Minister of Economy, Trade and Industry of their names and classifications of their products.

Also, under Consumer Product Safety Act, manufacturers and importers of consumer products who are responsible for consumer products distributed in Japan are obliged to report

to the government (Consumer Affairs Agency) within 10 days when they come to know serious product accidents have occurred with their consumer products. When sellers come to know the fact, they are required to notify manufacturers and importers.

Web references:

Notifications of Businesses (only in Japanese):
http://www.meti.go.jp/product_safety/producer/system/02.html

Reports of Serious Product Accidents (only in Japanese):
http://www.meti.go.jp/product_safety/producer/point/04-1.html

4. SOUTH KOREA

Legislative framework

The Framework Act on Product Safety (2013) and the individual acts according to product characteristics such as Quality Control and Safety Management of Industrial Products Act and Electrical Appliances Safety Control Act have the provisions to protect consumers from the risk of consumer products. Each law allows for the ban of products which may cause any danger or harm to consumers and the withdrawal of the products.

Also, the *Framework Act on Consumers* (2012) stipulates the surveillance by collecting injury data of every consumer goods regardless of types. According to the law, the authorities can propose or order a recall, a withdrawal on the products which don't have the safety standards to satisfy, if necessary to businesses.

Web reference:

www.kca.go.kr/web/img/kca/eng/laws/Framework_Act_on_Consumers.pdf

How are the rules for product requirements set?

The safety standards for consumer safety are established after promulgation and acceptance of opinions in accordance with *Administrative Procedures Act.*

How are goods prohibited from sale for safety reasons?

If the consumer products pose any danger or harm or do not conform to the safety standards, the goods can be prohibited according to the relevant provisions of the laws.

Moreover, regardless of product characteristics, the Framework Act on Consumers forbids products which are dangerous or are deemed to pose harm to consumers.

Web reference:

www.kca.go.kr/web/img/eng/10_1%20FRAMEWORK%20ACT%20ON%20CONSUMER.doc (see Articles 46 to 50), http://www.smartconsumer.go.kra, www.safetykorea.kr

The website provides information on quality comparisons and recall of all items.

Are there notification requirements?

Framework Act on Product Safety states that if any enterprise has found that there exist any seriously defective goods, it must report the defects to the head of the competent central administrative agency (including electronic report). In that case, the retailer should report about the defect of the products which do not have any standards to conform to the director as well. Other necessary matters which the enterprise is required to report can be determined by the Presidential Decree.

Web reference:

www.kca.go.kr/web/img/eng/10_1%20FRAMEWORK%20ACT%20ON%20CONSUMER.doc (see Article 47), http://www.smartconsumer.go.kra ,http://www.safetykorea.kr

The website provides information on quality comparisons and recall of all items.

Are there likely to be any changes to regulatory arrangements?

None

5. NEW ZEALAND

Legislative framework

Part 3 of the *Fair Trading Act 1986* (FTA) provides the Minister of Consumer Affairs with the power to ban products, set standards through regulation and order compulsory recalls. The *Consumer Guarantees Act 1993* also provides a civil 'guarantee' that consumer goods are safe. The FTA is administered by the Ministry of Business Innovation and Employment (MBIE) and enforced by New Zealand Customs Services and by the Commerce Commission post importation. These provisions cover all consumer products with the exception of food, gas and electrical products, motor vehicles and cosmetics that are regulated by other agencies under product specific legislation.

Web reference:

http://www.consumeraffairs.govt.nz/for-business/compliance/product-safety/requirements-for-importers-and-retailers

How are the rules for product requirements set?

MBIE draws on consumer complaints, marketplace sampling/testing and data and intelligence sourced from other organisations within New Zealand and overseas. The Minister is able to take action that ranges from interim bans of a product through to permanent regulations. The basis for the majority of these provisions are published standards. The preference is for New Zealand or joint Australia/New Zealand standards, the majority of which directly relate to the equivalent ISO standards.

Web reference:

http://www.consumeraffairs.govt.nz/for-business/compliance/product-safety/requirements-for-importers-and-retailers

How are goods prohibited from sale for safety reasons?

The unsafe goods notice provisions are the most frequent means of banning unsafe products. They provide for an 18 month interim ban after which the ban can be made permanent. The Minister of Consumer Affairs can rescind or amend the unsafe goods notice within that 18 month period.

Web reference:

http://www.consumeraffairs.govt.nz/for-business/compliance/product-safety/requirements-for-importers-and-retailers

Are there notification requirements?

No notification requirements are in force at present (but we see below) but in many cases, voluntary prior contact is made with MBIE by businesses contemplating a recall.

Web reference:

http://www.consumeraffairs.govt.nz/for-business/compliance/product-safety/recalls

Are there likely to be any changes to regulatory arrangements?

The Consumer Law Reform Bill (CLRB) is anticipated to be enacted within the next few months and once implemented will provide additional regulatory options including:

- enabling the Minister to issue product safety policy statements that whilst not compulsory are aimed at being persuasive and seek marketplace correction
- introducing compulsory notification of product recalls to MBIE
- giving additional powers for product safety officials.

http://www.consumeraffairs.govt.nz/legislation-policy/policy-development/consumer-law-reform?searchterm=Consumer+Law+Reform

6. UNITED STATES

Federal Government

- Federal government agencies vary in their methods and authorities for market surveillance of compliance
- Some agencies (e.g. NHTSA, CPSC) spot-check in the market by purchasing products randomly and testing them for compliance. These agencies can also conduct audits of manufacturers, either by inspection or written documentation reviews
- Some agencies (e.g. FDA) have a more European-style pre-market type approval process
- Some agencies (e.g. NHTSA, FDA) have incident reporting requirements
- Federal Trade Commission (FTC) monitors and enforces false advertising claims and

unfair competition claims

- All agencies can assess severe penalties for non-compliance with regulations

State Government

- Mote states have "FTC Acts" that authorize investigations and litigation against product manufacturers for false advertising or "unfair" trade practices
- Some states in the US have separate Consumer Protection Bureaus or Agencies; others enshrine this function within the Attorney General's office
- Some Federal statues (e.g. Consumer Product Safety Act) confer shared authority for safety regulatory enforcement with the State agencies

Industry Competitors

- Lanham Act: Federal law authorizing competitors to sue a company for false advertising.
- It has been used to challenge unsupported advertising claims and other forms of false advertising that are alleged to have harmed the plaintiff
- It does not authorize consumer lawsuits against product manufacturers
- Often a "cease and desist" letter citing the Lanham Act results in market corrections

Citizen suits

- Some US regulatory statutes authorize individual consumer to sue to enforce the regulations (more common in environmental sector). These laws are the exception, not the rule
- Ordinarily, individual consumers have no legal standing to sue to enforce federal safety regulations

Self-regulation

- Some US regulatory statutes provide for self-certification of compliance by product manufacturers
- A variation of this regulatory model is self-certification upon receipt of confirmatory testing from a government-approved third-party laboratory (Children's products regulated by the US CPSC)
- This regulatory model permits a product manufacturer to bring a consumer product to market without needing to await government type approval

Consumer Product Safety

Legislative framework

The Consumer Product Safety Act (CPSA) authorizes the Consumer Product Safety Commission (CPSC) to develop standards and bans and to pursue recalls under certain circumstances. The CPSC also administers the Consumer Product Safety Improvement Act (CPSIA) and a range of Acts that deal with specific products.

Web reference: www.cpsc.gov/en/Regulations-Laws--Standards/Statutes/

How are the rules for product requirements set?

The CPSC can promulgate consumer product safety rules to prevent or reduce an unreasonable risk of injury associated with consumer products. The rule may include requirements for performance, markings, warnings and/or instructions. The Administrative Procedure Act (APA) requires the CPSC to solicit input from the public on proposed regulations and to respond to public comments. The CPSC relies on voluntary standards whenever they eliminate or reduce the risk of injury and compliance with the standard is substantial. Voluntary standards can be referenced on an interim basis while the CPSC develops a final consumer product safety rule.

Rules can establish requirements for third party bodies that assess conformity to consumer product safety standards. The CPSC can also establish mandatory test programs for any product.

Web reference: www.cpsc.gov/en/Regulations-Laws--Standards/Rulemaking/

How are goods prohibited from sale for safety reasons?

The CPSC can make rules that ban the manufacture, importation, sale or advertisement of a consumer product that presents an unreasonable risk of injury and no feasible consumer product safety standard would adequately protect the public on a permanent or interim basis.

Web reference: http://www.cpsc.gov//PageFiles/105435/cpsa.pdf (see sections 8 and 9 of CPSA)

Are there notification requirements?

Suppliers must report to the CPSC within 24 hours if they obtain information that reasonably supports the conclusion that a product:

- fails to comply with a consumer product safety rule or a voluntary consumer product safety standard relied on by the CPSC
- fails to comply with any other rule, regulation, standard, or ban under the CPSA or any other statute enforced by the CPSC
- contains a defect which could create a substantial product hazard or
- creates an unreasonable risk of serious injury or death.

Suppliers must report certain choking incidents to the CPSC within 24 hours. Businesses must also report to the CPSC within 30 days if a product is subject to three successful civil law suits.

Web reference:

http://www.cpsc.gov//Global/Business-and-Manufacturing/Business-Education/RegulatedProductsHandbook.pdf (see chapter 9)

Suppliers may report via phone, e-mail, postal mail or online at:

www.saferproducts.gov/CPSRMSPublic/Incidents/ReportIncident.aspx

EUROPEAN
COMMISSION

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SWD(2017) 466 final

PART 3/4

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council

{COM(2017) 795 final} - {SWD(2017) 467 final} - {SWD(2017) 468 final} -
{SWD(2017) 469 final} - {SWD(2017) 470 final}

Contents

ANNEX 11: BACKGROUND INFORMATION ON OBJECTIVE 1 – REINFORCING MARKET SURVEILLANCE COOPERATION PROCEDURES

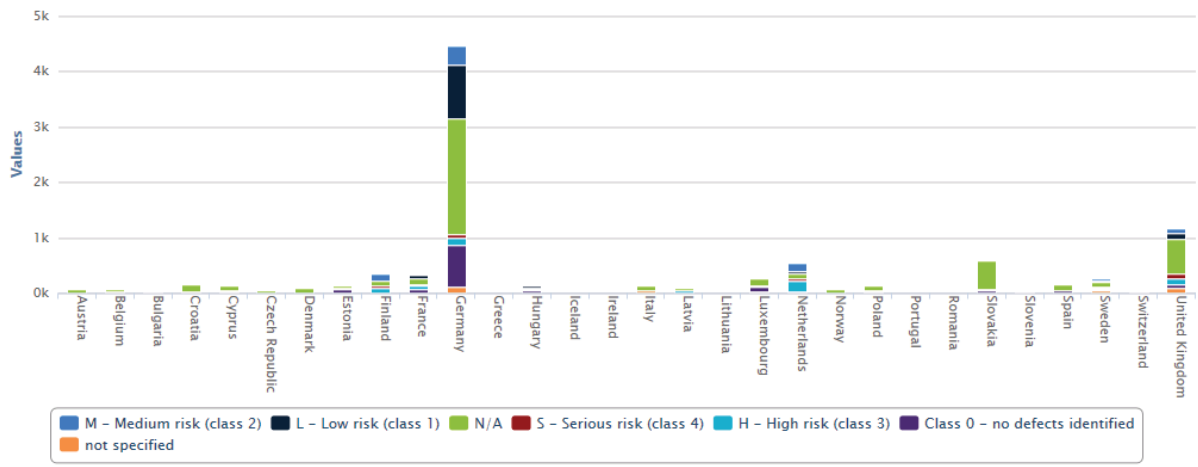
1. COORDINATION OF ENFORCEMENT OF PRODUCT LEGISLATION WITHIN THE EU (BASELINE)

The current section provides a short recollection of main legal, technical, administrative and financial tools currently available to optimise **cross-border cooperation and work sharing** among authorities.

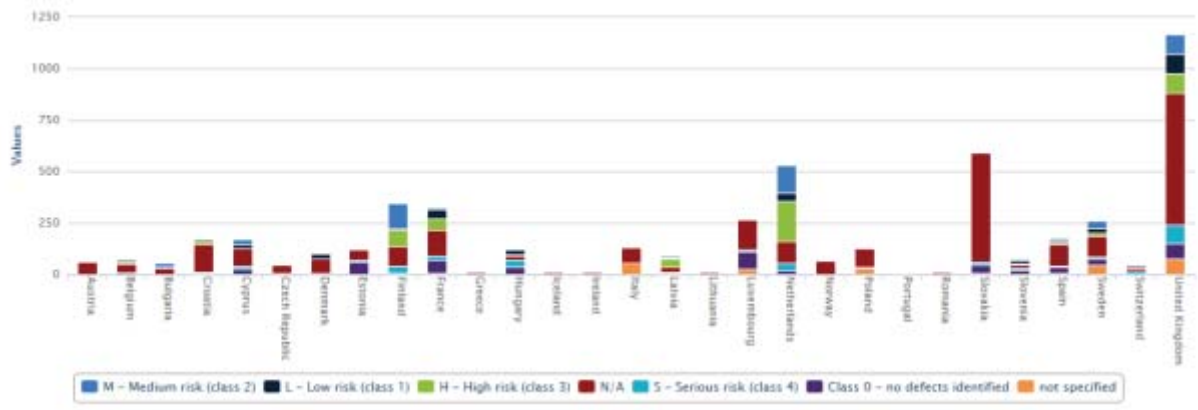
1.1. ICSMS

ICSMS (Information and Communication System for Market Surveillance) is the database for information concerning product compliance (ICSMS) referred to in Article 23 of Regulation (EC) No 765/2008 The Commission carries out continuous activities to facilitate the take up of the ICSMS system among authorities by means of trainings, the development of user guides and discussion in regular experts' groups meetings. More than 7 000 products are encoded in the system every year. In 2015 the database contained information on around 70 000 products and more than 250 000 files stored (i.e.: test lab reports, DoC, pictures, etc.). The Commission also examined the possibility of a convergence between ICSMS and RAPEX (see below).

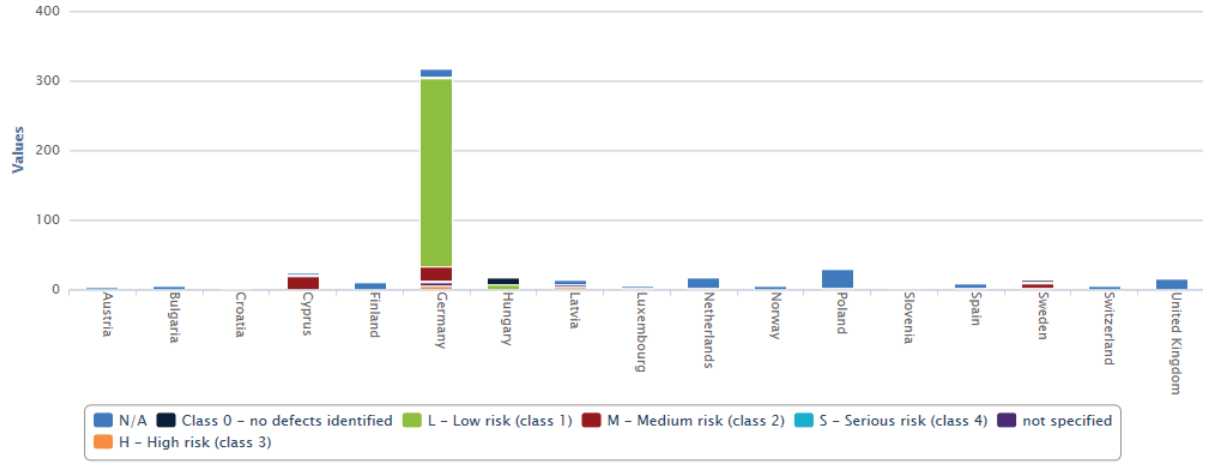
However, Member States use the system to different degrees, as shown in the diagrams below which show the numbers of product information input to the ICSMS system during 2016. Clearly the system is not used very well by many market surveillance authorities and some are not using the system at all. Even within member states, such as the UK and Germany, there is a great variance between different market surveillance authorities on their use of the system.



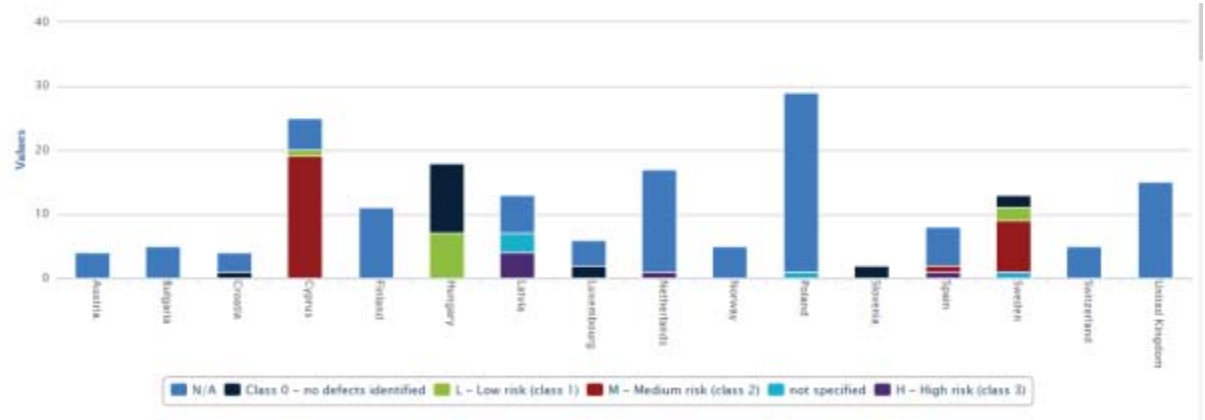
Use of ICSMS by all EU/EEA Member States in 2016 (2 with no entries)



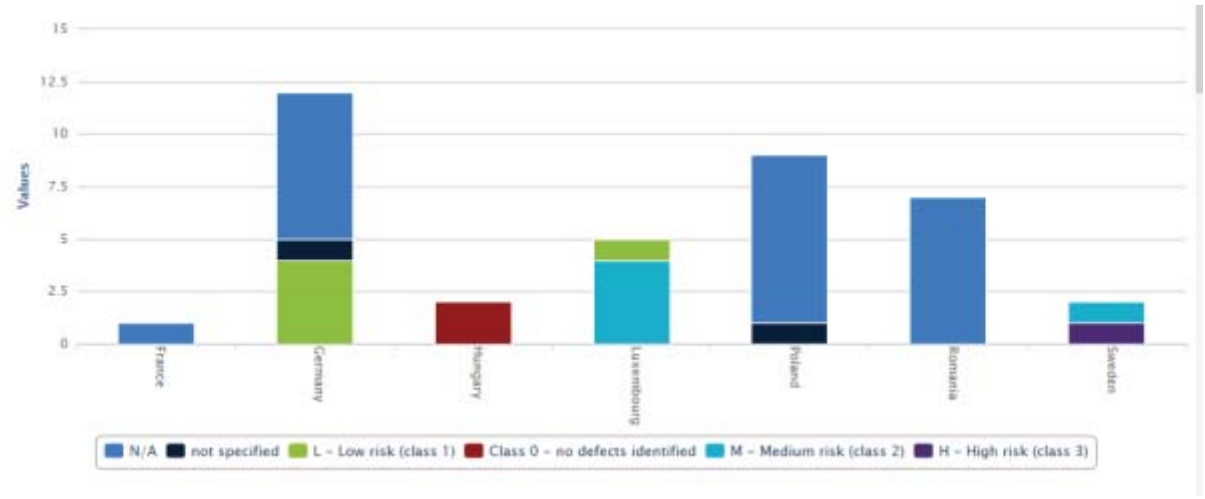
Use of ICSMS by EU/EEA Member States excluding Germany in 2016



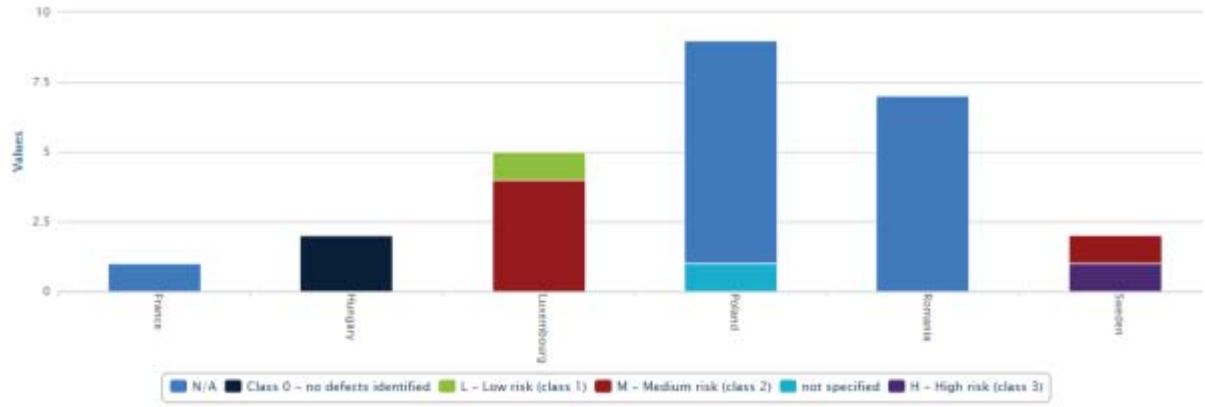
Use of ICSMS for EMC 2004 by all EU/EEA Member States in 2016 (15 with no entries)



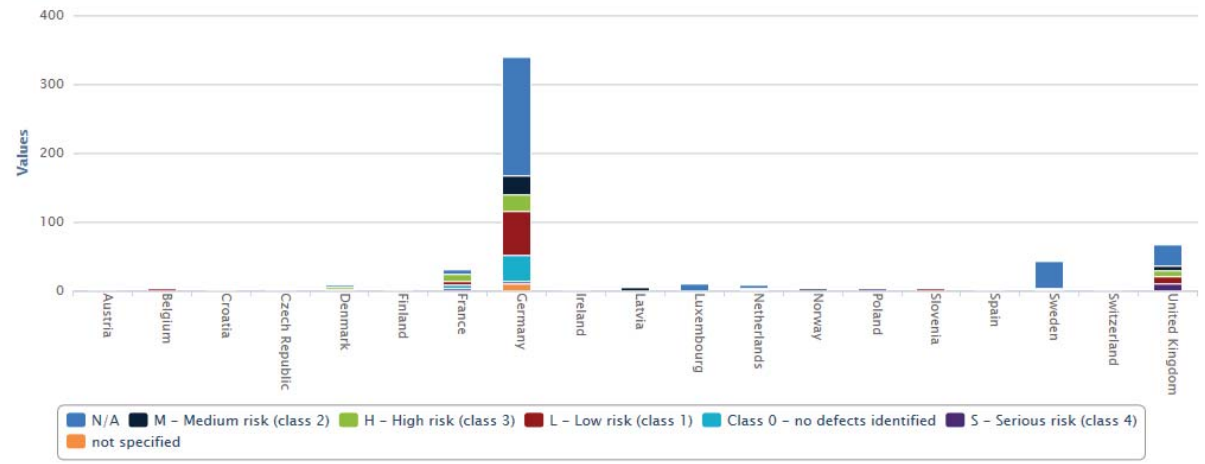
Use of ICSMS for EMC 2004 by EU/EEA Member States excluding Germany in 2016



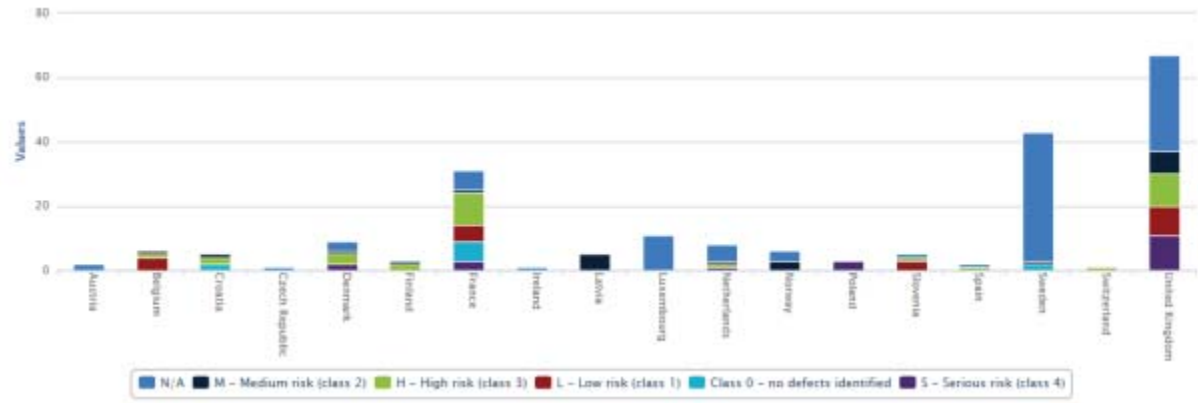
Use of ICSMS for EMC 2014 by all EU/EEA Member States in 2016 (25 with no entries)



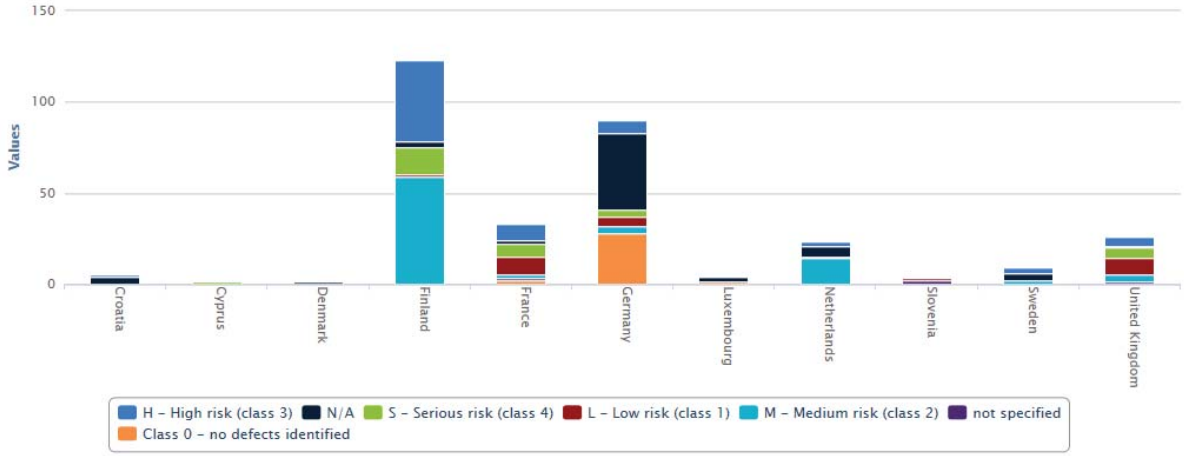
Use of ICSMS for EMC 2014 by EU/EEA Member States excluding Germany in 2016



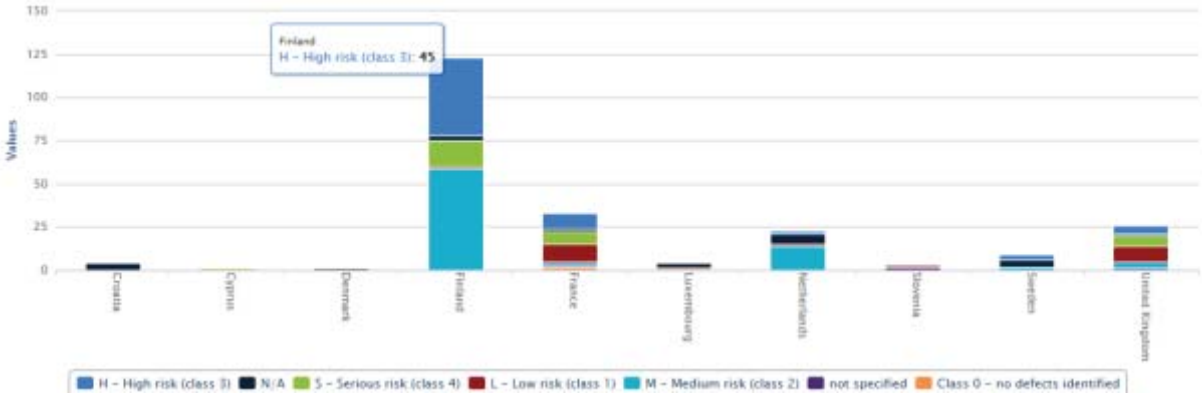
Use of ICSMS for Machinery by all EU/EEA Member States in 2016 (13 with no entries)



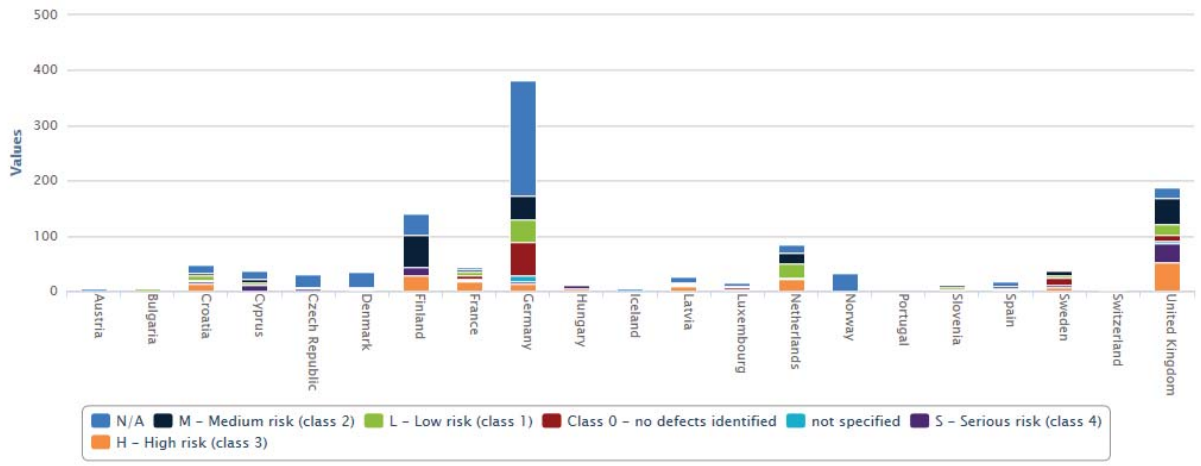
Use of ICSMS for Machinery by EU/EEA Member States excluding Germany in 2016



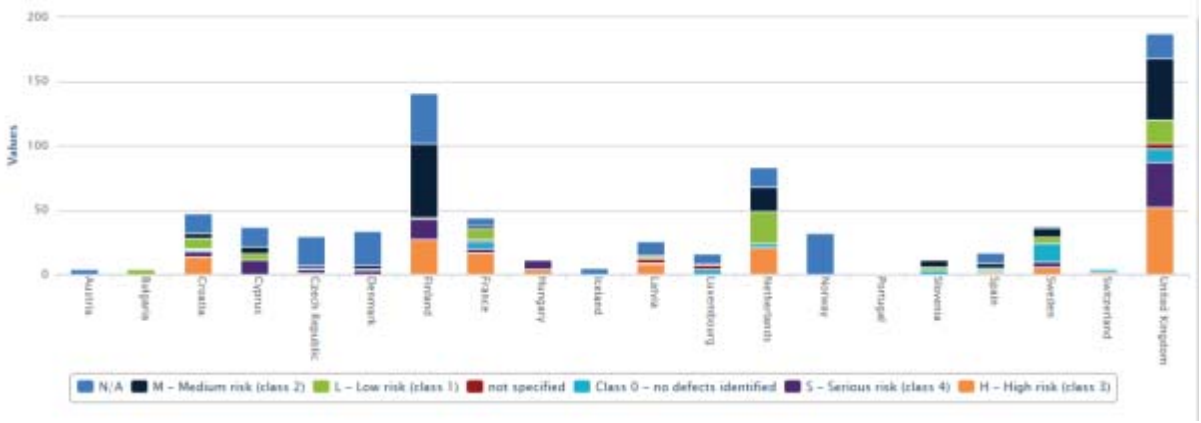
Use of ICSMS for LVD 2014 by all EU/EEA Member States in 2016 (21 with no entries)



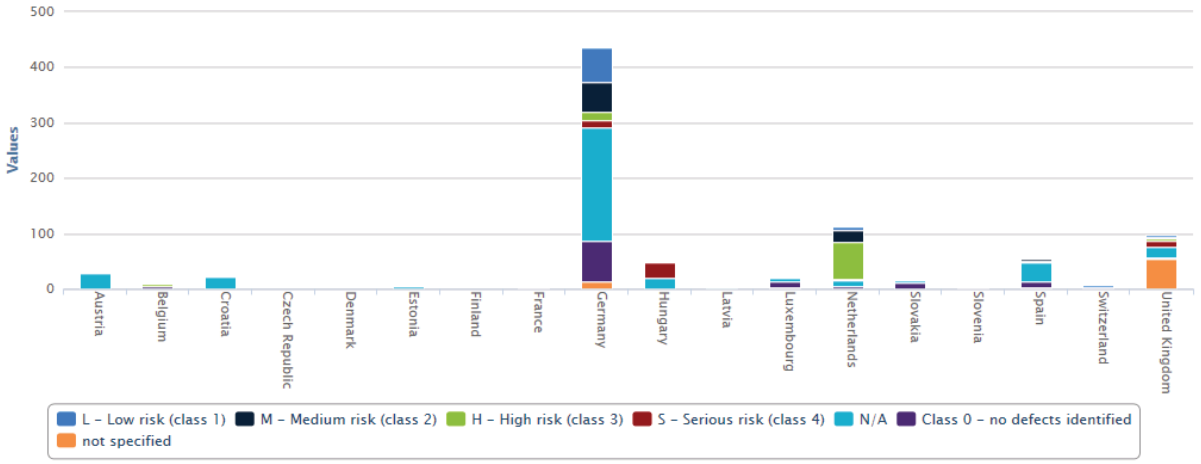
Use of ICSMS for LVD 2014 by EU/EEA Member States excluding Germany in 2016



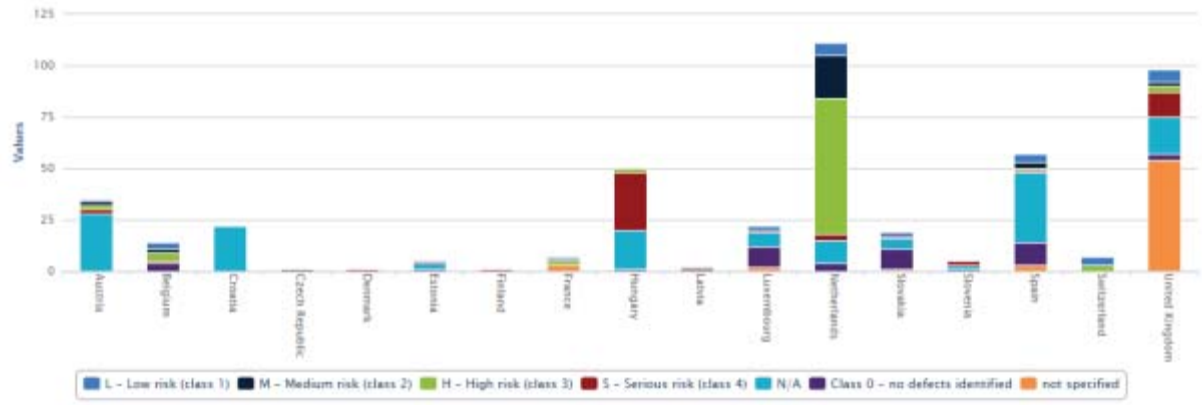
Use of ICSMS for LVD 2006 by all EU/EEA Member States in 2016 (11 with no entries)



Use of ICSMS for LVD 2006 by EU/EEA Member States excluding Germany in 2016



Use of ICSMS for GPSD by all EU/EEA Member States in 2016 (14 with no entries)



Use of ICSMS for GPSD by EU/EEA Member States excluding Germany in 2016

1.2. Official notification of measures to other Member States

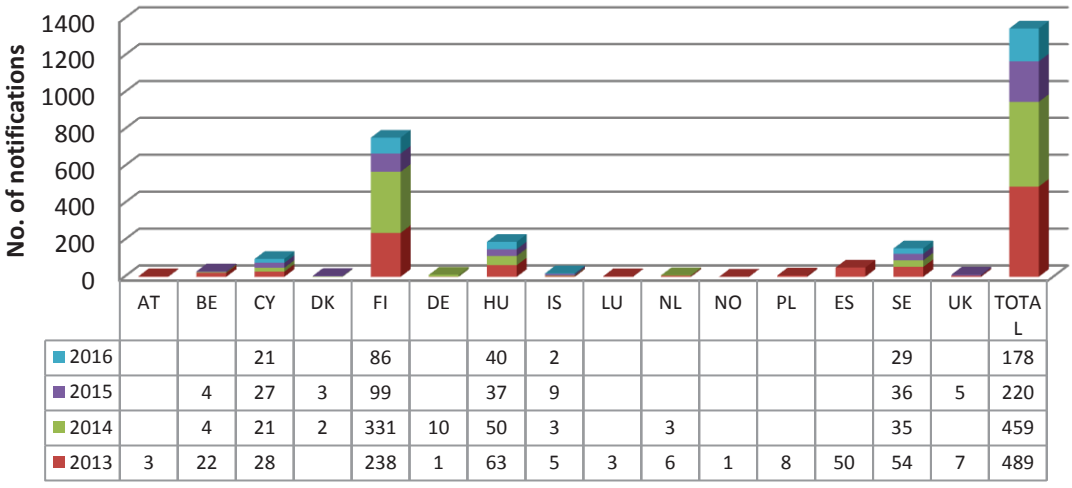
EU product legislation set out an obligation for Member States' competent authorities to communicate to the other Member States restrictive measures taken against non-compliant products. Furthermore, receiving Member States then have an obligation to 'follow up' on those notifications, i.e. adopt in turn appropriate measures in respect of their national territory. In many cases they also have the possibility to object to the measures notified and in this case the Commission will assess whether it was justified[1]. Recent guidance discussed at expert's working group level clarifies principles for cooperation based on the existing legal framework[2]. It also stresses the importance of this transmission mechanism to make sure that in relation to products available in various countries non-compliance found by a single authority could turn into effective corrective action across the whole Single Market.

However, with the exception of few sectors (notably low voltage equipment) only few notifications of restrictive measures are actually officially sent by national market surveillance authorities. Furthermore, even in these 'best case scenarios' sectors many Member States do not actually notify any measures and the number of notifications is decreasing overtime, as illustrated by the following figure.

1 The possibility of objections is set out in sector-specific legislation aligned to the reference provisions of Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.

2 Guidance on cross-border cooperation among EU market surveillance authorities (http://ec.europa.eu/DocsRoom/documents/17108/attachments/1/translations).

Figure 11-1: State of play of notifications of measures addressing non-compliant products under the Low Voltage Directive



	AT	BE	CY	DK	FI	DE	HU	IS	LU	NL	NO	PL	ES	SE	UK	TOTAL
2016			21		86		40	2						29		178
2015		4	27	3	99		37	9						36	5	220
2014		4	21	2	331	10	50	3		3				35		459
2013	3	22	28		238	1	63	5	3	6	1	8	50	54	7	489

In May 2016 the Commission included in ICSMS an IT tool to allow the simultaneous notification of restrictive measures adopted by a national authority to all Member States, which should facilitate the actual use of the notification mechanism by those Member States. Nevertheless, considering the level of take up of ICSMS and other difficulties faced by authorities, this IT improvement will not be sufficient to address the problem of low notifications.

Finally, there is no official information on the degree of follow-up to the notifications received by authorities. However, this is expected to be rather low.

In case of products presenting a serious risk a notification in the RAPEX Rapid Alert System is also required[3]. Since 2004, more than 20 000 measures taken against dangerous products have been raised in the Rapid Alert System.[4] During the 2010-2015 period Member States' authorities transmitted between 1 800 and 2 500 notifications per year. However the rate of response to each notification remains relatively small as for instance in 2015 each Member State reacted on average to 3% of notifications received.

Table 11-1: Notifications and reactions in RAPEX Rapid Alert System in 2015[5]

Country	Notifications		Reactions	
	Number	Percentage	Number	Percentage
Austria	17	0.82%	53	1.93%
Belgium	6	0.29%	29	1.06%
Bulgaria	151	7.25%	92	3.35%

3 Articles 20 and 22 of Regulation (EC) No 765/2008.

4 Source: RAPEX statistics and reports: http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/reports/index_en.htm

5 The figures reported represent an approximation as they disregards the fact that some of the reactions sent by Member States in 2015 relate to notifications filed in 2014 and vice versa some 2015 notifications received reactions in 2016.

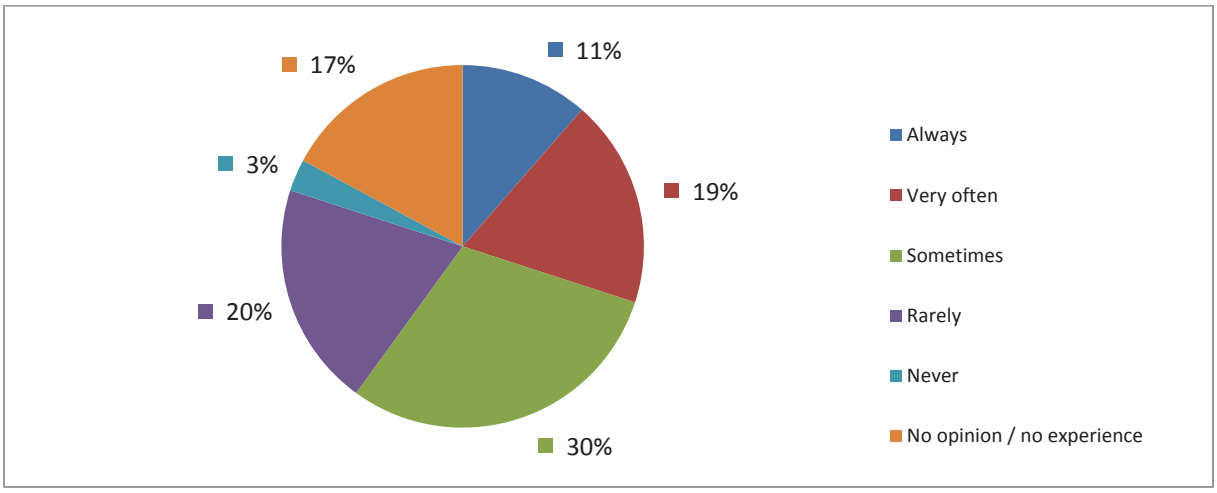
Country	Notifications		Reactions	
	Number	Percentage	Number	Percentage
Croatia	7	0.34%	138	5.03%
Cyprus	117	5.62%	17	0.62%
Czech Republic	109	5.24%	18	0.66%
Denmark	27	1.30%	209	7.61%
Estonia	21	1.01%	32	1.17%
Finland	52	2.50%	179	6.52%
France	135	6.48%	105	3.83%
Germany	208	9.99%	85	3.10%
Greece	14	0.67%	108	3.93%
Hungary	238	11.43%	56	2.04%
Iceland	14	0.67%	26	0.95%
Ireland	5	0.24%	106	3.86%
Italy	56	2.69%	24	0.87%
Latvia	60	2.88%	15	0.55%
Liechtenstein	0	0.00%	0	0.00%
Lithuania	74	3.55%	25	0.91%
Luxembourg	9	0.43%	11	0.40%
Malta	25	1.20%	30	1.09%
Netherlands	62	2.98%	203	7.40%
Norway	15	0.72%	186	6.78%
Poland	19	0.91%	3	0.11%
Portugal	42	2.02%	153	5.57%
Romania	25	1.20%	10	0.36%
Slovakia	74	3.55%	89	3.24%
Slovenia	21	1.01%	132	4.81%
Spain	239	11.48%	319	11.62%
Sweden	78	3.75%	181	6.59%

Country	Notifications		Reactions	
	Number	Percentage	Number	Percentage
United Kingdom	162	7.78%	111	4.04%
Average	67	3%	89	3%
Total	**2082**	**100,00%**	**2745**	**100,00%**

Source: Rapid Alert System 2015 results
(http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/reports/index_en.htm)

While progress was achieved in the legal framework and the actual practice concerning the notification of measures among authorities, there is a feeling that a more systematic follow up of measures notified by other Member States should be achieved. When asked how often authorities measure to restrict the marketing of products are adopted following the exchange of information a good 30% of authorities responding to the consultation still replied this happens 'rarely' or 'never' or declared 'no experience' (see figure 11-2).

Figure 11-2: In your experience or knowledge in the relevant product category(-ies) how often do national authorities restrict the marketing of a product following the exchange of information about measures adopted by another authority in the EU against the same product?



1.3. Mutual assistance between Member States' authorities

The current legal framework[6] makes possible mutual assistance among authorities in different Member States to supply each other with information or documentation and to carry out appropriate investigations or any other measure. The relevant provision does not provide any detail on the procedure (e.g. the means to be used, the language, the time to reply, etc.) to be followed to request and grant such assistance. Some guidance was recently developed on the applicable principles[2].

6 Article 24 of Regulation (EC) No 765/2008.

Although no structured information on requests for mutual assistance exists, informal feedback from national authorities experts involved in Administrative Cooperation Groups– see following section – indicate this happens only occasionally. Authorities able to produce figures mentioned in general less than 10 cases per year. An exception seems to be represented by the sector of medical devices where specific procedures have been gradually established and on average several[7] requests of mutual assistance are made annually. In the majority of cases, information on the use of the mutual assistance principle confirms a general tendency among authorities to focus their action exclusively on correcting non-compliance in the national territory.

According to information in their 2010-2013 reports on market surveillance[8], the practice of collaborating in inspections initiated by a specific Member States is virtually non-existent in most sectors. In the areas of cosmetics, machinery, electrical, electronic and radio equipment it is not completely absent but definitely still at an embryonic stage.

1.4. Administrative Cooperation Groups (AdCos)

In many sectors, cooperation between national administrations takes place in working groups set up under the Union harmonisation legislation. Discussions mainly focus on interpretation issues, but questions related to market surveillance and administrative cooperation are also dealt with.

The Expert Group on Internal Market for Products (IMP-MSG) deals with general policy questions related to the implementation and enforcement of Union harmonisation legislation at 'horizontal' level, i.e. without addressing issues arising in the particular sectors.

Cooperation between national administrations competent for carrying out market surveillance in specific sectors takes place by means of the so-called Administrative Cooperation groups (AdCos)[9]. It concerns a number of sectors.[10] AdCos participants discuss several issues related to the market surveillance, elaborate common guidance documents and sometimes carry out joint enforcement actions. An overview of the most recent concrete outcomes of common discussion can be found on the AdCo webpage hosted by the European Commission. [11]

Since 2013 the Commission provides logistical and financial support to the organisation of the groups' meetings. According to the feedback received from AdCo Chairs this support has proven beneficial to increase and stabilise the rate of participation of national authorities in the meetings. However not all Member states participate in administrative cooperation. During the 2014-2016 period for most AdCos (ATEX, CPR, EMC, LVD, MACHINE, PPE, PYROTECH, RCD, TOYS, WELMEC) about two thirds of Member States did take part in meetings (with a peak of 80% participation rate for the radio equipment group); however in others (GAD, LIFT, PED) only about 50% Member States participated in the meetings and in

7 The figure of 200 requests was mentioned during a meeting with national authorities.
8 See figures in Annex 9 Section 5.
9 https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups_en
10 Measuring instruments and non–automatic weighing instruments (WELMEC), low voltage equipment (LVD ADCO), Eco-Design ADCO Group, electromagnetic compatibility (EMC administrative cooperation), civil explosives (CIVEX), machinery, noise emissions by outdoor equipment (NOISE), medical devices (Vigilance Working Group and COEN – Compliance and Enforcement Group), construction products (CPR), PEMSAC (The Platform of European Market Surveillance Authorities for Cosmetics), Toy-ADCO (The Administrative Cooperation Group of toys), recreational craft (RCD), personal protective equipment (PPE), equipment for use in explosive atmospheres (ATEX), Radio and Telecommunications Terminal Equipment (RED), Cableways (CABLE), Energy Labelling and Eco-design (ENERLAB/ECOD), Gas Appliances (GAD), Lifts (LIFT), Marine Equipment (MED), Pressure equipment sector (PED/SVPD), Pyrotechnics (PYROTEC), Chemicals (REACH), Restriction of the use of certain hazardous substances (ROHS), Transportable Pressure Equipment (TPED), Labelling of tyres.
11 http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2798

the case of CABLE, NOISE and TPED only about 30-40% of Member States were involved. Details on Member States participation are illustrated in Table 11-2. Furthermore, according to the feedback received by AdCo Chairs many representatives of the Member States participating in the meetings do not get actively involved in common discussions and activities.

As regards the chemical sector a role analogous to that of the AdCos is played by the Forum of the ECHA authority (https://echa.europa.eu/about-us/who-we-are/enforcement-forum). In this case the Forum is a body of ECHA and some ECHA fulfil the role of secretariat for the Forum. The participation of Member States in the meetings of the Forum is very high (90%).

Table 11-2: Data on participation in AdCos meetings

AdCo	2014				2015				2016 (1st semester)			
	Partici-pants	Represented countries			Partici-pants	Represented countries			Partici-pants	Represented countries		
		MSs	Other	Total		MSs	Other	Total		MSs	Other	Total
ATEX	35	15	3	18	33	17	3	20	33	21	2	23
	33	17	3	20	33	17	2	19	33	14	2	16
CABLE	23	12	3	15	21	10	2	12	26	12	3	15
CIVEX	no data for 2014				30	20	1	21	October/November			
COEN	no data for 2014				no data for 2015				no data for 2016			
CPR	31	20	2	22	43	21	4	25	36	15	4	19
	46	23	3	26	44	25	2	27				
EMC	38	20	4	24	37	21	5	26	40	18	4	27
	36	19	4	23	34	22	4	26				
ENERLAB / ECOD	no data for 2014				32	22	1	23	43	21	1	22
					34	18	3	21				
GAD	18	14	0	14	15	8	2	10	19	12	2	14
	14	11	0	11	16	11	2	13				
LIFT	25	12	3	15	24	14	3	17	25	17	2	19
	21	14	2	16								
LVD	31	15	4	19	32	20	4	24	36	17	4	21
	33	19	3	22	34	22	3	25				
	31	18	4	22								
MACHINE	32	17	3	20	33	20	3	23	38	20	4	24
	33	15	3	18	30	19	3	22				

NOISE	22	10	2	12	23	9	2	11	Meeting October 2016			
PED	22	13	3	16	25	15	4	19	24	15	4	19
	25	18	3	21	15	11	1	12				
PPE	44	21	4	25	39	19	4	23	39	20	5	25
	37	19	4	23	40	21	4	25				
PYROTEC	30	14	0	14	34	17	0	17	32	19	1	20
	30	15	0	15	34	19	0	19				
RCD	35	17	2	19	22	15	2	17	31	19	2	21
	33	16	3	19	30	19	1	20				
RED	23	12	2	14	41	25	4	28	41	23	2	25
	40	24	2	26	41	22	4	26	40	25	2	27
	39	19	4	23								
	44	22	3	25								
TOYS	no data for 2014				37	18	5	23	32	15	4	19
					40	25	3	28				
TPED	12	9	0	9	23	12	1	13	21	8	3	11
	13	5	1	6								
WELMEC	no data for 2014				31	21	1	22	33	19	4	23
					36	19	4	23				

As regards the development of common market surveillance projects, the following table summarises the joint actions carried out or launched within different AdCos during the 2013-2016 period and number of countries participating in the action

Table 11-3: Joint actions organised within AdCos and number of Member States (MS) participating[12]

AdCo[10]	2013	2014	2015	2016
ATEX				
CABLE				
CIVEX				
COEN			Information and instructions on reprocessable products (12 MS)	Clinical data (7-8) Harmonising inspections (7-8 MS)
CPR	2012-2013: EPS (10 MS)	Smoke alarms (10 MS)	Windows (7 MS)	

12 Most joint actions are indicated under the year during which they were launched, although projects lasted two or more years.

ECOD / ENERLAB / ROHS	ECOD: Lighting and chain lighting (10 MS) ROHS: Toys (8 MS) and Kitchen appliances (10 MS)	ROHS: Cheap products (10 MS)	ROHS: Cables/USB/others (6 MS)	ECOD: Defeat devices (4 MS) ENERLAB: Collecting inspection data methodologies (6 MS)
EMC	Switching power supplies (19 MS)	Solar inverters (14 MS)		
GAD				Gas appliances (8 MS)
LIFT				
LVD			LED Floodlights* (13 MS)	
MACHINE[13]	2012-2013: Log Splitters (about 8 MS) 2012-2015: Firewood Processors (about 7-8 MS) 2011-2015: Impact Post Drivers (3-4 MS)	Boom saws (3 MS)		Portable chain-saws and vehicle servicing lifts* (9-10 MS)
NOISE				
PED		Air receivers for compressors (2 MS)		
PPE				
PYROTEC				
REACH	1 big action/year involving all Member States. Additional pilot actions on a smaller scale			
RED		Mobile phone repeaters (14 MS)	Drones (18 MS)	
RCD			Small inflatable crafts (6 MS)	
TOYS				
TPED				
WELMEC WG5		Electric energy meters* (11)	Heat meters* (10)	

* project co-financed by the European Commission.

1.5. Joint actions co-financed by the European Commission

As mentioned in the point above ADCO sometimes organise joint market surveillance campaigns; in a few cases those actions have been financed by the European Commission on the basis of financing provisions included in the current legal framework[14]. In particular, the following calls for proposals were made since 2013:

13 Joint actions organised in previous periods were: NOMAD Survey of machinery instructions on noise information and noise declarations (original survey work 2007-2012) about 10 Member States participating; Pinspotters/Pinsetters (machines in 10 pin bowling alleys), mostly between 2008 and 2012, about 5 Member States participating; Skid-steer Loaders, 2010-2012, 2-3 Member States; Scissor Lifts, 2010-2012, 5-6 Member States; Wind Turbine access (provision of lifts in towers), 2010-2012, about 4-5 Member States.

14 Chapter V of Regulation (EC) No 765/2008.

- In 2013 the Commission launched the first call for proposals for joint enforcement actions under the multi-annual plan for market surveillance of products in the EU. The grant was awarded to project focussed specifically on active electrical energy meters and heat meters. The grant took the form of a 70% reimbursement by the Commission of the eligible costs of the action (amount approximately allocated 350 000 EUR) and was fully managed by Member States. The action was carried out by a consortium of authorities under the coordination of a Spanish authority.

- In 2014 a new call for proposals for joint enforcement actions was launched and led to funding by the Commission of two proposed actions respectively the field of machinery safety and LED floodlights. The grants that have been awarded are in the form an 80% reimbursement by the Commission of the eligible costs of the actions (total amount allocated is approximately 1000 000 EUR). One of the actions was coordinated by a Finish authority, while the other was coordinated by the private company "Prosafe"[15].

- In July 2015 a call for proposals was launched with a maximum budget foreseen for EU financing of 500 000 EUR. One proposal was received by the deadline of 1 October 2015 but did not lead to the award of any grant since the proposal received did not address the objectives as stipulated in the call.

- In March 2016 a call for proposals was launched with a higher maximum budget foreseen for EU financing of 750 000 EUR to maximum 3 projects coupled with a maximum EU financing rate of eligible costs of up to 80% of the action for joint actions involving bodies from 10 or more EU-EEA Member States, and 50% involving bodies from less than 10 EU-EEA Member States. No proposal was received by the deadline of 9 June of this year.

- In July 2016 a further call for proposals was launched. The maximum budget of 540 000 EUR was set with maximum financing rates of 95% and 80% respectively. For this call no proposal was received by the deadline for submission of 30 September 2016.

When discussing with market surveillance authorities the reasons why three calls for proposals went void why authorities do complain about limited resources, authorities stressed they welcomed the principle of joint actions financed through grants, and also their outcomes. However they pointed out the administrative complexity of managing these projects (e.g. heavy administrative requirements, problems in coordinating work by partners in other Member State authorities, and taking financial commitments on their behalf). They pointed out that the Commission should offer an administrative framework for the management of these actions and of the available money - money is not enough if it is not accompanied by some sort of infrastructure to allow for the management of the project.[16]

Furthermore, joint actions are regularly financed by the Commission under the Consumer Programme[17]. The following table summarises those carried out or launched during the 2013-2016 period. The projects financed under the Consumer Programme have always been coordinated by Prosafe.

15 http://www.prosafe.org/about-us/contentall-comcontent-views/what-is-prosafe
16 http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=28611&no=1
17 http://ec.europa.eu/consumers/eu_consumer_policy/financial-programme/index_en.htm

Table 11-4: Joint actions financed under the Consumer Programme

	Member States + EFTA countries	Authorities	Product categories		Budget (in M€)	Grant (70%) (in M€)	Workdays
JA2010	21	23	5	Food imitation child-appealing products Children's Fancy Dresses (chemicals in textiles) Laser Pointers Ladders Visibility Clothing & Accessories	2.03	1.42	3462
JA2011	19	28	4	Child Care Articles Fireworks Battery chargers Lawnmowers	2.49	1.69	3995
JA2012	24	31	5	Nanotechnology and Cosmetics Childcare Articles- Highchairs, Cords and Drawstrings, Ladders, CO and smoke detectors)	2.14	1.48	3169
JA2013	21	25	5	Toys Children's Kick Scooters Childcare Articles- Cots, Chemicals risks in Clothing, Smoke Detectors	2.27	1.59	3664
JA2014	27	35	5	Noisy toys Fireworks Power tools CFL and LED Lighting Childcare Articles - Safety Barriers	2.87	1.99	4410
JA2015	26	35	5	Plasticised Toys Power Tools Electrical Appliances (incl. electric irons) Child Care Articles- Soothers and soother-holders; Playgrounds	3.12	2.18	243.35 person / month

The Commission has also financed the following initiatives under the Horizon2020 programme:

– ECOPLIANT[18] – joint action in the area of ecodesign legislation (many products covered) running from 2012 to 2015 and involving 10 Member States; cost of the project: approximately € 2.4 mln; grant by the European Commission: € 1.8 mln under the Intelligent Energy Europe program.

18 http://www.ecopliant.eu/wp-content/uploads/2012/10/Final-Publishable-Report.pdf

– EEPLIANT[19]– joint action in the area of ecodesign and energy labelling (heaters, LED lamps, printers): 2015-2017, 13 authorities from 12 MS- cost of the project: approximately € 2.5 mln entirely funded by the European Commission under the Horizon 2020 programme.

– INTAS (ecodesign, power transformers and large fans): 2016-2019, not a traditional joint action as about half of the 12 participants are not surveillance authorities, but energy agencies, research institutes, consultancies and civil society organisations cost of the project: approximately € 1.9 mln entirely funded by the European Commission under the Horizon 2020 programme.

– MsTyr15[20] joint action concerning tyre labelling launched in March 2016 (until February 2018) with 13 MS plus Turkey- cost of the project: approximately € 2 mln entirely funded by the European Commission under the Horizon 2020 programme.

The ECOPLIANT was successfully coordinated by a UK authority, however it revealed an important administrative burden for them. For the EEPLIANT and Ms Tyr15 projects the coordination was ensured by Prosafe. INTAS which does not constitute an enforcement activity is coordinated by an organisation with experience in managing projects from EU funds.

1.6. Views of market surveillance experts on cross-border cooperation

In the context of the consultation of market surveillance experts carried out within the IMP-MSG expert group prior to the 1 February 2016 meeting Member States expressed their views on the problems affecting cross-border cooperation and the possible solutions. The following excerpt is taken out of document 2016-IMP-MSG-07rev01 (section 4.3.3) summarising the results of this consultation:

*[Member State A] underlines the need for consistent implementation of the **guidelines on cross-border–cooperation**, complemented if necessary by the set-up of additional legal arrangements. Furthermore, under the **safeguard clause procedure** all European market surveillance authorities must take, where necessary, measures to enforce requirements under European law. [Member State A] also suggests that where a public authority prohibits the making available on the national market, this should **automatically apply in all MS,** with the ECJ possibly acting as appeal. Member States should reflect on the possibility of **specialising in specific fields**. In order to achieve an effective market surveillance system, the adaptation of **national legislation** to the EU legislation will be necessary in a number of areas (cross-border cooperation, mutual recognition of activities of the market surveillance authorities of other Member States - for example, recognition of test reports, etc.). The **organisation** of market surveillance **at national level** should be reconsidered in order to reduce the fragmentation of responsibilities.*

*[Member State B] stresses the need for **guidance on cross-border cooperation** to improve and optimize the results of authorities' actions. According to [Member State B], to achieve better results in trans-border cooperation between the Member States, in cases of non–compliant products a **contact points list for each product group** should be prepared which could provide fast and easily accessible communication.*

19 http://www.eepliant.eu
20 http://www.mstyr15.eu/index.php/en /

*According to [Member State C], a **mandatory harmonized procedure for MSA cooperation** will facilitate cases of cross-border cooperation and will further harmonize existing market surveillance approaches. The administrative burden for MSAs of this procedure should nevertheless be as minimal as possible.*

*[Member State D] stresses that prior to setting additional requirements for mutual change of information, the Commission should ensure that all Member States **actively use the present procedures** and notes that for example EMC and LVD notifications are made by only a few States.*

*[Member State E] would find it useful to receive **more feedback on safeguard notifications**. In general, more cooperation and exchange of information is needed at EU and **national level**.*

*[Member State F] notes that **'language borders'** are the main obstacle to day-to-day cooperation among authorities.*

2. PRODUCTS IMPORTED FROM THIRD COUNTRIES (BASELINE)

Points of entry to the EU are relevant to stop non-compliant and unsafe products coming in from third countries. Being the place where all products from third countries have to pass by, they are the ideal place to stop unsafe and non-compliant products before they are released for free circulation and subsequently circulate freely within the European Union. Thus, customs have an important role in supporting market surveillance authorities in carrying out product safety and compliance controls at the external borders.

The most effective way to avoid making available non-conforming or unsafe goods imported from third countries in the Union market is to carry out adequate checks during the import control process. This requires involvement of customs and cooperation between customs and market surveillance authorities.

The authorities in charge of the control of products entering the Union market, customs or market surveillance authorities depending on the national organisational structure, are very well placed to carry out initial checks, at the first point of entry, on the safety and compliance of the imported products. There are specific guidelines for import controls in the area of product safety and compliance. To ensure such controls, the authorities in charge of controls of products at the external borders need an appropriate technical support in order to carry out the checks on the characteristics of the products on an adequate scale. They can perform documentary, physical or laboratory checks. They also need appropriate human and financial resources.

2.1. The control procedure laid out in Regulation (EC) No 765/2008

Regulation (EC) No 765/2008 on checks for conformity with Union harmonisation legislation in the case of products imported from third countries requires the customs authorities to be closely involved in the market surveillance activities and information systems provided for under EU and national rules. Article 27(2) of Regulation (EC) No 765/2008 foresees the obligation for cooperation between customs officers and market surveillance officers. Obligations for cooperation are also included in Article 13 of the Community Customs Code which establishes that controls performed with customs and other authorities are undertaken in close cooperation between each other. In addition, the principles of cooperation between

the Member States and the Commission established in Article 24 of the Regulation are extended to authorities in charge of external controls, when relevant (Article 27(5)).

Cooperation at national level should allow for a common approach taken by customs and market surveillance authorities during the control process. This should not be hampered by the fact that various ministries and authorities may be responsible for the implementation of Regulation (EC) No 765/2008.

Customs authorities have the following responsibilities under Regulation (EC) No 765/2008:

– to suspend the release of products when there is a suspicion that the products present a serious risk to health, safety, environment or other public interest and/or do not fulfil documentation and marking requirements and/or the CE marking has been affixed in a false or misleading manner(Article 27(3)),

– not to authorise the release for free circulation for the reasons mentioned in Article 29,

– to authorise the release for free circulation for any product in compliance with the relevant Union harmonisation legislation and/or nor presenting risks to any public interest,

– where the release for free circulation has been suspended, customs have to immediately notify the competent national market surveillance authority which is given 3 working days to perform a preliminary investigation of the products and to decide:

– if they can be released since they do not present a serious risk to the health and safety or cannot be regarded as being in breach of Union harmonisation legislation,

– if they must be detained since further checks are necessary to ascertain their safety and conformity.

Customs authorities must notify their decisions to suspend release of a product to the market surveillance authorities, which in turn must be in a position to take appropriate action. Four hypotheses must be distinguished as from the moment of the notification.

1. The products in question present a serious risk

   If the market surveillance authority ascertains that the products present a serious risk, it must prohibit their placing on the EU market. The market surveillance authorities have to request the customs authorities to mark the commercial invoice accompanying the product, and any other relevant accompanying document, with the words ‘Dangerous product — release for free circulation not authorised — Regulation (EC) No 765/2008’. Member State authorities may also decide to destroy the products or otherwise render them inoperable, where they deem it necessary and proportionate. The market surveillance authority must use in those cases the system for rapid exchange of information — RAPEX. As a consequence, market surveillance authorities in all Member States are informed, and they may in turn inform the national customs authorities about products imported from third countries, which display characteristics giving rise to a serious doubt as to the existence of a serious risk. This information is of particular importance for customs authorities where it involves measures banning or withdrawing from the market products imported from third countries.

Feedback from market surveillance authorities on whether goods are considered as unsafe or non-compliant is crucial for customs risk management and control processes. It ensures controls can be concentrated on risky consignments, allowing for the facilitation of legitimate trade.

Furthermore, when non-compliant or unsafe products are found in the internal market, it is often extremely difficult to identify how they entered the EU. Cooperation between customs and market surveillance authorities is encouraged to improve tracing in those cases.

2. The products in question do not comply with Union harmonisation legislation

In this case the market surveillance authorities must take appropriate measures, if necessary prohibiting the placing on the market under the rules in question. In cases where placing on the market is prohibited, they must ask the customs authorities to mark the commercial invoice accompanying the products, and any other relevant accompanying document, with 'Product not in conformity — release for free circulation not authorised — Regulation (EC) No 765/2008'.

3. The products in question do not present a serious risk and cannot be considered as not conforming to the Union harmonisation legislation. In this case the products must be released for free circulation, provided that all the other conditions and formalities regarding release for free circulation are met.

4. The customs authorities have not been notified of any action taken by the market surveillance authorities.

If, within 3 working days of the suspension of release for free circulation, the market surveillance authority has not notified customs of any action taken by them, the product has to be released for free circulation provided that all the other requirements and formalities pertaining to such release have been fulfilled.

The entire procedure from the suspension until the release for free circulation or its prohibition by customs should be completed without delay to avoid creating barriers for legitimate trade but does not necessarily have to be completed within 3 working days. The suspension of release can remain valid for the time required by the market surveillance authority to carry out appropriate checks on the products and allow them to take the final decision. Market surveillance authorities must ensure that the free movement of products is not restricted to any extent greater than that which is allowed under Union harmonisation legislation or any other relevant EU legislation. To that end market surveillance authorities perform their activities regarding products originating from third countries — including the interaction with the relevant economic operators — with the same urgency and methodologies as for products originating from within the EU.

In this case, the market surveillance authority notifies customs within these 3 working days that their final decision on the goods is pending. The release for free circulation has to remain suspended until the market surveillance authority has made a final decision. That notification empowers customs to extend the initial suspension period. The products will remain under customs supervision even if they are allowed to be stored at another place approved by customs.

2.2. Cooperation and coordination of action among Customs

2.2.1. Administrative assistance

Customs cooperation based on the UCC enables exchanging information among customs to ensure correct application of the customs legislation and customs rules as well as creating a level playing field for business operators.

In 2015, almost 2 000 requests for administrative assistance were sent within the EU. There is an upward trend linked to cooperation in the form of administrative assistance between individual customs administrations.

2.2.2. The Customs Risk Management Framework (CRMF)

A sophisticated common customs risk management framework (CRMF) had been introduced into the previous customs legislation and is now covered by Article 46 UCC.

The CRMF is based on the recognition of a need to establish an equivalent level of protection in customs controls for goods brought into or out of the EU and to ensure a harmonised application of customs controls by the MS. It aims to support a common approach so that priorities are set effectively and resources are allocated efficiently with the aim of maintaining a proper balance between customs controls and the facilitation of legitimate trade.

The CRMF therefore comprises:

- the identification and control of high-risk goods movements using **common risk criteria -** see section 2.2.2.1.;
- the identification of **priority control areas** subject to more intense controls for a specific period; **-** see section 2.2.2.2;
- systematic and intensive **exchange of risk information** between customs- see section 2.2.2.3;
- the contribution of **Authorised Economic Operators** (AEO) in a customs-trade partnership to securing and facilitating legitimate trade; and
- **pre-arrival/pre-departure security risk analysis** based on cargo information submitted electronically by traders prior to arrival or departure of goods in/from the EU **specifically to cater primarily for security and safety risks.**

2.2.2.1.The common risk criteria and standards

The Commission has adopted a set of criteria to be applied in the Member States' risk analysis systems in order to continuously screen electronic advance cargo information for security and safety purposes. The criteria are set out in an implementing act based on the empowerment of Article 50(1) UCC, which is not public for obvious reasons. The CRC are aimed primarily towards identifying high-risk consignments/goods that could have serious implications for the security and safety of the EU and its citizens and providing equivalent protection throughout the external frontier based on common risk analysis.

While in all other types of movements, the customs office where goods and declaration are presented is responsible for the processing of the declaration and for the risk analysis, customs at the first point of EU entry has a legal obligation to carry out the security and safety risk analysis on all the cargo regardless of the country of EU destination. Consignments crossing the EU border are thus screened on the basis of those criteria 365 days a year.

2.2.2.2.Priority Control Areas

Priority Control Areas (PCAs) are the key mechanism in the CRMF allowing the Union to designate specific areas to be treated as a priority for customs control. The identified areas are subjected to reinforced customs controls carried out in a co-ordinated manner based on common risk assessment criteria and real-time exchange of risk information.

Priority areas may relate to any customs procedure, types of goods, traffic routes, modes of transport or economic operators. The chosen areas are to be subject to increased levels of risk analysis and customs controls for a pre-determined limited period with a start and end date and possibility for interim review.

Priority control areas have built-in assessment procedures and flexibility for Member States in order to ensure that the control action to be taken is not disproportionate or unduly disruptive in terms of the effect on trade flows within a Member State or a particular port or frontier point.

2.2.2.3.The exchange of risk information

The Common Customs Risk Management System (CRMS) is designed to provide a fast and easy-to-use mechanism to distribute and exchange customs control and risk-related information directly amongst operational officials and risk analysis centres in the 28 Member States.

It facilitates EU-wide customs intervention for the highest risks at the external frontier and inland and is thus an integral element in the development of a Union risk management framework. It consists of a form (Risk Information Form, called RIF) to be filled in on-line and instantly made available to all customs offices connected.

The RIF is a means of ensuring a consistent level of customs control is applied at the external frontier of the Union in relation to identified risks thereby offering the necessary level of protection to citizens and to the financial interests of the EU and MS while ensuring equivalent treatment of traders throughout the Union.

2.2.2.4. Authorised Economic Operators

The AEO concept is based on the Customs-to-Business partnership introduced by the World Customs Organisation (WCO). Traders who voluntarily meet a wide range of criteria work in close cooperation with customs authorities to assure the common objective of supply chain security and are entitled to enjoy benefits throughout the EU.

The EU established its AEO concept based on the internationally recognised standards, creating a legal basis for it in 2008 through the 'security amendments' to the "Community Customs Code" (CCC) (Regulation (EC) 648/2005) and its implementing provisions.

The programme, which aims to enhance international supply chain security and to facilitate legitimate trade, is open to all supply chain actors. It covers economic operators authorised for customs simplification (AEOC), security and safety (AEOS) or a combination of the two.

On the basis of Article 39 of the Union Customs Code (UCC), the AEO status can be granted to any economic operator meeting the following common criteria:

Conditions and criteria	**AEOC**	**AEOS**
Compliance with customs legislation and taxation rules and absence of criminal offences related to the economic activity.	X	X
Appropriate record keeping.	X	X
Financial solvency.	X	X
Proven practical standards of competence or professional qualifications.	X	
Appropriate security and safety measures.		X

The AEO status granted by one Member State is recognised by the customs authorities in all Member States (Article 38 (4) UCC). The conditions and criteria to grant the status do not take explicitly into account the economic operators' compliance with EU product harmonisation legislation.

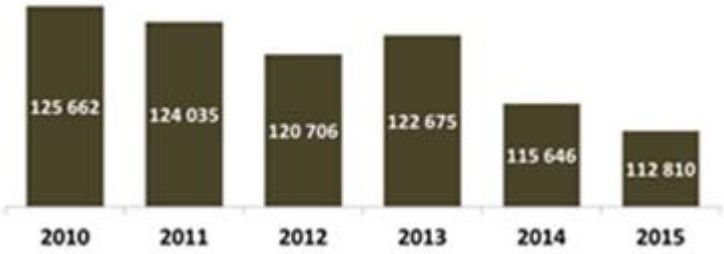
AEO benefits are an integral part of the EU legislation governing the AEO status. The AEO benefits, dependent on the type of the authorisation, are summarised in the table below:

Benefit	**AEOC**	**AEOS**
Easier admittance to customs simplifications	X	
Fewer physical and document-based controls • related to security & safety • related to other customs legislation	 X	 X
Prior notification in case of selection for physical control (related to safety and security)		X
Prior notification in case of selection for customs control (related to other customs legislation)	X	
Priority treatment if selected for control	X	X
Possibility to request a specific place for customs controls	X	X
Indirect benefits (Recognition as a secure and safe business partner, Improved relations with Customs and other government authorities; Reduced theft and losses; Fewer delayed shipments; Improved planning; Improved customer service; Improved customer loyalty; Lower inspection costs of suppliers and increased co-operation etc.)	X	X

Benefit	AEOC	AEOS
Mutual Recognition with third countries		X

2.2.2.5. Customs resources

Customs face a significant challenge to manage increasing volumes of goods and tasks while facing a downward trend in resources[21]. The total number of personnel working in Customs Administrations in EU was 112.8 thousand at the end of 2015, this is a 10% decline since 2010 and a reduction of 2% in comparison to 2014.



**When interpreting these figures, it should be taken into consideration that not all the MS are able to provide the exact data on the allocation of their staff. This could be due to merged organisations where the customs are mixed together with tax administrations, etc. In such cases, data was only estimated by the MS.*

3. RESOURCES AND EXPERTISE OF AUTHORITIES (BASELINE)

EU rules on market surveillance for products contain an obligation for Member States to entrust market surveillance authorities with the power, resources and knowledge necessary for the proper performance of their tasks. No definition is provided for the concept of 'proper performance' of the tasks of market surveillance authorities. The provision does not set out an obligation to indicate the desirable level of performance or the amount of resources allocated. Common rules simply specify that authorities' should perform 'checks on the characteristics of products on an adequate scale'. In order to increase transparency on available resources the Commission in collaboration with Member States has proposed specific market surveillance indicators concerning budget and staff and developed methodology to estimate them.

3.1. Information on resources based on national reports for the 2010-2013

The analysis[22] of the information on budget and staff provided by the member states for the 2010- 2013 period allowed the identification of the following findings:

- The total **budget available to MSAs** in nominal terms at EU level:[23]
- The total **budget available to MSAs** in nominal terms at EU level:[24]
  - Decreased during 2010-2013 (from €133.4 mil. to €123.8 mil.),

21 Developing the EU Customs Union and its governance, COM(2016)813 final, 21.12.2016.
22 Source: Final report of the Ex-post evaluation of the application of market surveillance provisions of regulation (EC) No 765/2008.
23 Not all EU-28 Member States provided reliable data for this indicator. Therefore, figures do not include Austria, Cyprus, Estonia, Greece, Croatia, Luxembourg, Slovenia, the United Kingdom and Hungary.
24 Not all EU-28 Member States provided reliable data for this indicator. Therefore, figures do not include Austria, Cyprus, Estonia, Greece, Croatia, Luxembourg, Slovenia, the United Kingdom and Hungary.

- It was concentrated in a reduced number of countries and large differences could be noticed in terms of budget available to each country during the four year-period;

- It represented around 0.1-1.33%[25] out of the total national budget;

- A similar evolution was registered by the **human resources**. During the period 2010-2013 a reduction of FTEs available to MSAs can be registered as well as a concentration of FTEs on a reduced number of countries;

- However, the analysis revealed an increasing trend in the **number of inspectors**, though specific interviews are needed to further investigate differences across countries and to triangulate data.

More details on each of these findings are presented below. Moreover, they should be considered only preliminary findings that will be further investigated and correlated with results from other study activities (market analysis and field research).

3.1.1. Financial resources available for market surveillance activities

As for the **total budget available to MSAs in nominal terms**, the data indicates reduced annual fluctuations at the EU level, though in a negative direction. The figures refer to 19 out of 28 EU Member States, as Austria, Cyprus, Estonia, Greece, Croatia, Luxembourg, Slovenia and United Kingdom have not included this data in their national reports. Moreover, Hungary has reported values since 2011, therefore it was not considered the lack of data for 2010 would have created a different perspective on the 2010-2013 trends.

Table 11-5: Budget available to market surveillance authorities in nominal terms (€) for selected sectors in the 2010-2013 period

Sectors	Number of Member States providing budget information	Average amount of resources per Member State and per year (simple average)	Average amount of resources per 1000 inhabitants (population on 1 January 2015)[26]
SECTOR 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	8[27]	1,391,889 €	34.14 €
SECTOR 2 - Cosmetics	8[28]	4,993,718 €	43.21 €
SECTOR 3 - Toys	8[29]	1,917,787 €	17.48 €

25 The figures refer to 10 countries that provided reliable data, precisely: Denmark, Estonia, Spain, Finland, Italy, Latvia, Malta, Poland, Sweden and Slovakia.

26 Population on 1 January 2015 as provided by Eurostat

27 Denmark, Ireland, Cyprus, Latvia, Portugal, Slovenia, Finland and Sweden.

28 Denmark, France, Hungary, Portugal, Slovenia, Slovak Republic, Finland and Sweden

29 Bulgaria, Denmark, Ireland, France, Hungary, Slovenia, Finland and Sweden. For Ireland, the budget across is the total NCA budget for all activities (excluding financial awareness and education), since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities. For France, the number provided doesn't include the budget for product testing. Slovenia has provided the overall authority budget. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

Sectors	Number of Member States providing budget information	Average amount of resources per Member State and per year (simple average)	Average amount of resources per 1000 inhabitants (population on 1 January 2015)[26]
SECTOR 4 - Personal Protective Equipment	7[30]	270,913€	2.53 €
SECTOR 5 - Construction Products	8[31]	425,273 €	3.39 €
SECTOR 6 - Aerosol dispensers	4[32]	9,635 €	0.50 €
SECTOR 7 - Simple pressure vessels and Pressure Equipment	6[33]	355,540 €	3.39 €
SECTOR 8 - Transportable pressure equipment	6[34]	274,912 €	2.86 €
SECTOR 9 - Machinery	7[35]	564,028 €	5.27 €
SECTOR 10 - Lifts	4[36]	425,111 €	15.08 €
SECTOR 11 - Cableways	2[37]	741,722 €	57.67 €
SECTOR 12 - Noise emissions for outdoor equipment	4[38]	169,647 €	1.94 €
SECTOR 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	6[39]	210,451 €	2.04 €
SECTOR 14 - Pyrotechnics	5[40]	336,074 €	3.90 €
SECTOR 15 - Explosives for civil uses	4[41]	196,517€	2.44 €
SECTOR 16 - Appliances burning gaseous fuels	8[42]	186,410 €	1.70 €

30 Bulgaria, Denmark, France, Hungary, Slovenia, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

31 Bulgaria, Denmark, France, Cyprus, Hungary, Romania, Finland and Sweden.

32 Bulgaria, Denmark, Cyprus and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

33 Bulgaria, Denmark, France, Hungary, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

34 Bulgaria, Denmark, France, Cyprus, Hungary and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

35 Bulgaria, Denmark, France, Hungary, Slovenia, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

36 Bulgaria, Denmark, Hungary and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

37 Bulgaria and Denmark. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

38 Bulgaria, Italy, Hungary and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

39 Bulgaria, Denmark, France, Hungary, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

40 Bulgaria, Denmark, France, Cyprus and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

41 Bulgaria, France, Cyprus and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

42 Belgium, Bulgaria, Denmark, France, Cyprus, Hungary, Slovenia and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

Sectors	Number of Member States providing budget information	Average amount of resources per Member State and per year (simple average)	Average amount of resources per 1000 inhabitants (population on 1 January 2015)[26]
SECTOR 17 - Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	8[43]	331,374 €	2.87 €
SECTOR 18 - Electrical equipment under EMC	11[44]	1,213,247 €	5.51 €
SECTOR 19 - Radio and telecom equipment under RTTE	11[45]	1.630.901 €	7.37 €
SECTOR 20 - Electrical appliances and equipment under LVD	10[46]	663,663 €	5.74 €
SECTOR 21 - Electrical and electronic equipment under RoHS, WEEE and batteries	5[47]	191,120 €	5.83 €
SECTOR 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)	7[48]	145,000 €	1.50 €
SECTOR 23 - Ecodesign and Energy labelling	8[49]	215,344 €	1.99 €
SECTOR 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	4[50]	120,924 € €	2.65 €
SECTOR 25 - Recreational craft	4[51]	284,264 €	2.86 €
SECTOR 26 - Marine Equipment	2[52]	75,854 €	2.97 €
SECTOR 27 - Motor vehicles and tyres	6[53]	456,843 €	4.30 €
SECTOR 28 - Non-road mobile machinery	2[54]	14,324 €	0.73 €
SECTOR 29 - Fertilisers	9[55]	135,641 € €	1.06 €

43 Bulgaria, Denmark, France, Hungary, Austria, Slovenia, Finland and Sweden. Bulgaria calculated the budget by multiplying the number of staff available to market surveillance authorities by the average amount per unit applicable to the year concerned. France included budget only for pre-packaged products.

44 Belgium, Bulgaria, Denmark, Germany, France, Cyprus, Hungary, Romania, Slovenia, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

45 Belgium, Bulgaria, Denmark, Germany, Estonia, France, Portugal, Romania, Slovenia, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

46 Belgium, Bulgaria, Denmark, France, Cyprus, Latvia, Hungary, Slovenia, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities. For Slovenia, the number of the budget includes also the costs of laboratory tests and payment for samples taken, with a corresponding claim from the liable party for the reimbursement of costs in the case of a compliant product.

47 Bulgaria, Denmark, Ireland, Hungary and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

48 Denmark, Ireland, France, Latvia, Hungary, Slovenia and Finland.

49 Belgium, Bulgaria, Ireland, France, Cyprus, Hungary, Slovenia and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

50 Belgium, Ireland, Hungary and Romania.

51 Bulgaria, France, Romania and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

52 Denmark and Romania.

53 Belgium, Bulgaria, Denmark, France, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

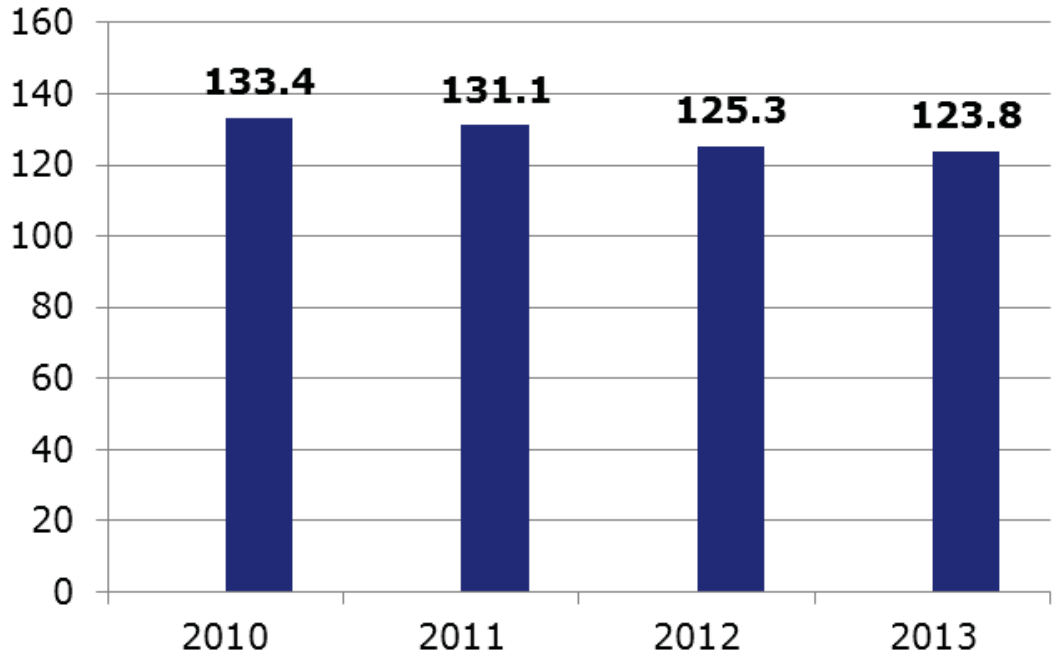
54 Hungary and Sweden.

55 Czech Republic, Denmark, France, Latvia, Hungary, Romania, Slovenia, Slovak Republic and Finland. Belgium provided also figures but this has not been taken into account, since the FASFC submitted its total annual budget which covered integrated inspection services covering the whole of the food chain.

Sectors	Number of Member States providing budget information	Average amount of resources per Member State and per year (simple average)	Average amount of resources per 1000 inhabitants (population on 1 January 2015)[26]
SECTOR 30 - Other consumer products under GPSD	5[56]	1,514,284 €	15.26 €

Source: national reports

Figure 11-3: Total budget available to MSAs in nominal terms during 2010-2013, € millions [57]



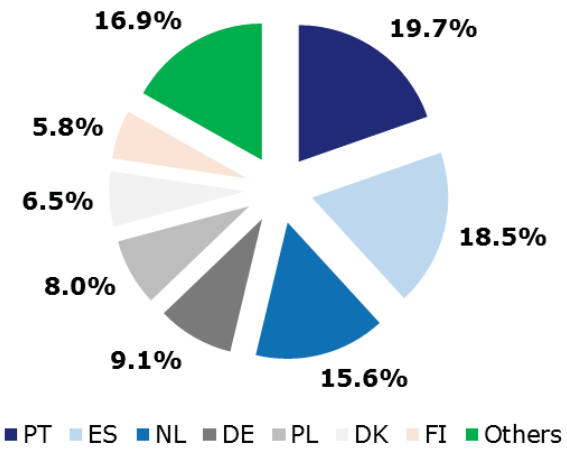
Source: National reports

As emerged from the national reports, the budget reflects all financial resources assigned to market surveillance and enforcement activities, including related infrastructures as well as projects and measures aimed at ensuring compliance of economic operators with product legislation. These measures range from communication activities (consumer/business information and education) to pure enforcement and market surveillance activities. They include the remuneration of staff, direct costs of inspections, laboratory tests, training and office equipment cost. Enforcement activities at regional/local level should also be reported. Other activities undertaken by these authorities not related to the enforcement of product legislation should be excluded from the calculation.

56 Bulgaria, France, Hungary, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

57 The data correspond to 19 out of 28 EU Member States (please see the explanation in the paragraph above the figure)

Figure 11-4: Contribution of each MS to the total budget available in nominal terms to MSA at EU level over 2010-2013[58]

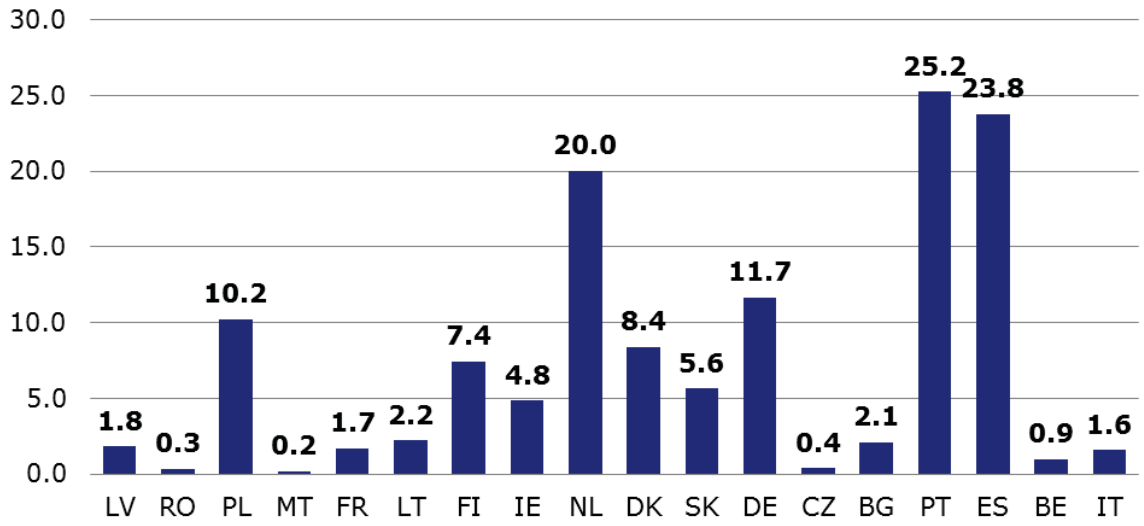


Source: National reports

At country level, during 2010-2013, the following findings emerged:

- More than 80% of the total budget available to the 18 MSAs reporting data in nominal terms is concentrated in seven Member States;
- More than half of the Member States providing data had an available annual budget smaller than €10 million;
- Only three countries (Portugal, the Netherlands, and Spain) declared an annual budget allocated to market surveillance activities equal to or greater than €20 million.

Figure 11-5: Annual budget available to MSA in nominal terms, average 2010-2013, € millions



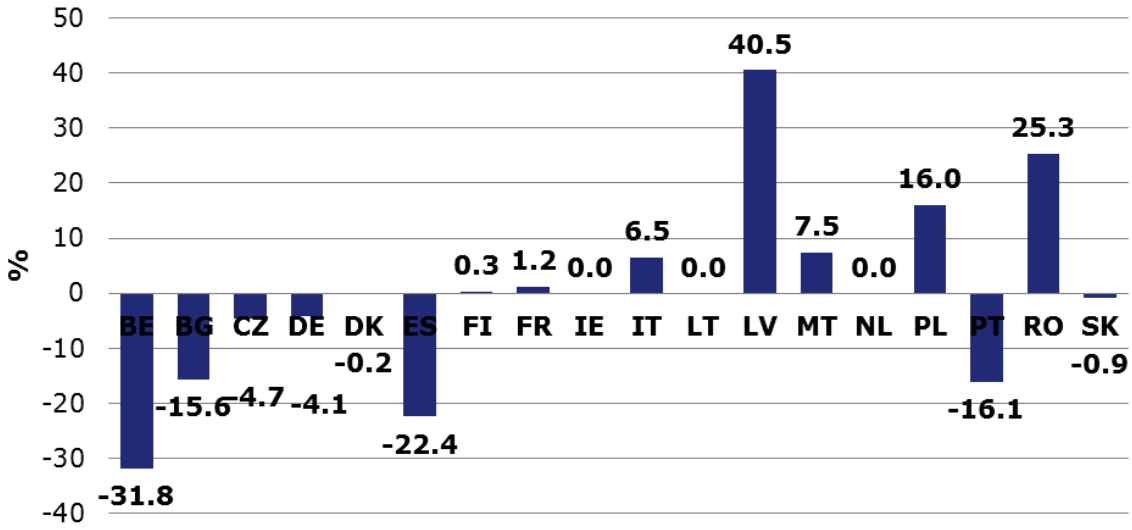
Source: National reports

58 Please consider that data for the UK are not available. "Others" includes France.

As shown in the figure below, over the period considered the total budget allocated annually to market surveillance activities increased in eight Member States[59] and decreased in seven Member States.[60] In other countries (Ireland, the Netherlands and Lithuania) the budget remained stable over the period 2010-2013. The magnitude of reduction and increase of the total budget available to national MSAs also differs. On a three-dimension scale (0-10% – limited, 10-30% – moderate, 40-50% – high) the variation of total budget (both in positive and negative terms) was:

- High in two Member States (Belgium -32% and Latvia +40.5%);
- Moderate in five Member States (increase in Romania and Poland, reduction in Bulgaria, Spain and Portugal);
- Limited in more than half of the Member States, i.e. in 12 out of 18.

Figure 11-6: Variation (%) of the average annual budget available to MSAs in nominal terms average 2010-2013, € M



Source: National reports

Compared to the total national budget, the total budget allocated per country for market surveillance activities (**total budget available to MSAs in relative terms**) represents no more than 0.2% in half of Member States reporting data. There are also countries that concentrated a higher percentage of financial resources on the functioning of market surveillance activities, namely: Estonia (an average of 0.52%) and Poland (1.33%). Bulgaria and the Czech Republic also provided data on the total budget available to MSAs in relative terms, though they were not considered in the analysis as their reliability is questionable (the values being significantly higher than the ones reported by the other Member States: the national authorities from Bulgaria declared values that amount to an average of 47.2%, while the Czech authorities values around 92.58% of the total national budget). As mentioned also for the first indicators, Hungarian authorities have not reported data for 2010, therefore the country was not included in the analysis.

59 FI, FR, IT, LT, LV, MT, PL, RO.
60 BE, BG, CZ, DE, ES, PT, SK.

3.1.2. Human resources available for market surveillance activities

The **staff available to MSAs (FTE units)** is another indicator relevant for computing the enforcement costs incurrent by national authorities. The uninterrupted negative trend registered by the budget available for MSA expressed in nominal terms can be observed also in this case, potentially as a result of the budget decrease. Consequently, the costs incurred by the national authorities in their endeavours to enforce the implementation of the Regulation related to the staff are lower starting in 2013 compared with 2010. Nineteen countries compliant with the Regulation provision to provide the data for all four years have been considered in the data processing; Hungary, as stated before, did not provide all necessary data.

Table 11-6: Staff available to market surveillance authorities for selected sectors in the 2010-2013 period

Sectors	Number of Member States providing staff information	Average amount of staff available per Member State and per year(simple average)	Average amount of staff available per 1000000 inhabitants (population on 1 January 2015)[61]
SECTOR 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	12[62]	58.60	0.46
SECTOR 2 - Cosmetics	11[63]	255.55	1.33
Sector 3 - Toys	9[64]	32.28	0.26
Sector 4 - Personal Protective Equipment	8[65]	12.38	0.10
SECTOR 5 - Construction Products	11[66]	17.94	0.11
SECTOR 6 - Aerosol dispensers	6[67]	21.82	0.53
SECTOR 7 - Simple pressure vessels and Pressure Equipment	8[68]	23.40	0.18
SECTOR 8 - Transportable pressure equipment	8[69]	23.27	0.21
Sector 9 - Machinery	8[70]	71.67	0.41

61 Population on 1 January 2015 as provided by Eurostat
62 Czech Republic, Denmark, Ireland, Italy, Cyprus, Latvia, Hungary, Portugal, Slovenia, Slovak Republic, Finland and Sweden.
63 Czech Republic, Denmark, Ireland, France, Italy, Hungary, Portugal, Slovenia, Slovak Republic, Finland and Sweden.
64 Bulgaria, Denmark, Ireland, Greece, France, Hungary, Slovenia, Finland and Sweden. For Ireland, the number includes the number of authorised officers in Product Safety Unit with additional authorised officers available to assist on specific projects if required. Slovenia has submitted the total number of employees. Bulgaria has submitted the total number of employees.
65 Belgium, Bulgaria, Denmark, Greece, France, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.
66 Belgium, Bulgaria, Czech Republic, Denmark, Greece, France, Cyprus, Hungary, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.
67 Belgium, Bulgaria, Denmark, Greece, Cyprus and Finland. Bulgaria has submitted the total number of employees.
68 Belgium, Bulgaria, Denmark, Greece, France, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.
69 Bulgaria, Denmark, Greece, France, Cyprus, Hungary, Slovenia and Finland. Bulgaria has submitted the total number of employees.

Sectors	Number of Member States providing staff information	Average amount of staff available per Member State and per year(simple average)	Average amount of staff available per 1000000 inhabitants (population on 1 January 2015)[61]
SECTOR 10 - Lifts	5[71]	22.51	0.58
SECTOR 11 - Cableways	6[72]	18.41	0.42
SECTOR 12 - Noise emissions for outdoor equipment	6[73]	13.54	0.14
SECTOR 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	7[74]	12.41	0.12
SECTOR 14 - Pyrotechnics	9[75]	10.30	0.06
SECTOR 15 - Explosives for civil uses	8[76]	9.62	0.08
SECTOR 16 - Appliances burning gaseous fuels	9[77]	9.82	0.08
Sector 17 - Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	9[78]	10.91	0.09
SECTOR 18 - Electrical equipment under EMC	11[79]	17.45	0.08
SECTOR 19 - Radio and telecom equipment under RTTE	11[80]	18.49	0.08
Sector 20 - Electrical appliances and equipment under LVD	10[81]	16.64	0.13

70 Bulgaria, Denmark, Greece, France, Italy, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.France provided an estimate of the staff available to market surveillance activities. Sweden submitted numbers for both the Swedish Work Environment Authority and the Swedish National Board of Housing, Building and Planning.

71 Bulgaria, Denmark, Greece, Hungary and Finland. Bulgaria has submitted the total number of employees.

72 Bulgaria, Denmark, Portugal, Slovak Republic, Finland and Sweden. Bulgaria has submitted the total number of employees.

73 Bulgaria, Denmark, Italy, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

74 Bulgaria, Denmark, France, Cyprus, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

75 Bulgaria, Czech Republic, Denmark, Ireland, Greece, France, Italy, Cyprus and Finland. Bulgaria has submitted the total number of employees.

76 Bulgaria, Czech Republic, Ireland, Greece, France, Cyprus, Hungary and Finland. Bulgaria has submitted the total number of employees.

77 Belgium, Bulgaria, Denmark, Greece, France, Cyprus, Luxembourg, Hungary and Finland. Bulgaria has submitted the total number of employees.

78 Bulgaria, Denmark, France, Hungary, Austria, Slovenia, Slovak Republic, Finland and Sweden. Bulgaria has submitted the total number of employees.

79 Belgium, Bulgaria, Denmark, Germany, Greece, France, Cyprus, Hungary, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.

80 Belgium, Bulgaria, Denmark, Germany, Estonia, France, Cyprus, Portugal, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.

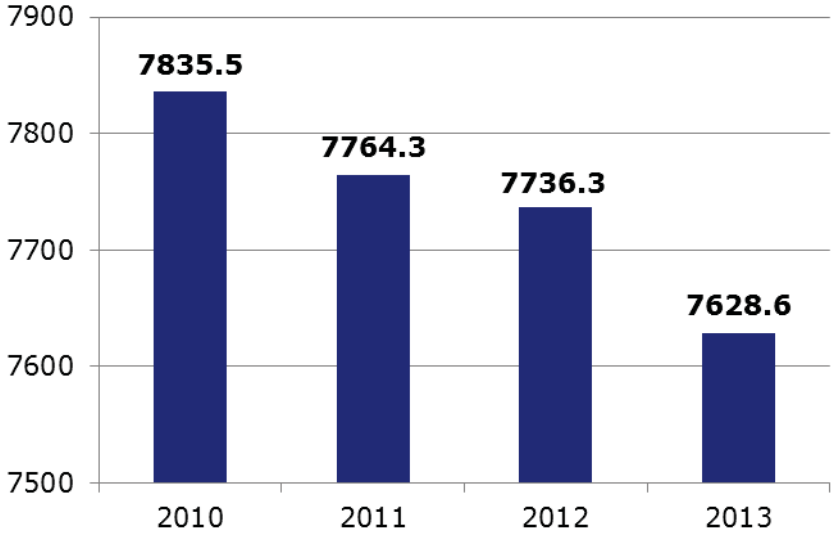
81 Belgium, Bulgaria, Denmark, Greece, France, Cyprus, Latvia, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

Sectors	Number of Member States providing staff information	Average amount of staff available per Member State and per year(simple average)	Average amount of staff available per 1000000 inhabitants (population on 1 January 2015)[61]
SECTOR 21 - Electrical and electronic equipment under RoHS, WEEE and batteries	6[82]	13.54	0.31
SECTOR 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)	9[83]	64.44	0.55
SECTOR 23 - Ecodesign and Energy labelling	10[84]	14.53	0.11
SECTOR 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	6[85]	9.18	0.15
SECTOR 25 - Recreational craft	7[86]	12.35	0.12
SECTOR 26 - Marine Equipment	5[87]	1.58	0.01
SECTOR 27 - Motor vehicles and tyres	10[88]	17.43	0.12
SECTOR 28 - Non-road mobile machinery	3[89]	0.43	0.02
SECTOR 29 - Fertilisers	12[90]	9.19	0.06
SECTOR 30 - Other consumer products under GPSD	5[91]	46.94	0.47

Source: national reports

82 Bulgaria, Denmark, Ireland, Greece, Hungary and Finland. Bulgaria has submitted the total number of employees.
83 Czech Republic, Denmark, Ireland, Greece, France, Latvia, Hungary, Slovenia and Finland.
84 Belgium, Bulgaria, Czech Republic, Ireland, Greece, France, Cyprus, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.
85 Belgium, Ireland, Greece, Hungary, Romania and Finland.
86 Bulgaria, Denmark, Greece, France, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.
87 Denmark, France, Italy, Romania and Finland.
88 Belgium, Bulgaria, Denmark, France, Cyprus, Portugal, Romania, Slovenia, Finland and Sweden. Bulgaria has submitted the total number of employees.
89 Denmark, Hungary and Sweden.
90 Belgium, Czech Republic, Denmark, Ireland, Greece, France, Latvia, Hungary, Romania, Slovenia, Slovak Republic and Finland.
91 Bulgaria, France, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

Figure 11-7: Total staffs available to MSAs (FTE units) during 2010-2013 at EU level[92]



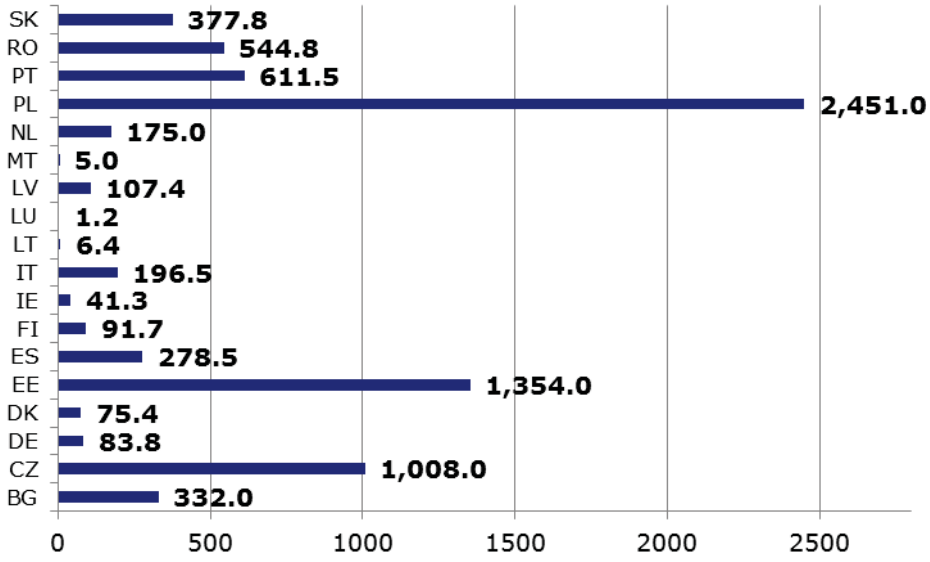
Source: National reports

The analysis at country level concerning the total staffs available to MSAs (FTE units) revealed the following:

- On average, 7,741 staff resources (FTEs) were available for the MSAs of 18 EU countries during the period 2010 – 2013;
- 86.3% of staff resources (6,679) were based in seven Member States (Poland, Estonia, the Czech Republic, Portugal, Romania, Slovakia, and Bulgaria;
- More than 30% of total staff resources were based in one country (Poland;
- There were large differences among countries in terms of total staff resources available over the period 2010-2013. On the one hand, a large number of Member States (15 out of 18) involve less than 1,000 FTEs in market surveillance activities. On the other hand, Poland reported a significantly greater number of FTEs available to the MSAs, more than five times higher than staff resources declared by the majority of the countries.

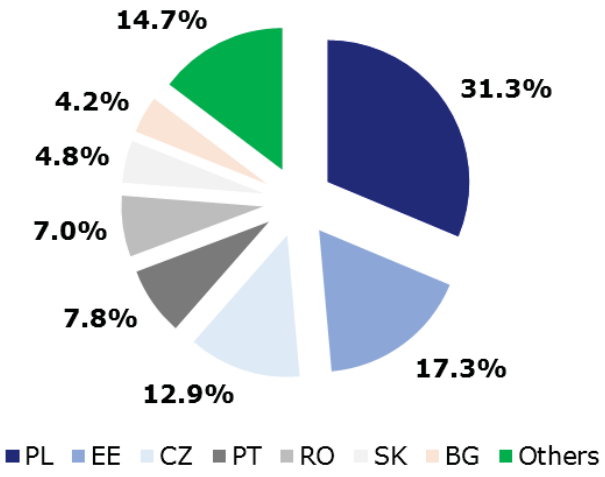
92 The analysis includes the following countries: Bulgaria, Czech Republic, Deutschland, Denmark, Estonia, Spain, Finland, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Poland, Portugal, Romania, Sweden, Slovakia; the other EU Member States have not provided complete and reliable data in their national reports

Figure 11-8: Total staff available to MSAs at country level (average 2010 – 2013), FTEs



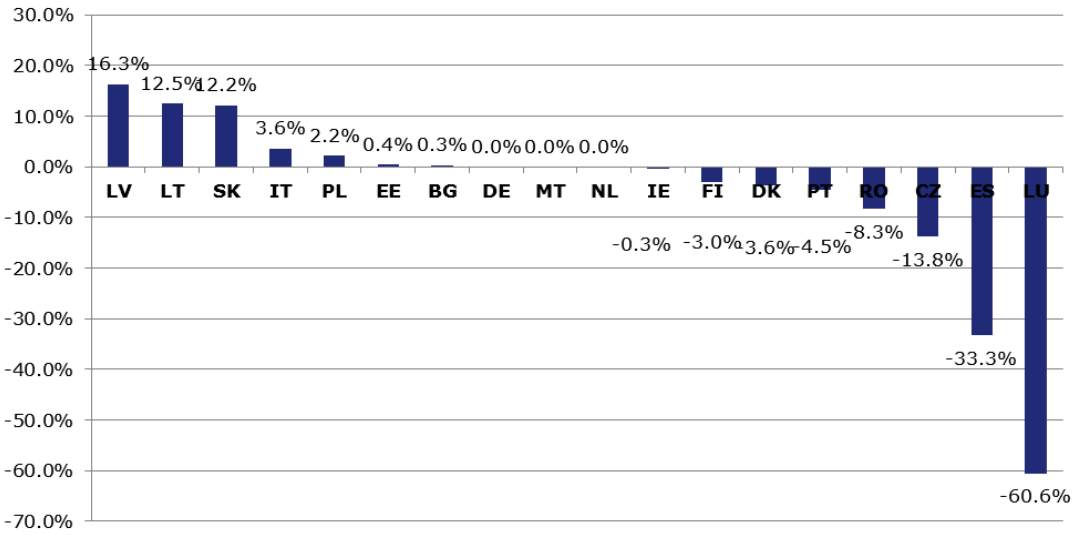
Source: National reports

Figure 11-9: Total staff available to MSAs (FTE units) per country over 2010-2013



Source: National reports

Figure 11-10: Variation of total staffs available to MSAs (FTE units) over 2010-2013



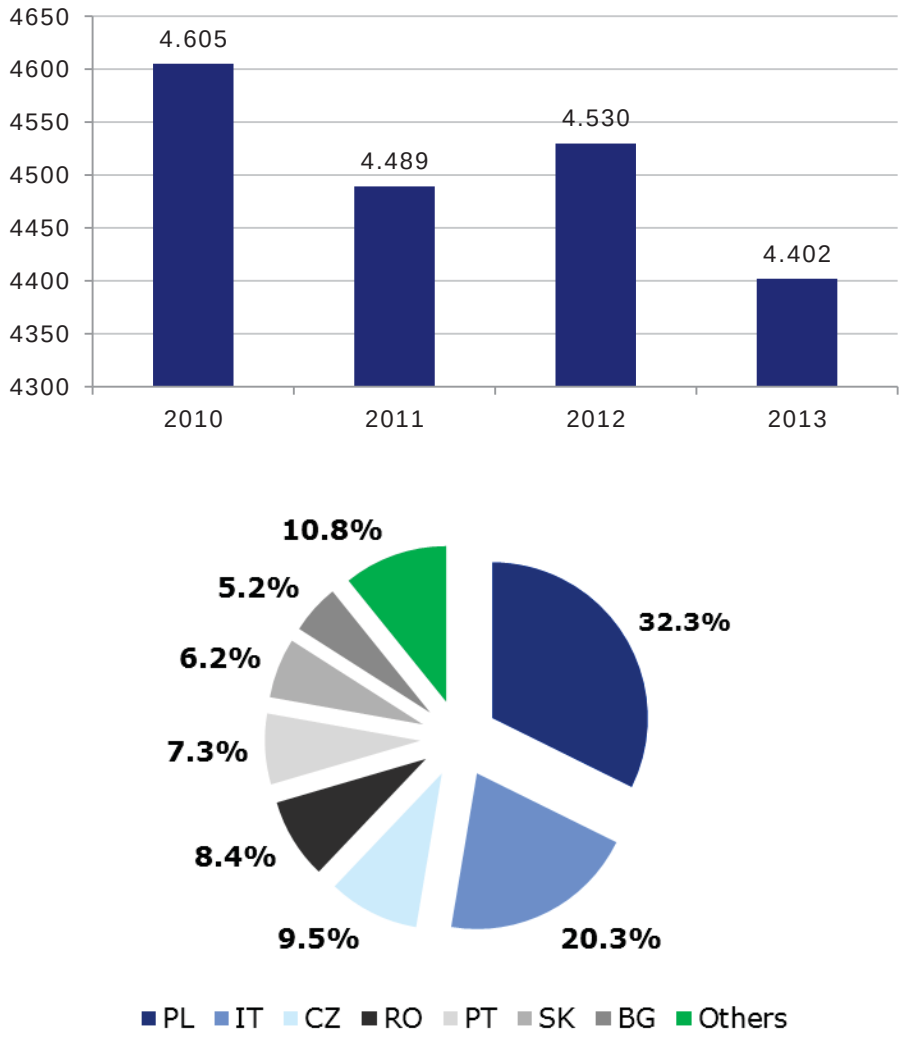
Source: National reports

The highlights of the analysis concerning the **variation** of total staff resources available to MSAs (FTE units) over the period 2010-2013 are:

- More than half of the Member States considered (11) displayed a relatively stable trend in the number of staff resources available to MSA (FTE units) with a variation of less than 5% of the value registered in 2010;
- three Member States (Latvia, Lithuania and Belgium) declared an increase between 12.2% and 16.3%;
- The magnitude of total staff reduction was very different: the largest percentage decrease (-60.6% - Luxembourg) was almost twice as high as the second largest percentage reduction (33.3% - Spain) and 202 times higher than the smallest reduction (0.3% - Ireland).

While at the EU level the budget available to market surveillance activities suffered continuous adjustments and the total staff resources available to MSAs (FTE units) registered a negative trend, the **number of inspectors (FTE units)** followed a fluctuating trend (decreasing one year, increasing in the next one, then decreasing again) which could be translated into fluctuating staff costs during this period (Figure 20). In this case, only 16 Member States provided completed data and were included in the analysis.

Figure 11-11: Total number of inspectors available to MSAs (FTE units) over 2010-2013 at EU level and Total number of inspectors (FTE units) available to MSAs per country over 2010-2013



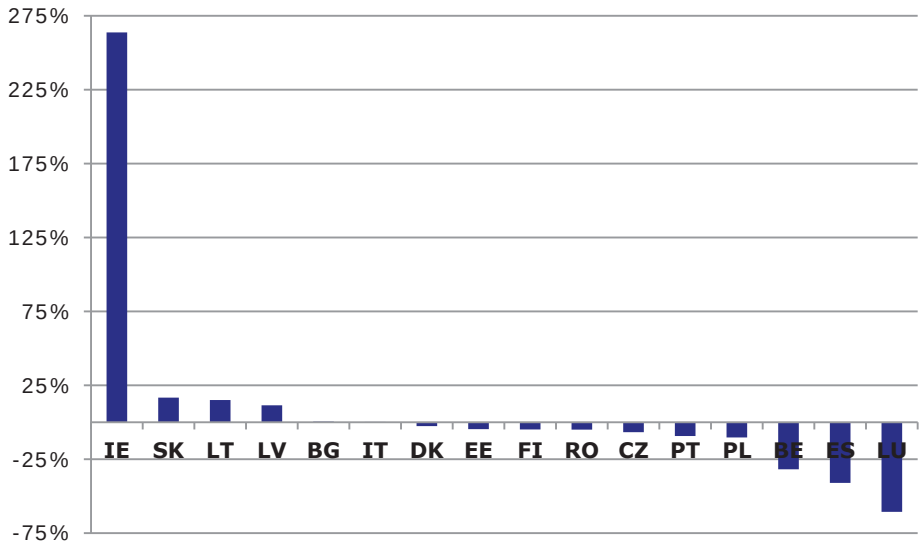
Source: National reports

Regarding the total number of inspectors (FTE units) available to MSAs over 2010-2013 at country level, the following emerged:

- On average, 4,506 inspectors were available to the 16 Member States considered for inspection activities;
- The majority (90%) of inspectors (4,019) were based in six Member States - Poland, Italy, the Czech Republic, Romania, Portugal, and Slovakia;
- Around half (2,372) of the FTEs dedicated to inspection activities were employed in two Member States (Poland, and Italy);
- The magnitude of the costs derived from the number of inspectors (FTE units) varies across Member States, as for instance in Luxembourg and Lithuania (included in the Others category) only 4.6 and 21.74 FTEs, respectively, have been allocated to market surveillance activities, while Poland involved 5,822 FTEs.

The reasons behind all of the differences presented in this section of the study will be further investigated during the interviews, the details to be required depending on the interviewee's experience and expertise.

Figure 11-12: Variation of total number of inspectors (FTE units) available to MSAs per year, during 2010-2013



Source: National reports

At country level, the analysis of the change in the number of inspectors available to MSAs annually reflects the following:

- In the majority of countries (10 out 16) the number of inspectors decreased;
- Six countries (Bulgaria, Italy, Denmark, Estonia, Finland, and Romania) had relatively stable trends, with the increase or decrease in the number of inspectors not being higher than 5% of the number of inspectors available to MSAs in 2010;
- A significant increase (263.8%) was registered in Ireland.
- Except for two countries (Ireland and Poland), the overall trend in the total inspectors available to MSAs during the four years considered tends to be aligned with the one for the total staff available to MSAs..
- On the basis of the figure on budgets and number of inspections provided by Member States the following estimates of costs of enforcement are provided. It is noted they are largely variable due to the limited number of data points and some issues of comparability.

Table 11-7: Indicative estimate of costs of inspections in Member States

MS	Nominal budget (Av. '10-'13) €	Δ% 2010 - 2013	Number of inspections (Av. '10-'13)	Δ% 2010 - 2013	Average cost of inspections €	Number of tests performed in laboratories (Av. '10-'13)	Δ% 2010 - 2013	Average cost of tests €
	(a)		(b)		(a)/(b)	(d)		(a)/(d)
BE	946,903	-32%	4,701	94%	201	386	-45%	2,452
BG	2,114,559	-16%	10,953	58%	193	466	21%	4,535
CZ	384,594	-5%	6,200	-4%	62	166	-55%	2,313
DK	8,386,750	0%	1,754	14%	4,782	561	0%	14,950
FI	1,417,861	0%	7,448	0%	996	2924	6%	2,537
FR	1,680,000	1%	16,119	-1%	104	1147	-1%	1,465
IE	4,825,000	0%	15,401	32%	313	193	-58%	25,000
IT	1,561,372	6%	6,110	11%	256	581	153%	2,690
LV	1,818,645	40%	3,221	-1%	565	361	63%	5,038
MT	163,592	7%	939	-7%	174	:	:	:
PL	10,229,088	16%	7,605	5%	1,345	926	44%	11,047
PT	25,229,517	-16%	12,670	174%	1,991	411	-9%	61,348
RO	320,108	25%	12,071	-14%	27	2716	-35%	118
SE	14,258,602	n/a	3,593	-3%	3,968	367	-14%	38,852
SK	5,634,232	-1%	3,610	-31%	1,561	352	-30%	15,995
Aver	5,264,722	0.92%	7,493	21%	703	770	-7%	6,837

Source: Evaluation study

3.2. Information on resources based on reports for the chemicals area

REACH and Classification and Labelling of Products regulation (CLP), 22 countries provided information on the resources allocated to enforcing authorities for tasks related to the enforcement of REACH. Among them, 12 indicated that it was difficult, and in most cases impossible to provide an estimate of the annual budget and staff dedicated to REACH enforcement, since inspectors carry out tasks related to more than 1 legislation, often in joint inspections, and no separate budget is allocated specifically to REACH. 15 countries provided an estimate of annual staff and/or budget dedicated to REACH enforcement.

Table 11-8: Staff and budget allocated to REACH enforcement

Country	Staff dedicated to REACH enforcement	Budget allocated to REACH enforcement
Austria	In average, a resource of 1 man-year is available for enforcement activities related to the whole chemical legislation in the competence of the inspectorates in each of the Lander (9 man-year in total).	
Croatia	4 inspectors on national level 30 inspectors on regional level	
Czech Republic	13 regional inspectors responsible for chemical legislation	
Denmark	The Chemical Inspection Service: 3 man-years enforcing REACH Danish Working Environment Authority special unit on market surveillance: 2 man-year enforcing SDS and ES; 0.1 man-year for general inspection in which REACH is discussed Danish Maritime Authority: 0.1 man-year for general inspection in which REACH is discussed	
France	Ministry of Ecology: 26 environment inspectors enforce REACH	
Greece	55 chemists in NEA perform tasks related to REACH	
Hungary	There are approximately 90 chemical safety inspectors responsible for the whole chemical safety legislation in the competence of the NEA	
Ireland	EPA: ~0.2FTE for work associated with REACH DAFM: 27 staff enforcing REACH related to pesticides HSA: 12.9 FTEs inspectors for chemical legislation (approximately 3.2 FTE for REACH and CLP)	EPA: Approximately €6,200 (not including labour costs) for REACH and Detergents Regulation HSA: 250,000 - 300,000 Euros (including only human resources)
Liechtenstein	1 inspector in NEA	
Lithuania	State environmental protection service has 3 inspectors specialised in enforcing chemical legislation	
Norway	There is approximately 8.6 FTE in the NEA working on REACH	
Poland	The Inspection of Environmental Protection has allocated 20 full-time jobs dedicated to enforcement of REACH to regional (Voivodship) inspectorates of Environmental Protection. The State Labour Inspectorate and the District Labour Inspectorates all have a REACH coordinator.	
Portugal	IGAMAOT has 7 inspectors allocated to REACH, CLP, Seveso Directive and other environmental legislation	

Country	Staff dedicated to REACH enforcement	Budget allocated to REACH enforcement
Slovenia	4 inspectors in NEA	
United Kingdom	The Compliance Team of HSE has 3 FTEs to work on REACH. There are other Enforcers also working on REACH. HSENI has 0.1 FTE. NIEA has 4 staff (not full time on REACH). Environmental Agency has 5.4 staff (not full time on REACH).	

Cells were left blank when CAs have not reported any information.

Out of the 22 countries which provided information on the level of resources dedicated to the Classification and Labelling of Products regulation (CLP), 13 have reported the same information as for the enforcement of REACH. As previously mentioned, a lot of countries do not have resources specifically allocated to the enforcement of CLP or REACH, which is covered by the CA's budget. 5 countries provided specific data for CLP:

Table 11-9: Staff and budget allocated to CLP enforcement

Country	Staff dedicated to CLP enforcement	Budget allocated to CLP enforcement
Belgium	Federal Environmental Inspection: 2011: 7 FTE; 2012: 5 FTE; 2013: 6 FTE; 2014: 7.2 FTE	General budget (including analysis) 2011: €276,000; 2012: €289,000; 2013: €223,000; 2014: €160,350 (total cost for the inspection service (inspectors, technical experts and controllers on the transit of waste).
Croatia	4 inspectors at national level 20 inspectors at regional level	
Denmark	2 man-year	
Iceland	0.1 FTE in the Environment Agency	
Latvia	Impossible to distinguish resources only dedicated to CLP. However Health Inspectorate has indicated that they have 10 persons involved in CLP control.	Annual budget of Health Inspectorate for enforcement of chemicals and cosmetics legislation is approximately 300,000 EUR.

ANNEX 12: BACKGROUND INFORMATION ON OBJECTIVE 2 – INCREASING OPERATIONAL ENFORCEMENT CAPACITY

1. PROBLEM ANALYSIS AND BASELINE

- *Low and increasingly constrained resource levels for market surveillance in Member States*

  Staff and budgets dedicated to market surveillance show a consistent **downward trend** throughout the EU Member States over the period 2010-2013[93]. A year after the adoption of Regulation (EC) N° 765/2008, 21 (of then 27) Member States had not allocated additional resources or considered resources sufficient[94]. The 2016 public consultation results confirm that lacking **human and financial resources** are now **a major factor constraining the market surveillance authorities' control activity** (51% of all respondents, and 63% of authorities themselves). While imports are on the increase[95] and constitute a source of non-compliant goods entering the EU[96], customs faced a 10% decline in human resources in the period 2010-2015[97].

  The lack of sufficient **technical means**, in particular lacking testing capacity, is also at play, be it to a somewhat lesser extent (by all respondents 36% and by 44% of authorities themselves). In case a market surveillance authority lacks in-house testing capacity, it can in principle purchase tests from private laboratories and obtain the necessary substantive compliance tests. However if the authorities' financial resources are limited also this option is compromised.

  Laboratory, physical testing of product samples constitutes a major cost component especially for complex products or certain type of tests. Costs of testing equipment and (outsourced) laboratory test represented 30 to 50% of recent co-funded projects[98]. Moreover, availability of testing capacities is not ensured in all member states and/or for all type of products and tests: MSA and customs survey results[99] show that in-house is often not available to authorities and sharing of laboratory capacity between MSA and customs does not often occur.

93 Annex 11 Technopolis, Final report, Ex-post evaluation of the application of the market surveillance provisions of Regulation N°765/2008, May 2017.

94 Page 19, European Parliament, DG Internal Policies of the Union, study Effectiveness of market surveillance in Member States, 2009 http://www.europarl.europa.eu/document/activities/cont/201108/20110825ATT25294/20110825ATT25294EN.pdf

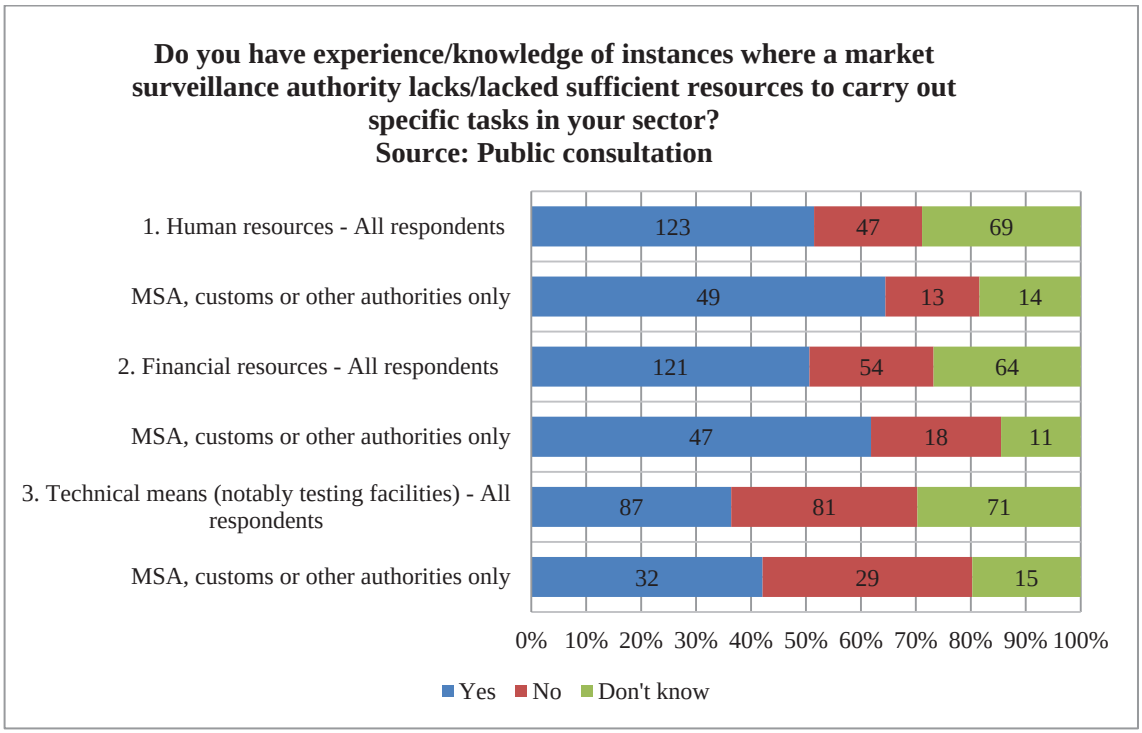
95 Technopolis, Final report, Ex-post evaluation of the application of the market surveillance provisions of Regulation N°765/2008, May 2017

96 In the period 2010-2016 68% to78% of all RAPEX notifications concerned imported products.

97 Annex 11.2; Developing the EU Customs Union and its governance, COM(2016)813 final, 21.12.2016.

98 Joint actions on heat and electricity measuring instruments; LED floodlights; vehicle service lifts, chain saws resulting from the 2013and 2014 call for proposals, DGGGROW.

99 Technopolis, Final report, Ex-post evaluation of the application of the market surveillance provisions of Regulation N°765/2008, May 2017; Report Mapping the differences in dealing with safety and compliance controls for products entering the Union, DGTAXUD, June 2016.



The state-of-play of available resources for market surveillance shows an **uneven coverage of sectors and significant variance in member states.** In general there is **a low level of human and financial resources** with on average a few euros (1-5€) per thousand inhabitants (with the exception in particular of medical devices, cosmetics and toys) and from 0 to maximum 0.5 inspectors per million inhabitants dedicated to market surveillance in the EU member states[100].

While co-funding possibilities exist in principle for joint projects of several Member Sates' authorities[101], options for funding support to national market surveillance controls and capacity building are rare, unlike in other areas such as food chain controls[102] [103].

- *Limited resources negatively impact control activities and reduce the deterrence effect of market surveillance*

The level of **available resources to market surveillance authorities directly influences the number of control activities** they can undertake and hence on the possible intelligence gathering, detection, investigation and ultimately sanctioning of instances of non-compliance. **Respondents place more and more efficient use of resources among the top 3 ways to improve deterrence** (72 and 73% agree or strongly agree, more publicity to restrictive measures ranking first with 75% agree or strongly agree answers). Authorities rank an increase in their resources as the best way to improve deterrence (87%). Resources constraints also impact on the possibilities for

100 Annex 11.
101 See Annex 11, co-funding sources for cross-border projects have been e.g. Consumer Programme, research programme Horizon 2020, and dedicated call for proposals by DGGROW, Internal market budget line dotation.
102 https://ec.europa.eu/food/funding_en;
103 Although there are no specific examples of use for products' market surveillance and actual control campaigns, EU funding sources could be available under the objective institutional capacity building (objective open for certain Member States in the European social fund) or compliance assistance activity by market surveillance authorities could be part of support programmes for SME. The Commission proposed programme to support structural reform could be also of relevance for institutional capacity building http://ec.europa.eu/europe2020/pdf/2016/ags2016_structural_reform_support_programme.pdf

authorities to engage in pro-active guidance and compliance assistance schemes for economic operators[104].

There is no simple reference to determine a sufficient or necessary level of controls and a corresponding budget. Although Regulation (EC) N° 765/2008 requires Member States to ensure controls at an "adequate level", both in domestic markets and for controls on product entering the EU, this requirement is not further specified. An overall indicative target, linked to population size and covering all products, applies in Germany and is found to be useful to plan and benchmark controls and resources in the different Länder[105]. Most member states rely on risks assessments to determine priorities and voice reservations on the validity of a single, **prescriptive quantitative target** to cover all product sectors. Customs controls also rely on risk-based assessment to select consignments for inspection without a pre-set quantitative target of inspections[106]. Besides risk profiles of products, market surveillance authorities and customs confirm that they **determine the "adequate scale" of controls mainly on the rationalisation of financial and human resources available**[107].

- *Weak information on financing and enforcement gaps in Member States to target controls better and exploit efficiency gains*

Despite the important limitation to enforcement stemming from resources constraints, the large majority of respondents (67% of all replies, 65% of authorities) could not provide a reliable quantitative estimate the **financial resources gap** that the market surveillance authorities face[108]. This mirrors the findings of the assessment of Member State reports on the implementation of Regulation (EC) N° 765/2008 which show a great variability in the available human resources, budgets and the number or inspections performed. The budgets member states allocated to market surveillance over the past years show little correlation with the size of the markets or the number of enterprises active in harmonised product sectors[109]. Similar findings and persistent difficulties to obtain coherent data sets on enforcement resources and activity and to correlate resources to output figures are also reported from other policies areas[110]. Nonetheless across the variety of member states, authorities and their economic context, a **positive trend linking increased resources to the issuing of more enforcement decisions** is observed in the competition policy area[111]. That being said, at present the research into the **effectiveness of market surveillance systems** does not allow a conclusion on an authoritative model linking resources input to an optimum level of controls and their ultimate effectiveness[112]. However the setting of objectives and

104 BSI, Study on Good practices in the area of Compliance assistance and compliance schemes (Annex 14.3)

105 The target applies to pro-active controls and is indicative: actual levels of controls are not achieved to the target level across the sectors or in all Länder. The depth and type of inspection (documentary check, testing, etc.) and the selection of sectors and operators is based on risks assessment, complaints and other information.

106 Article 46, Regulation (EU) N°952/2013, Union Customs Code http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0952&rid=1

107 Technopolis, Final report, Ex-post evaluation of the application of the market surveillance provisions of Regulation 765/2008, May 2017.

108 The remaining responses do not give a clear pattern with estimates of financial gaps ranging from 5 to over 50%.

109 Technopolis, Ex-post evaluation of the application of the market surveillance provisions of Regulation (EC)n° 765/2008, Final report, May 2017.

110 European Competition Network ECN+ draft impact assessment - Annex XIV (to be published); Consumer conditions scoreboards, 5th edition 2011 and 7th edition 2012; ICF Consulting Services, Support study for the impact assessment on the review of the CPC Regulation 2006/2004/EC, 2015. http://ec.europa.eu/consumers/consumer_evidence/consumer_scoreboards/index_en.htm

111 European Competition Network ECN+ draft impact assessment - Annex XVI (to be published).

112 Market Surveillance Model Initiative, UNECE working party on Regulatory Cooperation and Standardization Policies; Annex, point 1.

targeting of enforcement action based on intelligence and evidence stand out as critical elements of effectiveness.

Respondents in the public and targeted consultations recognise that simply adding "more" resources will be difficult in a context of overall pressure on public budgets. Among alternative ways to increase resources to fund market surveillance, **additional administrative fees** levied on operators are the least favoured option (only 26% agreement and 65% disagreement[113]). Such general administrative fees would merely place additional costs on law-abiding businesses, who already operate in a difficult economic climate and who are facing stark competition from 3rd country imports and rogue traders. However, by working differently, market surveillance authorities could achieve efficiency gains or savings and this could help to alleviate pressure on their resources. Authorities identify **more dialogue with businesses and better targeting of enforcement actions** as the areas where most **efficiency gains** can be obtained (70% of the respondents in the targeted surveys in the ex-post evaluation of Regulation (EC) N°765/2008. 61% sees potential efficiency gains in the inspection process itself). Practical ways to realise efficiency gains may include **pooling of efforts** between authorities in Member States and between different Member States in intelligence and knowledge gathering to underpin priority setting or cooperation agreements with intermediaries[114] and sharing of work in joint investigations. Another way is adopting different approaches to the enforcement intervention in Member States, with more emphasis on regular auditing of manufacturers as well as large importers, and coordination of such audits between Member States for economic operators who sell their products in several Member States[115].

The current reporting mechanism in Regulation (EC) n° 765/2008 focusses on communication of control programmes (Article 18(5)) and ex-post reviews and assessment of market surveillance programmes (Article 18(6)). While authorities see the reporting as a useful tool and starting point for coordination action, the administrative burden compared to the benefits is an area flagged for potential improvements[116]. The report template is being revisited to facilitate information collection. With clearer **information on compliance and enforcement gaps**, the reports' usefulness for coordination and strategic priority setting would further improve.

- *Limited resources for coordinated enforcement and tackling of cross-border infringements*

The enforcement landscape in the Single market is fragmented, with over 500 market surveillance authorities. This fragmentation is compensated only to a moderate extent by coordination structures in Member States, as evidenced by the difficulties they experience to report on enforcement activities or to provide assessments of compliance

113 The responses to this point in question 11 in the public consultation reveal particularly strong disagreement by businesses: 83% strongly disagrees or disagrees, 10% strongly agrees or agrees. On the same question, 50% of public authorities express agreement viz 39% disagreement. By contrast the recovery of control costs is supported more generally by all respondent categories in the case of non-compliant products – see measure 3 (f) cost recovery to add deterrence to enforcement tools.

114 E.g. Cooperation of customs with express carriers to obtain information on small parcels ordered online from 3rd countries; the use of big data analytics in Rotterdam port to significantly reduce the number of controls that do not result in any findings (false positives). Partial information on import controls from a selection of Member States show potential for improved targeting of controls and referral to market surveillance authorities for in-depth checking (DGTAXUD - Customs and MSA limited Report on customs controls in the field of product safety and compliance in 2015, July 2016)

115 E.g. Compliance assistance schemes and audit practice by surveillance authorities in France, Netherlands (BSI study, 2017; Annex 14.3); the Authorised economic operator scheme under the Union customs code.

116 Technopolis, Final report, Ex-post evaluation of the application of the market surveillance provisions of Regulation (EC) n° 765/2008, May 2017.

gaps in their markets. From a Single Market perspective, this leads to a **lack of comprehensive risks assessment and overview** to identify priorities and target enforcement action[117]. Conversely market surveillance authorities would benefit from more exchanges with other Member States on market trends and intelligence that may also be or become relevant in their national or sectoral context[118]. Similar trends can be seen regarding controls at the external borders. Customs would be better prepared for current and future challenges with stronger coordination mechanisms and common priority setting, supported by considerably expanded common IT tools to ensure that controls are based on more comprehensive risk assessment and increased risks information exchanges[119]. While fragmented risk information hampers prioritisation and may thus weaken detection of infringements, also at the other end of the enforcement spectrum the **visibility of enforcement** effort may be adversely impacted if information is scattered (stakeholders ranked publicity to restrictive measures as the best way to improve deterrence).

Despite simplifications in the grant management rules for EU co-funded projects and increased co-funding rates, market surveillance authorities have **difficulties taking up funding made available in the form of project grants**[120] [121]. Projects span over a relatively short time, but require intensive preparations. For each project a new partnership has to be constituted and associated administrative effort is incurred anew. The management of a project partnership with market surveillance authorities of other member states places a considerable burden on the lead authority, beyond the core inspection business and requires dedicated project management skills. Due to pressures on staff resources, authorities refocus on domestic priorities. Cross-border cooperation projects may seem more burdensome and their benefits may seem more diffuse and not delivered in the short term. As a result the co-funded joint actions cover only a few sectors, without continuity over time or recurrence of controls and with varying participation of Member States. Although the need for resources for cross-border joint actions is real, the current funding mechanism can only provide a patchy response.

Coordinated market surveillance campaigns are conducted in the context of Administrative Cooperation Groups. These campaigns rely on the input from participating authorities without EU co-funding[122]. However only in 2 sectors regular yearly campaigns can be organised, one sector being chemicals for which the administrative support is made available through the Enforcement Forum of the European Chemicals Agency[123]. Market surveillance authorities find it also increasingly

117 In a national context Ph. Hampton reports that the organisation of inspection in many, scattered services led to a failure to use risks assessment comprehensively and consistently, and as a consequence lack of overview and ineffective targeting of controls (in: Reducing administrative burdens: effective inspection and enforcement, UK HM Treasury, 2005). The Dutch Court of auditors points out that authorities insufficiently share intelligence and lack sufficient market information to conduct robust risk assessment (Algemene rekenkamer, Producten op de Europese markt: CE-markering ontrafeld, January 2017 http://www.courtofaudit.nl/english/Publications/Audits/Introductions/2017/01/Products_sold_on_the_European_market_unraveling_the_system_of_CE_marking).

118 Technopolis – Final report Ex-post evaluation, May 2017; Prosafe - Lesson's learned and ways foreward, International product safety week, Brussels, November 2016.

119 Developing the EU Customs Union and its governance, COM(2016)813 final, 21.12.2016.

120 Since 2013 the calls launched by DGGROW only resulted in 3 joint actions (1 in 2013, 2 in 2014). Calls for proposals in 2015 and 2016 failed to attract applications from market surveillance authorities in the area of industrial products.

121 Other funding opportunities are sometimes used. On a regular basis the Consumer Programme co-funds joint actions for a value of around 2 M€/year related to the General Product Safety Directive, but which can often be in conjunction with harmonised product legislation. A few projects under the research programme H2020 included compliance verification issues (eco-design (3 projects) and tyre labelling (1 project)).

122 The Commission provides funding for meetings of the administrative cooperation groups through a service contract. This contract covers reimbursement of travel costs, meeting room hire, etc.

123 See Annex 11.

difficult to take up the function of chair of an administrative cooperation group or can only do so for a shorter period of time[124].

The pressure on resources in national authorities thus compromises cross-border cooperation and limits coordinated actions authorities should take together to stop non-compliant products from circulating in the Single Market.

Informal networks, ngo's or professional associations can help to design and manage cross-border projects to a certain extent[125]. The recurrent and prolonged funding of an association or informal network can be problematic viz. the requirements of the Financial Regulation. For reasons of transparency and accountability the role of informal networks or associations will be limited when it comes to aspects of enforcement cooperation that touch on the exchange of (sensitive) enforcement information, such as inspection reports, (draft) restrictive measures against operators or risk profiles.

2. MEASURES TO REINFORCE OPERATIONAL ENFORCEMENT CAPACITY

The Commission recognises the essential role of enforcement networks and set out to encourage and help Member States to improve their capacity to enforce EU law and make sure that administrative authorities and inspectorates are sufficiently and adequately equipped to perform their tasks[126].

The problem analysis above shows that **resources constraints are a main barrier** to overcome both **within member states** regarding enforcement in domestic markets **as well as in relation to coordination and cross-border enforcement** in the Single Market.

In the baseline scenario, EU level support for market surveillance is mostly provided by Commission services. The 2013 proposed Market surveillance regulation formalised the existing ad-hoc coordination, expert and administrative cooperation groups into a 'Forum'. Although a slight evolution in the baseline could be possible in terms of some further reallocation of staff and financial support to coordinated market surveillance actions, significant additional operational support capacity to market surveillance activity throughout the Single Market, as warranted by the scale of the problem, would go beyond the administrative support structures that can readily be made available within the Commission without dedicated additional resources. For the purposes of this impact assessment measures are evaluated to deliver **significantly more operational enforcement capacity** throughout the Single Market and hence explore in addition to the baseline, new delivery mechanisms to increase better enforcement performance information, funding for national controls' activity and a new governance structure[127] to provide direct operational support to joint market surveillance actions of market surveillance authorities.

124 E.g. reported in ADCO Chairs Meeting, 14 December 2016.

125 E.g. Prosafe acts regularly as "lead" partner in EU co-funded projects and has thus been instrumental in supporting cross-border projects and dissemination of best-practice. Despite this, the obligations on participating authorities in a co-funded project remain high and cause them to refrain from taking part in joint actions.

126 Commission Communication "EU Law: Better Results through Better Application", 13.12.2016, Pages 5-6.

127 Reviews of customs and taxation cooperation confirmed the importance of an adequate governance structure and resources to effectively support operational cooperation, address problems of sub-optimal use of time/resources, and improve the management of IT systems, information/best-practices exchanges and uniformity of action. Different tasks or component considered in isolation may provide insufficient critical mass to overcome fragmentation and would not be viable options. See: Future business architecture for the Customs union and cooperative model in the taxation area in Europe - Final report Task 3 – Business case of selected options, Deloitte study for DGTAXUD, June 2011.

As set out in paragraph 1 of this annex, a *general administrative fee* levied on all harmonised products in the EU could provide resources for market surveillance. However such a measure would merely place additional costs on law-abiding businesses, and may further place EU manufacturers at a disadvantage over foreign manufacturers. The measure was consequently rated unfavourably in the public consultation and not further examined in this impact assessment. Also a single *prescriptive quantitative target* for controls by all member states to cover all product sectors would not be feasible and be contrary to risks assessment principles (e.g. of the Union Customs Code). Risk assessment criteria could however be better specified and Member States could share more information on how priority areas for controls are selected. This could be done as part of national enforcement strategies.

Two measures are considered for this impact assessment:

2.1. National Enforcement Strategies

Enforcement strategies would be proposed by Member States according to their needs and specificities, and based on an **assessment of actual enforcement and capacity gaps** they may face. The strategies would detail how risks assessment principles are applied and priorities for controls selected. Performance indicators could be built to compare enforcement across member states. The market context and needs, in closing enforcement gaps and capacity building of Member States may be very different, depending on various parameters (e.g. compliance gaps, number of operators, presence or not of large point of entry for imports, available governance and coordination structures).

Parameters to distinguish different Member States' market surveillance profiles and possible best-practice benchmarks could be as follows[128]:

In the future these **national comprehensive enforcement strategies** could also be the basis for **funding support** to Member States, covering **capacity building**, modernisation and alignment of control systems as well as funding of **testing and control**s in the Member States.

Elements that could be part of such enforcement strategies and supported by funding would cover the full spectrum of enforcement activity (strategy building, enhancing coordination and technical capacities and the performance of actual control campaigns):

128 Based on the requirements on market surveillance set out in Regulation (EC) n° 765/2008; ISO/IEC 17020 General criteria for the operation of various types of bodies performing inspection; OECD (2014) Best Practice Principles for Regulatory Policy Regulatory Enforcement and Inspections; and goods markets assessment and statistics in Technopolis (2017) final report ex-post evaluation of Regulation (EC) n° 765/2008.

- Investments to improve the knowledge of domestic markets and the evidence basis for enforcement;

- National coordination fora, cooperation protocols;

- Toolkits and training for inspectors;

- IT tools, investments in testing and internet investigation capabilities in national market surveillance authorities;

- Development and implementation of compliance assistance schemes for businesses;

- National control campaigns, including laboratory tests and public communication of the results and restrictive measures.

Regulation (EC) N° 765/2008 contains funding provisions that provide the legal basis for funding support. To increase the level of funding and make it easier to access for national authorities, this option examines the type of funding and its delivery mechanisms via Member State 'strategies' rather than co-funding on the basis of projects that have been privileged for cross-border actions and little resources directed at enforcement in domestic contexts.

The possibility and in particular the definitive size of a fund or an enforcement component in a new, larger EU fund (e.g. COSME, Consumer programme) is not examined as such in this impact assessment given that such an option would depend on the new multi-annual financial framework for the EU budget from 2021 onwards for which the outlines will only become available in the next year(s).

2.2. EU Product Compliance Network

2.2.1. Scope, tasks and structure of the EU Product Compliance Network

The EU Product Compliance Network would provide an administrative support structure to coordinate and help implementing cross-border **joint enforcement activities of Member States** (e.g. joint sweeps, coordinated control campaigns or other coordinated forms of inspections).

The role of the Network would be to support coordination and the practical management of joint enforcement actions of Member State authorities. It will not modify, replace or in any way supersede the responsibilities for market surveillance that remain the competence of member states.

Based on the existing cooperation support activities and the consultation results, **the key tasks** of an EU Network would be as follows (a detailed breakdown is given in the further background element in this annex, points 3.2 and 3.3):

- Intelligence gathering and knowledge sharing to underpin a strategy and priorities for the joint actions;

- Coordination and management of joint actions, including cooperation with customs;

- International cooperation;

- Best-practice, compliance assistance promotion, guidance development and dissemination;

- Information and communication systems development and maintenance (e.g. ICSMS), including inter-linkage with customs;

- Development and delivery of common training programmes.

The public consultation showed that respondents rated sharing of intelligence and coordination *between* Member States higher than similar measures within Member States. The core tasks of the Network concur with measures that were rated strongly positively in the public consultation, and perceived to increase resources and efficiency for market surveillance (~ 80% strongly agree/agree, see point 3,2 below for detailed responses).

The **structure of the Network** would be as follows, building on existing groups and activities in the baseline:

- An EU Product Compliance **Board** - composed of Member States and Commission representatives. Where relevant the Board would invite business, consumer or other representatives to participate to its meetings. The 'Board' would steer the network and supervise the Network's activity. It would meet several times a year. This would build on the experience with the current Expert group on Market surveillance.

- Administrative **Cooperation Groups** (ADCO) – thematic and sectoral groups of market surveillance authorities' representatives. This part of the Network would consolidate and expand the current 25 ADCOs to more sectors, adding possible cross-cutting issues, and more participating Member States. These groups would conduct and coordinate common market surveillance campaigns, ensure coordinated application of product legislation, develop common practices, on identified issues of common interest.

- A **Secretariat** – to manage the network and IT tools, prepare the Network's priorities, prepare and assist the implementation of joint market surveillance campaigns, carry out all the technical, legal analysis necessary to the Network's actions, and take care of the administrative and financial handling of joint actions and meetings. This part of the Network would be the most significant new addition.

For the **size variants of the Network**, 3 scenarios are developed for the staffing and operational resources of the Network's secretariat.

The 3 scenarios are:

- a **lower estimate** of 32 FTE and 5.7 M€/year operational budget (~10M€ in total);

- a **medium estimate** of 59 FTE and 9.95 M€/year operational budget (~18 M€ total);

- and a **high estimate** of 90 FTE and 13.9 M€/year operational budget (~26 M€ total).

The most significant tasks and resources of the agency would be concentrated on the management of coordinated actions, market studies and common priority setting for these actions, as well as the management of communication and IT systems. The initial set-up costs of the interfacing between customs systems (DGTAXUD) and ICSMS and national market

surveillance systems amounts in addition to 3,2M€ over a 5 year period[129]. However, the depth and impact of the tasks carried out critically depend on the staffing level and operational budget chosen (details of content and expected results by tasks, cost assumptions and phasing in of the Network over time are given in further background elements in this annex point 3.3).

The **Staffing profiles** envisaged for the Network secretariat would be predominantly **AD** staff (~75%): for Head of the Secretariat, market surveillance technical, legal analysis, IT and data-systems.
AST staff (~15%): Support staff for meeting organisation, financial management tasks
Contract agents (CA, ~10%): Supporting external staff for routine IT maintenance and specific development projects.

Seconded National Experts (**SNE**) could be valuable to the Network, but is more difficult to factor in specifically for the start-up of the Network. The number of staff that authorities could second to form a structural part of the Network is uncertain. A key problem which the Network should overcome is the very limited resources that authorities can make available for cross-border cooperation (i.e. limited candidates for ADCO chairs, project coordinators, and limited skills for EU project coordination). The possibility for secondments should nonetheless be kept open and in due course, SNE could be useful to support the coordination with the Single Liaison offices of market surveillance in MS that the proposal establishes.

2.2.2. Governance and hosting of the EU Product Compliance Network

As to the **form of governance for the EU Network**, two variants are considered to host the EU network: within the **Commission** and by an **existing agency** (decentralised body or executive agency). These variants, Commission and a formal body, would both provide sufficient transparency and accountability needed for the coordination of enforcement involving the handling of sensitive information. The variant hosting within the Commission would involve additional, dedicated resources[130], not merely a limited, incremental progression to the baseline.

The variant of outsourcing the Network to informal networks (associations like Prosafe) is not further considered in detail as it would provide insufficient guarantees for the handling of sensitive enforcement information and it may lack authority to engage more Member States cooperation so that the variant would be unlikely to make a substantial difference to the baseline itself.

In theory a separate, new agency could be considered, however this variant is discarded, as it is unlikely to be a realistic option in the current political and budget context and the limitations to new bodies or agencies that can be proposed.

Governance mapping:

Variants	Strength	Weakness
1. Baseline, i.e. management of	• No additional administrative or	• Only limited resources can be mobilised

129 An interface of ICSMS and the RAPEX Rapid Alert notification system for product safety of consumer product was developed from 2013-2016 and became operational early 2017 (baseline).

130 The role of the Commission needs moreover to be carefully balanced. Respondents to the public consultation we more favourable to enforcement decisions taken in close coordination via a product compliance forum (63% strongly agree/agree) than enforcement decisions taken by the Commission (42% strongly agree/agree). Public consultation, section Cross-border market surveillance in the EU, Question 8. See also option 4.

the Network by Commission	political costs	• Insufficient response to solve the problem • It does not attain the objectives
2. Outsourcing, i.e. Network hosted by an association or informal network of Member States' authorities (e.g. Prosafe)	• Full ownership by Member States who can design and dimension the platform to fit it to their level of ambition for coordinated action • The private structure will have more flexibility in hiring staff and managing procurement processes	• The association or network will be depended on EU funding (grants) • Insufficient accountability, in particular for the handling of sensitive enforcement information and management restricted IT systems • Informal character (lack of authority) may be a weak incentive for Member States to participate and more strongly engage in coordinated cross-border enforcement
3. Hosting within the **Commission**, i.e. with more resources in dedicated unit(s) to manage the Network	• Enhancement in management of support contracts for meetings, enforcement projects and IT tools • Hosting in the Commission facilitates contacts and coordination on product legislation issues	• Additional administrative costs and staff, reverting the current trend of decreasing resources in DG GROW in particular (lead on most of the sector legislation and coordinating role for the internal market for products) • Commission remains de facto in the driving seat with heavy involvement in daily, operational enforcement activity by and between Member States
4. Hosting of the Network by a **formal body**, i.e. 4(a) an executive agency such as EASME/CHAFEA or 4(b) an existing agency or body (e.g. EU-IPO)	• Transparent and accountable governance structure, offering Member States a clear steer on operational priorities as well as due Commission participation to ensure consistency and coordination on legislation related issues • Progressive, significant upscaling of resources in the medium to long term providing sufficient critical mass to impact on the problem of non-compliance	• Significant upscaling of costs for staff and operational actions to be covered by EU budget - including COM supervisory staff for executive agency; which are set up for time-limited periods (risks of discontinuity); - in the case of integration in a fully self-financing agency, a zero or reduced charge to the EU budget could be possible if the mandate and funding sources of the agency would be extended to cover market surveillance. • Adaption and set-up costs to allow existing body to carry out the new additional activities
5. New agency	• Same as formal body with additional visibility due to the single focus on product compliance	• Higher set-up costs and less opportunities for overhead sharing compared to integration in an existing structure • Contrary to limitations on the set up of new structures and unlikely to be feasible in current budget and political context

Regarding the variant hosting by an existing **regulatory agency**[131], currently only in the area of chemicals (REACH/CLP) a structure supporting enforcement coordination exists by way of the 'enforcement forum' in the **European Chemicals Agency**. To a smaller extent the **Maritime Safety Agency** could cover some enforcement support and coordination tasks related to the Marine Equipment Directive[132]. Although both agencies have experience in enforcement of product legislation, their scope is rather specific. Hosting of the Network would imply in both cases a considerable extension to numerous new different products domains.

The EU intellectual property office (**EU-IPO**) does not directly implement harmonised product legislation, however its scope of activities[133] in supporting enforcement and

131 https://europa.eu/european-union/about-eu/agencies_en

132 Coordination with these structures remain relevant (e.g use of ICSMS, combined risks assessment and joint actions targeting for instance dangerous chemicals present in industrial products in conjunction with other risks/non-compliance issues.

133 EU-IPO tasks portfolio includes for instance: promotion of best-practices and common cooperation tools, stakeholder engagement, knowledge gathering and sharing ("Observatory"), enforcement information exchanges, including with customs and international partners (law enforcement databases), and training ("EU-IPO academy").

cooperation in the internal market, e.g. against counterfeited products, has significant similarities with enforcement and compliance for industrial products and could offer a good basis to host the Network. Counterfeit/IP infringements and non-compliance are often interlinked (cheap, imitation products; imports are an important source of infringements). The Office has strong experience in knowledge gathering and sharing and managing of robust and secure IT systems.

The law enforcement agency **EUROPOL** would offer strong experience and capability for coordination of enforcement action and intelligence gathering, including e-commerce and international enforcement cooperation. Its remit and operational focus however is primarily linked to organised crime and criminal law investigations.

The scope of the harmonised product legislation in the scope of this initiative extends to over 60 legislative acts and product families. Other than the cases of chemicals and marine equipment and intellectual property, the currently existing EU decentralised bodies or agencies operate in quite distinct policy areas. Among the existing regulatory agencies **EU-IPO** offers the most synergies on policy and activities, and would constitute the most viable option to host the Network.

Executive agencies are set up to manage specific tasks, usually in relation to programme management and remain under supervision of the European Commission. They are set-up for a defined period of time. Currently existing agencies that already manage tasks in policy areas relevant for enforcement, product compliance and/or the internal market are EASME[134] (internal market, support to SMEs/businesses, eco-efficiency/design) or CHAFEA[135] (consumer protection and product safety, certain actions in food safety).

The type of tasks and staffing profiles of the Network would be predominantly technical and legal AD staff with market surveillance expertise. A smaller part only would be support staff for meeting logistics, financial handling of joint actions etc. Tasks which can be attributed to executive agencies are recurrent, administrative and financial handling, linked to programmes in particular. This implies that apart from the envisaged support staff, these agencies would have insufficient possibilities to recruit other technical profiles to constitute the full range of staff profiles that would be needed for the Network. As a consequence, the hosting of the Network by an executive agency would not be a viable solution.

2.2.3. Comparison of hosting of the Network in the Commission versus EU-IPO

This section looks at the implications and pro's and con's of the most viable options to host the Network, either the Commission or the EU-IPO. The outputs of the Network would primarily depend on the resources that are allocated to it (see point 3(b) below, outputs by the 3 different size scenarios for the Network).

- Hosting option in the Commission

  Hosting in the Commission would facilitate the contacts and coordination with product legislation issues. The Commission would retain firm control over policy issues, but invest in working with Member States on daily operational enforcement activities. While the Commission has relevant available expertise in product legislation and policy, technical market surveillance expertise is not readily available.

134 https://europa.eu/european-union/about-eu/agencies/easme_en
135 https://europa.eu/european-union/about-eu/agencies/Chafea_en

In this option the **legislative proposal** would refer to the Commission ensuring the Secretariat of the Network.

All **costs** would fall to the EU/Commission budget, for a total of 10 M€/year (low estimate size of the Network), 18 M€/year (medium estimate), 26 M€/year (high estimate).
- *Staffing* chargeable to the administrative budget (heading 5): 4M€/year (low estimate), 8 M€/year (medium estimate), 12 M€/year (high estimate);
- *Operational budget*, mostly charging the Internal Market lines (current budget heading 1A): 6M€ (low estimate), 10 M€/year (medium estimate), 14 M€/year (high estimate).

Although the integration of the Network into the Commission could be feasible as such, limitations on resources affect all staff categories in the Commission and are likely to continue beyond 2020. This could reduce the possibilities to reach and maintain sufficient staffing/resources levels for the Network. In particular, in the current situation there would be less flexibility within the existing establishment plan allocated to DGGROW (responsible for most of the product legislation), so that additional posts would need to be redeployed from other policy areas and/or additional ones requested. Some synergies with other DGs/services could be exploited, e.g. with other DGs with responsibility for product legislation and controls (ENER, ENV, MOVE, TAXUD), JUST for general product safety and the JRC for its technical expertise in certain product areas. In due course, topping up of staff with seconded national experts or additional contract agents could also be considered (although also these staff categories are subject to resource ceilings in the Commission). The lower estimate Network (32 FTE) could be feasible with significant redeployment effort; a fortiori, the medium and higher estimates (60-90 FTE) would need additional posts allocations.

- Hosting option in EU-IPO

Hosting in a decentralised agency would allow Member States to take more ownership of coordination among themselves and fit their aspirations better. An agency would be more appropriate to attract the technical, professional specialised staff that would be needed to make the Network successful and is geared to deliver operational outputs. EU-IPO has a strong track record in delivering high quality outputs, supporting Member States, stakeholder engagement and large scale networks.

In this option the **legislative proposal** would have to including amending provisions to add the market surveillance tasks, such as envisaged for the Network, to the EU-IPO's tasks set out in Article 151 of Regulation (EU) 2017/1001 of the European Parliament and the Council[136]. Subject to integration of market surveillance among the tasks in the EU-IPO founding regulation, its resources can be used to cover new tasks associated with the Product Compliance Network. The existing formal governance structures of the agency (management board, executive director) would remain unaffected. For the market surveillance tasks, the dedicated EU Product Compliance Board would steer the Network, and ensure a sufficient representation of Member States' market surveillance policy perspective. Moreover, in the case of a (partial) subsidy or ad-hoc grant for specific projects, additional provisions would need to the

136 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R1001

added to the EU-IPO regulation to reinforce financial controls required for EU bodies receiving subsidies (e.g. possibility to receive grants in well circumscribed cases, repayment of any un-used part of a subsidy, discharge procedure via the budget authority and possible further alignment of the agency's financial rules to the framework financial regulation for agencies).

The **costs to the EU-IPO budget** for the Network would be the similar as for the Commission option. Only staff costs are slightly lower as they are corrected for cost-of-living at the location of the agency (coefficient for Spain: 88,1). In total the Network costs to the EU-IPO budget would be: 9,5 M€/year (low estimate size of the Network), 17 M€/year (medium estimate), 24 M€/year (high estimate).

The **costs for the EU budget** could be zero in the case of full self-financing of the market surveillance tasks using existing EU-IPO resources. On a case by case basis, ad-hoc grants could be foreseen to cover specific costly investments in certain years (e.g. IT developments). Alternatively a mixed financing model (part subsidy/part use of existing EU-IPO resources) could be applied in case in future years the own resources of EU-IPO would not suffice, up to - in the extreme - full subsidising of market surveillance tasks in EU-IPO.
Limited one-off set-up costs for the Commission budget would need to be factored in relating to the hand-over and integration of the new tasks to the agency, including migration of IT systems[137].

Given the existing budget and human resources[138] availability in EU-IPO, the integration into the EU-IPO of the lower estimate variant of the Network (32 FTE) is considered to be feasible, without the need for a balancing subsidy from the EU budget. The medium and high estimated variants (60-90 FTE) could require additional external and/or statutory staff, including possibly new posts to be made available on the establishment plan of the EU-IPO[139]. While currently the EU-IPO budget runs a surplus, in case of need, in future years a partial or balancing subsidy from the EU-budget could be foreseen (e.g. to cover specific market surveillance tasks), or on an ad-hoc basis a specific grant (e.g. specific IT developments involving important costs in a short period of time)[140].

The advantage of this hosting variant is that upscaling to at least the medium size variant of the Network would be feasible. For a similar sized Network the charge to the EU budget would be far less than in the Commission hosting variant.

137 Overall less than €70.000 one-off costs. Estimated adaptation costs: 0,15 FTE*€138,000; IT systems migration 1*0,15FTE*€138,000 + 2*0,15FTE*€70,000. In addition some meeting and travel costs Brussels-Alicante, where EU-IPO is located. The changes to formal regulations would be part of a possible legal proposal resulting from this impact assessment and not included in these operational start-up costs.

138 End 2016 854 statutory staff, 62 national experts; yearly budget volume around 400M€ (average 2014/2015/2016), accumulated surplus 182 M€ https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/contentPdfs/about_euipo/annual_report/ar_2016_annex_01_en.pdf

139 The current agreement that requires EU decentralised agencies and bodies to streamline staff levels (-5% for EU-IPO), ends 2017.

140 Informal contacts in the preparation of this impact assessment between the Commission and the EU-IPO Executive director have confirmed that in principle the lower size Network up to a cost of 10 M€ could be integrated without additional resources, and without prejudice to further exploiting synergies with existing tasks and activities of EU-IPO. Indicatively for further upscaling its preference would be to continue working on a self-financing model (i.e. using EU-IPO resources, possibly ad-hoc grants for specific investments or projects) which allow EU-IPO to have more certainty early on in the planning cycle over yearly allocated resources and retain more flexibility in programming specific resources as needed to deliver the Network outputs.

In summary:

The Commission hosting option would be easier as regards the legislative proposal, but a strong Commission role in operational enforcement may not meet with Member States' aspirations to retain political oversight of the Network's activities. The main drawback is the uncertainty over resources, especially human resources that could be redeployed, and the limited flexibility to recruit additional or specific expertise to form a Network of sufficient size. The resourcing would furthermore be subject to the new multi-annual financial framework.

The EU-IPO hosting option would lead to a more complex legislative proposal, as the founding regulation of the agency would need to be amended which in turn may reopen discussions over the level and use of EU-IPO trademark fees[141]. The main advantage of this hosting variant are the higher flexibility for the agency to recruit expertise, more certainty and available resources so that upscaling to at least the medium size of the Network could be envisaged, hence providing for more critical mass for the Network to make a difference. For a similar size Network the charge to the EU budget would be far less, and limited to possibly an ad-hoc grant or subsidy in the future in case EU-IPO own resources would not suffice. The impact of the future multi-annual financial framework would primarily concern a possible subsidy from the EU budget.

3. FURTHER BACKGROUND AND COST/RESOURCING ELEMENTS

1. Market surveillance model

Over the last decade market surveillance experts have examined modelling to find answers to their questions on how optimum level of controls and associated resources could be determined to achieve the best results. In 2009 the UNECE working party on Regulatory Cooperation and Standardization Policies updated the **Market Surveillance Model Initiative** proposing an outline of a market surveillance effectiveness model as a more quantitative modelling tool for MSA's to assess the effectiveness of their market surveillance actions[142]. The working group recognised the need for relating technical requirements (technical legislation, standards), risk assessment, statistical aspects (sampling), along with conformity assessment aspects (measurement uncertainty), including non-tangible effects of public relation actions (visibility to the public/stakeholders).

The UNECE Advisory Group on Market Surveillance (MARS Group) recently reviewed the model and discussed ways to **improve foresight and prioritisation of market surveillance actions**[143]. At present research does not allow concluding unequivocally what constitutes an effective market surveillance system. Against this background, regulatory frameworks typically do not clearly define outcomes of MS actions, i.e. what is the need on human and financial resources to get an effective market surveillance system. The setting of objectives in market surveillance actions stands out however as a key factor pre-conditioning successful and effective market surveillance interventions.

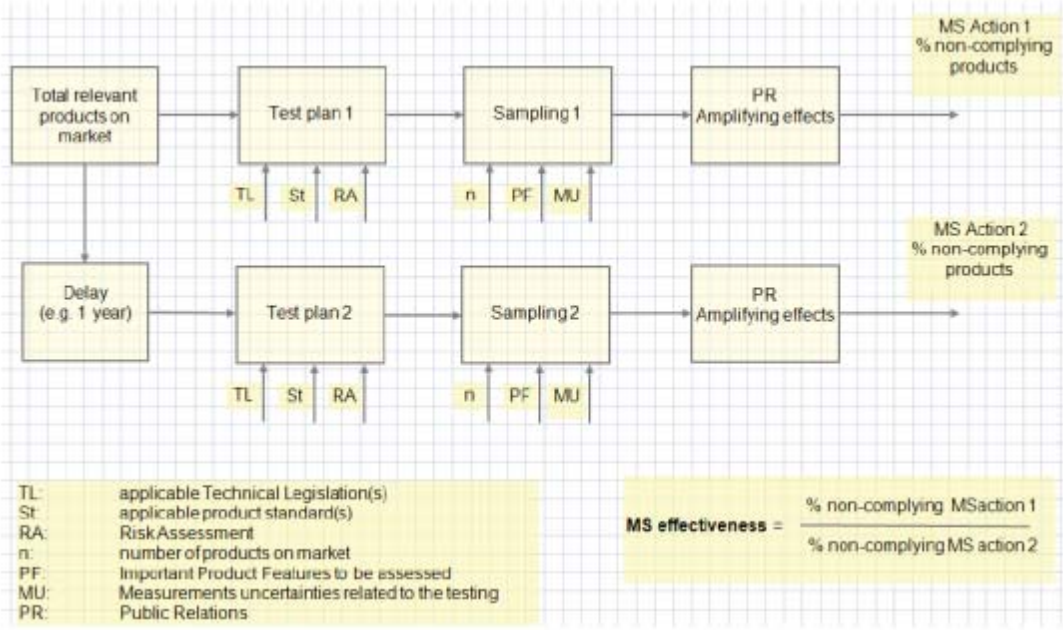
Improvements to the model were discussed, in particular by the use of dynamic models in order to capture the 3-party dimension of market surveillance (economic operator, end-user and surveillance authority) and to include economic assessments of the costs of doing

141 The trademark regulations have recently been amended; Regulation (EU) No 2015/2424 entered into force in March 2016.
142 https://www.unece.org/fileadmin/DAM/trade/wp6/documents/2009/wp6_09_GMS_012E.pdf
143 14th meeting of the MARS group, 26-27 September, Geneva; http://www.unece.org/index.php?id=43283#/

testing/sampling together with the costs of incorrect decision making. Applying this approach to market surveillance actions, the model could become a tool to show if and when resources for market surveillance are sufficient.

Based on the first experiences with the enhanced model, the experts underline that simple conclusions cannot be made, in particular they caution that a larger budget does not necessarily mean a better market surveillance system. Besides continued research on the role of resources viz. market surveillance, the way forward would lie in promoting a broader view on critical elements that would underpin effective market surveillance systems and incorporating these into the Model like: setting objectives ("SMART" based general market surveillance strategy), setting and reporting on compliance rates, entry conditions, verification testing (sampling, pre-compliance testing), elements of a quality management system for market surveillance authorities and update to latest regulatory/standards developments.

Market surveillance effectiveness model (source, UNECE 2009[144]):



144 https://www.unece.org/fileadmin/DAM/trade/wp6/documents/2009/wp6_09_GMS_012E.pdf

2. Public consultation: rating of measures to increase or improve efficient use of resources

Question 11: How could the resources for market surveillance activities be increased in your sector?; and Question 13: How could the resources for market surveillance activities be used more efficiently in your sector?				
Results for all respondents, sorted by percentage of agreement (strongly agree or agree)				
All respondents	Strongly agree or agree	Disagree or strongly disagree	No opinion	**% Agree of total**
13.6. Market surveillance authorities of different Member States should share more intelligence	207	15	17	**87%**
13.1. Market surveillance authorities should have more knowledge about the relevant sector (type and number of economic operators, market trends, etc.)	201	17	21	**84%**
13.8. Market surveillance authorities of different Member States should better coordinate action	201	16	22	**84%**
13.4. Market surveillance authorities' inspectors should receive more standardised training across the EU	189	24	26	**79%**
13.5. Market surveillance authorities within a Member State should share more intelligence	187	24	28	**78%**
13.7. Market surveillance authorities within a Member State should better coordinate action	185	27	27	**77%**
13.3. Market surveillance authorities' inspectors should receive better training	185	23	31	**77%**
11.3. Programmes at European level should finance sufficient laboratory capacity in each Member State	174	33	32	**73%**
13.9. Market surveillance authorities within a Member State should share capacity of testing laboratories	170	23	46	**71%**
13.10. Market surveillance authorities of different Member States should share capacity of testing laboratories	159	34	46	**67%**
11.1. Revenues obtained through sanctions should be allocated to market surveillance activities	155	52	32	**65%**
13.2. Market surveillance authorities should have stronger powers	125	76	38	**52%**
11.2. Market surveillance authorities should levy administrative fees on operators in their sector to finance controls	63	155	21	**26%**

3 (a) Key tasks and scope of a possible EU Product Compliance Network

Key tasks EU Body	Staffing levels			Operational budget		
	Lower estimate	*Medium estimate*	*Upper estimate*	*Lower estimate*	*Medium estimate*	*Upper estimate*
1. Work programme - strategy and priorities for coordinated actio	1	3	5			
Market studies, intelligence gathering, knowledge sharing	2	3	5	1,000,000	2,000,000	3,000,000
2. Coordination joint actions, including online - support to MS network of authorities and sectors (ADCOs) and cooperation with customs	15	25	35	1,000,000	1,500,000	2,000,000
Management cooperation projects including financial support, studies, mapping lab capacities and joint procurement (e.g. testing capacity)				2,000,000	3,000,000	4,000,000
3. International cooperation	2	5	10	150,000	300,000	400,000
4. Best-practice, guidance, information and dissemination, promotion of compliance assistance	1	5	10	200,000	400,000	500,000
5. IT systems development and maintenance (incl. linkage to new customs systems)	10	15	20	600,000	750,000	1,000,000
- Information and communication system						
- Common digital tools						
6. Development and delivery of training programmes	1	3	5	750,000	2,000,000	3,000,000
Total	**32**	**59**	**90**	**5,700,000**	**9,950,000**	**13,900,000**
average staff costs including overheads: 133.000€	*4,256,000*	*7,847,000*	*11,970,000*			
TOTAL HR, overhead, operational budget				*9,956,000*	*17,797,000*	*25,870,000*

	Baseline	Projection references
1	Indicators, collection MS programmes, reporting (1 FTE); IMP-Market surveillance group and coordination (0.5 FTE)	
	none	Consumer programme scoreboards and market studies avg. 3M€ /year; EU-IPO Observatory 4M€/yr
2	Meeting support ADCO groups (1.5 M€/year, approx 50 meetings); 20 ADCO groups; customs-MSA meetings and guidance action plan activities TAXUD 1 FTE	Enforcement forum ECHA avg 7M€/yr (nb includes projects); EUROJUST operational expenses 5-6M€ (EJN, joint investigation teams meetings)
	Management 0.5 FTE - operational budget : approx. 2 M€/year project co-funding, studies (various sources GROW, consumer programme, H2020)	Product safety project grants 2-2.5M€
3	*limited*	RAPEX China, Authorised economic operators scheme/equivalence 3rd countries, EUROJUST/EUROPOL international operational MoUs
4	*ad-hoc/limited - BP guide, action plan activity online guidance JUST/GROW 1 FTE, 100K€/yr*	
5	ICSMS 600.000 €/year (400K development and 200K maintenance), 1.5 FTE oversight/coordination	Eurojust annual ICT projects, soft hardware,maintenance avg 2.5M€; interfaces and alignment Member States systems to ICSMS
	Digital single gateway; otherwise limited - website EUROPA	
	none - only circabc for information exchange	
6	*none - ad-hoc best practice dissemination*	Better training for safer food (SANTE/CHAFEA: 5 FTE; operational funding 16M€/yr); Customs/Fiscalis 2020 e-learning B-Train 10M€/4yr; Consumer law e-enforcement materials 2M€; consumer exchange of officials programme 150K€/yr

Notes:
An average **staff/overhead costs of 133,000 €/year** is used, covering all staff types – statutory (AD/AST) and contract staff. This average is based firstly on an assessment of the staff compositions and corresponding budgets in existing EU bodies and decentralised agencies (a sample of 26 bodies of different sizes, Single programming documents 2017-2019, titles 1 and 2 expenditure per capita of all AD/AST/Contract staff, corrected to a 100-weighting factor for location, i.e. corresponding to Brussels/Luxemburg). Secondly, the current applicable reference rates for Brussels/Luxembourg based Commission staff costs, which are: 138,000€/year per official and 70,000 €/year for contract agents (these amounts cover staff, plus building and office costs ("habillage"), November 2016, circular note DGBUDG). The proportion of administrative support or contract staff varies in the existing EU decentralised agencies and bodies examined for this impact assessment, but could be estimated at around 25% for the EU Network envisaged (meeting, administrative and IT support functions). An average cost of 133,000€ corresponds to these criteria and estimations.

The **estimations for the tasks** are based on extrapolating the Commission's experience in the implementation of the baseline with the current network of Member States (expert groups

IMP-Market Surveillance Group, ICSMS) and Administrative Cooperation Groups (ADCOs, ADCO Chairs group) and references from other relevant programmes and policy areas to gauge an adequate level of resources to fulfil the tasks (specific references are indicated in the table above).

The most significant tasks and resources would be **concentrated on the management of coordinated actions, market studies and common priority setting** for these actions, as well as the management of **communication and IT systems**.

Regarding coordinated enforcement actions, a significant increase in staff is projected to make human resources available to coordinate and assist in the management of cross-border actions. The lack of such resources is the main problem identified behind the low number of coordinated controls and the weak uptake of cross-border actions in the baseline:

(i) in the lower estimate a stable number of ADCO groups, alternatively a larger number of ADCO groups and one FTE for 2 groups (lower estimate) or one FTE for each group (medium/higher estimates) is assumed given current demand and that more sectors need to be covered as well as new similar groups for cross-sector or cross-cutting issues (e.g. novel or complex product involving several legislations, customs, online issues). Additional staff are projected for overall work programme, direction, coordination and priority setting, which in the baseline accounts only for limited resources.

(ii) meeting costs (e.g. travel) would need to increase with more groups and participants. A stable level to moderate increase is projected to take into account that digital communication tools (web-meetings, collaborative IT tools) could be exploited instead of reliance on physical meetings alone in the baseline;

(iii) operational funding for actual coordinated control campaigns (e.g. test costs in such coordinated actions) is projected to be stable (lower estimate) to at least a moderate increase or doubling over the baseline (medium to higher estimates). With more available human resources to manage such funding, its effective uptake should be feasible. Resources for market studies, knowledge gathering are projected to comparable levels in consumer and intellectual property rights policy that are adequate proxies as regards type and scale of such actions.

Regarding communication and IT systems, only a moderate progression is projected in the lower estimate compared to the baseline (staff levels corresponding to current contractual expenditure, additional operational budget only to cover hard/software needs etc.). A more significant increase in resources compared to the baseline is projected in the medium and higher estimates to take into account that

(i) the level of ICSMS usage by market surveillance authorities should increase, with mandatory use of ICSMS to improve enforcement coordination. This will require more capacity (higher numbers of concurrent users, storage), enhanced assistance to link up member states' systems and technical assistance to users (training, helpdesk);

(ii) the functionalities of ICSMS, and its public website interface, would need to expand to support more extensive information exchange and monitoring of enforcement actions, requiring significant additional new programming (e.g. joint actions instead of single product/case records, adaptation to workflows, monitoring and reporting functionalities). In addition to direct input in the ICSMS database, also interfaces for

automatic data-feeding needs to be developed to allow more efficient inputs for Member States;

(iii) the linkage with relevant customs systems is currently non-existent, several complex databases and communication systems would be involved and subject to strong data-protection and security requirements.

In addition to the running costs for the Network and its IT tools, the initial developments to allow interfacing of ICSMS and customs systems (including development of the Single Window environment) amounts to around 3,2M€ over a 5 year period, or ~640 000€/year (user requirements mapping and design, development, testing, and deployment - DGTAXUD). A similar interfacing of ICSMS with the Rapid alert system RAPEX was developed in 2013-2016 and is operational since 2017 (-DGJUST).

The phasing in over time of the Network, starting at the earliest from 2020 could be spread over 2 years (low estimate scenario), 3 years (medium estimate scenario) and 5 years (high estimated scenario).

EU Product Compliance Network																			
Low scenario (32 FTE)						Medium scenario (59 FTE)						High scenario (90FTE)							
Total	32	of which:				Total	59	of which:				Total	90	of which:					
	20	AD					42	AD					60	AD					
	7	AST					10	AST					20	AST					
	5	CA					7	CA					10	CA					
Phasing in over 2 years:			2020	2021	2022 and onwards	Phasing in over 3 years:			2020	2021	2022	2023 and onwards	Phasing in over 5 years:			2020	2021	2022	2023	2024	2025 and onwards
1	AD 9-15		1	0	0	1	AD 9-15		1	0	0	0	2	AD 9-15		1	1	0	0	0	0
19	AD 5- 12		12	7	0	41	AD 5- 12		17	15	9	0	58	AD 5- 12		20	15	10	8	5	
7	AST		4	3	0	10	AST		4	3	3	0	20	AST		5	5	4	3	3	0
5	AC (FG III/IV)		3	2	0	7	CA (FG III/IV)		3	2	2	0	10	CA (FG III/IV)		4	3	3	0	0	0
	Added staff/year		20	12	0		Added staff/year		25	20	14	0		Added staff/year		30	24	17	11	8	0
	Cumulative total		20	32	32		Cumulative total		25	45	59	59		Cumlative total		30	54	71	82	90	90

3 (b) Output by task of a possible EU Product Compliance Network

EU Product Compliance Network	Description tasks	**Low** Estimate	Outputs low estimate	**Medium** Estimate	Outputs medium estimate	**High** Estimate	Outputs high estimate
		Total staffing:32 FTE Operational budget: 5,7 M€/year Total: ~10 M€		**Total staffing: 59 FTE Operational budget: 9,95 M€/year Total: ~18 M€**		**Total staffing: 90 FTE Operational budget: 13,9 M€/year Total: ~26 M€**	
Work programme – Strategy Market studies, intelligence gathering, knowledge sharing	• Organisation of EU Product Board meetings • Preparation of the work programme with priorities for joint actions • Performance indicators and peer review of member states' market surveillance strategies • Collecting statistics, drafting reports, terms of reference and procurement of market studies, dissemination • Consultation of the Network and stakeholders (e.g. emerging trends)	3 staff 1 M€	• 1 Board meeting/ year • 1 market study/year • 3 in-depth peer reviews/ year (10 year cycle to cover all MS)	6 staff 2 M€	• 2 to 3 meetings of the Board/year • 2 to 3 market studies/year • 5 in-depth peer reviews/year (6 year cycle to cover all MS)	10 staff 3 M€	• 3 to 4 meetings of the Board/year • 3 to 5 market studies/year • 7 in-depth peer reviews/year (4 year cycle to cover all MS)
Coordination of joint actions - Support to ADCO groups, customs cooperation - Management of joint projects, procurement	• Organisation of ADCO group meetings, establishment new sectoral groups and thematic groups (e.g. online sales) - agenda, preparation legal/technical discussion documents, reports) • Preparation of joint actions of MSA and MSA/customs (research on topics, prepare product survey protocols, monitoring and reporting of results) • Monitoring and coordination of mutual	15 staff 3 M€	• 15 coordinated control campaigns /year i.e. 1 every 2 years per existing product coordination groups • 1 joint procurement/ partnership project (over a 5 year period)	25 staff 4,5 M€	• 30 to 40 coordinated control campaigns /year i.e. 1/year per existing product coordination groups and controls on cross-cutting issues (online, joint actions with customs) • 2 to 3 joint procurement/partner-ship projects (over a 5 year period)	35 staff 6 M€	• 70 to 80 coordinated control campaigns /year i.e. 2-3/year per existing product coordination groups and controls on cross-cutting issues (online, joint actions with customs) • 5 joint procurement/partner-ship projects (over a 5 year period)

EU Product Compliance Network	Description tasks	**Low** Estimate	Outputs low estimate	**Medium** Estimate	Outputs medium estimate	**High** Estimate	Outputs high estimate
	assistance requests • Financing of joint control campaigns • Coordination and development of partnership projects, memoranda of understanding with MSA and stakeholders (in areas of EU level relevance, e.g. internet platforms) • Mapping of laboratory testing capacity and needs • Joint procurement of tests for MSA						
Operational enforcement information **exchange with 3rd countries authorities** *These tasks could phase in later – to alleviate resources in start-up period*	• Exchange of information on cases and best-practice / guidance	2 staff 0,15 M€	• Ad hoc review and exchange of cases	5 staff 0,3 M€	• 2/year review and exchange of cases *(building on e.g. RAPEX China experience)*	10 staff 0,4 M€	• 3-5 cooperation protocols over 5 year period with 3rd country/international partners, structural exchange of case information in priority areas
Best-practice, guidance, **dissemination** *These tasks could phase in later – to alleviate resources in start-up period*	• Prepare publications and disseminate reports, guidance, public information for professional and general public audiences (factsheets, website content)	1 staff 0,2 M€	• Ad-hoc dissemination and information provision activity	5 staff 0,4 M€	• ~25 disseminations on actions/year (including control campaign results every month)	10 staff 0,5 M€	• Information and variety of disseminations on activities based on communication strategy by target audience (consumers, businesses, authorities, policy makers) • ~25 disseminations on actions/yea

EU Product Compliance Network	Description tasks	**Low** Estimate	Outputs low estimate	**Medium** Estimate	Outputs medium estimate	**High** Estimate	Outputs high estimate
							r (including control campaign results every month) and sub-outputs for different audiences; • 1 to 2 thematic communication campaigns/ year • Guidance and on-line compliance assistance tools for businesses (product checklists) ~ basic set of tools in 5 years
IT systems development and maintenance - Information and communication systems - Common digital tools	• Maintenance and development of ICSMS and collaborative tools • Development of interfaces with MS market surveillance systems • Web-portal to relay publication of restrictive measures by MS • Linkage to customs IT systems (information exchange between customs and MSA – e.g. products/operators with high risk of non-compliance, suspension/refusal to release goods)	10 staff 0,6 M€	• Increased number of investigation/ evidence records (+50%) • Development of ICSMS to meet basic regulatory requirements • Additional functionalities and connection to MS and customs systems on an ad-hoc basis	15 staff 0,75 M€*	• Increased number of investigation/evidence records (+75-100%) • In 5 years use by all MS and authorities (including interfaces with national systems) • In ~5-7 years : interface with relevant customs systems and public website (restrictive measures, banned products)	20 staff 1 M€*	• Increased number of investigation/evidence records (+125-150%) • In 3 years use by all MS and authorities (including interfaces with national systems) and public website (restrictive measures, banned products) • In 5 years : interface with relevant customs systems
Development and delivery of **training**	• Mapping of training needs in different	1 staff 0,75 M€	In 5 years: training mapping and basic	3 staff	• Training programme set-up in 1-	5 staff 3 M€	• Training programme set-up in 1-

EU Product Compliance Network	Description tasks	**Low** Estimate	Outputs low estimate	**Medium** Estimate	Outputs medium estimate	**High** Estimate	Outputs high estimate
programmes	MS/sectors • Development of training levels and skills (grid) • Development/Procurement of training packages (e-learning, workshops) • Management of training programmes		programme design; procurement for outsourced delivery of basic trainings	2 M€	2 years • Build-up of e-learning resources: 5-10 courses/e-learning modules/year • 3 to 4 learning events/year (workshop, webinars)		2 years • Build-up of e-learning resources: 20-25 courses/e-learning modules/year • 10-15 learning events/year (workshop, webinars)

* Additional set-up costs: 3,2 M€ over 5 years, i.e. 640K€/year for the initial development of the MSA-customs systems interfacing, including the Single Window environment.

In the event of hosting in EU-IPO, synergies could possibility be exploited with existing staff working on a number of activities in EU-IPO, in particular the Observatory (studies, intelligence gathering, outreach to stakeholders, enforcement database/links to customs) and the EU-IPO academy.

Similarly in the Commission hosting variant synergies could be exploited within the services of Commission. This corresponds more or less to the baseline situation, in which in addition to DGGROW staff specifically allocated to coordination of market surveillance and implementation of Regulation 765/2008 is complemented with varying resources in product sector units and scattered over other DGs. In addition, additional resources are made available as part of service contracts (especially for IT, logistics of meetings).

EU Product Compliance Network	Estimate sizes of the EU Network				
	Low estimate 32 FTE **Total ~10 M€**	Medium estimate 59 FTE **Total ~18 M€**	High estimate 90 FTE **Total ~26 M€**	**Indicative** potential **synergies** with existing COM staff (baseline) ~10 staff	**Indicative** potential **synergies** with existing EU-IPO resources ~ 20 FTE
Work programme – Strategy Market studies, intelligence gathering, knowledge sharing	3 staff 1 M€	6 staff 2 M€	10 staff 3 M€	~2 staff	~ 2 staff *Knowledge sharing, studies (Observatory)*
Coordination of joint actions - Support to ADCO groups, customs cooperation - Management of joint projects, procurement	15 staff 3 M€	25 staff 4,5 M€	35 staff 6 M€	~ 5 product sector staff ~ 1-1,5 customs experts	-
Operational enforcement information **exchange with 3rd countries authorities**	2 staff 0,15 M€	5 staff 0,3 M€	10 staff 0,4 M€	-	~ 3 staff *Cooperation 3rd countries, agencies*
Best-practice, guidance, **dissemination**	1 staff 0,2 M€	5 staff 0,4 M€	10 staff 0,5 M€	-	~ 3 staff *Outreach, Observatory*

IT systems development and maintenance - Information and communication systems - Common digital tools	10 staff 0,6 M€	15 staff 0,75 M€	20 staff 1 M€	~1,5 staff	~ 10 staff *Extensive IT systems, enforcement databases (incl. customs)*
Development and delivery of **training programmes**	1 staff 0,75 M€	3 staff 2 M€	5 staff 3 M€	-	~ 2 staff *Trainings (EU-IPO academy)*

ANNEX 13: BACKGROUND INFORMATION ON OBJECTIVE 3 – STRENGTHENING THE ENFORCEMENT TOOLBOX

1. POWERS OF AUTHORITIES

1.1. Baseline

As regards to the tools currently available to market surveillance authorities to promote compliance and discourage non-compliance EU rules on market surveillance provides authorities (including customs) with the following powers**:**

a) *Require economic operators to provide information and documentation, enter the premises of economic operators, take the necessary samples of products*.[145] The relevant provisions do not specify if authorities can take the samples for free or if they are expected to pay for them.

b) Take *measures to restrict the marketing of products* found to compromise the health and safety of users or those which are in any case non-compliant.[146] Restrictive measures are subject to proportionality and other relevant requirements[147]. The relevant provisions do not regulate the publication of the measures. Information on restrictive measures are shared among authorities by means of official notification mechanisms (see Annex 13 section 1.2), but it is limited to authorities. Measures concerning products presenting a serious risk are shared among Member States through the Rapid Alert system RAPEX[148], however only information about the product is published on the Commission's website[149] while the actual text of the measures and the name of the businesses concerned are not.

c) Current rules do not state any common principles for *cost recovery* by market surveillance authorities. As regards customs Articles 189, 197 and 198 of the Union Customs Code regulate the sharing or recovery of costs related to the transport of goods to the place of examination, the handling and the taking of samples, as well as costs related to the confiscation or the destruction of goods.

Furthermore, the EU legal framework contains the obligation for Member States to:

d) Ensure that market surveillance authorities *seek in the first place the cooperation of undertakings* and, only if the latter fail to take adequate action, adopt compulsory measures. As a matter of fact, where surveillance authorities find that the product does not comply with the requirements laid down in the Union harmonisation legislation, require the relevant economic operator to take voluntary corrective action to bring the product into compliance with those requirements, to withdraw the product from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe. Where the relevant economic operator does not cooperate to take adequate corrective action, the market surveillance authorities has to take all appropriate provisional measures to prohibit or restrict the product's being made available on their national market, to withdraw the product from that market or to recall

145 Article 19(1) of Regulation (EC) No 765/2008.
146 Articles 16(2) and 20(1) of Regulation (EC) No 765/2008.
147 Article 21 of Regulation (EC) No 765/2008.
148 Article 22 of Regulation (EC) No 765/2008.
149 https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/main/?event=main.listNotifications

it[150]. Authorities can also destroy or render inoperable products presenting a serious risk. The relevant provisions do not regulate the issue of the cost of controls and corrective measures in case of lack of cooperation.

e) Adopt rules on *penalties applicable to infringements by economic operators* of the provisions of national law adopted pursuant to the relevant Directive or Regulation. Member States must also take all measures necessary to ensure that these rules are enforced[151]. The general principle throughout EU harmonisation legislation is that the penalties provided for have to be effective, proportionate and dissuasive and may be increased for repeated infringements.[152]The specific procedural rules and penalties applicable by market surveillance authorities are defined in national legislation.

As mentioned in the problem definition section authorities can use these powers vis-à-vis a broad range of economic operators making available products, however it is unclear whether new economic actors emerging in the online environment can also addressed. Furthermore, a major challenge for authorities in the use of their powers is the fact that in the case of products supplied on line from third countries the relevant business may not be present in the EU and could not be forced to reimburse costs or pay penalties.

1.2. Possible common powers - Availability of power in Member States

A number of legal principles that are expected to help increasing incentives to comply, according to the academic literature on responsive regulation , and facilitate detection and corrective action by authorities (notably in relation to on-line sales imports from third countries). In particular, the following elements are identified:

- Recovery of market surveillance costs (e.g. for laboratory tests or product destruction) in case products checked are found to be non-compliant products

- A regime of publicity for decisions to restrict the marketing of products

- Rights of consumers/end users to return non-compliant products or to have them fixed at no charge,

- Possibility for authorities to request businesses on a case-by-case basis to compensate consumers and other end users

- Powers and corresponding businesses obligations allowing authorities to detect non-compliant products and take corrective action , notably in relation to on-line sales and imports from third countries. These include: powers to carry mystery shopping; the possibility for authorities to ask for information and request cooperation for corrective action to any party enabling the supply of products; the obligation for manufacturers located in a third country to have authorised representative (only) if they place products directly in the EU and not via an EU importer or manufacturer; when no manufacturer or authorised representative or importer is located in the EU, authorities could request customs declarant to cover the relevant costs.

150 Summary of reference provision R31 of Annex I of Decision No 768/2008/EC.

151 A more detailed overview of the provisions on penalties in Union harmonisation legislation is set out in Annex 1. Annexes 2, 3 and 4 set out how the provisions on penalties in the Directives on the safety of toys and on Pyrotechnic articles were transposed by the Member States.

152 Article 41 of Regulation (EC) No 765/2008.

- Specification of existing common criteria for penalties (e.g. proportionality, deterrence) that would lead to basic EU common principles for sanctions determined in Member States' legislation and applied by national authorities.

Table 13-1: Available investigative powers in Member States (based on ex-post evaluation Regulation (EC) No 765/2008)[153]

Powers of Inspection	MS having this power in 14 or more sectors	MS who have this power in more than 14 sectors	MS who had this power in less than 14 sectors	MS who do not have the power in any sectors
*Carry out sector inquiries**	17	BE, BG, CY, CZ, DE, DK, EE, FI, HR, LT, LU, NL, PL, RO, SE, SI, UK	AT, ES, IE, LV	0
*Do mystery** shopping*	10	BG, CY, CZ, EE, FI, LV, NL, SE, SI, UK	AT, DK, IE, IT, LT, LU	BE
Request info/ cooperation by any possible natural or legal person	14	BG, CY, CZ, DE, DK, EE, LT, LU, NL, PL, RO, SE, SI, UK	AT, BE, ES, FI, HR, IE, IT, LV	0
*Seize and detain products**	14	CY, CZ, DE, DK, EE, FI, HR, LU, LV, NL, PL, RO, SE, UK	AT, BE, BG, ES, IE, LT, SI	0
*Seize documents**	13	CY, CZ, DE, EE, FI, HR, LU, NL, PL, RO, SE, SI, UK	AT, BE, BG, DK, ES, IE, LT, LV, SI	0
*Take samples for free****	13	CZ, CY, DE, DK, EE, FI ,HR, LT, LV, NL, PL, SE, SI	AT, BE, BG, ES, IE, IT, LU, UK	0
*Make use of test reports made by other MSAs*****	13	BG, CY, CZ, DE, DK ,EE, FI, LT, LU, LV, SE, SI, UK	AT, BE, HR, IE, NL, PL	0

* No information available for IT
** No information available for DE, ES, HR, PL and RO
*** No information for RO
**** No information for Es, IT, RO

153 Ex-post evaluation Regulation (EC) N °765/2008, section 6.1.2.2 and Annex 1, section 5.2.2.2.

Main Conclusions

22 Member States reported information.

- The investigative powers are widely available in the Member States, however not always in all or a majority of product sectors.
- On average 13 of the 22 reporting member states had all 7 powers in a majority of sectors (14 or more sectors).
- On average 7 of the 22 reporting Member States had the investigative powers in less than 14 sectors.
- Toys, electrical appliances and PPE were the most common sectors in which to have the various powers. Powers in these 3 sectors were commonly available.
- The following sectors have 2 of the powers: Recreational craft, machinery, and construction products and radio and telecommunications equipment.
- The following sectors have 1 of the powers: Medical devices, cableways and biocides, so powers in these sectors were less available.

Notes:

- For 6 member states there was no or too little information: EL, FR, HU, PT and SK are missing (5 member states) and there was very limited information available for Malta.
- All 33 sectors were covered.

Table 13-2: Available enforcement powers in Member States (based on ex-post evaluation Regulation (EC) No 765/2008)

	MS having this power in more than 14 sectors	**MS having this power in 14 or more sectors**	**MS having this power less than 14 sectors**	**MS who do not have this sanction**
Destroy products	15	BG, CY, CZ, DE, DK, EE, FI, HR, LT, LV, NL, PL, RO, SI, UK	AT, BE, ES, IE, LU, SE	IT
Impose administrative economic sanctions (without resorting to national courts)	14	BG, CY, CZ, EE, HR, LT, LU, LV, NL, PL, RO, SE, SI, UK	AT, BE, DE, FI, IE, IT	DK, ES
Impose compensation for consumers/users of non-compliant products	2	PL, SI	BE, BG, CY, CZ, DE, ES, FI, HR, IE, LT, SE, UK	AT, DK, EE, IT, LU, LV, NL, RO
Impose provisional measures pending investigations	13	BG, CY, CZ, DE, EE, FI, HR, LT, LU, LV, PL, SE, SI	AT, BE, DK, ES, IE, IT, UK	NL, RO

	MS having this power in more than 14 sectors	MS having this power in 14 or more sectors	MS having this power less than 14 sectors	MS who do not have this sanction
Publish decisions on restrictive measures	14	BG, CY, CZ, DE, EE, FI, HR, LT, LU, LV, NL, PL, SE, SI	AT, BE, DK IE, IT, RO, UK	ES
Recover from economic operators costs borne to test products found to be non-compliant	14	BG, CY, CZ, DE, EE, FI, HR, LT, LU, LV, PL, RO, SE, SI	AT, BE, DK, IE, IT, NL, UK	ES
Sanction economic operators that do not cooperate	15	BG, CY, CZ, DE, EE, HR, LT, LU, LV, NL, PL, RO, SE, SI, UK	AT, BE, DK, ES, FI, IT, IE,	0
*Shut-down websites**	1	LV	BE, BG, CY, EE, IE, UK	AT, CZ, DE, DK, ES, FI, HR, IT, LT, LU, NL, PL, SE, SI
*Take off or require to take off illegal content from a websites**	8	BG, CZ, FI, LU, LV, NL, SI, UK	BE, CY, DE, DK, EE, HR, IE, LT, PL, SE	AT, ES, IT

* No information for RO

Main Conclusions

22 Member States reported information.

- With the exception of the power to order compensation for consumers and the power to take off content or to shut down websites, the enforcement are widely available in the Member States, however not always in all or a majority of product sectors.
- While sanctions are generally available in a majority of member states, some Member States lacked sanctioning powers.
- On average, 11 of the 22 reporting member states had all 9 enforcement powers in a majority of sectors (14 or more sectors).
- On average, 7-8 member states had the enforcement powers in a minority of sectors (less than 14 sectors).
- The majority of sanctions were available in the majority of sectors, except "*impose compensation for consumers/users of non-compliant products*" and" *shut-down websites*", which were available in a minority of sectors.

Notes:

- All 33 sectors were covered.
- EL, FR, HU, PT, MT and SK are missing (6 member states).

Conclusions on investigative and enforcement powers by Member States

While powers are generally widely availability, there is a variation by coverage of sectors and in particular some Member States currently have fewer powers in place than others. For each power the details are given in tables 13-1 and 13-2.

By Member State, this shows that 15 (68%) of the 22 reporting Member States have 10 to 14 of the total 16 powers. However **a group of 7 Member States have less than 10 of the 16 powers**, and would thus have to adapt more than others to these new powers if these powers would become part of the minimum toolbox for all market surveillance authorities.

Member States that currently report the least powers (either none or in fewer than 14 sectors) are: AT, BE, ES, IE, and IT (0-1 of the 16 powers in over 14 sectors). DK and RO have few powers (only to 6-8 of the 16 powers in over 14 sectors). For Italy and Romania information was provided but missing for specific powers – the conservative assumption taken here is that these powers would be lacking, but the categorisation of these Member States could be better than the available information suggests.

For 6 Member States no information was provided (EL, FR, HU, PT, MT and SK). No assumption is made for these Member States[154].

1.3. Power to order compensation to consumers

The fragmentation of competences has important consequences on the efficiency and effectiveness of controls by market surveillance authorities. First of all, when restrictive measures are ordered, market surveillance authorities find it is difficult to enforce their decisions in other Member States due to the territorial scope of administrative decisions, their enforceability and language issues. Respectively 52% and 55% of authorities participating in the consultation confirmed that businesses located in another Member State do not reply to requests for information/documentation and for corrective actions[155] [156]. Thus, in practice authorities can effectively address non-compliance issues only with businesses located in their national territory (e.g. national or local distributors)[157]. Second, this atomisation of competences implies that authorities focus on products available in their jurisdiction and therefore a product that is found to be non-compliant in one Member State may in practice still be made available in another Member State. Thirdly, market surveillance authorities can reach easier manufacturers within jurisdictions of MS, than manufacturers established outside the EU. Last but not least, the increasing volume of online sales also triggers a significant share for personal imports from third countries (B2C).

As regards liability of traders vis-à-vis consumers for product non-compliance, national jurisdictions in the MS provide for non-contractual liability of manufacturers. Where a

154 Some of these member states indicated that their absence of response to the evaluation survey on powers was due to time constraints, and have indicated (e.g. FR) that the powers would be generally available.

155 Taking action against non-compliant products traded by businesses located in another EU Member State was considered difficult businesses do not reply to requests for information/documentation (**52%** of authorities agreed/strongly agreed, 22% disagreed/ strongly disagreed, 26% no opinion/no experience /no answer) and for corrective actions (**55%** of authorities agreed/strongly agreed, 19% disagreed/ strongly disagreed, 26% no opinion/no experience /no answer). Furthermore **57%** of authorities declared no experience in imposing penalties on businesses located in another Member State, while 25% of authorities agreed/strongly agreed enforcement of penalties is difficult, 7% disagreed/ strongly disagreed, 12% provided no answer. The previous percentages are based on the total number of participants to the consultation, including those not replying to this particular question.

156 Major high costs components for market surveillance authorities are collecting/assessing information from businesses, interacting with authorities from other member states perceived often to lead to a dead end (study on the impact of digital compliance, VVA April 2017, annex 14.

157 Interestingly, 26% of authorities participating in the consultation believe they are not even entitled to contact a business outside its jurisdiction.

consumer good is not in conformity with the contract, Directive 1999/44/EC provides for the rights of the consumer vis-à-vis the seller, i.e. contractual liability of the consumer's contract partner. Moreover, enforcement powers in the revised Consumer Protection Cooperation Regulation will provide the basis for the competent enforcement authorities to obtain commitments from trader to offer adequate remedies to the consumers, where appropriate (Article 9(4)(c)), and, where applicable, the power to inform consumers that claim that they have suffered harm as a consequence of an infringement covered by the Regulation about how to seek compensation under national law (Article 9(4)(d))[158]. On a case-by-case basis the enforcement authorities can thus establish whether in specific cases as part of remedies a compensation would be adequate (e.g. for extra costs incurred due to an infringement) and request trader's commitment in this regard.

Consumers and other stakeholders often lack information about the compliance of products they respectively purchase, use, distribute or compete with. The general public and individual consumers are normally not aware of issues relating to product compliance, which are often not visible to non-experts, unless the product would be clearly dangerous[159]. For instance compliance does not appear to be a main criterion when choosing a product to purchase.

According to Union legislation on products, distributors must act with due care in relation to the requirements applicable when they make a product available on the market. Thus they potentially play an important role in preventing the marketing of non-compliant products[160]. In practice however, provided that distributors, who are to a large extent SMEs, are aware of the relevance of compliance, they rely mostly on documentation from the manufacturer or the importer, and only a minority of them uses information on non-compliant products such as the Rapex notifications or newsletters by association or consumer organisations[161].

According to the review of the EU consumer law (Fitness Check)[162], consumer organisations emphasised in the public consultation that enforcement of EU consumer rules must be clearly linked with substantive remedies/redress[163] and that the absence of contractual remedies of the Unfair Commercial Practices Directive 2005/29/EC was recognised as a gap[164].

For certain products non-compliance could result in additional financial costs for the consumer. For example non-compliant measuring instruments[165] could lead to inaccurate measurements and consequently erroneous cost or price calculations (e.g. scales, electricity meters, fuel pumps). Wrongly labelled products may similarly lead to undue costs for consumers (e.g. additional energy costs due to underperformance of a product compared to the declared energy class[166]). Establishing financial compensation for such cost would require amongst others the identification of additional financial costs incurred by consumers that

158 http://www.consilium.europa.eu/en/press/press-releases/2017/11/30/consumer-protection-in-the-digital-age/

159 See figure 7 in Anne 9 to the Evaluation SWD.

160 The general rule is that, before making a product available on the market, distributors have to verify that the product bears the required conformity marking or markings, that it is accompanied by the required documents and by instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the product is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in the applicable Union harmonisation legislation.

161 Study on the promotion on the use of RAPEX information by importers, distributors and retailers in the field of consumer product safety, with a particular focus on SMEs, CIVIC Consulting, August 2015, p. 42.

162 Commission Staff Working Document SWD(2017) 209 final, http://ec.europa.eu/newsroom/just/item-detail.cfm?item_id=59332

163 Ibid. pp. 118 and 128.

164 Ibid. p. 118.

165 Based on EU product rules (in particular the Measuring Instruments Directive (MID, 2014/32/EU); Non-automatic Weighing Instruments Directive (NAWID, 2014/31/EU), consumers and professional users should be able to trust that measuring instruments are accurate and safe to use.

166 Relevant EU harmonisation legislation includes Regulation (EU) 2017/1369 of 4 July 2017 which sets out a framework for energy labelling http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.198.01.0001.01.ENG&toc=OJ:L:2017:198:TOC

could be linked to a confirmed non-compliance, a timescale over which to calculate such costs, and the possible evidence that could reasonably be asked from consumers to substantiate a request for compensation. These elements will vary from case-to-case and are highly depend on the type of product and usage. A definition of sufficiently clear and enforceable common criteria for fair and proportionate financial compensation to consumers across all harmonised products covered in this initiative is not feasible and consequently not further pursued. Other policy instruments may need to be considered when non-compliance leads to additional financial costs for the consumer

Avoiding court action seems to be further supported by business responses to the online public consultation in the review of the EU consumer law, with 80% of them indicating among benefits of complying with EU consumer rules the following: 'Consumers whose rights are respected come back', 'consumers whose rights are respected bring/attract other consumers' and 'consumers whose rights are not respected discourage other consumers', and 8 % indicating 'other' benefits such as avoiding lawsuits or other administrative procedures; comparing more favourably against competitors; and increasing consumer trust [167].

In practice not all consumers take action following the discovery of a faulty product, across the EU, and when they do they either address the seller or the manufacturer[168]. The financial loss due to a faulty product is on average EUR 81, including travel costs, cost of repairs, cost of expert advice, reduction in value of the product, depending on the type of product.[169]

Consumer detriment or harm arises when market outcomes fall short of their potential, resulting in welfare losses (financial, health, etc.) for consumers. As regards financial detriment, the consumer bear the cost of the original product; the cost associated with the reduced functioning of the goods concerned as a result of the problem; costs associated with actions taken to sort out the problem – including travel and legal costs, other type of expert advice or assistance, but also the cost of buying a replacement/substitute product, lost earnings, consequential damages to the consumer's property[170]. To these, non-financial detriments are to be added, including loss of time and psychological detriment.

According to sectoral instruments of Union harmonisation legislation on products, distributors must act with due care in relation to the applicable requirements. They must verify, for example, that the products are accompanied by instructions and safety information and that the manufacturer or importer has complied with some packaging requirements. Where distributors have reasons to believe that the product does not meet the essential requirements, sector legislation prohibits them to make the product available on the market until it has been brought into conformity.

By way of concluding, the current framework provided by national jurisdictions allowing non-contractual liability for manufacturers along with contractual liability of sellers vis-à-vis consumers purchasing goods for the lack of conformity with the contract within the meaning of Directive 1999/44/EC and enforcement powers for competent authorities in relation to remedies under the proposed revised Consumer Protection Cooperation Regulation is sufficient to ensure appropriate remedies in the event of a decision of market surveillance on a product being not compliant with provisions of Union harmonisation legislation on products.

167 Ibid. p. 38.
168 Study on the costs and benefits of the minimum harmonisation under the Consumer Sales and Guarantees Directive 1999/44/EC and of potential full harmonisation and alignment of EU rules for different sales channels, available at http://ec.europa.eu/newsroom/document.cfm?doc_id=44638 , p. 32.
169 Ibid, p. 32.
170 Ibid, pp. 69-70.

2. EXTRATERRITORIAL ENFORCEABILITY (OPTION 3(D))

2.1. Enforceability of Union Harmonisation Legislation and responsibilities of economic operators

a) Direct sales by manufacturers

In the traditional model, wholesalers made up an entire industry by serving as the middlemen between manufacturers and consumers. They would purchase items in bulk from the makers at a set price, then sell it to consumers at a higher rate, often doubling or tripling their output. Manufacturers continued this business model for years because it was the only way to get their products in front of customers. Wholesalers provided the manpower, infrastructure and retail space that the manufacturers just could not afford on their own. In this model, manufacturers made only small profits compared to wholesalers' profit margins. Because direct sale was their only option, manufacturers did not have much power to challenge the system. But with the internet's ability to connect them directly with people who want their goods, manufacturers can take the wholesalers' profits for themselves. Previously, companies needed interested wholesalers to be viewed as a legitimate company. They needed the validation of an established retailer to get in front of customers and make sales.

However, with the rise of the internet and small businesses leveraging websites, that business model is evolving rapidly. Manufacturers are increasingly skipping wholesalers altogether and are selling products directly to their consumers. With e-commerce, it is obvious that customers no longer buy just what is available; they are willing to seek out very specific items to meet their needs and interests. Companies of every size have made millions selling completely online, often shipping from private homes and garages. By skipping retail space costs and wholesaler fees, they can also afford to sell the products for a lower price, making them all the more attractive to consumers[171]. An online survey of 109 U.S. sales channel decision-makers at brand manufacturing organizations in 2014 showed that, overall, customer satisfaction drove manufacturers to launch a direct-to-consumer sales channel, with 72% of respondents citing a closer relationship with consumers as a reason for creating a direct-to-consumer sales channel. 82% of respondents said selling directly to consumers improved their customer relationships, and 76% reported that it improved customer experience[172]. For many manufacturers, an important reason to sell directly to consumers is the potential to collect massive amounts of customer data.

This constitutes a major challenge for the enforceability of market surveillance measures, especially when the manufacturer is established outside the EU.

b) Basic concepts of extraterritorial enforcement

In a world where businesses and individuals are increasingly operating in a global context, the issue of the extraterritorial application of legislation is assuming greater importance. Traditionally, the exercise of jurisdiction by a state was generally limited to persons, property and acts within its territory. However, the growth of multinational corporations doing business across borders and on a global scale, the ease of modern travel, the globalisation of banking and stock exchanges, technological developments such as the internet, and the emergence of transnational criminal enterprises and activities, have encouraged states to reflect on how to exercise jurisdiction beyond their territorial boundaries. The steady increase

171 https://www.thebalance.com/manufacturers-selling-directly-to-consumers-3975412
172 https://www.digitalcommerce360.com/2014/06/10/when-manufacturers-sell-directly-consumers-online-retailers/

in states exercising extraterritorial jurisdiction has not, however, resulted in an abatement of the controversies surrounding such exercises. Extraterritorial jurisdiction involves a fundamental dilemma. On the one hand, every state has the right to regulate its own public order, so it is entitled to legislate for conduct occurring within its territory. This principle is often considered to be a corollary of state sovereignty. On the other hand, businesses and individuals are increasingly acting, and producing effects, across state borders[173].

There are two approaches to distinguishing between different types of jurisdiction when exercised by a state. Outside the United States, the most common approach is to distinguish between prescriptive and enforcement jurisdiction. Prescriptive jurisdiction refers to the authority of a state to make its law applicable to particular persons or circumstances, usually through adopting legislation or, in some cases, through courts developing the law. Enforcement jurisdiction, which is the subject of this part of the impact assessment, refers to the authority of a state to take action to enforce those laws through, for example, arresting, detaining, prosecuting, convicting, sentencing and punishing persons for breaking those laws. There is general agreement that, subject to a permissive rule to the contrary, a state may not exercise executive jurisdiction in the territory of another state without the second state's consent. Thus, a state cannot investigate a crime, arrest a suspect, or enforce its judgment or judicial processes in another state's territory without the latter state's permission. That does not mean, however, that it cannot undertake enforcement measures within its own territory, such as by prosecuting an offender found within the state's territory even, potentially, for acts committed outside its territory. Nor would it prevent a state requesting extradition of a suspect from another state[174].

The starting point for jurisdiction is that all states have competence over events occurring and persons (whether nationals, residents or otherwise) present in their territory. This principle, known as the 'principle of territoriality', is the most common and least controversial basis for jurisdiction[175]. In addition, states have long recognised the right of a state to exercise jurisdiction over persons or events located outside its territory in certain circumstances, based on the effects doctrine[176], the nationality or personality principle[177], the protective principle[178] or the universality principle[179]. This list is not necessarily exhaustive, as other bases of

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173 International Bar Association, Report of the Task Force on Extraterritorial Jurisdiction (2009), p. 5.

174 International Bar Association, Report of the Task Force on Extraterritorial Jurisdiction (2009), p. 8-10.

175 The principle has both subjective and objective limbs. Subjective territoriality describes the jurisdiction of a state over conduct that occurs entirely within that state's borders. Objective territoriality refers to the jurisdiction of a state over conduct that only partially occurs in that state's territory.

176 Commentators on extraterritoriality often refer to the effects principle as an additional basis for asserting extraterritorial jurisdiction. The effects principle allows states to assert jurisdiction over conduct occurring extraterritoriality if that conduct has an effect on their territory. The effects principle is easily confused with objective territoriality. However, it differs from objective territoriality in that no constituent element of the offence takes place within the territory of the asserting state (Ireland-Piper D., 'Prosecutions of Extraterritorial Criminal Conduct and the Abuse of Rights Doctrine', http://www.utrechtlawreview.org | Volume 9, Issue 4 (September) 2013 | URN:NBN:NL:UI:10-1-112946, p. 78).

177 The nationality principle authorises extraterritorial jurisdiction by a state over its nationals, even where the conduct may have occurred extraterritorially. Like the territorial principle of jurisdiction, this principle also has two limbs. If jurisdiction is asserted over a national accused of being a perpetrator of extraterritorial conduct, this is described as 'active nationality'. If the national is a victim of extraterritorial conduct, then jurisdiction over that national is termed 'passive nationality' (Ireland-Piper D., 'Prosecutions of Extraterritorial Criminal Conduct and the Abuse of Rights Doctrine', http://www.utrechtlawreview.org | Volume 9, Issue 4 (September) 2013 | URN:NBN:NL:UI:10-1-112946, p. 73).

178 The protective principle is invoked to justify claims of extraterritorial jurisdiction by a regulating state for offences against its national interest. This might include the security, integrity, sovereignty or government functions of that state. In particular, a state may rely on the protective principle because acts that threaten its security or national interest may not be illegal in the state where they are being performed (Ireland-Piper D., 'Prosecutions of Extraterritorial Criminal Conduct and the Abuse of Rights Doctrine', http://www.utrechtlawreview.org | Volume 9, Issue 4 (September) 2013 | URN:NBN:NL:UI:10-1-112946, p. 77).

179 The universality principle refers to the right of states to assert jurisdiction over serious international crimes regardless of where the conduct occurs, or the nationality of the perpetrator(s). The theory is that some crimes are so offensive to international peace and security that all states are regarded as having a legitimate interest in their proscription and punishment.81 Unlike other grounds of extraterritorial jurisdiction, which demand some connection with the regulating state (such as the nationality of the perpetrator or the victim), this principle provides every state with a basis to prosecute certain international crimes (Ireland-Piper D., 'Prosecutions of

jurisdiction may be recognised in the future. Nor are all of these bases of jurisdiction equally well accepted.

In the online context, the enforcement of legislation about products is problematic: A country may lack the ability to enforce its laws against actors who are located outside the country and who locate their assets outside the country ("absent actors"). The internet makes it extremely easy for actors to act from remote locations, including from outside the country in which their internet acts cause effects, and to locate their assets outside the country. Although alternative means of enforcement exist that target other persons and entities, such as intermediaries, the alternative means also present challenges. There are at least two significant reasons to improve the enforceability of national laws on the internet and their enforceability against absent actors. First, as a general rule, effective laws require the possibility of effective enforcement; to the extent that laws should be followed, countries have to be able to enforce the laws, including laws in the online context and against absent actors. Second, improvements in the enforceability of national laws against absent actors are also desirable because alternative enforcement mechanisms have specific problems and cannot fully replace direct enforcement against absent actors[180]. Yet, the lack of enforceability of product legislation, especially in an online and global context, is incompatible with one of the key objectives of the Digital Single Market Strategy for Europe. A Digital Single Market is one in which the free movement of goods, persons, services and capital is ensured and where individuals and businesses can seamlessly access and exercise online activities under conditions of fair competition, and a high level of consumer and personal data protection, irrespective of their nationality or place of residence[181].

c) Basic concepts of enforcement of Union harmonisation legislation on non-food products

(1) Enforcement of Union Harmonisation Legislation is done by market surveillance authorities, i.e. the authorities responsible for carrying out activities and taking measures to ensure that products comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection. In most cases, their decisions and measures are of an administrative nature and neither judgements nor judicial decisions. Therefore, these decisions and measures usually fall outside the general framework of judicial cooperation and mutual recognition of judgements and judicial decisions.

(2) Market surveillance measures and decisions need to be enforceable not only to address the immediate risks related to the products that are found to be non-compliant, but also to ensure that the manufacturer takes, on the one hand, all corrective measures to eliminate the non-compliance of other products that were made available on the market and, on the other, all possible steps to prevent any further non-compliance to occur in the future. This latter aspect which aims at preventing any future non-compliance is not less important than the former, the objective of which is to eliminate the immediate risks. Any reasonably circumspect manufacturer who is confronted with findings of non-compliance which he/she prefers not to challenge will use these findings to adapt the manufacturing process, to revise the conformity assessment

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Extraterritorial Criminal Conduct and the Abuse of Rights Doctrine', http://www.utrechtlawreview.org | Volume 9, Issue 4 (September) 2013 | URN:NBN:NL:UI:10-1-112946, p. 76).

180 Trimble, Marketa, Extraterritorial Enforcement of National Laws in Connection with Online Commercial Activity (April 30, 2015). RESEARCH HANDBOOK ON ELECTRONIC COMMERCE LAW, John A. Rothchild ed., Edward Elgar, 2016; UNLV William S. Boyd School of Law Legal Studies Research Paper. Available at SSRN: https://ssrn.com/abstract=2600925, p. 1.

181 COM(2015)192.

procedure and/or to ensure that the storage or transport conditions do not jeopardise compliance.

(3) Union Harmonisation Legislation on products can only be enforced with respect to, on the one hand, products falling within its scope and, on the other, economic operators who have to meet certain obligations laid down in the legislation. These obligations are set out in most instruments of current Union harmonisation legislation on products. These instruments regulate the supply chain and are usually built on two concepts:

(a) **'placing on the market',** i.e. the first making available of a product on the Union market and

(b) **'making available on the market',** i.e. any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.

The core principles of **'placing on the market'** and **'making available on the market'** can be summarised as follows:

(1) **All products that are subject to Union harmonisation legislation on products and that are placed on the Union market must comply with the Union rules**. The placing on the market is the most decisive point in time concerning the application of the Union harmonised legislation. Union harmonisation legislation does not distinguish 'active' sales[182] and 'passive' sales[183]. It covers both. Products offered for sale online by sellers based outside the EU are considered to be placed on the Union market if sales are specifically targeted at EU consumers or other end users. The assessment of whether or not a website located inside or outside the EU targets EU consumers has to be done on a case-by case basis, taking into account any relevant factors such as the geographical areas to which dispatch is possible, the languages available used for the offer or for the ordering, payment possibilities, etc[184]. When an online operator delivers in the EU, accepts payment by EU consumers/end-users and uses EU languages, then it can be considered that the operator has expressly chosen to supply products to EU consumers or other end-users[185] (active sales). Products bought by a consumer in a third country while physically present in that country and brought by the consumer into the EU for the personal use of that person are not considered as being placed on the market[186].

(2) Products can be "**placed on the market**" either by **manufacturers** in the EU or in third countries or by an **importer**, defined as "*any natural or legal person established within the Union who places a product from a third country on the Union market"*.

182 'Active' sales mean actively approaching individual customers by for instance direct mail, including the sending of unsolicited e-mails, or visits; or actively approaching a specific customer group or customers in a specific territory through advertisement in media, on the internet or other promotions specifically targeted at that customer group or targeted at customers in that territory. Advertisement or promotion that is only attractive for the buyer if it (also) reaches a specific group of customers or customers in a specific territory, is considered active selling to that customer group or customers in that territory (Commission Guidelines on Vertical Restraints, SEC(2010)411).

183 'Passive' sales mean responding to unsolicited requests from individual customers including delivery of goods or services to such customers (Commission Guidelines on Vertical Restraints, SEC(2010)411).

184 Judgement of the CJEU of 12 July 2011, case C 324/09 L'Oréal/eBay.

185 Section 2.3 of Commission Notice — The 'Blue Guide' on the implementation of EU products rules 2016, OJ C 272, 26.7.2016, p. 1.

186 Ibidem.

(3) **The manufacturer and the importer are the only economic operators who are allowed to place products on the market**. The individual consumer is not an "importer" as he/she will not supply the product to anyone else (if they do, they become an "importer"). The concept of placing on the market refers to each individual product.

(4) Most Union harmonisation legislation places **responsibility for compliance on the manufacturer of the product** concerned. Even where the manufacturer is outside the European Union, and therefore out of legal reaches of the EU enforcement authorities, the manufacturer has certain obligations (e.g. quality control) which they cannot pass to other parties.

2.2. Enforceability: baseline

2.2.1. Enforceability within the EU

Hence, the manufacturer has a key role in ensuring the compliance of the product and, correspondingly, in the enforcement process. Market surveillance is the most effective when the problem can be solved at its source, i.e. when the product is manufactured or finalised in view of its placing on the EU market.

Countries typically rely on their own enforcement power to enforce their national laws. When legislators legislate national laws they assume that their country will have the power to enforce the laws. This is indeed the case when the country's courts and authorities have jurisdiction over an actor, and the actor or his assets are located within the country. In such circumstances courts and authorities of the country can apply the country's law and, if necessary, order various enforcement actions against the actor to force the actor to comply with the law[187]. Within the EU, the enforceability of market surveillance measures is feasible, though not always very easy in cross-border situations within the EU, with respect to manufacturers established in the EU, importers who, by definition, should be established in the EU and manufacturers outside the EU who appointed an authorised representative.

Manufacturers outside the EU who place major volumes of products on the EU market usually rely on an importer in the EU (scenario 1 in Table 13-3 below**) or an authorised representative** (scenario 2 in Table 13-3 below), **and/or use a distribution network in the EU**. Although there are no statistics on the number of importers and authorised representatives, it would be very difficult in practice to run a major commercial operation in the EU without an importer or an authorised representative who actually defends the exporters' commercial and legal interests in the EU, and without a distribution network.

In addition, there are several areas of the single market for products where enforceability of market surveillance measures can be effectively done, for example:

- through the withdrawal or the limitation of the type-approval of the motor vehicle,
- through the withdrawal or the limitation of the substance, mixture or article (REACH, CLP and biocidal products)
- where EU legislation already requires a responsible person in the EU (e.g. medical devices, cosmetics, energy efficiency labelling).

187 Trimble, M, o.c., p. 9.

2.2.2. Enforceability in other situations

However, market surveillance measures are very difficult to enforce when the product was placed on the market by a **manufacturer outside the EU without an importer, an authorised representative and without the involvement of a distributor in the EU** (scenario 3 in Table 13-3 below). In this case, the manufacturer remains outside the jurisdiction of European authorities. These manufacturers can easily ignore any measures taken against them and their products. Furthermore, the very short supply chain between the supplier and the consumer and the high number of small parcels that are used to ship the products to the consumers in the EU diminish the likelihood of market surveillance controls.

The lack of enforceability of market surveillance measures as regards manufacturers outside the EU is problematic for three reasons. The first is that the aim of Union harmonisation legislation is either to protect the Union consumers or the environment. The second is the level-playing field, i.e. the protection of Union-based businesses manufacturing non-compliant products against unfair competition from third country manufacturers who export products to the EU which do not comply with Union harmonisation legislation. EU manufacturers, importers, authorised representatives and distributors are subject to market surveillance, restrictive measures and possibly penalties while manufacturers outside the EU are not directly affected by market surveillance. The third is that it leads to undue costs for market surveillance authorities to implement their decisions.

Table 13-3: Summary

<table>
<tr><th colspan="2">Scenario 1</th><th colspan="2">Scenario 2</th><th colspan="2">Scenario 3</th></tr>
<tr><td colspan="6">Manufacturer established outside the EU</td></tr>
<tr><td colspan="2">↓
Importer (EU)</td><td colspan="2">↓
Authorised representative (EU)</td><td>↓
Fulfilment centre (EU) (3A)</td><td>(3B)
↓</td></tr>
<tr><td>↓
Distributor (EU)
↓</td><td>↓</td><td>↓
Distributor (EU)
↓</td><td>↓</td><td>↓</td><td></td></tr>
<tr><td colspan="6">EU Consumer</td></tr>
</table>

2.3. Cases in which enforceability is problematic (scenario 3)

Scenarios 1 and 2 are already covered by the baseline and therefore do not lead to additional obligations/costs. Scenario 3 is a steadily growing issue. The lack of enforceability of market surveillance measures against manufacturers established outside the EU mainly concerns items that are bought online from a supplier established outside the EU (section 3.1 below) which are then sent in small consignments to the consumer in the EU (section 3.2 below).

2.3.1. Items bought online from a supplier established outside the EU

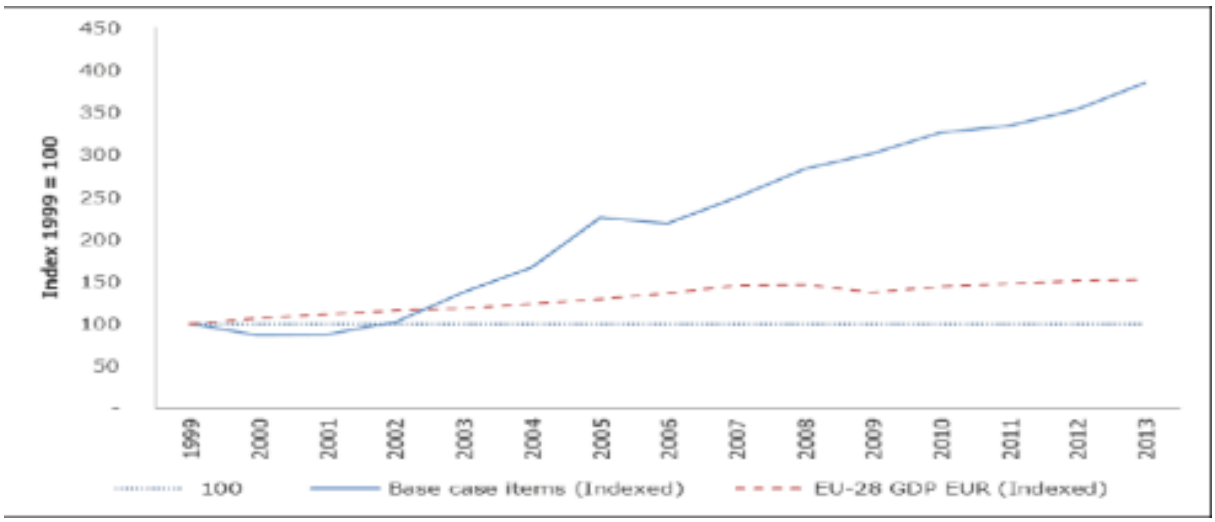
The e-commerce market is growing very rapidly within the overall retail sector. The value of retail e-commerce in the EU is estimated at €231 billion (around 1.8% of EU GDP)[188]. E-

188 SWD(2015)274 Estimate based on the results of the "Consumer surveys identifying the main cross-border obstacles to the Digital Single Market and where they matter most", GfK, 2015, http://ec.europa.eu/consumers/consumer_evidence/market_studies/obstacles_dsm/docs/21.09_dsm_final_report.pdf.

commerce in goods is estimated at €212 billion and represents by far the biggest share of the online market. Most of this trade (80%) currently concerns goods[189] produced domestically, while 13.6% (€28.8 billion) concerns cross-border e-commerce inside the EU28 and only a 5.6% share concerns (€11.8 billion[190]) purchases of goods originating outside the EU28. This includes both B2C and B2B trade.

However, over the last five years the number of European citizens ordering goods and services online has increased by 13 percentage points, to 53%[191].

Figure 13-1: Growth in international receipts of small consignments from outside the EU vs GDP growth from 1999 to 2013[192]



At very least a similar trend is expected over the next period. The share of goods purchased on line which is coming from countries other than the location of the purchasers is also expected to increase. Forecast show that by 2018, 83% of all EU cross-border buyers will choose to purchase from another EU country[193], due to natural market trends but also to policy (Digital Single Market strategy) aiming at removing existing barriers to cross-border trade. Based on the total volumes of international small consignment receipts originating from outside the EU in the table below, it is also reasonable to assume that the share of online trade from third countries will grow.

Table 13-4: Total volumes of international small consignment receipts originating from outside the EU (millions)[194]

The survey was carried out in the first half of 2015 and refers to purchases made by consumers in the precedent 12 months.

189 The estimate actually also includes in addition to goods also the purchases of off-line services (travel services and leisure events reservation).

190 Interestingly Forrester reports a similar value (€ 10.8 billion) for online purchases by EU consumers which are imported from outside the EU in 2015. Forrester (2015), Western European Online Cross-border Retail sales Forecast, 2013-2018, reported in: Copenhagen Economics, "e-Commerce imports into Europe: VAT and customs treatment", May 2016 https://www.copenhageneconomics.com/publications/publication/e-commerce-imports-into-europe-vat-and-customs-treatment

191 Digital progress report 2016, Internet use, Page 5 https://ec.europa.eu/digital-single-market/en/european-digital-progress-report

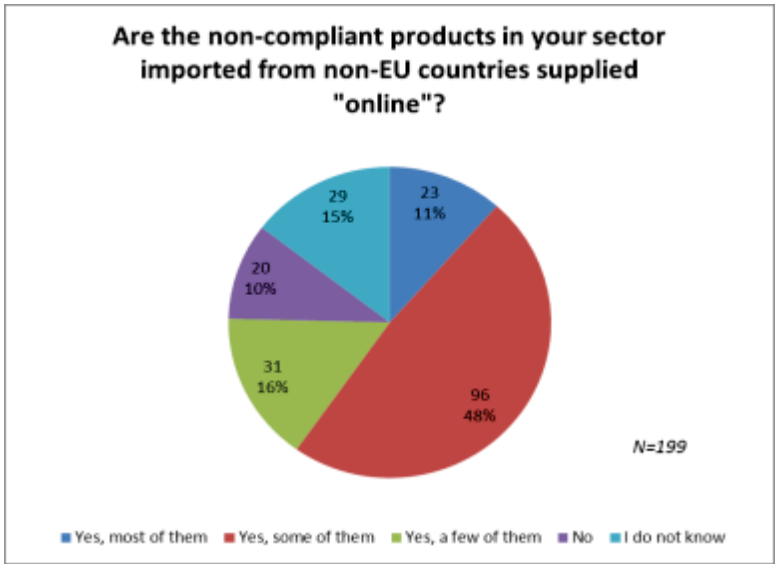
192 https://ec.europa.eu/taxation_customs/sites/taxation/files/docs/body/lvcr-study.pdf

193 https://www.forrester.com/European+Online+CrossBorder+Retail+Sales+To+Reach+40+Billion+By+2018/-/E-PRE8024

194 https://ec.europa.eu/taxation_customs/sites/taxation/files/docs/body/lvcr-study.pdf

	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Austria	1.84	1.86	1.45	1.52	2.22	2.88	4.40	4.27	4.70	5.30	5.26	5.38	4.89	4.96	5.51
Belgium	0.46	0.46	0.45	0.61	0.90	1.16	1.64	1.83	2.12	2.44	2.65	2.91	3.04	3.26	3.58
Bulgaria	0.22	0.24	0.21	0.25	0.27	0.30	0.41	0.29	0.43	0.48	0.51	0.48	0.49	0.44	0.49
Croatia	0.08	0.11	0.10	0.11	0.16	0.18	0.31	0.27	0.31	0.36	0.38	0.41	0.45	0.46	0.61
Cyprus	0.14	0.13	0.12	0.14	0.15	0.19	0.33	0.37	0.43	0.55	0.58	0.56	0.58	0.54	0.52
Czech Rep.	0.57	0.61	0.59	0.66	0.77	0.77	0.93	1.03	1.21	1.54	1.54	1.66	1.42	1.30	1.28
Denmark	3.41	3.44	3.52	2.91	3.45	3.60	5.48	5.27	5.78	6.50	6.42	7.27	6.51	6.55	7.28
Estonia	0.10	0.10	0.08	0.11	0.12	0.13	0.20	0.14	0.17	0.21	0.25	0.27	0.29	0.36	0.45
Finland	0.75	0.65	0.56	0.54	0.76	0.68	0.90	0.97	1.13	1.30	1.34	1.41	1.38	1.44	1.59
France	1.35	1.32	1.37	2.01	3.10	4.05	5.66	6.46	7.54	8.70	9.55	10.47	11.10	12.00	13.13
Germany	3.66	3.68	3.61	4.02	5.54	6.77	9.72	10.39	11.79	13.45	14.22	15.39	15.53	16.48	18.12
United Kingdom	10.17	5.92	6.88	9.50	12.12	14.74	17.02	11.92	14.10	15.48	16.85	18.30	19.97	21.31	22.81
Greece	0.40	0.37	0.39	0.49	0.60	0.76	0.99	1.13	1.31	1.49	1.62	1.76	1.84	1.98	2.17
Hungary	0.29	0.31	0.24	0.16	0.18	0.31	0.46	0.51	0.62	0.65	0.74	0.71	0.86	0.78	0.87
Ireland	0.80	0.95	1.11	0.77	1.17	1.47	1.62	1.77	2.04	2.35	2.55	2.78	2.91	3.12	3.42
Italy	0.84	0.70	0.66	1.10	1.51	1.95	5.23	5.36	5.68	6.46	6.78	7.19	6.90	7.07	7.74
Latvia	0.08	0.09	0.09	0.11	0.13	0.16	0.18	0.18	0.22	0.23	0.23	0.24	0.25	0.23	0.26
Lithuania	0.08	0.08	0.08	0.13	0.17	0.22	0.31	0.35	0.42	0.47	0.49	0.56	0.62	0.67	0.72
Luxembourg	0.26	0.31	0.38	0.51	0.63	0.71	0.84	0.96	1.08	1.13	1.05	1.15	1.26	1.36	1.50
Malta	0.06	0.06	0.05	0.04	0.05	0.05	0.09	0.08	0.12	0.16	0.19	0.17	0.15	0.14	0.15
Netherlands	0.79	0.80	0.82	1.18	1.54	1.89	2.10	2.25	2.49	2.89	3.24	3.59	3.91	4.26	4.65
Poland	1.06	1.14	1.19	0.59	0.80	0.91	1.33	1.50	1.68	2.09	2.16	2.20	2.07	2.43	2.79
Portugal	0.35	0.31	0.31	0.31	0.36	0.38	0.42	0.48	0.52	0.61	0.67	0.73	0.78	0.84	0.89
Romania	0.55	0.49	0.49	0.62	0.68	0.69	1.03	0.75	0.83	0.78	1.07	1.28	1.39	1.31	1.28
Slovakia	0.12	0.15	0.18	0.35	0.77	1.08	0.40	0.44	0.66	0.69	0.93	0.99	1.06	1.10	1.17
Slovenia	0.01	0.07	0.06	0.11	0.16	0.20	0.21	0.29	0.28	0.33	0.43	0.49	0.62	0.91	1.05
Spain	0.96	0.97	0.86	1.16	1.65	2.26	3.58	4.16	4.74	5.43	5.73	6.13	6.17	6.54	7.19
Sweden	0.40	0.40	0.39	0.57	0.87	1.14	1.60	1.81	2.10	2.43	2.42	2.92	3.07	3.31	3.64
Total	29.78	25.70	26.24	30.57	40.83	49.62	67.39	65.20	74.47	84.48	89.84	97.39	99.47	105.15	114.85

E-commerce concerning products coming from another country could be an important source of non-compliant products. Respondents in the public consultation confirmed that e-commerce is now a noticeable channel through which non-compliant products reach the EU from third countries. 75% of the respondents indicated that 'most' or 'some' non-compliant products imported from non-EU countries were supplied online[195].



Although market surveillance investigation campaigns on products sold online are not systematically or regularly conducted in all product sectors and Member States, results

195 Public consultation, question 3, section B5 Market surveillance of products imported from non-EU countries.

reported from past individual campaigns and projects nonetheless point to increasing trends of non-compliant and illegal products offered via e-commerce channels. For example, the OECD carried out an online 'product safety sweep' carried out in April 2015 that involved 25 countries inspecting a total of 1 709 products. Both in domestic and in cross-border e-commerce, the sweepers found that banned or recalled products could still be found for sale online (70% of inspected products), incorrectly labelled products (80%) and products that do not meet voluntary or mandatory safety standards (53%). In particular with respect to products that do not meet voluntary or mandatory safety standards, the level of non-compliance was twice as high at cross-border level (88% of inspected products) than at domestic level (44% of inspected products)[196].

2.3.2. Types of consignments sent from outside the EU to consumers in the EU

Items bought online from a supplier established outside the EU can be sent to the consumer by a fulfilment service provider established in the EU (scenario 3A above) or as a small consignment (scenario 3B).

2.3.2.1. Fulfilment service provider (scenario 3A)

Fulfilment centres are third party services that take care of fulfilling client orders on the business owner's behalf. Fulfilment centres take charge of receiving the products from the supplier, housing the inventory, receiving the orders from the business owner's clients, and packaging and shipping said orders to the business owner's clients.

The assumption is that these fulfilment centres are established in the EU and that the legislative proposal will ensure that they will be subject to market surveillance measures[197].

2.3.2.2. Small consignments (scenario 3B)

- Types of small consignments

For the purpose of this impact assessment, a small consignment consists of goods in a postal consignment, which benefit from a relief from import duty in accordance with Articles 23 to 27 of Regulation (EC) No 1186/2009[198].

The universe of small consignments is a playing field of both firms and consumers. Traditionally, the majority of recipients are businesses with a logistical need for fast and reliable import of goods in small quantities. However, the number of consumers has increased sharply in the past decade, following the rise of cross-border e-commerce.

Typical products sent in small consignments include spare parts, professional equipment, samples and consumer goods. Examples of highly traded consumer goods crossing international borders include books, electronic appliances (such as cameras and chargers), clothing and shoes, and sports equipment. The buyers in the universe of small consignments

196 OECD (2016), "Online Product Safety: Trends and Challenges", OECD Digital Economy Papers, No. 261, OECD Publishing, Paris. DOI: http://dx.doi.org/10.1787/5jlnb5q93jlt-en; OECD (2016), "Online Product Safety Sweep Results: Australian Competition and Consumer Commission", *OECD Digital Economy Papers*, No. 262, OECD Publishing, Paris. DOI: http://dx.doi.org/10.1787/5jlnb5q64ktd-en

197 See box 6 of the impact assessment and option 2(d).

198 Articles 138(f) and 141(3) of Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015 supplementing Regulation (EU) No 952/2013 of the European Parliament and of the Council as regards detailed rules concerning certain provisions of the Union Customs Code. Article 23 of Regulation (EC) No 1186/2009 specifies that any consignments made up of goods of negligible value dispatched direct from a third country to a consignee in the Community shall be admitted free of import duties, except alcoholic products, perfumes and toilet waters and tobacco or tobacco products. According to the Regulation, 'goods of negligible value' means goods the intrinsic value of which does not exceed a total of EUR 150 per consignment.

include large firms, SMEs and private consumers, and the market thus deals with both business-to-business (B2B) and business-to-consumer (B2C) trade. The sellers are in most cases multinational firms and, particularly in B2C, typically large e-commerce companies located for example in the USA, Europe and China. Small consignments are typically carried by express operators and mail operators, due, for example to the type and quantity of products shipped, and the logistics requirements of customers (e.g. urgency for spare parts). The main driver in the growth of the universe of small consignments is e-commerce, which is a globally burgeoning industry that has led to a dramatic increase in B2C online sales. Recent years have witnessed a substantial growth in cross-border e-commerce as both internet-only and multi-channel retailers turn to overseas markets for new sources of revenue. The rapid growth of e-commerce has significantly changed the transportation patterns and lead to a high growth of small consignments being shipped globally[199].

From the customs perspective the universe of small consignments is highly relevant, since it involves an increasingly large number of shipments, representing a significant workload. This issue has been mediated, mainly for customs duties, by the stipulations of international agreements and conventions such as the WCO Revised Kyoto Convention, WCO Immediate Release Guidelines, and WTO Bali Agreement. The Revised Kyoto Convention (RKC), by the World Customs Organization (WCO), calls for Customs administrations to set de-minimis thresholds below which duties and taxes are waived. Shipments falling into this category enjoy expedited release with minimum documentary requirements. The WTO Bali agreement of 2013 supports the future development of trade facilitation, including setting relevant de-minimis levels across the globe.

Currently the system of imports of tangible goods to consumers in the EU is highly complex, is open to abuse and provides a competitive advantage to non-EU suppliers. There are in effect 3 types of treatment of commercial consignments to consumers in the EU:

- Consignments supplied directly to consumers below EUR 10/22 which benefit from an exemption of customs duties and can benefit from a VAT exemption[200] i.e. they are supplied VAT free direct to consumers in the EU. It is estimated that in 2015 there was 144 million[201] consignments falling in this category (see table 13-5 below).

- Consignments between EUR 10/22 up to the customs duty exemption threshold of EUR 150 are subject to VAT but customs duties do not apply. It is estimated that there were 43 million such imports in 2015.

- Consignments above the customs threshold of EUR 150 require a customs declaration and are subject to VAT and customs duties if applicable. Similar to the situation above the customer is liable to the VAT and customs duties and is usually charged an administrative fee by the transport operator to cover the costs of clearing customs[202].

The volume and value of parcels imported to the EU from thirds countries due to B2C e-commerce purchases of EU consumers is set out in Table 13-5. This estimate relates to small

199 http://www.euroexpress.org/uploads/ELibrary/CDS-Report-Jan2015-publishing-final-2.pdf

200 Article 23 of Council Directive 2009/132/EC of 19 October 2009 provides that goods of a total value not exceeding EUR 10 shall be exempt on import. Member States may grant exemption for imported goods of a total value of more than EUR 10, but not exceeding EUR 22 and can exclude goods imported on mail order (including e-commerce channels). The exemption excludes excisable goods.

201 EY Study for the Commission - . http://ec.europa.eu/taxation_customs/resources/documents/common/publications/studies/execsummary_lvcr-study.pdf. The 2013 figure of 115 million consignments has been increased by the Commission in line with the growth in e-commerce.

202 Given the complexity of the interaction between customs duties and VAT with very different legal bases and rules, as well as to take a stepped approach it is considered that any amendments to the customs thresholds are beyond the remit of this initiative.

value consignments, i.e. parcels below the 10-22 EUR threshold, and parcels above the small value consignment threshold and below the Customs threshold, i.e. parcels between 10-22 EUR and 150 EUR. The estimates are based on the data provided by two recent studies on volume and corresponding value of small value consignments (parcels below 10-22 EUR) in 2013[203], and on the distribution of parcels by value[204]. The table below provides an overview of the volume and value of parcels below the customs threshold:

Table 13-5: Volume and value of parcels below the Customs threshold

	Volume	Value (EUR)
Small value consignments	144 067 840	2 967 797 504
Parcels between EUR 10-22 and EUR 150	43 220 352	1 685 593 728
Total parcels below EUR 150	187 288 192	4 653 391 232

- Customs treatment of small consignments

All EU Member States require a formal customs declaration for the importation of small consignments (below €150). The standard procedure applied in all EU Member States is the use of a Single Administrative Document (SAD). However, for consignments of negligible value under the VAT threshold, not all EU Member States require a formal customs declaration. For consignments of negligible value to be imported under the International Postal Agreements all EU Member States except for Portugal allow the replacement of the SAD with the form CN 22 which should be affixed to the consignment. Portugal allows for individual consignments (not being part of a combined shipment) with a value below EUR 1,000 to benefit from a simplification customs procedure called "Verbal or Mail Traffic Customs Declaration". In addition to the customs declaration (i.e. the SAD or form CN 22) further documentation is required to be available upon entry of the consignments evidencing that the consignments meet the criteria for application of the customs duty relief. All Member States allow the use of an invoice or other document identifying parties involved as well as description and price for the goods for this purposes[205].

National postal service providers generally use of the form CN 22/23 for customs clearance. On the CN 22/23 form the identification for exemption purposes is performed both on the basis of the goods description as well as the value declared thereof. Other operators, such as courier firms, generally use the paper based or electronic SAD. One of the elements enabling to identify in the SAD that these goods qualify as goods exempted from customs duty and/or VAT, is the mentioning of the additional customs procedure code 'C07' in box 37(2). Operators in Belgium and Denmark highlighted that in addition to the 'C07'-code, they also mention a specific generic commodity code under box 33. In order to evidence that the consignments meet the criteria for the application of the customs and/or VAT duty relief,

203 European Commission (2015), Assessment of the application and impact of the VAT exemption for importation of small consignments, prepared by EY, accessed at http://ec.europa.eu/taxation_Customs/resources/documents/common/publications/studies/lvcr-study.pdf on June 12th 2015

204 Hintsa J., Mohanty S., Tsikolenko V., Ivens B., Leischnig A., Kähäri P., Hameri AP., and Cadot (2014), The import VAT and duty de-minimis in the European Union – Where should they be and what will be the impact?, accessed at http://www.euroexpress.org/uploads/ELibrary/CDS-Report-Jan2015-publishing-final-2.pdf on January 26th 2015. The corresponding value was estimated using an average value of EUR 20 per parcel, in line with available literature. It should be noted that these estimates do not reveal the content of the consignments which, for example, also contain products that are not subject to Union harmonisation legislation (e.g. books, music, …).

205 https://ec.europa.eu/taxation_customs/sites/taxation/files/docs/body/lvcr-study.pdf, pp. 16-17.

postal service providers and courier firms are required to maintain and potentially submit various documents to the Customs Authorities. These documents include invoices, manifests, airway bills and any other documentation that contains the information that is relevant to identify whether this relief applies.

Table 13-6: Customs clearance procedure in practice

Value	Import duties	Customs declaration	
		National Postal service (under the UPU)	Courier firms
Below EUR 10-22	• No VAT • No customs duties	CN 22	Declaration by any other act, oral declaration, paper based or electronic manifest, simplified SAD
Above EUR 10-22, but below EUR 150	• VAT payable • No customs duties	CN 22	Simplified electronic declaration or SAD
Above EUR 150	• VAT payable • Customs duties payable	CN22/23 (depending on the value)	Full or simplified SAD

2.3.2.3. Other consignments

The postal operator may lodge a customs declaration for release for free circulation containing the reduced data set for postal consignments, the value of which does not exceed €1,000, provided inter alia that the goods are not subject to prohibitions and restrictions[206].

2.4. Possibilities to enforce market surveillance measures with respect to all manufacturers selling in the EU

The enforceability of product harmonisation legislation with respect to economic operators established in the EU is discussed in detail in the accompanying evaluation and in the impact assessment. Yet, the question arises how non-compliance with Union harmonisation legislation could be enforced on all products sold in the EU, including those arriving in the EU in small or postal consignments addressed directly to consumers in the EU.

Even when an actor and his assets are located outside the country, the country might not be without recourse in enforcing its laws; as long as other persons or entities are located within the country and the actor uses the goods or services of these persons or entities for the actor's online commercial activity, the enforcement efforts may instead target such persons or entities, who may be held secondarily liable for violations of the law and/or ordered to cease the provision of such goods or services to the actor[207].

Traditionally, the EU has relied on three categories of trigger to justify bringing individuals within the EU's legislative or regulatory net: the fact that a person engages in conduct in the EU, the fact that a person is legally or physically present within the EU, or the fact that a person holds the nationality of an EU Member State[208]. Whereas conduct and presence are

206 Article 144 of Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015 supplementing Regulation (EU) No 952/2013 of the European Parliament and of the Council as regards detailed rules concerning certain provisions of the Union Customs Code.

207 Trimble, Marketa, Extraterritorial Enforcement of National Laws in Connection with Online Commercial Activity (April 30, 2015). RESEARCH HANDBOOK ON ELECTRONIC COMMERCE LAW, John A. Rothchild ed., Edward Elgar, 2016; UNLV William S. Boyd School of Law Legal Studies Research Paper. Available at SSRN: https://ssrn.com/abstract=2600925, p. 1.

208 Scott J., 'The new EU 'Extraterritoriality', Common Market Law Review 51: 1343–1380, 2014.

strongly linked to the territorial principle, nationality forms a separate, well-established, jurisdictional base that is not relevant in this context.

Consequently, the following solutions could be considered, under the assumption that option 2d (Adapting the investigative and enforcement powers of market surveillance authorities to new market developments, the global supply chain and e-commerce'), option 2e ('additional enforcement tools') and option 3g ('mandatory digital publication of compliance information') are withheld:

2.4.1. Full control on imports of products from third countries to consumers

Union harmonisation legislation would be primarily enforced at the external borders of the EU, i.e. customs authorities would check systematically all incoming products and evaluate their compliance with Union law. Essentially, no distinction would be made between products sold by non-EU manufacturers to consumers and products to be placed on the market. Under this approach, the EU would be making the biggest effort to protect consumers, workers and Union-based businesses.

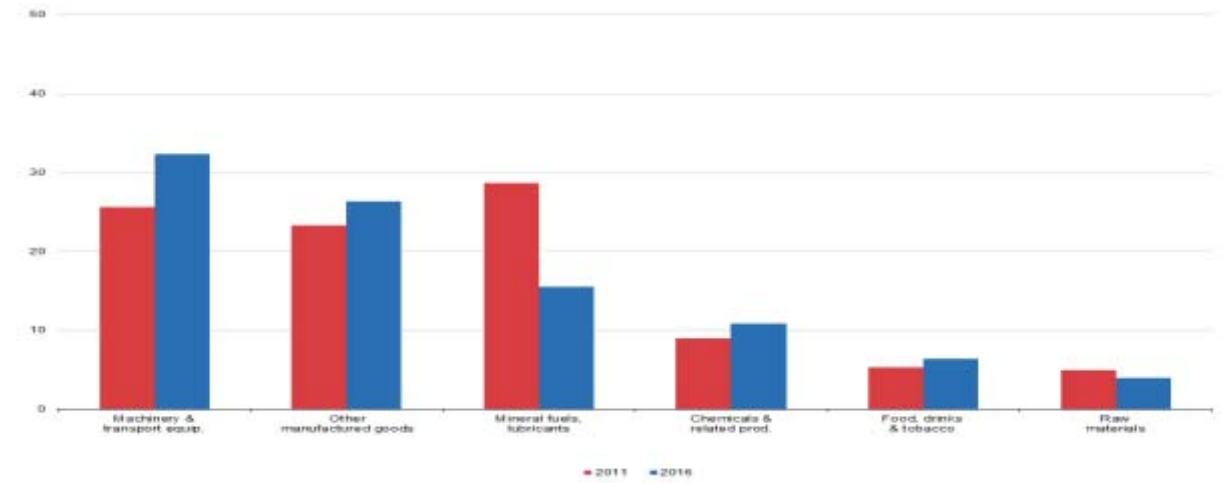
However, this approach completely ignores two main facts. Firstly, it ignores the fact that many products that arrive in the EU and are sent in small or postal consignments addressed directly to consumers in the EU actually comply with the applicable rules. Hence, there is no problem of enforceability for these products and no need to control all products. Secondly, it ignores the practical problem of very limited customs/market surveillance resources. Enacting such requirements is a far cry from effectively enforcing them. This approach may even offend the principle that unenforceable laws should not be enacted.

Table 13-7: Volume of parcels below the Customs threshold

	Total Volume	**25%**	**10%**
Small value consignments	144 067 840	36 016 960	14 406 784
Parcels between EUR 10-22 and EUR 150	43 220 352	10 805 088	4 322 035
Total parcels below EUR 150	187 288 192	46 822 048	18 728 819

Assuming that 25% of the small value consignments would contain products that are subject to Union harmonisation legislation, the volume of the small value consignments makes it impossible to control all parcels. Even in a very conservative assumption that only 10% of the parcels would contain products that are subject to Union harmonisation legislation, it is clear that this approach is neither feasible nor affordable for authorities. Furthermore, one of the largest changes between 2011 and 2016 in the structure of the EU-28’s imports was that the share of machinery and transport equipment rose from 25.6 % to 32.3 % while the share of other manufactured goods rose from 23.3 % to 26.3 %.

Figure 13-2: Main imports by product, EU-28, 2011 and 2016 (% share of extra EU-28 imports)



Source: Eurostat (online data code: ext_it_infratrd)

This approach may be also be disproportionate and an example of the 'nanny State' going too far. Purchasers in the Union may not mind if the camera they buy from the USA is not fully compliant with Union rules for cameras. They will be unhappy if a usable camera is confiscated or destroyed by customs because of an aspect of non-compliance which does not matter to them.

2.4.2. Registration of the product and person responsible for compliance information in the EU

This solution would mirror the obligations that are laid down in the Union legislation on cosmetics and medical devices.

2.4.2.1. Responsible person for cosmetics

Regulation (EC) N° 1223/2009 on cosmetic products is the main regulatory framework for finished cosmetic products when placed on the EU market. It strengthens the safety of cosmetic products and streamlines the framework for all operators in the sector. Only cosmetic products for which a legal or natural person is designated within the EU as a "responsible person" can be placed on the market.

The Regulation requires the designation, in the European Union, of a Responsible Person for every cosmetic product placed on the EU market. This person must take responsibility to ensure that every cosmetic product it/he places on the EU market complies with all the requirements of the Regulation. Once the product has been put on the market, if any questions about its safety, its packaging or its labelling arise, the responsible person will be considered liable. If it is found that the requirements of the Cosmetics Regulation have not been properly met, this person or company may be penalised. Corrective actions and penalties vary according to the severity of the infraction and are commensurate to the risk that the infraction has created for the consumer. A formal labelling infraction may simply result in a fine and an obligation to correct the label for future productions. Incorrect safety procedures could result in imprisonment. In case of substantiated risk, the product will be immediately removed from the market resulting in bad publicity and lost revenue.

The Responsible Person may be a natural or a legal person. His/its name (or style) and address must be printed on the primary (container) and secondary packaging of each product for which he/it takes responsibility.

The concept of a single person responsible for ensuring compliance with the cosmetic legislation was already a key pillar of the Cosmetics Directive. With the Regulation, the central role of the Responsible Person remains and is further specified.

Depending on whether the product is manufactured or imported in the EU, the Responsible Person can be the manufacturer or the importer or a mandated person. As a default, the manufacturer is the responsible person for products manufactured in the EU and the importer is the responsible person for the products he imports into the EU. In practice, manufacturers and importers have some flexibility to decide who shall fulfil the role of Responsible Person for their products. Under certain circumstances they may mandate any person to assume this role, provided this person is:

- registered and located in the EU;
- adequately mandated;
- in a position to assure compliance under the Cosmetics Legislation including competent authorities' access, as and when appropriate, to the Product Information File at the address mentioned on the cosmetic products by the Responsible Person;
- indicated as the Responsible Person on the label with his name and address.

It is the responsibility of the Responsible Person to ensure that every product he/it places on the EU market complies with the requirements of the Cosmetics Regulation. His duties relate to all aspects regulated under the EU cosmetics legislation: Article 3 (safety), Article 8 (good manufacturing practice), Article 10 (safety assessment), Article 11 (product information file), Article 12 (sampling and analysis), Article 13 (notification), Article 14 (restrictions for substances listed in Annex), Article 15 (substances classified as CMR substances), Article 16 (nanomaterials), Article 17 (traces of prohibited substances), Article 18 (animal testing), Article 19(1)(2) and (5) (labelling), Article 20 (product claims), Article 21 (access to information for the public), Article 23 (communication of serious undesirable effects) and Article 24 (information on substances).

2.4.2.2. Responsible person for medical devices

Where a manufacturer who places a medical device on the market under his own name does not have a registered place of business in a Member State, he is obliged to designate a single authorised representative in the European Union. The authorised representative means any natural or legal person established in the Union who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Union instead of the manufacturer with regard to the latter's obligations under the Directives which include Directive 93/42/EEC concerning medical devices (MDD), Directive 90/385/EEC on active implantable medical devices4 (AIMDD) and Directive 98/79/EC on in vitro diagnostic medical devices (IVDD).

The authorized representative is required to maintain and provide upon request certain regulatory documentation to the competent authorities for the purpose of market surveillance, including the Declaration of Conformity and the technical file for devices. Implicit in the requirement for authorized representatives to furnish documentation to authorities upon request is the need for the information to be up to date. The authorized representative also is required to promptly communicate information from the competent authority to the manufacturer.

The authorised representative has certain obligations as defined by the relevant Directives, such as:

– informing the competent authorities of his registered place of business (MDD: class I, procedure packs and custom made devices; AIMDD: custom made devices; IVDD), and of the devices and certificates (IVDD);

– keeping certain information at the disposal of the national authorities, such as declarations of conformity and technical documentation (AIMDD Annex II 6.1; MDD Annex II 6.1, Annex III Section 7.3, Annex IV Section 7, Annex V Section 5.1, Annex VI Section 5.1, Annex VII Section 2; IVDD Arts 9(7) and 10(3)).

The manufacturers may instruct his authorised representative to initiate certain procedures provided for in the conformity assessment annexes (IVDD Art 9(6), MDD Art 11(9), AIMD Art 9(3)).

As the directives do not include a detailed description of the role and obligations of an authorised representative it will be of vital importance to both the manufacturer and the authorised representative to set up a contract specifying the task and authority the manufacturer will delegate to the authorised representatives, also where the authorised representative is a daughter company of the manufacturer established outside the EU.

The appointment of an authorised representative does not change the responsibilities of the manufacturer. The authorised representative must be duly selected and supervised by the manufacturer. However, in some Member States the authorised representative will have responsibilities directly under national law. For instance he might have the responsibility to ensure that the appropriate conformity assessment procedure has been carried out, that the device is properly CE marked and that information is provided in a specified national language. Another example may be that the authorised representative must have a vigilance system in place which is compatible with that of the manufacturer. An authorised representative must therefore be fully informed about the legal obligations included in the national legislation of the Member State in which he has his residence / where devices are placed on the market. Those "national" obligations should be reflected in the above mentioned contract with the manufacturer. Given the Authorised Representative's limited role with regard to the placing on the market of a medical device, he cannot be held responsible for actions by the manufacturer over which it has no control, unless national legislation specifies otherwise[209].

These Directives on medical devices will be replaced by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Box 13-1: Summary of the role of the sole authorised representative in the new EU legislation on medical devices

Both Regulations (EU) No 2017/745 and 2017/746 confirm that, where the manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorised representative. The designation will constitute the authorised representative's mandate, it will be valid only when accepted in writing by the authorised representative and will be effective at least for all devices of the same generic device group.
Under the new legislation, the authorised representative will have to perform the tasks specified in the mandate

209 Guidance document. MEDDEV 2.5/10. January 2012

agreed between it and the manufacturer. The authorised representative will have to provide a copy of the mandate to the competent authority, upon request. The mandate must require, and the manufacturer must enable, the authorised representative to perform at least the following tasks in relation to the devices that it covers:

- verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;
- keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities;
- comply with the registration obligations laid down in the Regulations and verify that the manufacturer has complied with the registration obligations laid down in the Regulations;
- in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;
- forward to the manufacturer any request by a competent authority of the Member State in which the authorised representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;
- cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
- immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;
- terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation.

However, the mandate may not delegate several manufacturers' obligations. Where the manufacturer is not established in a Member State and has not complied with his obligations, the Regulations specify that the authorised representative will be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.
An authorised representative who terminates its mandate on the grounds that the manufacturer acts contrary to its obligations under the Regulation will have to immediately inform the competent authority of the Member State in which it is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.
Furthermore, the detailed arrangements for a change of authorised representative will have to be clearly defined in an agreement between the manufacturer, where practicable the outgoing authorised representative, and the incoming authorised representative. That agreement will have to address at least the following aspects:

- the date of termination of the mandate of the outgoing authorised representative and date of beginning of the mandate of the incoming authorised representative;
- the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;
- the transfer of documents, including confidentiality aspects and property rights;
- the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which it had been designated as authorised representative

2.4.2.3. Registration of the product

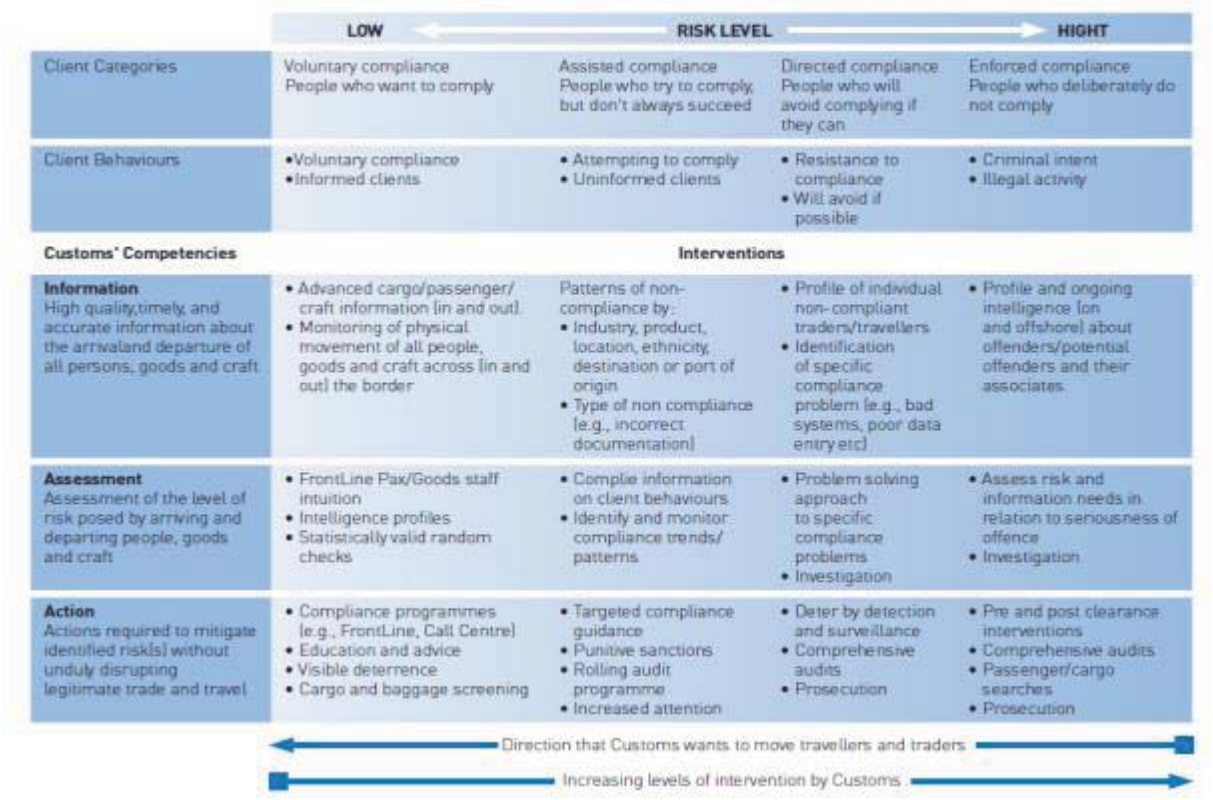
The various possibilities for a system registering products and compliance information can be found in the assessment in Chapters 5 and 6 of Annex 14, i.e. the option of mandatory basic compliance in a centralised database. These costs would have to be added to the costs of a person responsible for compliance information in the EU. There is no doubt that the registration of the product and essential compliance information (e.g. the declaration of conformity) would strengthen the effectiveness of any measure to ensure the enforceability of market surveillance measures and decisions, but this would entail some additional costs and administrative charges which, horizontally across all non-food sectors, might be disproportionate to achieve the objective of a better enforceability of market surveillance measures and decisions for products sold in the EU.

2.4.3. Controls on the basis of risk management

An intermediate solution would consist of targeted controls on the basis of a risk management system that would be closely connected to the common customs risk management framework (CRMF) laid down in Article 46 of the Union Customs Code[210].

2.4.3.1. Risk management system without a person responsible for compliance information in the EU

The benefits of a risk management system at the external borders are widely acknowledged and include better human resource allocation, increased customs revenue, improved compliance with laws and regulations, reduced release times and hence lower transaction costs and improved cooperation between traders and customs[211]. The key in relation to risk-based compliance management is to actively "steer" the client population towards the low-risk category. This can be achieved both by providing incentives for traders and travellers to comply, and by operating a credible enforcement regime which effectively and efficiently detects and punishes non-compliance. Affecting client behaviour and actively steering the population towards low risk will allow Customs to concentrate its control resources on high risks. The diagram below illustrates an example of a compliance management model[212].



The EU customs risk management policy and strategic objectives as defined in the EU Strategy and Action Plan COM(2014)527 were endorsed by the Council in December

210 http://ec.europa.eu/taxation_customs/general-information-customs/customs-risk-management/measures-customs-risk-management-framework-crmf_en

211 Dunne M., 'Getting to grips with risk management', WCO News, No 62/2010, www.wcoomd.org, p. 16.

212 http://www.wcoomd.org/~/media/wco/public/global/pdf/topics/enforcement-and-compliance/activities-and-programmes/risk-management-and-intelligence/volume-1.pdf?db=web

2014[213]. The Strategy covers all threats and risks connected with international goods movements. It aims to mitigate them at the most opportune time and place in the supply chain ('assess in advance, control where required'), to improve operational risk analysis capacities, to improve access to and exploitation of risk and intelligence information from non-customs authorities and to improve targeting of high risks and facilitation of legitimate trade through strengthened cooperation with economic operators. EU customs implement risk management and controls under the common Union framework by deploying their national risk management capacities and expertise. The Strategy acknowledges the need to work further on increasing the risk analysis operational capacities at the national and EU level. Two main challenges need to be addressed: overcoming capacity variances across the EU Member States to be able to implement common risk criteria and standards, and capability to more effectively tackle trans-national threats. Capacity variances arise due to the existence of 28 different national electronic risk analysis systems and differences in expertise across the EU Member States. More broadly, as the Strategy reflects very well, the customs authorities of the Member States need to significantly improve the capacity, tools and methods (organisation) to address transnational risks posed by cross-border crime and terrorist organisations[214].

Yet, a pure risk management system is unlikely to address satisfactorily the problem of the enforceability of market surveillance measures:

Table 13-8: Advantages and drawbacks of a risk management system without a person responsible for compliance information in the EU to address the lack of enforceability of market surveillance measures	
Advantages for the non-EU manufacturer	**Drawbacks for the non-EU manufacturer**
The non-EU manufacturer would still be able to sell and ship the product to the EU without any additional formality or cost.	Union harmonisation legislation would be enforced on the product itself, which would have to be seized and possibly destroyed.
Advantages for consumers	**Drawbacks for consumers**
--	The financial risk would be borne by the consumer who would not receive the product for which a payment was already made when the product would be seized.
Advantages for market surveillance authorities	**Drawbacks for market surveillance authorities**
Risk management system reduces non-compliance and hence the need to enforce market surveillance decisions.	Enforceability problem only partly solved: • Costs on customs and/or MSA to trace and contact the responsible foreign manufacturer, extra effort required to obtain information/responses to questions. • There would be a risk that the economic operator would continue placing non-compliant products on the EU market, in the absence of any feedback from enforcement authorities. • Uncertainty whether the manufacturer would actually take the findings of the enforcement authorities into account. • The possibility of a dialogue between the

213 See als Commission Progress Report COM(2016)476 on the implementation of the EU Strategy and Action Plan for customs risk management and the accompanying Commission SWD(2016)242.

214 http://ec.europa.eu/research/participants/data/ref/h2020/other/guides_for_applicants/h2020-sec-policybackground_en.pdf

	economic operator and the enforcement authorities would be minimal. Financial risk for customs or market surveillance authorities who would have to pay for the administration and destruction costs.

Consequently, this possibility puts the administrative and financial burden mainly on the authorities and the consumer.

2.4.3.2. Risk management system with a person responsible for compliance information in the EU

a) Preliminary assessment

Another possibility is that, whenever a product is placed on the market by a business outside the EU (i.e. when there is no importer or authorised representative) and when the product is not subject to any prior approval procedures, there should be a person responsible for compliance information in the EU[215]. This person could be the fulfilment centre or any other person appointed by the manufacturer.

The 'person responsible for compliance information' should be the person who represents the manufacturer established outside the EU for the implementation of the Regulation. The 'person responsible for compliance information' should be established in the jurisdiction of any of the market surveillance authorities and should be responsible for the following tasks:

Table 13-9: Possible tasks of a person responsible for compliance information in the EU

Obligations	Applicable legislation
• Keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities and cooperate with them at their request;	Only for products subject to 'New Approach legislation'
• Upon a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product;	All products
• Cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by products covered by their mandate.	All products

215 This possibility builds on the Commission's proposal COM(2016)757 amending Directive 2006/112/EC and Directive 2009/132/EC as regards certain value added tax obligations for supplies of services and distance sales of goods which proposes, inter alia, the removal of the existing VAT exemption for the importation of small consignments from suppliers in third countries. According to the proposal, a vendor not established in the Community should designate an intermediary except if he is duly authorised by the Member State of identification or if he is established in a country with which the EU has concluded an agreement on mutual assistance. Where VAT is declared under this special scheme, no VAT should be payable anymore upon importation of the goods. It is therefore necessary to provide for an exemption for such imports. This exemption is inserted in Article 143(1) of the VAT Directive. To allow customs to identify these consignments upon importation a valid VAT identification number proving that VAT is declared under the special scheme should be provided to customs at the latest upon lodging of the import declaration.

It is understood that manufacturers should make the identity and contacts details of the person responsible for compliance information with respect to the product publicly available either on their website or, in the absence of a website, by any other means that allows the information to be readily accessed by the general public in the Union free of charge. The identity and contact details of the person responsible for compliance information with respect to the product should also be indicated on or identifiable from information indicated on the product, its packaging, the parcel or an accompanying document.

The mere fact that the 'person responsible for compliance information' should be the person representing the manufacturer established outside the EU for the implementation of the Regulation implies that there would be no need for a 'person responsible for compliance information' in the following cases:

Table 13-10: Cases where no person responsible for compliance information should be appointed	
(1)	When there is an importer or an authorised representative, the manufacturer does not have to appoint a person responsible for compliance information (see scenarios 1 and 2 in table 13-3 above);
(2)	Where the manufacturer needs to obtain type-approval (motor vehicles) or needs to register a chemical substance (REACH), no person responsible for compliance information should be appointed;
(3)	When Union harmonisation legislation already provides for an obligatory authorised representative (medical devices) or a responsible person (cosmetics and Regulation (EU) No 2017/1369 on energy efficiency labelling), no other person responsible for compliance information should be appointed;
(4)	Where the product needs to be registered before being placed on the market (e.g. the registration of radio equipment types within some categories, as set out in Article 5 of the Radio Equipment Directive 2014/53/EU);

There are insufficient quantitative data to calculate the possible costs for appointing a person responsible for compliance information, also because the actual amount would depend upon the content of the mandate and the contractual arrangements between the parties (e.g. annual fees or payment per hour for services actually delivered). Businesses acting as authorised representatives consider their tariffs as commercially sensitive information. According to the result of the CATI interviews in the figure below for the purpose of Annex 14 Part 5, the cost of demonstrating compliance [i.e. administrative burden for answering requests from market surveillance authorities regarding documents needed to demonstrate compliance; Displaying (or publishing) the compliance information; Updating compliance information for existing products; Complying with different compliance procedures across Member States; IT costs; General labour cost] was estimated at 10% of the overall cost of compliance with Union harmonisation legislation. Furthermore, based on the Evaluation of the Internal Market Legislation for Industrial Products[216], the total cost of compliance with such legislation for a firm is approximately 0.48% of its turnover. The cost of demonstrating compliance is therefore estimated to be approximately 0.048% of turnover.

Considering Eurostat data from 2013[217], the turnover of the almost 350,677 companies within the scope of Annex 14 Part 5 is € 2.03 trillion (€2,026,565.10 million). Given this, a preliminary estimation shows that the total cost of demonstrating compliance is approximately € 842.374 m per year (€ 2.03 trillion* 0.48%*10%*86.6%incidence rate) or €1,807.41 per company per year on average. If one excludes the preparation and the updating

216 http://ec.europa.eu/smart-regulation/evaluation/search/download.do?documentId=9966151
217 Eurostat: http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=sbs_na_sca_r2&lang=en

of the technical file which corresponds on average to 80% of the cost, the total cost of the tasks set out in Table 13-9 could be estimated at €361.48 per company per year on average where there is a declaration of conformity and a technical file, and €180.74 in all other cases. Assuming a profit margin equal to the actual cost, the total cost of the tasks set out in Table 13-9 could be estimated at €722.96 per company per year on average where there is a declaration of conformity and a technical file, and €361.48 in all other cases. When the profit margin would be the double of the actual cost, the total cost of the tasks set out in Table 13-9 could be estimated at €1445.92 per company per year on average where there is a declaration of conformity and a technical file, and €722.96 in all other cases. This estimation, however, may differ in situations where the authorised representative also fulfils other commercial functions for the manufacturer and performing these tasks is just part of its overall commercial role, both for the manufacturer and for other economic actors in the downstream supply chain, or in situations where being an authorised representative for several manufacturers is part of the core business of the enterprise concerned. An informal survey in the field of medical devices, and in-vitro diagnostic medical devices and active implantable medical devices under the current legislation for the tasks set out under point 2.4.2.2 show that annual fees can range between €1,500 and €4,000 which could also include the specific notification requirements, which are incumbent to the manufacturer, but which can be delegated to the authorised representative (e.g. the registration of the authorised representatives, manufacturers and devices and registration of clinical investigations (MDD and AIMDD) and the registration of the authorised representatives, manufacturers, devices and certificates and the registration of performance evaluations (IVDD)).

The possible costs for market surveillance authorities, if any, would at most be negligible. Persons responsible for compliance information would be expected to be businesses who would act as service providers vis-à-vis the manufacturers. Consequently, they might have an EORI number[218] and, as a general rule, they should have a VAT identification number that should also be easily verifiable[219]. Companies acting as person responsible for compliance information should be registered in a business register[220] and easy to trace[221].

Consequently, there are no indications that a risk management system with a s in the EU might create unjustified financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens. Furthermore, the costs would be limited in relation to the business turn-over of the manufacturer and commensurate with the objective to be achieved.

In case of missing information, suspected non-compliance, the authorities would turn to the person responsible for compliance information in the EU, within their jurisdiction, instead of having to search and contact operator(s), possibly via intermediaries in the supply-chain in

218 Economic Operators Identification and Registration system (EORI) required by the Union Customs Code – See https://ec.europa.eu/taxation_customs/business/customs-procedures/general-overview/economic-operators-registration-identification-number-eori_en and http://ec.europa.eu/taxation_customs/dds2/eos/eori_home.jsp?Lang=en

219 http://ec.europa.eu/taxation_customs/vies/vieshome.do?selectedLanguage=EN - Articles 213 to 216 of Council Directive 2006/112/EC on the common system of value added tax, as amended.. See also Council Directive 2010/24/EU of 16 March concerning mutual assistance for the recovery of claims relating to taxes, duties and other measures, Council Regulation N° 904/2010/EU of 7 October 2010 on administrative cooperation and combating fraud in the field of value added tax and Council Directive 2011/16/EU of 15 February 2011 on administrative cooperation in the field of taxation and repealing Directive 77/799/EEC.

220 Directive 2009/101/EC of the European Parliament and of the Council of 16 September 2009 on coordination of safeguards which, for the protection of the interests of members and third parties, are required by Member States of companies within the meaning of the second paragraph of Article 48 of the Treaty, with a view to making such safeguards equivalent. The interconnection of business registers in the EU is put in place by Commission Implementing Regulation (EU) 2015/884 of 8 June 2015 establishing technical specifications and procedures required for the system of interconnection of registers established by Directive 2009/101/EC of the European Parliament and of the Council.

221 https://e-justice.europa.eu/content_find_a_company-489-en.do?clang=en

foreign jurisdictions and administrative cultures. Benefits of the measure are therefore expected to outweigh the costs on the authorities. Automated (pre)checks on customs declarations and documents would assist customs and market surveillance authorities to target controls and could be expanded in the future to cover specific indications related to product compliance (including person responsible for compliance information, but also other elements e.g. registration or authorisation codes for certain products).

Table 13-12: Advantages and drawbacks of a risk management system with a person responsible for compliance information in the EU to address the lack of enforceability of market surveillance measures

Advantages for the non-EU manufacturer	**Drawbacks for the non-EU manufacturer**
Better contacts with, and easier feedback from market surveillance authorities. Compliance issues could be swiftly addressed for any other products sold in the EU.	Where there is no authorised representative or importer, the manufacturer would have to seek a person responsible for compliance information and remunerate the person for the services performed.
Advantages for consumers	**Drawbacks for consumers**
Easier contacts in case of problems.	--
Advantages for market surveillance authorities	**Drawbacks for market surveillance authorities**
Market surveillance decisions would be enforceable vis-à-vis all businesses selling in the EU. Reduced costs relating to identifying, tracing, contacting and following-up compliance issues (simplification) The measure should incentivise foreign businesses trading non-compliant products to internalise costs (now borne by authorities/costs on the public purse to trace foreign businesses often leading to a dead end.. Costs on authorities would be lower – enforcement is based on risk assessment, minimal additional work, however costs savings and simplification for them	Risk of letter box companies although verifications could be made on the basis of the EORI number, the VAT identification number and the file opened in a central register, commercial register or companies register of the Member State.

b) Assessment of possible side-effects

Products may only be sold in the EU when they comply with the legislation applicable in the EU. When manufacturers design products that could be sold on the EU market, they ensure or should ensure that the products meet the European safety and environmental requirements and apply the conformity assessment procedures. They should also affix the marking provided for by EU legislation. Such marking is a key indicator (but not proof) of a product's compliance with EU legislation and enables the free movement of products within the EEA and Turkish market, whether they are manufactured in the EEA, Turkey or in another country.

Manufacturers who design products for the EU market normally do so for mass production or production in bigger series. Practice shows that many of them already place their products on the EU market through a representative (e.g. an importer or an authorised representative) and/or a distribution network (see Table 13-3 above), also to save transportation and logistics

costs and to ensure economies of scale. Products sold in volumes in the EU are stored in warehouses and distribution centres in the EU on behalf of the manufacturer or by a local branch or subsidiary, or in warehouses and distribution centres in the EU which are owned or managed by businesses that act as a representative for the supplier. These manufacturers would therefore already comply with the obligation of a person responsible for compliance information.

Yet, the question arises whether such obligation would discourage any other manufacturer or any other supplier to sell compliant products to the EU from outside the EU. As manufacturers normally provide for representation in the EU for products imported in larger volumes, this question would only be relevant for items that, at least in theory, fulfil two cumulative conditions, namely (1) (a) products that are not conceived to be sold primarily in the EU but nonetheless comply with the applicable EU harmonisation legislation, or (b) products that are conceived to be sold primarily in the EU in small volumes without a distribution network in the EU, and (2) sent in parcels or individual consignments to consumers in the EU.

Condition 1(a) is merely theoretical since for most products that are subject to EU product harmonisation legislation, specific obligations apply as regards technical documentation, the declaration of conformity and the CE marking[222] and additional markings and labelling requirements for the EU:

Box 13-2: Examples of additional markings required by EU legislation

- Directive 75/324/EEC relating to aerosol dispensers obliges the person responsible for the marketing of aerosol dispensers to affix the symbol '3' (inverted epsilon) to aerosol dispensers, as proof that they satisfy the requirement of the Directive and its Annex;
- Directives 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU and 2014/34/EU respectively specify that the identification number of the notified body must be affixed to pyrotechnic articles, explosives for civil use, simple pressure vessels, non-automatic weighing instruments, measuring instruments, lifts and equipment and protective systems intended for use in potentially explosive atmospheres, where the notified body was involved in the production control phase;
- The inscriptions referred to in point 1 of Annex III of Directive 2014/29/EU must be affixed to simple pressure vessels in accordance with Article 16 or point 1 of Annex III of the Directive;
- The inscriptions referred to in point 1 or in point 2 of Annex III of Directive 2014/31/EU must be affixed to the non-automatic weighing instruments concerned;
- The supplementary metrology marking must be affixed to measuring instruments pursuant to Article 22 of Directive 2014/32/EU;
- The information allowing identification of the lift or the safety component of for lifts must be indicated in compliance with Articles 7(5) or 8(5) of Directive 2014/33/EU;
- The specific marking of explosion protection, the symbols of the equipment-group and category and, where applicable, the other markings and information must be affixed to equipment and protective systems intended for use in potentially explosive atmospheres in accordance with point 1.0.5 of Annex II of

222 The list of product groups subject to CE marking is published on https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en. According to Article 30(1) of Regulation (EC) No 765/2008, the CE marking may be only affixed by the manufacturer or his authorised representative. Union harmonisation legislation also specifies that the CE marking must be fixed visibly, legibly and indelibly to the product. Where that is not possible or not warranted on account of the nature of the product, the CE marking must be affixed to the packaging and to the accompanying documents. Furthermore, the CE marking must be affixed before the product is placed on the market.

Directive 2014/34/EU;

- The identification number of the notified body must be affixed to radio equipment, where the conformity assessment procedure set out in Annex IV of Directive 2014/53/EU is applied, in accordance with Article 20 of the Directive;

- The identification number of the notified body involved in the production control phase as well as the marking and labelling referred to in point 3.3. of Annex I or point 3.3 of Annex I must be affixed to pressure equipment in accordance with Article 19 or point 3.3 of Annex I of Directive 2014/68/EU.

Box 13-3: Examples of specific labelling requirements in EU legislation

- The Toys Safety Directive 2009/48/EC contains the obligation that the manufacturers must ensure that their toys bear a type, batch, serial or model number or other element allowing their identification, or, where the size or nature of the toy does not allow it, that the required information is provided on the packaging or in a document accompanying the toy. Manufacturers must also indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy or, where that is not possible, on its packaging or in a document accompanying the toy. The address must indicate a single point at which the manufacturer can be contacted. Similar obligations exist for importers. In addition, Directive 2009/48/EC specifies that toys should be marked with general and specific warnings, as set out in Article 11 and Annex V.

- Textile products must be labelled or marked whenever they are made available on the market. With the exception of trademarks or the name of the undertaking, information other than that required by the regulation must be listed separately. The labelling or marking must be provided in the official language or languages of the Member State on the territory of which the textile product is made available to the consumer, unless the national legislation of that country provides otherwise.

- For footwear, labels must convey information relating to the upper, the lining and insole sock, and the outer-sole of the footwear article. The information must be conveyed by means of approved pictograms or textual information, as defined by the directive. The label must be legible, firmly secured and accessible, and the manufacturer or his authorized agent established in the Union is responsible for supplying the label and for the accuracy of the information contained therein. Only the information provided for in the directive need be supplied.

- The Cosmetics Regulation contains several labelling provisions. Containers and/or packaging (in certain cases) must bear, in indelible, easily legible and visible characters, the name, trade name and address, or registered office of the manufacturer or person responsible for marketing the cosmetic product within the Union, the nominal contents at the time of packaging (by weight or volume), the date of minimum durability indicated by "Best before end", for products with a minimum durability of less than 30 months (with a specific symbol), the period after opening during which the product can be used without harm to the consumer, for products with a minimum durability of less than 30 months (indicated by a symbol representing an open cream jar), particular precautions for use, the batch number or product reference, for identification, the product's function etc.

- Regulation 1272/2008/EC on the Classification, Labelling and Packaging of Chemicals specifies labelling rules for substances and mixtures that are classified as hazardous. The label elements regarding hazard pictograms, hazard and precautionary statements are highly standardized and reflect the UN Globally Harmonized System of Classification and Labelling of Chemicals. Labels need to bear a certain obligatory elements regarding the identification of the substance and mixture, name and address details of the supplier and the nominal quantity. For small packaging and very small quantities a certain number of labelling derogations apply. Some mixtures require specific additional labelling elements.

- Directive 2000/14/EC on noise emission in the environment by equipment for use outdoors obliges the equipment listed in Articles 12 and 13 and defined in Annex I to carry the indication of the guaranteed sound power level following the model set out in Annex IV of the Directive.

- The WEEE Directive provides for an obligatory symbol that must be displayed on all products that fall under this directive. The symbol indicates that the product is not to be discarded with normal household waste.

- Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators provides that all batteries, accumulators and battery packs should be appropriately marked with the symbol shown in Annex II of the Directive. In addition, the capacity of all portable and automotive batteries and accumulators must be indicated on them. Batteries, accumulators and button cells containing more than 0,0005 % mercury, more than 0,002 % cadmium or more than 0,004 % lead, have to be marked with the chemical symbol for the metal concerned: Hg, Cd or Pb. The symbol indicating the heavy metal content has to be printed beneath the symbol shown in Annex II of the Directive and must cover an area of at least one-quarter the size of that symbol.

- Regulation (EC) No 1222/2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters requires that tyre manufacturers declare fuel efficiency, wet grip and external rolling noise performance of C1, C2 and C3 tyres (i.e. tyres mainly fitted on passenger cars, light and heavy duty vehicles).

- Bottles used as measuring containers are regulated by directive 75/107/EEC and here again it is up to the manufacturers to decide whether to use this legislation, which in turn guarantees free movement of the bottles. The reversed epsilon marking "3" is placed on the bottom of the bottle alongside the indicated volume contained in the bottle and the distance from the brim to which the bottle must be filled in order to achieve the indicated volume. The legislation contains the procedures and tests that the authorities may apply during market surveillance.

- The voluntary e-mark acts as a metrological "passport" to facilitate the free movement of pre-packaged goods. It guarantees that certain liquids and other substances, as defined in directive 76/211/EEC, have been packed by weight or volume in accordance with the directive. Where the manufacturer chooses to use the directive, free movement throughout the EU is guaranteed for pre-packaged products that do comply with the provisions of the directive. Containers with an e-mark also bear an indication of the weight or volume of the product, known as its “nominal” weight or volume. The packer (or importer, if the container is produced outside the EU) is responsible for ensuring that the containers meet the directive’s requirements. The legislation contains the procedures and tests that the authorities may apply during market surveillance.

- Regulation (EC) No 66/2010 on the EU Ecolabel allows any producer, manufacturer, importer, service provider, wholesaler or retailer to place the EU Ecolabel on the product, provided that the operator concluded a contract with the competent body covering the terms of use of the EU Ecolabel. When the EU Ecolabel is placed on the product, the registration number must also be placed on the product.

- Directive 2008/43/EC sets up a system for the identification and traceability of explosives for civil uses. Each manufactured or imported article falling under the scope of this Directive shall bear a unique identification, comprising the mandatory information and components described in the Annex to the Directive.

- Implementing Directive 2014/58/EU sets up a system for the traceability of pyrotechnic articles. Pyrotechnic articles must be labelled with a registration number structured in a uniform way according to the indications of the Directive.

Consequently, there are hardly any products that could meet condition 1(a) as all products that are compliant with Union harmonisation legislation can only be products that are expressly designed to comply with this legislation as a result of an explicit decision by the manufacturer.

In theory, there could be many categories of products that fulfil condition 1(b), i.e. products that are conceived to be sold primarily in the EU in small volumes without a distribution network in the EU. In practice, however, this would be fairly exceptional since these products should be, to be economically viable or commercially meaningful, products that do not

require the involvement of so-called 'notified bodies', i.e. conformity assessment bodies approved by the authorities of the Member States. Products that do not require the involvement of so-called 'notified bodies' are subject to conformity assessment procedure of module A[223], i.e. essentially low voltage electrical equipment, products subject to electromagnetic compatibility requirements, pressure equipment of category I, personal protective equipment of category I, machinery not listed in Annex IV of Directive 2006/42/EC and other machinery that complies with harmonised standards that cover all essential health and safety requirements and the references of which were published in the Official Journal of the EU, and toys and radio equipment for which the manufacturer applied harmonised standards the references of which were published in the Official Journal of the EU. Footwear and textiles also fit in this general category.

Looking more specifically at the range of products that could fulfil condition 1(b), it is necessary to consider which of these products could be sent in small parcels or individual consignments to consumers in the EU as low value consignments. The value of pressure equipment of category I, some of the personal protective equipment of category I, and machinery not listed in Annex IV of Directive 2006/42/EC and other machinery that complies with harmonised standards that cover all essential health and safety requirements and the references of which were published in the Official Journal of the EU and most radio equipment is too high to be considered as small value consignments and are subject to the usual customs controls. Only some low voltage electrical equipment and some products subject to electromagnetic compatibility requirements, some personal protective equipment of category I, footwear, textiles, toys and some radio equipment for which the manufacturer applied harmonised standards the references of which were published in the Official Journal of the EU could be sent to consumers in the EU as low value consignments. Yet, it should be recalled that, according to the findings summarised in section 1.2 of the impact assessment, the level of non-compliance for many of these products is high. For instance, on the basis of data reported by Member States in the period 2010-2013 non-compliance was found on average in 32% of inspections conducted in the field of toys, 34% in the field of low voltage electrical equipment, 58% in the field of electromagnetic and radio equipment and 40% in the field of personal protective equipment. The complete overview on non-compliance found by national authorities during national inspections in 30 different groups of sectors can be found in section 5 of Annex 9.

Overall, it is highly unlikely that an obligation to appoint a person responsible for compliance information in the EU would discourage any manufacturer who, before having placed the product on the EU market, took the necessary steps to design a product that meets the EU safety and environmental requirements, who affixed all markings as set out above and who applied the labelling requirements as set out above, who made the technical documentation and who signed the EU declaration of conformity. This obligation, however, might discourage the sales of products that are not designed to be sold in the EU or that do not meet the EU safety and environmental requirements. This discouraging effect should be counterbalanced by the consideration that compliance and the corresponding business opportunities of selling

223 See Annex II of Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC. The other conformity assessment modules require the intervention of a notified body. Modula A is internal production control, i.e. the conformity assessment procedure whereby the manufacturer fulfils some specific obligations laid down in detail in the module and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them. It would be quite unlikely that a manufacturer would seek the intervention of a notified body for products which would be sold only in very small volumes. It should be noted that most Union harmonisation legislation, with the exception of the Low Voltage Directive, allows the manufacturer to opt for another conformity assessment procedure than modules A or C. These other modules presuppose the intervention of a notified body in the EU.

in the EU might require a prior investment in safety and environmental protection or at least a reflection by the supplier whether selling illegal products and engaging in illegal activities is sustainable and fair business model. Therefore, having a person responsible for compliance information within the EU to represent the manufacturer who sells products in the EU does not go beyond what is necessary to achieve the enforceability of market surveillance measures within the EU.

3. DETERRENCE AND SANCTIONS

3.1. The traditional deterrence approach[224]

Traditionally the deterrence approach assumes that enterprises will only do "the right thing" to the extent it is in their self-interest to do so. For example, critical theorists, Pearce and Tombs (1990, 1997, 1998) argue that since all corporations have profit-maximisation as their main goal, they will always be "amoral calculators" who only ever comply with regulatory requirements when the penalties are heavy enough to ensure their calculations come up with the correct answer. Law and economics theorists see compliance as the outcome of an equation of the benefits of non-compliance versus the probability of being discovered and punished, and the severity of the penalty (e.g. Becker, 1968; Cooter & Ulen, 1988, p. 533ff; Stigler, 1970; see Ogus, 1994, pp. 90-92 for a summary). On the whole the assumption is that deterrence motivates via fear of punishment or rational calculations of the potential cost of penalties or sanctions. As a consequence, efficient compliance requires making violations unattractive by increasing the cost of non-compliance (Garcia Quesada (2014), p. 336).

According to the standard economic model of rational and selfish human behaviour (i.e., homo economicus), people carry out dishonest acts consciously and deliberatively by trading off the expected external benefits and costs of the dishonest act. People would be honest or dishonest only to the extent that the planned trade-off favours a particular action. In addition to being central to economic theory, this external cost-benefit view plays an important role in the theory of crime and punishment, which forms the basis for most policy measures aimed at preventing dishonesty and guides punishments against those who exhibit dishonest behaviour. In summary, this standard external cost-benefit perspective generates three hypotheses as to the forces that are expected to increase the frequency and magnitude of dishonesty: higher magnitude of external rewards, lower probability of being caught and lower magnitude of punishment (Mazar, Amir and Ariely (2008), pp. 4-5; Wils (2006), p. 12).

Economic theory assumes that the offender weighs the costs and the benefits in deciding whether or not to commit a crime. The rational prospective offender is assumed to be a profit maximizer who weighs the costs and the benefits of committing a crime and does not undertake illegal action unless the expected benefits of the crime exceed the expected costs. From this point of view, it can be said that the function of penalties is simply to increase the expected costs in order to deter the prospective offender (Bowles (1982), p. 54-105; Wils (2006-1), pp. 12-17).

According to the Becker's model in calculating the expected costs two important factors should be taken into account: One is the authorities' ability to catch and convict the offender (p); the other is the expected maximum punishment (S). The multiplication of these factors then constitutes the expected costs of the crime to the offender. From a different angle, economic theory indicates that the public's decision variables to combat illegal behaviour are its expenditures on police, courts, etc., which help determine the probability (p) that an offense is discovered and the offender apprehended and convicted, the size of the punishment for those convicted (f), and the form of the punishment: imprisonment, probation, fine, etc. Optimal values of these variables can be chosen subject to, among other things, the constraints imposed by three behavioural relations. One shows the damages caused by a given number of illegal actions, called offenses (0), another the cost of achieving a given p, and the third the effect of changes in p and f on 0 (Becker (1968), p. 43).

224 OECD (2000), pp. 68-70.

Based on this landmark paper, a large empirical literature has developed to test the degree to which potential offenders are deterred. The literature falls into three general categories. The first category analysed the responsiveness of crime to the probability that an individual is apprehended. This concept has typically been operationalized as the study of the sensitivity of crime to police, in particular police manpower or policing intensity. A second group examined the sensitivity of crime to changes in the severity of criminal sanctions, through an assessment of the responsiveness of crime to sentence enhancements, three strikes laws, capital punishment regimes and policy-induced discontinuities in the severity of sanctions faced by particular individuals. The third group examines the responsiveness of crime to mainly local labour market conditions, generationally operationalized using either the unemployment rate or a relevant market wage, in order to determine whether crime can be deterred through the use of positive incentives rather than punishments. The three categories measure the degree to which individuals can be deterred from participation in criminal activity. Chalfin and McCrary (2014) concluded from their literature review that there is robust evidence that crime responds to increases in police manpower and to many varieties of police redeployments. They also noted that, while the evidence in favour of a crime-sanction link is generally mixed, there does appear to be some evidence of deterrence effects induced by policies that target specific offenders with sentence enhancements..

Ultimately, the model proposed by Becker yields three main behavioural predictions: 1) the supply of offences will fall as the probability of apprehension rises, 2) the supply of offences will fall as the severity of the criminal sanction increases and 3) the supply of offences will fall as the opportunity cost of crime rises. In other words, more active enforcement occurs when monitoring to prevent rule breaking is more frequent and when more breaches are accompanied of a sanction. If enforcement is more active, the degree of compliance with EU harmonisation legislation is expected to improve, as businesses will avoid getting caught and facing sanctions.

3.2. Problems with simple deterrence theory

While the deterrence approach holds some attraction as an explanation of how regulated enterprises decide whether to comply, it is also now clear that it will only apply in very narrow circumstances. One of the leading empirical researchers of deterrence and business regulation (Scholz, 1997; see also Aalders & Wilthagen, 1997) has argued that the basic model of deterrence is only valid when the following assumptions are true:

- Corporations are fully informed utility maximizers.
- Legal statutes unambiguously define misbehaviour.
- Legal punishment provides the primary incentive for corporate compliance.
- Enforcement agents optimally detect and punish misbehaviour given available resources.

Scholz (1997), and other researchers, have concluded from empirical tests of the deterrence model that mostly these assumptions do not hold true, and that a simple model of deterrence is therefore mostly not a helpful explanation of what motivates organisations to comply with the law.

One reason for this is that regulatory agencies are often not as powerful and efficient as they would need to be in order for deterrence to work. It is well established in deterrence research that the deterrent effect of sanctions will depend on their certainty, severity, celerity, and uniformity, especially certainty (DiMento, 1989, p. 225; Friedrichs, 1996, p. 342f). Another reason is that because so many kinds of business law-breaking have high rewards and low penalties, the threatened application of sanctions is not a severe enough threat to deter non-compliance (Coffee, 1981; Ogus, 1994, p. 93).

In order to cope with these realities, researchers have abandoned the simple economic model of deterrence as an explanation for compliance in favour of a more sophisticated analysis of how deterrence works, and how it interacts with a number of other factors that also affect compliance.

3.3. Bounded rationality

The research has shown that, contrary to the assumption that corporations are fully informed utility maximizers, economic costs of non-compliance which do not draw attention to themselves by generating some kind of crisis are often overlooked by busy management (see Hopkins, 1995, pp. 88-95).

For example, Scholz and Gray's (1990; see also Weil, 1996) very comprehensive research into the effectiveness of OSHA enforcements found only a modest reduction in injury rates in all plants following an increase in enforcement activity. However individual plants that were inspected and penalised experienced a 22% decline in injuries over the next three years, despite extremely low average fines. The fact that they have been inspected and penalised in a particular year should not have affected the probability and cost-benefit calculations of those firms penalised if they had been acting purely rationally, although it might have a general deterrent effect on the whole population. Scholz and Gray conclude that imposing penalties results in improved safety for these particular firms because the imposition of a penalty focuses managerial attention on risks that would otherwise have been overlooked. Normally, the "bounded rationality" of organisations and top management – the limited capacity of people and organisations to process information in decision making (March & Simon, 1958, p. 169) - means that many do not make rational cost-benefit calculations about compliance at all. It is only when something happens to bring the risks of non-compliance to their attention, that deterrence becomes effective.

In her investigation of health and safety programmes in UK companies Genn (1993, p. 223) finds that it is "when there is a potential for a catastrophe of either an economic or political nature, and also where companies are large, well established, highly visible and thus mindful of their public image" that they are more likely to have an occupational health and safety system in place. Similarly, McCaffrey and Hart (1998, p. 87) find that in the wake of major regulatory scandals in their industry, firms will make heavier investments in compliance than they otherwise would have, suggesting that the deterrent threat of enforcement is much more effective when a major scandal draws it to people's attention.

3.4. The effects of negative publicity

The research on deterrence also shows that when individuals or management do think about the disadvantages of non-compliance, they do not make a simple calculation based on the direct economic costs of non-compliance. Rather other factors, particularly the indeterminate costs of bad publicity on the firm's reputation and morale are very significant. This

contradicts the basic premise of deterrence theory that the size of the expected financial penalty directly relates to the level of compliance.

For example, Scholz and Gray (1990) found that although workplace safety in plants inspected by OSHA improves after penalties are imposed, the size of the penalty has little impact on safety improvements (indeed most of the penalties were very low). Davidson et al (1995) measured the stock markets' reaction to OSHA announcements of sanctions on the companies receiving them (adjusting for overall stock market movement). The study found a stock market decline average of -0.46% on the days immediately before and after the announcement. However they could find no relationship at all between the size of the fine and the stock market reaction, suggesting that negative publicity was the important factor. Fisse and Braithwaite (1983) studied the impact of publicity on corporate offenders in seventeen high profile cases in great detail. They found that adverse publicity is of concern not so much by reason of its financial impacts but because of a variety of non-financial effects, the most important of which is loss of corporate prestige" and that "corporations fear the sting of adverse publicity attacks on their reputations more than they fear the law itself" (Fisse & Braithwaite, 1983, pp. 247, 249).

Indeed a series of studies have found that maintaining or advancing the corporate reputation and counteracting negative publicity is an important reason for enterprise interest in ensuring compliance (e.g. Bardach & Kagan, 1982, p. 164; Genn, 1993; Parker, 1999a, but cf Haines, 1997, pp. 188-190). It appears that, even where regulators only have small penalties at their disposal, actual, or potential bad publicity can overcome bounded rationality, put compliance issues on management agendas and improve compliance rates.

3.5. Informal sanctions and shame

The evidence also suggests that in general informal sanctions have a greater deterrent impact than formal legal sanctions (Ekland-Olson et al, 1984; Paternoster & Simpson, 1996; Tittle, 1980, p. 241), and that regardless of what kind of social control is attempted it is not its formal punitive features that make a difference, but its informal moralising features (Schwartz & Orleans, 1967).

Informal sanctions include negative publicity, public criticism, gossip, embarrassment, and shame. Formal sanctions are official sanctions such as fines, compensation, licence revocations and restrictions and prison sentences. There is however an interaction effect: formal sanctions will often trigger informal sanctions such as bad publicity. The "restorative justice" approach to dealing with corporate law-breaking relies on the effectiveness of shame and informal sanctions to reduce non-compliance (Braithwaite, 1999). […]

3.6. The significance of maintaining legitimacy

Another body of research that is very consistent with the research on the effects of informal sanctions, negative publicity and shame shows that many enterprises are often motivated to comply with the law, or at least to appear to comply, in order to maintain their legitimacy in the eyes of government, industry peers, and the public. This body of research suggests that the possibility of fines, sanctions, and inspections acts less as a deterrent threat than as a way to focus management attention on institutional expectations that may affect the legitimacy and operation of their enterprise. This is the concern of the "new institutional" scholarship in economics, political science, and organisational theory (Scott, 1995). "New institutional" theory in economics, for example, attempts to recognise that individuals and enterprises do

not always make decisions solely on the basis of financial calculations, but a variety of other social and environmental factors including their own values and the expectations of others will affect their actions. As Suchman and Edelman (1997, p. 919) explain it, 'Institutional factors often lead organisations to conform to societal norms even when formal enforcement mechanisms are highly flawed. Frequently cited institutional influences include historical legacies, cultural mores, cognitive scripts, and structural linkages to the professions and to the state. Each, in its own way, displaces single-minded profit-maximisation with a heightened sensitivity to the organisations embeddedness within a larger social environment.'

This does not mean that financial and legal considerations are not important, but that they are not the sole explanation for organisational action. DiMaggio and Powell (1991) have described three forms of "institutional isomorphism" that explain how organisations adopt practices and structures from their social environments beyond what is strictly required by the technical and financial parameters under which they operate: "mimetic isomorphism" occurs when organisations copy the apparently successful practices of other, similar organisations; "coercive isomorphism" occurs when organisations submit to the demands of powerful external actors, such as the regulatory agencies of the state; and "normative isomorphism" occurs when organisations import the practices of professionals and other organised value carriers. Each of these mechanisms can mean that enterprises adopt compliance even when it is not strictly in their financial interest.

There is a growing body of empirical evidence that this theory does help explain corporate compliance with regulation. Edelman and various co-authors (Dobbin et al. 1988; Edelman, 1990; Edelman et al., 1993) have used neo-institutional theory to explain the growth of employee due process rights designed to protect against indiscriminate firing, safety violations, unequal discipline, sexual harassment, and discriminatory employment opportunity structures in US companies.

Hoffman's (1997) study of corporate environmentalism in the US petroleum and chemicals industry uses neo-institutional theory to explain why the growth in corporate attention to environmental issues did not follow trends in volume of new environmental laws and regulations nor growth in industrial expenditure on environmental issues as deterrence theory would predict, but rather rose and declined with public concern with environmentalism (see Hoffman, 1997, p. 144). Similarly, Rees' (1997) study of the emergence of the US Chemical Manufacturers' Association, Responsible Care, selfregulatory programme also finds that it was the imperatives of institutional legitimacy that forced chemical companies to regulate themselves after the Bhopal accident, rather than a simple model of deterrence (see also Heimer, 1996, for an application of neo-institutionalism to health care regulation).

However, a number of the scholars who have researched in this area have pointed out that often a concern with legitimacy can motivate enterprises to manage their image of compliance, without necessarily complying substantively with the requirements of the regulation (e.g. Edelman et al., 1993; Shearing, 1993, pp. 75-76).

3.7. Co-operation and trust

The basis for the theory that co-operative, persuasive regulatory enforcement strategies should be used rather than punitive ones is the assumption that most individuals/businesses are "ordinarily inclined to comply with the law, partly because of belief in the rule of law, partly as a matter of long-term self-interest" (Kagan and Scholz, 1984, p. 67; see also Bardach and Kagan, 1982, p. 66). However this claim is often based on anecdotal rather than systematic

evidence and seems to depend partially on defining being "in compliance" as being substantially in compliance, and ignoring smaller ongoing violations (cf Brown, 1994).

Nevertheless, some impressive evidence has been collected by researchers which shows that, although co-operative and persuasive strategies are not always appropriate, when they are successful they are superior to punitive sanctions in effectively and efficiently accomplishing long term compliance. A large body of empirical sociological and psychological research converges on the finding that non-coercive and informal alternatives are likely to be more effective than coercive law in achieving long term compliance with norms, and coercive law is most effective when it is in reserve as a last resort. For example, there is significant psychological evidence for a "minimal sufficiency principle" that the less powerful the technique used to secure compliance, the more likely is long term internalisation of a desire to comply. Such internalisation is discouraged by the use of rewards and punishments; reasoning and dialogue promote it (Boggiano et al., 1987; Kohn, 1993; see also Brehm & Brehm, 1981).6 Thus Honneland (1998) found that compliance can be secured despite weak sanctions through "discourse" persuasion and co-operation at the enforcement level among fishermen in the Svalbard restricted fishing zone. Braithwaite, Makkai, Braithwaite, and Gibson's programme of research on nursing home regulation is probably the most systematic quantitative empirical study of regulation and compliance conducted to date. Results from this study shows that co-operative strategies of trust, restorative shaming, and praise are more effective at increasing business compliance with regulation than the application of formal sanctions (Braithwaite & Makkai, 1991, 1994, Makkai & Braithwaite, 1993, 1994a, 1994b).

A noteworthy theme of this research is the importance of trust in securing compliance. In a famous book, Francis Fukuyama (1995) argued that capitalism needs trust to work efficiently and effectively. A number of social researchers now find trust to be an essential resource in all sectors of society (e.g. Putnam 1993). This is especially important in relations between regulators and regulatees.

Trust between regulator and regulatee simultaneously builds efficiency and improves the prospect of compliance. If regulatees trust regulators as fair umpires who administer and enforce laws or regulations that have important substantive objectives, then the evidence is that compliance will be higher, and resistance and challenges to regulatory action will be low (see DiMento, 1989, p. 225). For example Scholz and Lubell (1998; see also Levi, 1988) found that tax compliance increases as trust toward the government increases and also that the sense of duty to pay taxes increases when government policies prove beneficial to the taxpayer. If regulatees feel that regulators treat them as untrustworthy, then defiance and resistance build up so that inefficiency and non-compliance both increase (see V. Braithwaite, 1995; Paternoster, et al., 1997; Sherman, 1993).

However, it should also be noted that most accounts that find people to be compliant in response to co-operation, goodwill and trust also find that deterrence is necessary as a back-up for the minority of organisations that do not voluntarily comply (see discussion of pyramids below). They also find that co-operative compliance is generally contingent upon persuading those of goodwill that their compliance will not be exploited by free riders who will get away with the benefits of noncompliance without being held to account for it (see Levi, 1988; Scholz, 1997, p. 262). Thus deterrent and punitive sanctions must still be available in the background.

More recently there has been considerable interest in another enforcement model that involves government 'regulating at a distance' by risk managing the risk management of individual

enterprises. This implies requiring or encouraging enterprises to put in place their own internal controls and management (via systems, plans and risk management more generally). These are then scrutinized by regulators, who take the necessary action to ensure that these mechanisms are working effectively.

3.8. Effective motivations for compliance vary among people and contexts

The strands of research summarised above give us a more complex picture of what motivates people to comply with regulation than the simple deterrence model. This picture is further complicated by the finding that effective motivations for compliance vary between persons and contexts. There are a wide variety of motivations likely to apply in different enterprises, in different parts of the same enterprises and at different times in the same enterprise.

Paternoster and Simpson (1996) looked at intentions to commit four types of corporate crime by MBA students, and found that these intentions were affected by sanction threats (formal and informal), moral evaluations and organisational factors. They find that where people do hold personal moral codes, then these will be more significant than rational calculations in predicting compliance. If moral inhibitions are high then cost-benefit calculations are virtually superfluous. But when moral inhibitions are low, then deterrence became relevant. Similarly Fisse and Braithwaite (1983, 1993) find that companies will frequently be responsive to weak sanctions including publicity and shame because there are usually a variety of actors associated with any wrongdoing. Some will be "hard targets" who cannot be deterred even by maximum penalties. But others will be "vulnerable targets" who can be deterred by penalties, and still others will be "soft targets who can be deterred by shame, by the mere exposure of the fact that they have failed to meet some responsibility they bear, even if that is not a matter of criminal responsibility." (Fisse & Braithwaite, 1993; p. 220). Differing motivations and responses will also be partially determined by economic circumstances and place in the structure as well as by individual dispositions of particular corporate managers. A consistent research finding is that larger enterprises are more likely to implement compliance systems and to be more compliant than smaller enterprises (e.g. Ashby & Diacon, 1996; Genn, 1993; Haines, 1997).

In summary the picture of the organisation as an amoral calculator moved by appropriate deterrence to 'do the right thing' must be supplemented by the facts that organisations can sometimes be persuaded to do the right thing, that some influential actors within organisations will be highly motivated to be legal or socially responsible for its own sake, that the existence of deterrence threats will not necessarily be a feature of daily decision making, that many organisations will behave in ways that they feel maintain their legitimacy in the eyes of industry peers, customers or governments irrespective of individual cost and efficiency calculations, and that even where formal sanctions are applied, it is their informal ramifications (shame and negative publicity) that are more effective motivators.

3.9. Evaluation

As part of the exploration of options for the impact assessment the *investigation by the Commission* (*instead of* member states market surveillance authorities) and ultimately imposition of sanctions was assessed.

Similar to a coordinated approach at EU level relying on inputs from Member State authorities (through e.g. Product Compliance Network), such an option would eliminate the duplication of work linked to the need to carry out different proceedings in different Member

States. However the Commission would have to create from scratch an ad hoc investigative capacity (e.g. recruiting new staff, setting new procedures) in all the product sectors and to maintain this capacity stand-by to perform investigations, take enforcement decision and sanctions separate from and in addition to capacities in Member States authorities that would in any event continue to be needed for the bulk of product investigations. The additional costs for the Commission to avail of such a separate capacity would outweigh possible savings that could be made at national level for the cases concerned and as such the option would unlikely to be efficient. Moreover, according to the views expressed by some Member States this option brings about a negative impact on them because it would imply a transfer of national sovereignty towards the EU and so have a negative impact on subsidiarity. This option is therefore not further examined in the impact assessment.

3.10. Overview of the provisions on penalties in Union harmonisation legislation

Directive/Regulation	Provision on penalties
Directive 69/493/EEC on the approximation of the laws of the Member States relating to crystal glass; Directive 75/107/EEC on the approximation of the laws of the Member States relating to bottles used as measuring containers; Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers; Directive 76/211/EEC on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products; Directive 80/181/EEC on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC; Directive 92/23/EEC relating to tyres for motor vehicles and their trailers and to their fitting (valid until 31 October 2017); Directive 92/42/EEC on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels;	No provisions on penalties in the Directives. This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing these directives.

Directive 94/11/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer; Directive 97/68/EC on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery	
Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC;	Article 9a - Penalties Member States shall determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive. The penalties determined must be effective, proportionate and dissuasive.
Directive 2000/14/EC on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors	No provisions on penalties in the Directive. This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing this directive.
Regulation (EC) No 2003/2003 relating to fertilisers	Article 36 - Penalties The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.
Directive 2004/42/CE on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC	Article 10 - Penalties Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take the necessary measures to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those rules and measures to the Commission by 30 October 2005 at the latest, and shall notify it without delay

	of any subsequent amendment affecting them.
Directive 2004/52/EC on the interoperability of electronic road toll systems in the Community	No provisions on penalties in the Directive. This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing this directive.
Regulation (EC) No 552/2004 on the interoperability of the European Air Traffic Management network (the interoperability Regulation)	No provisions on penalties in the Regulation. This, however, does not necessarily mean that national law does not lay down penalties for infringing the Regulation.
Regulation (EC) No 648/2004 on detergents	Article 18 - Penalties Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. This may also include appropriate measures allowing the competent authorities of the Member States to prevent the making available on the market of detergents or surfactants for detergents that fail to comply with this Regulation. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions and any subsequent amendment affecting those provisions to the Commission without delay. Those rules shall include measures allowing the competent authorities of Member States to detain consignments of detergents that fail to comply with this Regulation.
Regulation (EC) No 850/2004 on persistent organic pollutants and amending Directive 79/117/EEC	Article 13 - Penalties Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission one year after entry into force of this Regulation at the latest and shall notify it without delay of any subsequent amendment affecting them.

Directive 2005/64/EC on the type-approval of motor vehicles with regard to their reusability, recyclability and recoverability and amending Council Directive 70/156/EEC	No provisions on penalties in the Directives. This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing these directives.
Directive 2006/40/EC relating to emissions from air conditioning systems in motor vehicles and amending Council Directive 70/156/EEC	
Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery	Article 23 - Penalties Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 29 June 2008 and shall notify it without delay of any subsequent amendment affecting them.
Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC	Article 25 - Penalties Member States shall lay down rules on penalties applicable to infringements of national provisions adopted pursuant to this Directive and shall take all necessary measures to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those measures to the Commission by 26 September 2008 and shall inform it without delay of any subsequent amendment to them.
Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC,	Article 126 - Penalties for non-compliance Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later than 1 December 2008 and shall notify it without delay of any subsequent amendment affecting them.

93/105/EC and 2000/21/EC	
Directive 2007/45/EC laying down rules on nominal quantities for pre-packed products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC	No provisions on penalties in the Directive. This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing this directive.
Directive 2007/46/EC establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles	Article 46 - Penalties Member States shall determine the penalties applicable for infringement of the provisions of this Directive, and in particular of the prohibitions contained in or resulting from Article 31, and of the regulatory acts listed in Part I of Annex IV and shall take all necessary measures for their implementation. The penalties determined shall be effective, proportionate and dissuasive. Member States shall notify these provisions to the Commission no later than 29 April 2009 and shall notify any subsequent modifications thereof as soon as possible.
Regulation (EC) No 715/2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information	Article 13 - Penalties 1. Member States shall lay down the provisions on penalties applicable for infringement by manufacturers of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 2 January 2009 and shall notify it without delay of any subsequent amendment affecting them. 2. The types of infringements which are subject to a penalty shall include: (a) making false declarations during the approval procedures or procedures leading to a recall; (b) falsifying test results for type approval or in-service conformity; (c) withholding data or technical specifications which could lead to recall or withdrawal of type approval;

	(d) use of defeat devices; and (e) refusal to provide access to information.
Directive 2008/2/EC on the field of vision and windscreen wipers for wheeled agricultural or forestry tractors (Codified version) Directive 2008/57/EC on the interoperability of the rail system within the Community	No provisions on penalties in the Directive. This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing this directive.
Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006	Article 47 - Penalties for non-compliance Member States shall introduce penalties for non-compliance with this Regulation and shall take all measures necessary to ensure that this Regulation is applied. The penalties must be effective, proportionate and dissuasive. Member States shall notify the Commission of the provisions for penalties by 20 June 2010 and shall notify it without delay of any subsequent amendment affecting them.
Directive 2009/34/EC relating to common provisions for both measuring instruments and methods of metrological control	No provisions on penalties in the Directive. This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing this directive.
Directive 2009/48/EC on the safety of toys	Article 51 - Penalties Member States shall lay down rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements of the national provisions adopted pursuant to this Directive, and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement of this Directive. The Member States shall notify the Commission of those rules by 20 July 2011, and shall notify it without delay of any subsequent amendment to

	them.
Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products	Article 20 - Penalties The Member States shall lay down the rules applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive, taking into account the extent of non-compliance and the number of units of non-complying products placed on the Community market. The Member States shall notify those provisions to the Commission by 20 November 2010 and shall notify it without delay of any subsequent amendment affecting them.
Regulation (EC) No 78/2009 on the type-approval of motor vehicles with regard to the protection of pedestrians and other vulnerable road users, amending Directive 2007/46/EC and repealing Directives 2003/102/EC and 2005/66/EC	Article 13 - Penalties 1. Member States shall lay down the provisions on penalties applicable for infringement by manufacturers of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 24 August 2010 and shall notify it without delay of any subsequent amendment affecting them. 2. The types of infringements which are subject to a penalty shall include at least the following: (a) making false declarations during the approval procedures or procedures leading to a recall; (b) falsifying test results for type-approval; (c) withholding data or technical specifications which could lead to recall or withdrawal of type-approval; (d) refusal to provide access to information.
Regulation (EC) No 79/2009 on type-approval of hydrogen-powered motor vehicles, and amending Directive 2007/46/EC	Article 15 - Penalties for non-compliance 1. Member States shall lay down the provisions on penalties applicable for infringement by manufacturers of the provisions of this Regulation

	and its implementing measures and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. By 24 August 2010, Member States shall notify those provisions to the Commission, and shall notify it without delay of any subsequent amendment affecting them. 2. The types of infringement which are subject to a penalty shall include at least the following: (a) making false declarations during an approval procedure or a procedure leading to a recall; (b) falsifying test results for type-approval or in-use compliance; (c) withholding data or technical specifications which could lead to recall or withdrawal of type-approval; (d) refusal to provide access to information; (e) use of defeat devices.
Regulation (EC) No 595/2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC	Article 11 - Penalties 1. Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and its implementing measures and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 7 February 2011 and shall notify it without delay of any subsequent amendment affecting them. 2. The types of infringements by manufacturers which are subject to a penalty shall include: (a) making false declarations during the approval procedures or procedures leading to a recall; (b) falsifying test results for type-approval or in-service conformity; (c) withholding data or technical specifications which could lead to recall or withdrawal of type-approval;

	(d) use of defeat strategies; (e) refusal to provide access to information. The types of infringements by manufacturers, repairers and operators of the vehicles which are subject to a penalty shall include tampering with systems which control NOx emissions. This shall include, for example, tampering with systems which use a consumable reagent. The types of infringements committed by operators of the vehicles which are subject to a penalty shall include driving a vehicle without a consumable reagent.
Regulation (EC) No 661/2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor	Article 16 - Penalties for non-compliance 1. Member States shall lay down the rules on penalties applicable to infringement by manufacturers of the provisions of this Regulation and its implementing measures and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. By 20 February 2011 or, as appropriate, 18 months from the date of entry into force of the relevant implementing measure, Member States shall notify those provisions to the Commission, and shall notify it without delay of any subsequent amendment affecting them. 2. The types of infringement which are subject to a penalty shall include at least the following: (a) making false declarations during an approval procedure or a procedure leading to a recall; (b) falsifying test results for type-approval; (c) withholding data or technical specifications which could lead to recall or withdrawal of type-approval.
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	Article 29 - Penalties Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member

	States shall notify those provisions to the Commission by 30 June 2011 at the latest and shall also notify it without delay of any subsequent amendment affecting them.
Regulation (EC) No 1222/2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters	No provisions on penalties in the Regulation. This, however, does not necessarily mean that national law does not lay down penalties for infringing the Regulation.
Regulation (EC) No 1223/2009 on cosmetic products	Article 37 - Penalties Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 11 July 2013 and shall notify it without delay of any subsequent amendment affecting them.
Regulation (EC) No 66/2010 on the EU Ecolabel	Article 17 - Penalties Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission without delay and shall notify it without delay of any subsequent amendment affecting them.
Directive 2010/30/EU on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products	Article 15 - Penalties Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and its delegated acts, including unauthorised use of the label, and shall take the necessary measures to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. The Member States shall notify these provisions to the Commission by 20 June 2011 and shall notify the Commission without delay of any subsequent

	amendment affecting those provisions.
Directive 2010/35/EU on transportable pressure equipment	Article 14 - General principles of the Pi marking […] 7. Member States shall ensure correct implementation of the rules governing the Pi marking and shall take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use. Article 41 - Obligations on Member States Member States shall take the necessary measures to ensure that the economic operators concerned comply with the provisions set out in Chapters 2 and 5. Member States shall also ensure that the necessary implementing measures are taken in respect of Articles 12 to 15.
Regulation (EU) No 1007/2011 on textile fibre names and related labelling and marking of the fibre composition of textile products and repealing Council Directive 73/44/EEC and Directives 96/73/EC and 2008/121/EC of the European Parliament and of the Council	No provisions on penalties in the Regulation. This, however, does not necessarily mean that national law does not lay down penalties for infringing the Regulation.
Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment	Article 15 - Rules and conditions for affixing the CE marking […] 3. Member States shall build upon existing mechanisms to ensure the correct application of the regime governing the CE marking and take appropriate action in the event of improper use of the CE marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use. Article 23 - Penalties The Member States shall lay down the rules on penalties applicable to infringements of the

	national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 2 January 2013 and shall notify it without delay of any subsequent amendment affecting them.
Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products	No provisions on penalties in the Regulation. This, however, does not necessarily mean that national law does not lay down penalties for infringing the Regulation.
Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)	Article 22 - Penalties The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 14 February 2014 at the latest and shall notify it without delay of any subsequent amendment affecting them.
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products	Article 87 - Penalties Member States shall lay down the provisions on penalties applicable to infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later than 1 September 2013 and shall notify the Commission without delay of any subsequent amendment affecting them.
Regulation (EU) No 167/2013 on the approval and market surveillance of agricultural and forestry vehicles	Article 72 - Penalties 1. Member States shall provide for penalties for infringement by economic operators of this Regulation and the delegated or implementing acts adopted pursuant to this Regulation. They shall take all measures necessary to ensure that the penalties are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify those

	provisions to the Commission by 23 March 2015 and shall notify the Commission without delay of any subsequent amendment affecting them. 2. The types of infringements which are subject to a penalty shall include: (a) making false declarations during approval procedures or procedures leading to a recall; (b) falsifying test results for type-approval or in-service conformity; (c) withholding data or technical specifications which could lead to recall, refusal or withdrawal of type-approval; (d) use of defeat devices; (e) refusal to provide access to information; (f) economic operators making available on the market vehicles, systems, components or separate technical units subject to approval without such approval or falsifying documents or markings with that intention.
Regulation (EU) No 168/2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles	Article 76 - Penalties 1. Member States shall provide for penalties for infringement by economic operators of this Regulation and the delegated or implementing acts adopted pursuant to this Regulation. They shall take all measures necessary to ensure that the penalties are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 23 March 2015 and shall notify the Commission without delay of any subsequent amendment affecting them. 2. The types of infringements which are subject to a penalty shall include: (a) making false declarations during approval procedures or procedures leading to a recall; (b) falsifying test results for type-approval; (c) withholding data or technical specifications which could lead to recall, refusal or withdrawal

	of type-approval; (d) use of defeat devices; (e) refusal to provide access to information; (f) economic operators making available on the market vehicles, systems, components or separate technical units subject to approval without such approval or falsifying documents or markings with that intention.
Directive 2013/29/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles	Article 45 - Penalties Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all the measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements. The penalties provided for shall be effective, proportionate and dissuasive.
Directive 2013/53/EU on recreational craft and personal watercraft and repealing Directive 94/25/EC	Article 53 - Penalties Member States shall lay down rules on penalties which may include criminal sanctions for serious infringements, applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator or the private importer has previously committed a similar infringement of this Directive.
Directive 2014/28/EU on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses	Article 50 - Penalties Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements. The penalties provided for shall be effective,

	proportionate and dissuasive.
Directive 2014/29/EU on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels	Article 40 - Penalties Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements. The penalties provided for shall be effective, proportionate and dissuasive.
Directive 2014/30/EU on the harmonisation of the laws of the Member States relating to electromagnetic compatibility	Article 42 - Penalties Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements. The penalties provided for shall be effective, proportionate and dissuasive.
Directive 2014/31/EU on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments	Article 42 - Penalties Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements The penalties provided for shall be effective, proportionate and dissuasive.
Directive 2014/32/EU on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments	Article 49 - Penalties Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements. The penalties provided for shall be effective,

	proportionate and dissuasive.
Directive 2014/33/EU on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts	Article 43 - Penalties Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements. The penalties provided for shall be effective, proportionate and dissuasive.
Directive 2014/34/EU on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres	Article 40 - Penalties Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements. The penalties provided for shall be effective, proportionate and dissuasive.
Directive 2014/35/EU on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits	Article 24 - Penalties Member States shall lay down rules on penalties, applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements. The penalties provided for shall be effective, proportionate and dissuasive.
Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC	Article 46 - Penalties Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements. The penalties provided for shall be effective,

	proportionate and dissuasive.
Directive 2014/68/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment	Article 47 - Penalties Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. Such rules may include criminal penalties for serious infringements. The penalties referred to in the first paragraph shall be effective, proportionate and dissuasive.
Directive 2014/90/EU on marine equipment and repealing Council Directive 96/98/EC	No provisions on penalties in the Directive. This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing this directive.
Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006	Article 25 - Penalties 1. Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 1 January 2017 at the latest and shall notify it without delay of any subsequent amendment affecting them. 2. In addition to the penalties referred to in paragraph 1, undertakings that have exceeded their quota for placing hydrofluorocarbons on the market, allocated in accordance with Article 16(5) or transferred to them in accordance with Article 18, may only be allocated a reduced quota allocation for the allocation period after the excess has been detected. The amount of reduction shall be calculated as 200 % of the amount by which the quota was exceeded. If the amount of the reduction is higher than the amount to be allocated in accordance with Article 16(5) as a quota for the allocation period after the excess has been detected, no quota shall be allocated for that allocation period and the

	quota for the following allocation periods shall be reduced likewise until the full amount has been deducted.
Regulation (EU) No 540/2014 on the sound level of motor vehicles and of replacement silencing systems, and amending Directive 2007/46/EC and repealing Directive 70/157/EEC	No provisions on penalties in the Regulation. This, however, does not necessarily mean that national law does not lay down penalties for infringing the Regulation.
Regulation (EU) 2016/424 on cableway installations and repealing Directive 2000/9/EC	Article 45 - Penalties 1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of the provisions of this Regulation and of national law adopted pursuant to this Regulation. Such rules may include criminal penalties for serious infringements. The penalties provided for shall be effective, proportionate and dissuasive and may be increased where the relevant economic operator has previously committed a similar infringement of this Regulation. Member States shall notify those rules to the Commission by 21 March 2018, and shall notify it without delay of any subsequent amendment affecting them. 2. Member States shall take all measures necessary to ensure that their rules on penalties applicable to infringements by economic operators of the provisions of this Regulation are enforced.
Regulation (EU) 2016/425 on personal protective equipment and repealing Council Directive 89/686/EEC	Article 45 - Penalties 1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of the provisions of this Regulation. Such rules may include criminal penalties for serious infringements. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify those rules to the Commission by 21 March 2018, and shall notify it without delay of any subsequent amendment affecting them. 2. Member States shall take all measures necessary to ensure that their rules on penalties applicable to infringements by economic operators

	of the provisions of this Regulation are enforced.
Regulation (EU) 2016/426 on appliances burning gaseous fuels and repealing Directive 2009/142/EC	Article 43 - Penalties 1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of the provisions of this Regulation. Such rules may include criminal penalties for serious infringements. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify those rules to the Commission by 21 March 2018 and shall notify it without delay of any subsequent amendment affecting them. 2. Member States shall take all measures necessary to ensure that their rules on penalties applicable to infringements by economic operators of the provisions of this Regulation are enforced.
Directive (EU) 2016/802 relating to a reduction in the sulphur content of certain liquid fuels	Article 18 - Penalties Member States shall determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive. The penalties determined shall be effective, proportionate and dissuasive and may include fines calculated in such a way as to ensure that the fines at least deprive those responsible of the economic benefits derived from the infringement of the national provisions as referred to in the first paragraph and that those fines gradually increase for repeated infringements.

3.11. EU mechanisms already in place regarding recognition and enforcement of financial penalties

This section contains an explanation of the EU mechanisms already in place regarding recognition and enforcement of financial penalties.

a) Council framework decision 2005/214/JHA

The recognition and enforcement of financial penalties imposed by judicial or administrative authorities is subject to Council framework decision 2005/214/JHA (hereafter 'The Decision'). The Decision applies the principle of mutual recognition to financial penalties, enabling a judicial or administrative authority to transmit a financial penalty directly to an authority in another EU country and to have that penalty recognised and executed without any further

formality. The Decision had to be implemented by Member States by 22 March 2007 (article 20).[225] The Decision has been implemented by most Member States, including the United Kingdom and Denmark.[226] As far as records show, it has not been implemented in Italy and Ireland yet, but should be implemented in the near future.[227] Implementation in Greece has not taken place and is unclear when this will change.[228]

The Decision has been amended in 2009 by Council Framework Decision 2009/299/JHA of 26 February 2009 amending Framework Decisions 2002/584/JHA, 2005/214/JHA, 2006/783/JHA, 2008/909/JHA and 2008/947/JHA, thereby enhancing the procedural rights of persons and fostering the application of the principle of mutual recognition to decisions rendered in the absence of the person concerned at the trial, which had to be implemented 28 March 2011.

The measures as included in the Decision make it possible that, for example, fines imposed in Member State A for a violation of EU product legislation committed in Member State A by an economic operator with its registered seat in Member State B, have to be recognised and enforced by Member State B if Member State A makes a request for enforcement with Member state B.

b) Which financial penalties are subject to mutual recognition?

The mechanisms as imposed by this decision apply also to *'offences established by the issuing State and serving the purpose of implementing obligations arising from instruments adopted under the EC Treaty or under Title VI of the EU Treaty*' (art. 5 (1) sub 39). Since EU product safety regulations qualify as such instruments and require Member States to lay down rules on penalties for economic operators,[229] this framework decision applies to decisions of Member State (authorities or judiciaries) on financial penalties for violations of European product legislation.

In most Member States the penalties on violation of EU product legislations have been regulated via administrative legislation (i.e. civil penalties) and/or criminal legislation (i.e. criminal penalties). The framework decision is not limited to criminal fines but also includes administrative fines: The principle of mutual recognition applies to all offences in relation to which financial penalties can be imposed.[230] The penalties must be imposed by the judicial or

225 The decision has been evaluated in 2008: COM/2008/0888 final - Report from the Commission based on Article 20 of the Council Framework Decision 2005/214/JHA of 24 February 2005 on the application of the principle of mutual recognition to financial penalties.

226 a.o. PIFP, Implementation of the Framework Decision of the Council of the European Union of 24 February 2005 (2005/214/JHA) of the application of the principle of mutual recognition to financial penalties. 2010. Publication date: 03/06/2011. http://www.ejn-crimjust.europa.eu/ejn/libdocumentproperties.aspx?Id=225 and Answers received by the General Secretariat in reply to the Questionnaire on "Implementation of the Framework Decision of the Council of the European Union of 24 February 2005 (2005/214/JHA) of the application of the principle of mutual recognition to financial penalties". March 2012. Publication Date 10/12/2012. http://www.ejn-crimjust.europa.eu/ejn/libdocumentproperties.aspx?Id=1044

227 In the latest answers to the questionnaire on the implementation Ireland indicated that a draft bill that is apparently still pending. Answers received by the General Secretariat in reply to the Questionnaire on "Implementation of the Framework Decision of the Council of the European Union of 24 February 2005 (2005/214/JHA) of the application of the principle of mutual recognition to financial penalties". March 2012. Publication Date 10/12/2012. http://www.ejn-crimjust.europa.eu/ejn/libdocumentproperties.aspx?Id=1044 And furthermore: http://www.ejn-crimjust.europa.eu/ejn/EJN_Library_StatusOfImpByCou.aspx?CountryId=293

228 http://www.ejn-crimjust.europa.eu/ejn/EJN_Library_StatusOfImpByCou.aspx?CountryId=293

229 According to article 41 of Regulation (EC) 2008/765 Member States shall lay down rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements of the provisions of this regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement of the provisions of this Regulation. Sector specific regulations and/or directives include similar provisions.

230 Paragraph 2 of the preambules and article 1(a) (ii) and (iii) of the Decision. See also: http://ec.europa.eu/justice/criminal/recognition-decision/financial-penalties/index_en.htm, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:l16003, https://e-justice.europa.eu/content_mutual_recognition_of_financial_penalties-388-en.do.

administrative authorities of the Member States and this decision must be final, i.e. there is no longer any possibility to appeal the decision.

Some Member States do not (always) impose fines for violations of EU product safety legislation, but (instead) recover the costs for the enforcement measures taken. The definition of financial penalty includes *'a sum of money in respect of the costs of court or administrative proceedings leading to the decision'* (art. 1 (b) (iii))[231] but excludes *'orders for the confiscation of instrumentalities or proceeds of a crime*' (which could be the product itself or the profits earned therewith) or *'orders that have a civil nature and arise out of a claim for damages and restitution and which are enforceable under* [Brussel Ibis]' (civil and commercial matters) (article 1 (b) second paragraph, second bullet). Depending on how restitution is regulated in the Member State, there could be a possibility that such costs may also qualify as financial penalty and may be recognised (for example if it is not regulated as compensation but has a penalty element in it). This is a matter of interpretation of the Member States national laws as well as the definitions of the Regulation.

c) How does mutual recognition and enforcement work?

If Member State A (the issuing state) wants to enforce one of its decisions in Member State B (the receiving state), the decision, together with a certificate as provided for in the Framework Decision (Annex 1), may be transmitted to the competent authorities in Member State B. A decision may be transmitted to the competent authorities of a Member State in which the natural or legal person against whom a decision has been passed has property or income, is normally resident or has its registered seat (article 4(1)) Therefore, a request may also be made if there are only assets of the Economic Operator present in a Member State.

Each Member State has designated one or more authorities that are competent under its national law for the management of the transmission of decisions on issuing financial penalties in cross-border cases. The competent authorities and details on the national procedures may be found here: http://www.ejn-crimjust.europa.eu/ejn/libcategories.aspx?Id=25. Please note that the actual enforcement procedures may differ per Member State. Standardised c.q. translated forms may also be found here (see article 16 on the language of the form and translation of the decision required. Please note that the documents on the aforementioned website show that some authorities except translations in languages other than their own like English.

In principle, Member State B may not refuse the enforcement and has to take **forthwith** all the necessary measures for its execution in Member state B (article 6).

Only in limited cases (article 7) the recognition and/or enforcement may be refused. One of these circumstances is when the acts have been committed outside of the territory of the issuing State and the law of the executing state does not allow prosecution for the same offences when committed outside its territory (article 7 (2) (d) (ii)). Other grounds for refusal may be if the certificate provided for is not produced or is incomplete (article 7 (1), the offence in Member State A does not constitute an offence under the laws of Member State B (article 7 (2) (b)), the person concerned was put with limits for a legal remedy (article 7 (2) (g) (i), the financial penalty is below EUR 70 (article 7 (2) (h)) etc.

231 Germany has asked questions in the Council in 2012, stating that there appears no legal basis for isolated enforcement of the costs of criminal proceedings in a foreign country by means of mutual assistance in enforcement. Note of the German Delegation of 26 September 2012, http://www.ejn-crimjust.europa.eu/ejn/libdocumentproperties.aspx?Id=990.

The amount to be paid may be reduced by the Member State, if the acts were not carried out in the issuing state's territory, to the maximum amount provided for acts of the same kind under national law of the executing state (article 8).

The execution of the decision is governed by the law of the executing state (article 9). It can impose imprisonment or other penalties provided for by national law in the event of non-recovery of the financial penalty (article 10). Monies obtained from the enforcement of decisions will accrue to the executing state, unless otherwise agreed by the respective Member States (article 13). Member states may not claim from each other the refund of costs from application of this framework decision (article 17).

d) Other useful instruments regarding mutual recognition in criminal matters

In case of suspected serious infringements of EU product legislation that have a cross border character or element to it, other cross-border cooperation mechanisms in criminal matters could apply. Most of these mechanisms and instruments regard cooperation between judges and/or prosecutors in different Member States and regard, for example:

- the European Arrest Warrant,[232]
- the European Evidence Warrant,[233]
- Freezing of assets and evidence,[234]
- Confiscation orders,[235]
- Exchange of information on convictions/criminal records,[236]
- Decisions on (non-custodial) pre-trial supervision measures,[237]
- Mutual recognition and execution of convictions, both custodial and non-custodial,[238]
- Mutual recognition of protection measures.[239]

232 Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States - Statements made by certain Member States on the adoption of the Framework Decision

233 Council Framework Decision 2008/978/JHA of 18 December 2008 on the European evidence warrant for the purpose of obtaining objects, documents and data for use in proceedings in criminal matters

234 Council Framework Decision 2003/577/JHA of 22 July 2003 on the execution in the European Union of orders freezing property or evidence.

235 Council Framework Decision 2001/500/JHA of 26 June 2001 on money laundering, the identification, tracing, freezing, seizing and confiscation of instrumentalities and the proceeds of crime. COUNCIL FRAMEWORK DECISION 2005/212/JHA of 24 February 2005 on Confiscation of Crime-Related Proceeds, Instrumentalities and Property. COUNCIL FRAMEWORK DECISION 2006/783/JHA of 6 October 2006 on the application of the principle of mutual recognition to confiscation orders. COUNCIL DECISION 2007/845/JHA of 6 December 2007 concerning cooperation between Asset Recovery Offices of the Member States in the field of tracing and identification of proceeds from, or other property related to, crime. DIRECTIVE 2014/42/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 April 2014 on the freezing and confiscation of instrumentalities and proceeds of crime in the European Union.

236 Council Framework Decision 2009/315/JHA of 26 February 2009 on the organisation and content of the exchange of information extracted from the criminal record between Member States. Council Decision 2009/316/JHA of 6 April 2009 on the establishment of the European Criminal Records Information System (ECRIS) in application of Article 11 of Framework Decision 2009/315/JHA.

237 Council Framework Decision 2009/829/JHA of 23 October 2009 on the application, between Member States of the European Union, of the principle of mutual recognition to decisions on supervision measures as an alternative to provisional detention

238 Council Framework Decision 2008/947/JHA of 27 November 2008 on the application of the principle of mutual recognition to judgments and probation decisions with a view to the supervision of probation measures and alternative sanctions

239 Directive 2011/99/EU on the European Protection Order (EPO). Regulation (EU) No. 606/2013 on mutual recognition of protection measures in civil matters.

Although such cooperation often cannot be forced by Market Surveillance Authorities themselves, it does not prevent Market Surveillance Authorities from filing informal requests with judges and/or public prosecutors in their own Member State for cooperation with their colleagues in other Member States when necessary. Market Surveillance Authorities have the best overview regarding the whole distribution chain, product locations and parties involved. Their information and files may be useful in the investigation phase and/or for the completion of a case regarding criminal prosecution in other Member States. At the same time, the help of judges and/or prosecutors in other Member States might be necessary for successful Market Surveillance in the Market Surveillance Authorities home country in the investigation as well as the prosecution phase. Cooperation at those levels is therefore highly encouraged.

3.12. Overview of the recent Jurisprudence of the Court of Justice on penalties

Judgement	Extract
Judgment of the Court of 26 November 2015. SC Total Waste Recycling SRL v Országos Környezetvédelmi és Természetvédelmi Főfelügyelőség. Case C-487/14. ECLI identifier: ECLI:EU:C:2015:780	[…] 51. In that regard, it is appropriate to state that Article 50(1) of Regulation No 1013/2006 requires the Member States to lay down 'the rules on penalties applicable for infringement of the provisions of [that] regulation … . The penalties provided for must be effective, proportionate and dissuasive'. It is clear that that regulation does not contain more precise rules with regard to the establishment of those national penalties and, in particular, that it does not establish any express criterion for the assessment of the proportionality of such penalties. 52. According to settled case-law, in the absence of harmonisation of EU legislation in the field of penalties applicable where conditions laid down by arrangements under that legislation are not complied with, Member States are empowered to choose the penalties which seem to them to be appropriate. They must, however, exercise that power in accordance with EU law and its general principles, and, consequently, in accordance with the principle of proportionality (see, inter alia, judgment in Urbán, C‑210/10, EU:C:2012:64, paragraph 23 and the case-law cited). 53. In that regard, it should be borne in mind that, in order to assess whether the penalty in question is consistent with the principle of proportionality, account must be taken inter alia of the nature and the degree of seriousness of the infringement which the penalty seeks to sanction and of the means of establishing the amount of the penalty (see, inter alia, judgment in Rodopi-M 91, C‑259/12, EU:C:2013:414, paragraph 38 and the case-law cited). The Member States are thus required to comply with the principle of proportionality also as regards the assessment of the factors which may be taken into account in the fixing of a fine (judgment in Urbán, C‑210/10, EU:C:2012:64, paragraph 54). 54. However, it is ultimately for the national court, by taking into account all the factual and legal circumstances of the case

	before it, to assess whether the amount of the penalty does not go beyond what is necessary to attain the objectives pursued by the legislation in question. As regards the specific application of that principle of proportionality, it is for the national court to determine whether the national measures are compatible with EU law, the competence of the Court of Justice being limited to providing the national court with all the criteria for the interpretation of EU law which may enable it to make such a determination as to compatibility (see, inter alia, to that effect, judgment in Profaktor Kulesza, Frankowski, Jóźwiak, Orłowski, C‑188/09, EU:C:2010:454, paragraph 30 and the case-law cited). 55. As regards the penalties imposed for infringement of the provisions of Regulation No 1013/2006, which aims to ensure a high level of protection of the environment and human health, the national court is required, in the context of the review of the proportionality of such penalty, to take particular account of the risks which may be caused by that infringement in the field of protection of the environment and human health. 56. Accordingly, the imposition of a fine penalising the illegal shipment of waste, such as that referred to in Annex IV to that regulation, in the country of transit at a border crossing point which differs from that provided in the notification document, having been consented to by the competent authorities, of which the basic amount is the same as the fine imposed for a breach of the requirement to obtain consent and to give prior notification in writing, is to be considered to be proportionate only if the circumstances of the infringement make it possible to find that they involve equally serious infringements. 57. In the light of the foregoing considerations, the answer to the fourth question referred is that Article 50(1) of Regulation No 1013/2006, according to which the penalties applied by the Member States for infringement of the provisions of that regulation must be proportionate, must be interpreted as meaning that the imposition of a fine penalising the illegal shipment of waste, such as that referred to in Annex IV to that regulation, in the country of transit at a border crossing point which differs from that provided in the notification document which had been consented to by the competent authorities, of which the basic amount is the same as the fine imposed for a breach of the requirement to obtain consent and to give prior notification in writing, is to be considered to be proportionate only if the circumstances of the infringement make it possible to find that they involve equally serious infringements. It is for the national court to determine, by taking into account all the factual and legal circumstances of the case before it, and, in particular, the risks which may be created by that infringement in the field of the protection of the environment and human

	health, whether the amount of the penalty does not go beyond what is necessary to attain the objectives of ensuring a high level of protection of the environment and human health. […]
Judgment of the Court of 16 July 2015. Robert Michal Chmielewski v Nemzeti Adó- és Vámhivatal Dél-alföldi Regionális Vám- és Pénzügyőri Főigazgatósága. Case C-255/14. ECLI identifier: ECLI:EU:C:2015:475	[…] 16. As Regulation No 1889/2005 lays down harmonised rules for the control of movements of cash entering or leaving the European Union, it is necessary to examine the legislation at issue in the main proceedings first of all in the light of the provisions of that regulation. 17. As is apparent from Article 1(1) of Regulation No 1889/2005, read in conjunction with recitals 1 to 3 in the preamble thereto, in the context of promoting harmonious, balanced and sustainable economic development throughout the European Union, that regulation seeks to supplement the provisions of Directive 91/308 by laying down harmonised rules for the control of cash entering or leaving the European Union. 18. In accordance with recitals 2, 5 and 6 in the preamble to Regulation No 1889/2005, the regulation seeks to prevent, discourage and avoid the introduction of the proceeds of illegal activities into the financial system and their investment after laundering by the establishment, inter alia, of a principle of obligatory declaration of such movements allowing information to be gathered concerning them. 19. To that end, Article 3(1) of that regulation lays down an obligation, for any natural person entering or leaving the European Union and carrying an amount of cash equal to or more than EUR 10 000, to declare that amount. 20. Under Article 9(1) of that regulation, each Member State is to introduce penalties to apply in the event of failure to comply with the obligation to declare. According to that provision, the penalties are to be effective, proportionate and dissuasive. 21. In that regard, it should be noted that, according to the Court's settled case-law, in the absence of harmonisation of EU legislation in the field of penalties applicable where conditions laid down by arrangements under such legislation are not complied with, Member States are empowered to choose the penalties which seem to them to be appropriate. They must, however, exercise that power in accordance with EU law and its general principles, and consequently in accordance with the principle of proportionality (see judgments in Ntionik and Pikoulas, C‑430/05, EU:C:2007:410, paragraph 53, and Urbán, C‑210/10, EU:C:2012:64, paragraph 23). 22. In particular, the administrative or punitive measures permitted under national legislation must not go beyond what is necessary in order to attain the objectives legitimately pursued

	by that legislation (see judgments in Ntionik and Pikoulas, C‑430/05, EU:C:2007:410, paragraph 54, and Urbán, C‑210/10, EU:C:2012:64, paragraphs 24 and 53). 23. In that context, the Court has stated that the severity of penalties must be commensurate with the seriousness of the infringements for which they are imposed, in particular by ensuring a genuinely dissuasive effect, while respecting the general principle of proportionality (see judgments in Asociația Accept, C‑81/12, EU:C:2013:275, paragraph 63, and LCL Le Crédit Lyonnais, C‑565/12, EU:C:2014:190, paragraph 45). 24. In respect of the dispute in the main proceedings, it should be noted that the effectiveness and dissuasiveness of the penalties provided for in Paragraph 5/A of Law No XLVIII have been contested neither before the referring court nor before this Court. 25. In that context, it suffices to note that penalties such as those at issue in the main proceedings seem to be an appropriate means of attaining the objectives pursued by Regulation No 1889/2005 and of ensuring effective enforcement of the obligation to declare laid down in Article 3 of that regulation, since they are likely to dissuade the persons concerned from breaching that obligation. 26. Moreover, a system under which the amount of the penalties imposed in Article 9 of that regulation varies in accordance with the amount of undeclared cash does not seem, in principle, to be disproportionate in itself. 27. As regards the proportionality of penalties imposed by the legislation at issue in the main proceedings, it should be noted that the amount of the fines is graduated according to the amount of undeclared cash. 28. In contrast to what is maintained by the European Commission, the requirement that the penalties introduced by the Member States under Article 9 of Regulation No 1889/2005 must be proportionate does not mean the competent authorities must take account of the specific individual circumstances of each case. 29. As noted by the Advocate General in points 79 to 81 of his Opinion, under Article 9(1) of that regulation, Member States enjoy a margin of discretion concerning the choice of penalties which they adopt in order to ensure compliance with the obligation to declare laid down in Article 3 of that regulation, provided that a breach of that obligation can be penalised in a simple, effective and efficient way, and without the competent authorities necessarily having to take account of other

	circumstances, such as intention or recidivism. 30. However, in the light of the nature of the infringement concerned, namely a breach of the obligation to declare laid down in Article 3 of Regulation No 1889/2005, a fine equivalent to 60% of the amount of undeclared cash, where that amount is more than EUR 50 000, does not seem to be proportionate. Such a fine goes beyond what is necessary in order to ensure compliance with that obligation and the fulfilment of the objectives pursued by that regulation. 31. In that regard, it must be noted that the penalty provided for in Article 9 of Regulation No 1889/2005 does not seek to penalise possible fraudulent or unlawful activities, but solely a breach of that obligation. 32. In that context, it should be noted that, as stated in recitals 3 and 15 in the preamble to that regulation, the latter seeks to ensure more effective control of movements of cash entering or leaving the European Union, in order to prevent the introduction of the proceeds of unlawful activities in the financial system, whilst respecting the principles recognised by the Charter of Fundamental Rights of the European Union. 33. It should also be noted that Article 4(2) of Regulation No 1889/2005 provides for the possibility to detain, by administrative decision in accordance with the conditions laid down under national legislation, cash which has not been declared in accordance with Article 3 of that regulation, in order, inter alia, to allow the competent authorities to carry out the necessary controls and checks relating to the provenance of that cash, its intended use and destination. Therefore, a penalty which consists of a fine of a lower amount, together with a measure to detain cash that has not been declared in accordance with Article 3 thereof, is capable of attaining the objectives pursued by that regulation without going beyond what is necessary for that purpose. In this case, it is apparent from the file submitted to the Court that the legislation at issue in the main proceedings does not make provision for such a possibility. 34. In light of the foregoing considerations, it is not necessary to examine whether there exists a restriction within the meaning of Article 65(3) TFEU. 35. In those circumstances, the answer to the questions referred is that Article 9(1) of Regulation No 1889/2005 must be interpreted as precluding national legislation, such as that at issue in the main proceedings, which, in order to penalise a failure to comply with the obligation to declare laid down in Article 3 of that regulation, imposes payment of an administrative fine, the amount of which corresponds to 60% of

	the amount of undeclared cash, where that sum is more than EUR 50 000. […]
Judgment of the Court of 13 November 2014. Ute Reindl v Bezirkshauptmannschaft Innsbruck. Case C-443/13. ECLI identifier: ECLI:EU:C:2014:2370	[…] 32. It must be observed that Article 3(1) of Regulation No 2073/2005 states that the food business operators must ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I at each stage of food production, processing and distribution, including the retail sale stage. 33. However, although Regulation No 2073/2005 sets the microbiological criteria with which foodstuffs must comply at all stages in the food chain, that regulation does not contain any provisions relating to the rules on the liability of food business operators. 34. In that connection, it is appropriate to refer to Regulation No 178/2002. Article 17(1) thereof provides that food business operators at all stages of production, processing and distribution within the businesses under their control must ensure that foods satisfy the requirements of food law relevant to their activities. 35. Article 17(2) of Regulation No 178/2002 provides that Member States must lay down the rules on measures and penalties applicable to infringements of food law. The measures and penalties provided for must be effective, proportionate and dissuasive. 36. It follows that EU law and, in particular, Regulations No 178/2002 and No 2073/2005 must be interpreted as meaning that, in principle, they do not preclude national legislation, such as that at issue in the main proceedings, which penalises food business operators active only at the distribution stage for placing on the market foodstuffs which fail to comply with the microbiological criteria mentioned in Annex I, Chapter 1, Row l.28, to Regulation No 2073/2005. 37. However, by laying down rules on the sanctions applicable in the event of failure to comply with the microbiological criterion, the Member States are bound to observe conditions and limits laid down by EU law, including that laid down, in the present case, by Article 17(2) of Regulation No 178/2002, which requires penalties to be effective, proportionate and dissuasive. 38. According to settled case-law, whilst the choice of penalties remains within their discretion, Member States must ensure that infringements of EU law are penalised under conditions, both procedural and substantive, which are analogous to those applicable to infringements of national law of a similar nature and importance and which, in any event, make the penalty effective, proportionate and dissuasive (see to that effect, judgment in Lidl Italia, C‑315/05, EU:C:2006:736, paragraph

	58, and Berlusconi and Others, C‑387/02, C‑391/02 and C‑403/02, EU:C:2005:270, paragraphs 65 and the case-law cited). 39. In the present case, the measures imposing penalties permitted under the national legislation at issue in the main proceedings must not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by that legislation; when there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see, judgment in Urbán, Case C‑210/10, EU:C:2012:64, paragraph 24 and the case-law cited). 40. In order to assess whether a penalty is consistent with the principle of proportionality, account must be taken of, inter alia, the nature and the degree of seriousness of the infringement which the penalty seeks to sanction and of the means of establishing the amount of the penalty (see judgment in Equoland, C‑272/13, EU:2014:2091, paragraph 35). 41. Legislation, such as that at issue in the main proceedings, providing for a fine if food stuffs unfit for human consumption are placed on the market, may help to attain the fundamental objective of food law, that is, a high level of protection of human health, as set out in paragraph 28 of the present judgment. 42. Even if the system of penalties in the case in the main proceedings is a system of strict liability, it must be recalled that, according to the case-law of the Court, such a system is not, in itself, disproportionate to the objectives pursued, if that system is such as to encourage the persons concerned to comply with the provisions of a regulation and where the objective pursued is a matter of public interest which may justify the introduction of such a system (see judgment in Urbán, EU:C:2012:64, paragraph 48 and the case-law cited). 43. It is for the national court to determine, in the light of that information, whether the penalty at issue in the main proceedings observes the principle of proportionality referred to in Article 17(2) of Regulation No 178/2002. 44. Having regard to all the foregoing, the answer to the second and third questions is that EU law, in particular Regulations No 178/2002 and 2073/2005, must be interpreted as meaning that, in principle, it does not preclude national law, such as that at issue in the main proceedings, which imposes a penalty on a food business operator active only at the distribution stage for placing a foodstuff on the market, on account of the failure to comply with the microbiological criterion laid down in Annex

	I, Chapter 1, Row 1.28, to Regulation No 2073/2005. It is for the national court to determine whether the penalty at issue in the main proceedings observes the principle of proportionality referred to in Article 17(2) of Regulation No 178/2002. […]

3.13. Application of penalties by market surveillance authorities in the 2010-2013 period

Sectors	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SL	SK	FI	SE	UK
Sector 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)		7.75	62.00				0.00						0.00				0.75			0.00	9.25	7.25		0.25	0.00	0.00		
Sector 2 - Cosmetics			70.75	2.00			0.25			38.50				1			62.75					27			0.75	0		8.00
Sector 3 - Toys		64.25	384.00	1.50		0.00		6.50		43.25	80.00		1.00	32.75		0.00	154.25				24.50	21.25	1,356	77.00	80.00	0.00	0.25	27.50
Sector 4 - Personal Protective Equipment		15.50	177.25	0.00				1.00		6.00				10.00			59.50			0.00	1.50	5.00	16.25	48.75	39.00	0.00	1.00	
Sector 5 - Construction Products	1.00	76.25	96.75			0.25		4.00		63.75			2.5	24.5			154			0.75	22	4.25	7.5	42.25	25	6		
Sector 6 - Aerosol dispensers		10.25	574.50	0.00				3.00					0.00					0.00		0.00	0.00	3.50	1.00	1.00		0.00		
Sector 7 - Simple pressure vessels and Pressure Equipment		2.00	4.00	0.00				2.25		0.00				2.50			0.00				0.25	4.25	3.00			0.00		
Sector 8 - Transportable pressure equipment		4.33	1.50	0.00				1.00		0.00				9.00			0.00				0.00		0.25	20.00		0.00		
Sector 9 - Machinery		9.50	64.50	0.00			1.00	12.25		14.00				0.75			22.75			0.50	0.25	6.75	35.25	9.00		0.00	5.00	
Sector 10 - Lifts		1.00	2.25	0.00													1.00			0.00	0.00		0.25	2.75		0.00		
Sector 11 - Cableways		2.00	2.00	0.00						0.00				0.00				0.00		0.00	0.00		0.25	8.50		0.00		
Sector 12 - Noise emissions for outdoor equipment			11.50	0.00										0.75			14.25			0.00	0.00	6.25	14.50	2.75		0.00		
Sector 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres			1.00	0.00						0.25							0.00				0.25		5.50	0.00		0.00		

Sectors	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SL	SK	FI	SE	UK
Sector 14 - Pyrotechnics		15.33	62.00	0.00		0.25	0.00			0.00		0.00	0.00				0.00				0.00		3.75		22.00	0.00		
Sector 15 - Explosives for civil uses			2.67				0.00			0.00		0.00	0.00				0.25				0.00		0.50		0.00	0.00		
Sector 16 - Appliances burning gaseous fuels		4.00	9.00	3.00				4.25		0.00				4.00			0.25			0.00	0.25	4.00	1.50	5.00	35.00	0.00	6.00	
Sector 17 - Measuring instruments, Non-automatic weighing instruments and Pre-packaged products		5.75	75.50	2.00		0.00	0.00	11.00		85.25	62.00			2.25		0.00	20.50			153.25	0.00	54.25	25.50	0.00	28.00	0.00		
Sector 18 - Electrical equipment under EMC		19.00	105.75	9.25	574.50					8.75			15.67	9.75		0.00	7.25			0.00	0.25	6.75	6.00	2.75		0.00		
Sector 19 - Radio and telecom equipment under RTTE		23.00	103.75	9.25	574.50	0.25		101.25		0.00		158.50	0.25	1.00		0.00	43.25			2.75	1.50	22.25	23.00	4.75		0.00		
Sector 20 - Electrical appliances and equipment under LVD	28.00	135.00	272.50							48.50			15.67	12.75		0.00	297.25			0.00	11.50	19.25	329.50	31.00	130.00	0.00		
Sector 21 - Electrical and electronic equipment under RoHS, WEEE and batteries			2.00	2.00			0.00							9.75			2.75					29.25	16.25	0.00		0.00		
Sector 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)		0.50	3.00	1.25			0.00	35.00		7.75				15.50			45.50							1.50	10.75	0.00		
Sector 23 - Ecodesign and Energy labelling		4.50	55.00	3.67			0.00			4.75		6.67	24.50	9.75		0.00	4.25			0.00	0.75		110.50	1.25	0.00	0.00		
Sector 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels							0.00	2.50									0.00						0.00			0.00		
Sector 25 - Recreational craft			1.67	0.00				2.00		0.00				0.00						0.00	0.00			0.25	0.00	0.25	5.00	
Sector 26 - Marine Equipment				0.00						0.00		0.00								0.00	0.00	1.25	0.00			0.00	0.00	
Sector 27 - Motor vehicles and tyres		33.50		0.25						4.00				3.33			0.00			0.00			546.25	4.00	0.00	0.00		

Sectors	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SL	SK	FI	SE	UK
Sector 28 - Non-road mobile machinery														2.00			0.25						9.50	2.50				
Sector 29 - Fertilisers	0.75	3.25	1.25		2.00		0.00			0.50	5.00						6.75				17.5	6	9	14	10.75	0		
Sector 30 - Other consumer products under GPSD		446.50	1.67					54.75		5.50				6.00		0.00	390.00					34.75	7.25			0.00	1.00	

3.14. Overview of the penalties in the field of toy safety

Introduction

In view of gathering information on the enforcement of Union harmonisation legislation in the Member States and the extent of any differences that may exist, the Commission drew up a questionnaire for Member States on penalties for infringements of the national provisions adopted pursuant to Directive 2009/48/EC on the safety of toys. In particular, this questionnaire concerned the implementation of article 51 of Directive 2009/48/EC.

Twenty-seven Member States responded to the questionnaire. Also, two EEA countries – Norway and Iceland - submitted responses.

The following general conclusions may be drawn from the replies provided:

- At national level, the focus is clearly on ensuring that non-compliant toys are not available on the market. Whenever a non-compliant toy is found, action by national authorities is directed at withdrawing/recalling the toy as appropriate, sometimes by issuing warnings. However, national authorities do not necessarily follow these actions with infringement proceedings which would lead to the imposition of a penalty on the responsible economic operator.

- It is not clear whether the measures reported as penalties by national authorities do have a punitive element and thus should be in practice classified as such (i.e. withdrawing a product from the market).

- Whilst in most countries a certain choice of penalties is available, these are not really imposed in practice in many countries. The information provided on the penalties imposed per year is not sufficiently comparable, since the time periods are not the same in all the replies and in some cases they are provided in absolute numbers while in others they are provided only as a percentage of non-compliances found. However, it can be seen that there are a number of countries with a stronger focus on enforcement and where penalties, and in particular economic sanctions, are often imposed whilst in some other countries the focus of the authorities is not in the imposition of penalties. Similarly, the maximum economic penalty that can be imposed in theory varies greatly across the EU.

Distinction by the legislation between the different 'types' of infringements - formal non-compliance vs. non-compliance with essential requirements

- More than half of the countries that replied– 17 out of 29- reported that their legislation makes a distinction between these different types of infringements (BG, CZ, EL, ES, HR, IT, LV, LT, LU, NL, AT, PT, RO, SI, SK, FI and IS).

- Other countries indicated that the legislation did not make such distinction (BE, DE, FR, PL, MT, CY, IE, EE, DK, SE, UK and NO).

For the following situations, several actions may be taken by the national authorities. It is not clear whether many of these may be defined as a penalty. The degree of discretion for national authorities varies across the EU. In some cases, the legal provisions on the applicable penalties are graduated depending on whether the infringement at hand was a formal non-compliance or a non-compliance with the essential requirements. In other cases, it is the up to the authorities to make these adjustments depending on the circumstances of the case. In particular, the actions taken due to a formal non-compliance will likely be less stringent at first, with more serious measures being taken if the formal non-compliance is not remedied.

a. Formal non-compliance

i. The CE marking has been affixed in violation of Article 16 or 17 of the TSD

- A warning may be sent to the economic operator – BE, NL, SI
- Measures taken against the product: product recall or withdrawal– EL, IT, NL, IE, RO, UK NO, IS
- A fine may be imposed – BG, CZ, EE, EL, HR, FR, CY, LU, PT, RO, SK, UK, MT, ES, IE
- Imprisonment – UK, MT

ii. The EC declaration of conformity has not been drawn up correctly

- A warning may be sent to the economic operator- BE, NL, SI
- Measures taken against the product: product recall or withdrawal - EL, IT, IE, NL, RO, SE, UK, IS, NO
- A fine may be imposed - BG CZ, EE, EL, HR, FR, IT, CY, LU PT, RO, SK, UK, MT, SE, ES, IE
- Imprisonment – UK, MT

iii. The EC declaration of conformity has not been drawn up

- A warning may be sent to the economic operator- BE, NL, SI
- Measures taken against the product: product recall or withdrawal – BE, EE, EL, IE, IT, NL, RO, SE, UK, IS, NO
- A fine may be imposed – BG, CZ, EE, EL, ES, IE, HR, CY, LU, LV, FR, PT, RO, SK, MT, SE, UK
- Imprisonment – UK, MT

iv. The CE marking has not been affixed

- A warning may be sent to the economic operator BE, NL, SI
- Measures taken against the product: product recall or withdrawal – BE, BG, EL, LV (confiscation), HR, IT, RO, FI, SE, IS, NO
- A fine may be imposed – BG, CZ, EE, EL, FR, IT, HR, MT, CY, LU, PT, RO, SK, UK, ES, IE, LV, SE
- Imprisonment – UK, MT

v. <u>The technical documentation is either not available or not complete</u>

- A warning may be sent to the economic operator - BE, NL, SI
- Measures taken against the product: product recall or withdrawal – BE, EL, IE, HR, IT, IS, NL, RO, SE, UK, NO, LV (confiscation)
- A fine may be imposed – BG, CZ, EE, FR, IT, CY, LU, PT, RO, SK, UK, HR, ES, EL, LV, MT, SI, SE
- Imprisonment – UK, MT

b. Failure to meet one or more essential requirements set out in the TSD

- A warning may be sent to the economic operator BE, NL
- Measures taken against the product: product recall or withdrawal BE, EL, HR, IT, NL, UK, BG, IE, RO, FI, SE, IS, NO. Confiscation/destruction: LV, LU, IS
- A fine may be imposed – BG, CZ, EE, EL, FR, HR, IT, LU, PT, RO, SK, UK, ES, IE, LV, MT, NL, AT, SI, SE
- Publication of penalties/public warning – NO, ES
- Criminal prosecution possible- IE, CY, LU, PL, ES
- Imprisonment – UK, FR, IT, LV, MT, IS

c. Failure to comply with the applicable conformity assessment procedures

- A warning may be sent to the economic operator - BE, NL
- Measures taken against the product: product recall or withdrawal - BE, EL, HR, IT, NL, ES, IE, RO, FI, SE, UK, IS, NO. Confiscation LV, LU
- A fine may be imposed – BG, CZ, EE, EL, HR, FR, PT, RO, SK, UK, ES, IE, LV, MT, NL, AT, SE
- Criminal prosecution possible – LU, PL

- Imprisonment – UK, LU, MT

Most common types of toy safety related infringements

The most common TSD-related infringements were reported to be the following:

- Administrative deficiencies
    - Lack of or incomplete technical file – BE, NL
    - Formal non-compliance in general- EL, CY, SE, NO
    - Problems with the warnings (absence or incorrect languages), safety information or labelling errors – BE, BG, EE, CZ, IE, ES, FR, LV, LT, AT, PL, PT, SI, SK, UK, IS
    - Problems with EU Declaration of conformity- PL, SK
    - Problems with the contact details of manufacturers/importers – BE, BG, CZ, LV, PL, SK
    - CE marking – IE, ES, FR, HR, IT, MT, PT, IS
- Non-compliance with essential requirements
    - In general – FR, ES, HR, CY, NL, AT, RO, FI, UK
    - Requirements for children under 3 – BE, BG, IE, LT, IS
    - Chemical properties – EE
    - Sound levels - EE

Cases of infringement (as a percentage on a yearly basis) actually pursued all the way to imposition of an economic penalty

Member States have not been able to provide information on a yearly basis in many cases and the information provided is unfortunately difficult to compare. In some cases, the information is provided in absolute numbers (without referring to the actual number of overall non-compliance cases found) and in others it is provided as a percentage. From the information provided, it can be observed that in most Member States the enforcement of the Toy Safety Directive is focused on ensuring that non-compliant toys are not available on the market.

In cases where an infringement of the Directive is observed, no economic penalties are imposed in many MS (LU, NO, SE, MT, IE or PT). Some other MS have not been able to provide any estimation on percentages or absolute numbers for penalties imposed in past periods (BE, DE, FR, IT, CY, RO, FI, SK, UK).

In cases where this information is provided, it ranges between a handful of cases (2 since the entry into force of the Directive in DK, 3 to 10 per year in IS) to a much higher number per year (314 cases in a given year (2013) in ES or 600 per year in CZ).

Finally, even in those cases where Member States have declared to have taken measures, it is not clear that the measure should be considered as such as a penalty or just a corrective measure to remove the product from the market.

Detailed information:

- Unknown / No information– BE, DE, FR, IT, CY, RO, FI, SK, UK
- No cases where penalties were imposed – LU, NO, SE, MT (10 per year with measure, ban or withdrawal but no penalty) IE (no penalties but toys withdrawn), PT

Reporting in absolute numbers

- DK: 2 cases since the entry into force of the Toy Safety Directive
- IS: 3-10 per year
- BG: 213 between 2011 and May 2014
- CZ: 600 per year
- ES: 314 in 2013 with imposition of penalty
- NL: 29 in 2013
- HR: 31 penalties between 2011 and 2014 –
- LT: 54 administrative penalties and 12 economic sanctions out of 145 infringements in 2013
- PL: 23 out of 132 in 2013 but not clear it is a penalty
- SI: 99 out of 1540 inspections in 2013

Reporting in percentage figures

- EL: from 1% to 10% per year
- AT: 20% - 25% - administrative penalties or corrections to products being made (not clear these are classified as penalties)
- 30% - 40% per year EE (between 2010 and July 2014) and LV in 2013

- 50% - 60% per year for LV in 2014.

Nature of the penalties that are in force to fulfil the criteria of article 51 TSD of "effective proportionate and dissuasive" penalties

Regarding whether the penalties imposed are of an administrative or criminal nature, the following answers were provided in the different countries:

a) Only administrative penalties – BG, CZ, LT, PT, RO, SK, SE

b) Only criminal penalties – DK, MT, NO, PL

c) Both criminal and administrative penalties. – BE, EE (criminal only in case of danger to human life or health), EL, ES, FR, IT, CY, LV, LU, NL, AT, SI, FI, IS

Penalties or sanctions that can be imposed

Twenty-six Member States as well as IS and NO reported to have the possibility of imposing economic sanctions.

Twenty-four Member States and IS and NO reported to also have the possibility of imposing other than economic sanctions.

In particular:

a. Economic sanctions – BG, BE, CZ, DK, EE, IE, EL, ES, FR, HR, IT, CY, LV, LT, LU, MT, NL, AT, PL, PT, RO, SI, SK, FI, SE,UK, IS,NO

b. Imprisonment – EE, IE, EL, IT, CY, LV, LU, MT, NL, SI, UK,IS, NO

c. Seizure or destruction of the product – BG, CZ, DK, EE, IE, EL, ES, FR, HR, IT, CY, LV, LU, NL, AT, PT, RO, FI, SE, UK,IS, NO

d. Publication of the fines imposed or of the judgment –BE, IE, EL, ES, CY, NL, AT, SK, UK,IS

e. Temporary or permanent disqualification from the practice of industrial or commercial activities, including stopping production –BE, ES, FR, HR, LV, LU, MT, NL, AT, RO, SE, IS

f. Others:

    i. Measures on the product (withdrawal) BE, BG, EL, FR, FI

    ii. Community service: LV

Highest level of economic penalty foreseen

The highest level of economic penalty is:

a) **Below €10.000:** in BG (€7673), RO (€2229) and UK (€6896).

b) **Between €10.000 and €50.000:** in HR (€13.097), LV (€14.000), NL (€20.250), LT (€23.169), MT (€23.293), EL (€40.000), CY (€40.000), PT (€ 44. 891) and IT (€50.000).

c) **Above €50.000:** in IS (€70.793), BE (€150.000), IE (€500.000), LU (€500.000), ES (€660.000), CZ (€ 1.850.365) and EE (€16.000.000).

No specific amount was indicated for DK, SI, SK, FI, SE, NO.

Aggravating or mitigating circumstances taken into account when setting a penalty

- Several countries (IE, MT, PL, UK and NO) indicated that such circumstances are not foreseen in the law, but they are for the Court to appreciate when determining the level of a fine.

- Five MS indicated that neither aggravating nor mitigating factors are taken into account (HR, IT, RO, FI, SE) when setting the penalty.

- CY, EL, NL and SI take into account mitigating factors and the rest of the countries indicated to take into account both aggravating and mitigating circumstances (BG, CZ, DK, EE, ES, FR, LV, LT, IS, LV, AT, PT, SK).

As aggravating circumstances, the following are taken into account:

- Having previously committed an offense in BG, CZ, ES, FR, LV or SK.

- The seriousness of the damage caused in EE, ES, LV, PT, SK.

- The intent or degree of fault in ES, AT, PT or FR.

As mitigating factors, the following are taken into account:

- Negligence in NL or PT

- Voluntary compensation for any damage or efforts by the economic operator to provide redress in EE, SI, SK, LT, LV

- Willingness to cooperate with the relevant authorities in SL, LT, LV and CY.

Effect of the recidivism on the level of the penalty

The majority of the respondents reported that the recidivism affected the level of penalty imposed (BE, BG, CZ, DK, EE, EL, ES, FR, HR, CY, LV, LT, LU, MT, NL, AT, PT, RO, SK, IS). Some of the respondents explicitly specified that the imposition of penalties is within the jurisdiction of a national criminal court (IE, PL, UK, NO). In four cases (FI, SI, SE, IT), it was indicated that recidivism is not taken into account.

Enforcement of penalties imposed on economic operators based in another MS for infringements committed in the national Member State

The majority of the countries reported that that they enforce penalties only to economic operators established in their respective country (BG, CZ, DK, DE, EE, IE, ES, FR, HR, CY, LV, LT, PL, RO, SK, FI, SE, UK, IS, NO). However, in some cases they ask for assistance from, or send a notification to the authorities in other countries (CZ, DE, IE, MT, SI, NL, PL, and RO)

Several Member States specified they the measures apply to the economic operator responsible for making the product available on the national market (EL, LU, PT) irrespectively of where the economic operator is based. Once the penalty is imposed the respective Member State informs the Member State where the economic operator is based (BE, IT, LV, LU, PT).

Problems in enforcing penalties imposed on economic operators based in another Member States

- The majority of the respondents reported that they have no precedent in this regard or that this is not applicable due to the national legislative system (BG, CZ, DK, DE, EE, IE, EL, FR, HR, IT, CY, LT, LU, NL, PL, RO, SI, SK, FI, SE, NO)

- Two Member States (MT, UK) reported they didn't have any problems to report.

The problems reported in enforcing penalties imposed on economic operators based in different Member States for infringements committed in another Member State were:

- Economic operators do not respond to registered letters (BE)

- No means for enforcing such penalties (ES, LV, NO)

- communicating the procedural documents, given the language barrier was considered problematic (PT)

- Economic costs (PT)

- Information flow in between the MS and EEA in terms of imposition of penalties was considered problematic (IS)

Prosecution of infringements committed by online retailers located outside the EU

The majority of the MS and NO reported that they do not have precedent in pursuing infringements committed by online retailers located outside the EU (BE, BG, CZ, DK, DE, EE, IE, EL, ES, FR, HR, IT, CY, LV, LT, NL, PL, RO, SI, SK, FI, UK, NO).

BE indicated that action is taken under the E-commerce Directive but that retailers outside the EU rarely cooperate. DE mentioned that action against non-compliant products from online retailers established outside the EU is taken indirectly under the customs procedures by

imposing an import ban. ES, SI, SE, IS and LU indicated that these situations fall within the scope of EU legislation, however they highlight that compliance is difficult to enforce. LU acts, in cooperation with customs authorities, against the product present in the national territory. Other States report to only inform the country of origin about infringements (AT, FI).

3.15. Penalties for non-compliance with the legislation on toys safety

Country	National legislation (transpositions of Article 51 of Directive 2009/48/EC
Austria	Federal Act against Unfair Competition 1984 § 32: up to 2900 € Food Safety and Consumer Protection Act § 90: up to € 20,000, in case of recurrence 40,000 € or Imprisonment up to 6 weeks
Belgium	Art. XV.69. 1 Les dispositions du Livre Ier du Code pénal sont applicables aux infractions visées par le présent Code sous réserve de l'application des dispositions spécifiques mentionnées ci-après. Art. XV.70. Les infractions aux dispositions du présent Code sont punies d'une sanction pouvant aller du niveau 1 au niveau 6. - La sanction de niveau 1 est constituée d'une amende pénale de 26 à 5 .000 euros. - La sanction de niveau 2 est constituée d'une amende pénale de 26 à 10. 000 euros. - La sanction de niveau 3 est constituée d'une amende pénale de 26 à 25 .000 euros. - La sanction de niveau 4 est constituée d'une amende pénale de 26 à 50 .000 euros. - La sanction de niveau 5 est constituée d'une amende pénale de 250 à 100.000 euros et d'un emprisonnement d'un mois à un an ou d'une de ces peines seulement. - La sanction de niveau 6 est constituée d'une amende pénale de 500 à 100.000 euros et d'un emprisonnement d'un an à cinq ans ou d'une de ces peines seulement. Art. XV.71. Lorsque les faits soumis au tribunal font l'objet d'une action en cessation, il ne peut être statué sur l'action pénale qu'après qu'une décision coulée en force de chose jugée a été rendue relativement à l'action en cessation.

	Art. XV.72. En cas de récidive dans les cinq ans à dater d'une condamnation coulée en force de chose jugée du chef de la même infraction, le maximum des amendes et des peines d'emprisonnement est porté au double. Art. XV.73. Les sociétés et associations ayant la personnalité civile sont civilement responsables des condamnations aux dommages-intérêts, amendes, frais, confiscations, restitutions et sanctions pécuniaires quelconques, prononcées pour infraction aux dispositions du présent Code contre leurs organes ou préposés. Il en est de même des membres de toutes associations commerciales dépourvues de la personnalité civile, lorsque l'infraction a été commise par un associé, gérant ou préposé à l'occasion d'une opération entrant dans le cadre de l'activité de l'association. L'associé civilement responsable n'est toutefois personnellement tenu qu'à concurrence des sommes ou valeurs qu'il a retirées de l'opération. Ces sociétés, associations et membres peuvent être cités directement devant la juridiction répressive par le ministère public ou la partie civile. Art. XV.74. A l'expiration d'un délai de dix jours à compter du prononcé, le greffier du tribunal ou la cour est tenu de porter gratuitement à la connaissance du ministre, par lettre ordinaire ou par voie électronique, tout jugement ou arrêt faisant application d'une disposition du présent livre. CHAPITRE 2. - Les infractions sanctionnées pénalement Section 2. - Les peines relatives aux infractions au Livre IV Art. XV.80. Toute infraction aux articles IV.13 et IV.14 est punie d'une sanction de niveau 2. Toute infraction à l'arrêté visé à l'article IV.15 est punie d'une sanction de niveau 5. L'utilisation ou la divulgation, à d'autres fins que l'application du Livre IV et des articles 101 et 102 du TFEU, des documents ou renseignements obtenus en application des dispositions du Livre IV, est punie d'une sanction de niveau 5. Toute infraction aux articles IV.34 et IV.35 est également punie d'une sanction de niveau 5. Section 3. - Les peines relatives aux infractions au Livre V Art. XV.81. Sont punis d'une sanction du niveau 5, ceux qui, étant tenus de fournir les renseignements en vertu du Livre V, titre 2 du présent Code, ne remplissent pas les obligations qui leur sont imposées. Art. XV.82. Sont punis d'une sanction du niveau 6, ceux qui commettent une infraction à l'article V.8 ou ne se conforment pas ou refusent leur

	collaboration à l'exécution de ce que dispose une décision prise en application des articles V.4, V.5, V.11 et V.12 et V.14, § 3, du présent Code. Section 6. - Les peines relatives aux infractions au Livre VIII Art. XV.99. Sont punis d'une sanction du niveau 2 : 1° ceux qui, en employant des manoeuvres frauduleuses, obtiennent ou tentent d'obtenir d'un organisme accrédité en vertu du Livre VIII, titre 2, un certificat ou un rapport d'évaluation de la conformité; 2° ceux qui accordent un certificat ou un rapport d'évaluation de la conformité en infraction aux dispositions du Livre VIII, titre 2, ou de ses arrêtés d'exécution; 3° ceux qui utilisent ou tentent d'utiliser un certificat ou un rapport d'évaluation de la conformité en infraction aux dispositions du Livre VIII, titre 2, ou de ses arrêtés d'exécution; 4° ceux qui, en employant des manoeuvres frauduleuses, notamment par des agissements qui peuvent prêter à confusion, donnent faussement l'impression qu'un produit, un service ou un processus bénéficie d'un certificat ou un rapport d'évaluation de la conformité délivré par un organisme accrédité en vertu du Livre VIII, titre 2. Art. XV.100. Sans préjudice de l'application, s'il y a lieu, des peines prévues par le Code pénal, notamment par l'article 184 en matière de contrefaçon de marques, sont punis d'une sanction du niveau 2 : 1° ceux qui ont contrevenu aux dispositions du Livre VIII, titre 3, ou à ses arrêtés d'exécution ou aux règlements pris en vue de son exécution, ainsi qu'aux conditions accompagnant les dérogations accordées en vertu de l'article VIII.56; 2° ceux qui détiennent ou emploient des instruments de mesure manifestement inexacts, dans les lieux précisés à l'article VIII.45; 3° ceux dont les activités comportent une référence abusive au Réseau visé à l'article VIII.55, § 4, 2°. Art. XV.101. Sans préjudice de l'application des règles relatives à la saisie et la confiscation, les instruments de mesure dont la détention ou l'usage constituent des infractions aux dispositions du Livre VIII, titre 3, ou à ses arrêtés d'exécution ou aux règlements pris en vue de son exécution peuvent être détruits. Section 7. - Les peines relatives aux infractions au Livre IX Art. XV.102. § 1er. Sont punis d'une sanction du niveau 2, ceux qui

	enfreignent l'article IX.9. § 2. Sont punis d'une sanction du niveau 3 : 1° ceux qui mettent sur le marché des produits dont ils savent ou dont ils auraient dû savoir, sur la base de normes européennes ou belges, qu'ils ne présentent pas les garanties visées à l'article XI.2 en ce qui concerne la sécurité et la protection de la santé; 2° ceux qui enfreignent l'article IX.8; 3° ceux qui enfreignent les articles IX.4, IX.5, IX.6 et IX.7 ou un arrêté pris en exécution des articles IX. 4, §§ 1er à 3 et IX.5, §§ 1er et 2; 4° ceux qui ne donnent pas suite aux avertissements visés à l'article XV.31. 5° ceux qui commettent des infractions aux règlements de l'Union européenne qui ont trait à des matières relevant, en vertu du Livre IX, du pouvoir réglementaire du Roi. Section 12. - Entrave au contrôle Art. XV.126. Tout empêchement ou entrave volontaire à l'exercice des fonctions des agents visés à l'article XV.2 ou des fonctionnaires de police de la police locale et fédérale est, en application des dispositions du présent Code, puni d'une sanction du niveau 4. Toute nouvelle infraction telle que visée à l'alinéa 1er commise avant que cinq années ne se soient écoulées depuis l'accomplissement de la peine ou de la prescription de celle-ci pour la même infraction, est punie d'une sanction du niveau 5. CHAPITRE 3. - Les peines complémentaires [...] Section 2. – Confiscation Art. XV.130. Sans préjudice de l'application des articles 42 à 43quater inclus du Code pénal, en cas de condamnation pour une infraction aux Livres VIII et IX les Cours et Tribunaux sont autorisés à prononcer la confiscation, même lorsque le propriétaire de l'objet de l'infraction est une tierce personne. Sans préjudice de l'application des articles 42 à 43quater du Code pénal, ils ont également la faculté de prononcer, même s'ils sont la propriété d'un tiers, la confiscation des moyens de production, de transformation, de distribution, de transport et d'autres objets quelconques destinés ou ayant servi à produire, fabriquer, transformer, distribuer ou transporter les biens faisant l'objet de l'infraction ainsi que des moyens nécessaire pour prester les services. Lorsque l'objet de l'action en confiscation est la propriété d'un tiers, ce tiers

	est appelé à la cause et, si aucune preuve de sa mauvaise foi n'est apportée, la confiscation n'est pas prononcée ou est annulée. Les cours et tribunaux peuvent en outre ordonner la confiscation des bénéfices illicites réalisés à la faveur de l'infraction. Section 3. - L'affichage du jugement ou de l'arrêt Art. XV.131. En cas de condamnation pour une infraction aux Livres VIII et IX les cours et tribunaux peuvent ordonner l'affichage du jugement, de l'arrêt ou du résumé qu'ils en rédigent pendant le délai qu'ils déterminent, aussi bien à l'extérieur qu'à l'intérieur des établissements du contrevenant et aux frais de celui-ci, de même que la publication du jugement, de l'arrêt ou du résumé aux frais du contrevenant dans des journaux ou de toute autre manière.
Bulgaria	**Chapter Six ADMINISTRATIVE PENAL PROVISIONS (Bulgarian Law on Technical Requirements to Products)** Art. 50. (amended — SG No 93 of 2002, SG No 45 of 2005, SG No 86 of 2007) any person that violates the provisions of Articles 3 or 4 shall be punishable by a fine of BGN 1000 to 5000 or a financial penalty of BGN 5000 to BGN 15 000. Art. 51. (amended — SG No 93 of 2002, SG No 86 of 2007) a person who draws up and/or used a declaration of compliance with content which does not comply with the content defined in the Regulations referred to in Articles 7 and/or the implementing measures referred to in Article 26a or with new approach Directives shall be punishable by a fine of BGN 300 to 1000 or a financial penalty of BGN 1000 to 5000 if the act is not an offence. Article 51a. (New — SG No 93 of 2002, amended in SG No 45 of 2005) any person who places on the market and/or puts into service products with conformity marking in breach of the Regulation referred to in Article 24 shall be punishable by a fine of BGN 300 to 800 or a financial penalty of BGN 500 to BGN 1000. Article 51b. (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, supplemented in SG No 86 of 2007) any person who places on the market and/or puts into service products with conformity marking and supplementary marking or declaration of conformity without having assessed their compliance with the essential requirements laid down in the Regulations referred to in Articles 7 and/or with the eco-design requirements laid down in implementing measures under Article 26a, shall be liable to a fine of BGN 3000 to 8000 or a financial penalty of BGN 5000 to BGN 10 000. Article 51c. (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, supplemented in SG No 86 of 2007) any person who places on the market and/or puts into service products without marking, without

	additional markings or without declaration of conformity, when requested, under the provisions of Article 7 and/or with the eco-design requirements laid down in implementing measures under Article 26a, shall be liable to a fine of BGN 500 to 800 or a financial penalty of BGN 1500 to BGN 3000. Article 51d. (New — SG No 86 of 2007, amended in SG No 38 of 2011) any person who places on the market and/or puts into service products marked contrary to the requirements of Regulation (EC) No 106/2008 of the European Parliament and of the Council of 15 January 2008 on a Community programme for labelling the energy efficiency of office equipment (OJ L 39/1 of 13 February 2008) shall be punishable by a fine of BGN 3000 to 8000 or a financial penalty of BGN 5000 to BGN 10 000. Art. 52. (amended — SG No 93 of 2002, SG No 45 of 2005, SG No 86 of 2007) any person that fails to fulfil its obligations under Articles 25 or 26, paragraph 1 or 2 shall be punishable by a fine of BGN 500 to 1000 or a financial penalty of BGN 5000 to BGN 10 000. Article 52a. (New — SG No 93 of 2002, amended in SG No 45 of 2005, SG No 86 of 2007) any person who places on the market and/or puts into service products without indicated on them the name and/or its head office or without instruction and/or instruction for use in Bulgarian shall be punishable by a fine of BGN 200 to 500 or a financial penalty of BGN 500 to BGN 2000. Article 52b. (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, amended in SG No 86 of 2007) a trader who makes products without conformity marking or without additional marking, when such marking is required in the Regulations referred to in Articles 7 and/or the implementing measures referred to in Article 26a, shall be liable to a fine or penalty payment of BGN 250-1000 Article 52c. (New — SG No 93 of 2002, amended in SG No 45 of 2005, amended and supplemented in SG No 86 of 2007) a trader who makes products without declaration of conformity, when requested, under the provisions of Article 7 and/or implementing measures under Article 26a, shall be liable to a fine or penalty payment of BGN 250-1000 Article 52d. (New — SG No 93 of 2002, amended in SG No 45 of 2005, SG No 86 of 2007) a trader who makes products without indication of name or address of management to the person who places on the market and/or put into service is punishable by a fine or penalty payment of BGN 250-1000 Article 52e. (New — SG No 93 of 2002, amended in SG No 45 of 2005, SG No 86 of 2007) a trader who makes products without instruction and/or instruction for use in Bulgarian, shall be liable to a fine or penalty payment of BGN 250-1000 Article 52f. (New — SG No 86 of 2007, amended in SG No 38 of 2011) a

	trader who makes products marked contrary to the requirements of Regulation (EC) No 106/2008 of the European Parliament and of the Council of 15 January 2008 on a Community programme for labelling the energy efficiency of office equipment, shall be punishable by a fine of BGN 250 or confiscation of property worth BGN 1000. Art. 53. (amended — SG No 93 of 2002, supplemented in SG No 45 of 2005, amended in SG No 86 of 2007, SG No 38 of 2011) for non-compliance or infringement of the compulsory rules referred to in Article 30a, paragraph 1, 2, 4 and 5 and Art. 30c, paragraph 1 shall be fined BGN 300 to 1000 or a financial penalty of BGN 1000 to BGN 5000. Article 53a. (New — SG No 86 of 2007) for other infringements of the provisions of Article 7 and/or implementing measures under Article 26a shall be punishable by a fine of BGN 300 to 1000 or a financial penalty of BGN 1000 to BGN 5000. Art. 54. Article 219. (1) (Amended — SG. — SG No 93 of 2002, SG No 45 of 2005, SG No 95 of 2005, amended and supplemented in SG No 86 of 2007) Statements establishing infringements under Articles 50, 51, 51a to 51d, 52, 52a to 52f, 53, 53a and 56 shall be drawn up by officials designated by the President of the State Agency for Metrological and Technical Surveillance. (2) (supplemented, — SG No 45 of 2005, amended in SG No 95 of 2005) the penalty decrees shall be issued by the State Agency for Metrological and Technical Surveillance or officials authorised by him. (3) (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, repealed in SG No 77 of 2012, in force since 9.10.2012). Art. 55. (1) (amended and supplemented. — SG No 93 of 2002) in breach of the provisions of Articles 36, 44, 46 paragraph 1, 1, 6 and 7 or paragraph 2 and of the coercive administrative measure referred to in Article 49, paragraph 1, natural persons are liable to a fine of BGL 500-10 000, and legal persons and sole traders, financial penalty in the same order. (2) (supplemented, — SG No 93 of 2002) for other breaches of Chapter Five of the law and its implementing regulations, the penalty shall be a fine or penalty payment of BGN 100 to BGN 2000. Art. 56. (Supplemented — SG No 86 of 2007) that prevents or does not provide the documents referred to in Art. 30 g (1) (4 market surveillance authorities and technical surveillance authorities to perform their duties is punishable by a fine of BGN 200 to 2000. Art. 57. Where breaches of this Law or its implementing regulations are committed by those serving equipment with increased risk, infringers may be

	deprived from the acquired competence for a period of one month to two years. Art. 58. (1) (supplemented, — SG No 45 of 2005) the infringements chapter 5 of law and its implementing provisions and infringements under Article 56 shall be established by an official report drawn up by the staff of the Directorate-General for Inspection for government technical supervision". Article 219. (2) (Amended — SG. — SG No 95 of 2005) the penalty decrees shall be issued by the State Agency for Metrological and Technical Surveillance or officials authorised by him. (3) (New — SG No 93 of 2002, repealed in SG No 77 of 2012, in force since 9.10.2012). Article 58a. (New — SG No 45 of 2005) (1) (amended, — SG No 86 of 2007) for the breach is ascertained in accordance with Article 14a or 14b be penalised by a financial penalty of BGN 600. (2) (New — SG No 86 of 2007) in the event of a repeated infringement under paragraph 1 shall be liable to a penalty or a fine of BGN 1000. Article 219. (3) (Amended — SG. — SG No 95 of 2005, former subparagraph 2, No 86 of 2007, amended in SG No 66 of 2013, in force as of 26.07.2013, SG No 66 of 2013, in force as of 26.07.2013) Statements establishing infringements under paragraphs 1 shall be drawn up by determined by the President of the State Agency for Metrological and Technical Supervision of the Minister of Investment Design, officials of the relevant administration. Penalty enactments shall be issued by the State Agency for Metrological and Technical Supervision of the Minister of investment design. Art. 59. The procedure for establishing infringements, issuing, appealing and implementing penalty enactments shall be as set out in the Administrative Infringements and Penalties Act. Article 59a. (New — SG No 86 of 2007) (1) Where the infringer does not arrive to drafting the Act on administrative violation by the control authorities, the act shall be sent immediately for service by the municipality or mayoralty of the registered office of the legal person or sole proprietor. They are obliged to notify the infringer with communication with acknowledgement of deposited Act and within 14 days from the date of receipt to be served. No show of the infringer this statement should be signed by an authorised officer of the municipality or mayoralty and will be forfeited. Upon return of the Act within two months is issued and shall enter into force from the date of issue. (2) The penal orders indicate that the fine or financial penalty imposed, as well as the costs for taking and testing of samples of products shall be payable to the bank account of the State Agency for Metrological and Technical

	Surveillance and serve as a formal reminder after their entry into force. (3) Where the infringer is not found at the address indicated in the service of infringement notices, or has left the country, or has indicated address only abroad, an order will be forfeited. It shall be considered effective two months as of its issue. (4) (Repealed. — SG No 38 of 2012, in force since 1.07.2012).
Croatia	Directive on safety of toys are prescribed in Article 42 and 44 of the Act on Common Use Items which is published in the Official Gazette of the Republic of Croatia No 39/2013. (found in http://narodne-novine.nn.hr/clanci/sluzbeni/2013_04_39_719.html - Google translate) **V. PENAL PROVISIONS** **Article 42** (1) A fine of the amount of HRK 50,000.00 to 100,000.00 shall be imposed on a legal person as a business operator in general use if : 1. Puts on the market defective or incompatible consumer goods contrary to the Article 4 of this Act; 2. Puts on the market consumer goods that have no information on the product in accordance with Article 6 of this Act; 3. Puts on the market consumer goods contrary to Article 7 of this Act; 4. Advertises smoking accessories contrary to the provisions of Paragraph 3 of Article 9 of this Act; 5. Acts contrary to the Article 10 of this Act; 6. Performs internal control in accordance with Article 13 of this Act; 7. Acts contrary to the Article 15 of this Act; 8. Provides to the consumer goods which serve as a carrier for the transport of food used for other purposes in contravention of Article 16 Paragraph 2 of this Act; 9. Does not perform laboratory testing products and keep records of the testing performed, or does not examine the microbiological purity of production in accordance with Article 18 paragraphs 1 and 2 of this Act; 10. As competent inspector does not make available the required quantity of samples for laboratory testing in accordance with Article 22

	Paragraph 2 of this Act; 11. Produces and markets detergents, cosmetic products and materials and articles intended to come into direct contact with food, contrary to the specific requirements of Articles 25, 26 and 27 of this Act; 12. Imports items of general use, contrary to Article 30 of this Act. (2) For the offense referred to in paragraph 1 of this Article a fine of 5,000.00 to 10,000.00 shall be imposed on the responsible person or the legal person. (3) For the offense referred to in paragraph 1 of this Article any natural person - craftsman shall be punished as business operator with general use as business operator with general use by a fine of HRK 5,000.00 to 15,000.00. (4) For the offense referred to in paragraph 1 of this Article any natural person shall be punished by a fine of HRK 3,000.00 to 10,000.00. **Article 43** (1) A fine in the amount of 5,000.00 to 10,000.00 shall be imposed on the operator dealing with general use if he does not provide or does not use the prescribed protective clothing and footwear (Article 17 , paragraph 1) . (2) For the offense referred to in paragraph 1 this Article a fine in the amount of 2,000.00 to 5,000.00shall be imposed on the responsible person of the legal person. **Article 44** (1) A fine in the amount of HRK 1,000.00 shall be imposed on the responsible person in a legal entity or a natural person engaged in economic activities for non-compliance with hygiene requirements and other conditions set forth in the regulations of the governing sanitary control. (2) If a person repeats an offense under paragraph 1 of this Article within six months, he/she shall be fined with an amount of HRK 3,000.00 .
Cyprus	**Article 48 Penalties** The competent authority shall lay down penalties for economic operators, which may include criminal sanctions for serious infringements pursuant to Articles 52 and 53 of the Law. The competent authority shall notify the Commission of those rules by 20 July 2011, and shall notify it without delay of any subsequent amendment to them.
Czech	**Article 19 Administrative Offences**

Republic	A natural person shall commit a misdemeanour by misusing the CE marking or another established marking, certificate or other document under this Act, or by counterfeiting or altering a certificate or other document under this Act. A fine of up to CZK 20 000 000 may be imposed for a misdemeanour under paragraph (1)(a), and a fine of up to CZK 1 000 000 for a misdemeanour under paragraph (1)(b) or (c). A legal person or a natural person engaged in business shall commit an administrative offence by misusing the CE marking or another established marking, certificate or other document under this Act, or by counterfeiting or altering a certificate or other document under this Act, by carrying out conformity assessment activities reserved for the purposes of this Act for an authorised person without authorisation pursuant to Section 11(1), or by carrying out conformity assessment activities reserved for the purposes of this Act for an authorised person without certification pursuant to Section 16(1). A manufacturer, importer, authorised representative or distributor shall commit an administrative offence by placing on the market, putting into service, or distributing specified products without the CE marking or another established marking or document provided for by a government regulation, or with a marking or document in conflict with Section 13, failing to comply with a safeguard measure issued in accordance with Section 18a(1), (3) or (4), or failing to comply with an obligation set by a surveillance body under Section 18(2)(c) or (d). A legal person or a natural person engaged in business shall commit an administrative offence by, as an importer, failing to fulfil the obligation under the second sentence of Section 13(1), a distributor, failing to fulfil any of the obligations under Section 13(9), a manufacturer or importer, failing to fulfil any of the obligations under Section 13(10), a manufacturer, importer or distributor, failing to fulfil any of the obligations under Section 13(11), a manufacturer, importer, distributor or authorised representative, failing to fulfil the obligation under Section 13(12), or an importer or distributor, failing to fulfil the obligation under Section 13(13). The following fines shall be imposed for administrative offences: • up to CZK 50 000 000 for an administrative offence under paragraph (3), • up to CZK 20,000,000 for an administrative offence under paragraph (1)(a), (d) or (e), • up to CZK 500 000 for an administrative offence under paragraph (4). **Common Provisions on Administrative Offences** A legal person shall not be held liable for an administrative offence if it proves that it made all efforts that could reasonably be expected of it to

	prevent the infringement of the legal obligation. When assessing the amount of a fine to be levied, factors to be taken into account shall be the seriousness of the administrative offence, in particular the manner in which it was perpetrated, its consequences, and the circumstances under which it was perpetrated. A legal person shall not be held liable for an administrative offence if the administrative body fails to initiate proceedings within three years of the date on which it learned of the administrative offence, but no later than five years from the date on which the administrative offence was committed. Administrative offences under Section 19(1)(b) and (c), Section 19a(1)(b), (c), (d) and (e), and Section 19a(2) shall be heard in the first instance by the Office; administrative offences under Section 19(1)(a) and Section 19a(1)(a) and Section 19a(3) and (4) shall be heard in the first instance by the surveillance body. Provisions of this Act applying to a legal person's responsibility and sanctions shall apply to the responsibility for any action that occurs during the business activities of an undertaking who is a natural person, or in direct relation to such activities.
Denmark	**Article 68.** 1. Any person who, 1) in contravention of § 4, cf. § 27(1) or (2), or § 28(1), (2) or (3), or § 13, cf. § 27(1) or (2), or § 28 (1), (2) or (3), deliberately places a toy on the market, 2) deliberately fails to provide a toy with identification, cf. §8 (1),(2) or (3), or § 16(1) or (2), 3) in contravention of § 20, cf. § 27(1) or (2), or § 28(1), (2) or (3), deliberately makes a toy available on the market, 4) deliberately fails to provide a toy with warnings, cf. § 9(1) cf. § 29(1), (2) or (3), or § 30(1), (2), (3), (4) or (5), 5) deliberately fails to ensure that a toy, where relevant, is accompanied by instructions and safety information in Danish, cf. § 9(2), 6) deliberately fails to ensure that the requirements concerning warnings, instructions and safety information are met, cf. § 14(1) No 3, cf. § 9(1) cf. § 29(1), (2) or (3), or § 30(1), (2), (3), (4) or (5), or § 9(2), 7) deliberately fails to comply with the essential safety requirements laid down in § 27(1) or (2), § 28(1), (2) or (3), 8) deliberately or through gross negligence fails to provide the surveillance authority with the information referred to in § 59(1), 9) fails to keep documentation in accordance with § 6, cf. § 5(1), (2) or (3), or § 42(1), (2), (3) or (4), § 18 or § 26(1) or (2),

	10) fails to inform the surveillance authorities in accordance with § 10(2), § 15(2) or § 19, cf. § 10(2) shall be liable to a fine, unless a more severe penalty is incurred under other legislation,. 2. The unauthorised use of the CE mark, either deliberately or through gross negligence, and where the infringement led to or was intended to lead to a financial advantage for the party concerned or a third party, shall be punishable by a fine, unless a more severe penalty is incurred under other legislation. 3. Companies etc. (legal persons) may be held criminally liable under the rules set out in Chapter V of the Criminal Code.
Estonia	**§ 58. Specifics for issue of precept and penalty payment rate** (1)Before a precept is issued for withdrawal of a product from the market or recall thereof from consumers or before a relevant act is performed, economic operators shall be notified of the possibility to lodge objections. Economic operators need not be provided with the possibility to lodge objections if a market surveillance authority is obliged to apply measures immediately. (2) If the possibility to lodge objections was not provided to an economic operator before the issue of a precept for withdrawal of a product from the market or recall thereof from consumers or before the performance of a relevant act for the reason that the market surveillance authority was obliged to apply measures immediately, the opinion of the economic operator shall be asked for within reasonable time after the issue of the precept or the performance of the act. (3) When applying measures in a precept laying down the requirement for recalling a product from consumers or withdrawing the product from the market and in the case of performing an act, the participation of the distributors, users and consumers shall be fostered. (4)Filing a challenge against a precept or an act shall not exempt an economic operator from the obligation to comply with the precept. (5)If the precept is not complied with, the maximum penalty payment applied in accordance with the procedure laid down in the Substitutive Enforcement and Penalty Payment Act shall be EUR 10 000.
Finland	The toys sold in Finland must meet the requirements set in the Toy Safety Act. The Act (1154 /2011) entered into force on 1st of January 2012, and its chemical requirements came into force on 20th of July 2013. The requirements laid down in the Toy Safety Directive (2009/48/EY) are brought into force in Finland by the Toy Safety Act. The Toy Safety Act lays down

	requirements for operators (manufacturers, importers and distributors) as well as the structural and chemical safety of toys. The Government Decree (1218 /2011) issued under the Toy Safety Act contains more detailed requirements for toy structure and composition as well as the warnings which should accompany the toy. Also issued under the Toy Safety Act is the Ministry of Employment and the Economy Decree on the requirements concerning certain chemicals in toys (1352/2011). According to the Toy Safety Act, (Chapter 6, Sections 56 and 57), the market surveillance authorities of the Toy Safety Act are the authorities of the Consumer Safety Act (Finnish Statute book 920/2011) and the Consumer Safety Act applies to the market surveillance of toys safety. The Consumer Safety Act (920/2011) repealed the Act on the Safety of Consumer Products and Services (75/2004)). Please see the unofficial translation of the Consumer Safety Act (920/2011) http://www.tem.fi/files/31314/Kuluttajaturvallisuuslaki_en.pdf. There are only a few provisions under the Consumer Safety Act which somehow deal with or refers to the penalties (Sections 45 and 50). The criminal sanctions for serious infringements are regulated in the Criminal Code of Finland (in Chapter 44, Section 1). In practise the criminal sanctions have never been applied in a question of toys safety. Consumer Safety Act, Chapter 7, Section 50 states the following: “Section 50 Penal provisions Penalties for a health offence committed in violation of the provisions of this Act or provisions or regulations issued by virtue of it are included in Chapter 44, Section 1, of the Criminal Code. Anyone who deliberately or through gross negligence violates a prohibition or order referred to in Sections 34–44 shall be issued with a fine for a consumer safety offence, unless a more severe punishment is provided for the offence elsewhere under law. Anyone who violates a prohibition or an order, imposed under Sections 34–44, that has been intensified by a conditional fine need not be sentenced to a penalty for the same act.” “Criminal Code of Finland, Chapter 44 – Offences endangering health and safety (400/2002): Section 1 – Health offence (921/2011) - (1) A person who intentionally or through gross negligence in violation of 1. the Plant Protection Act (1563/2011) or Regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, referred to in the following as the plant protection regulation, 2. the Consumer Safety Act (920/2011), 3. the Chemical Act (744/1989), Regulation (EC) No 1907/2006 of the

	European Parliament and of the Council concerning the registration, evaluation, authorization and restriction of chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/ED and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, hereinafter the REACH Regulation, or Regulation (EC) No. 1272/2008 of the European Parliament and of the 4. Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EEC, and amending Regulation (EC) No. 1907/2006, referred to in the following as the CLP regulation, 5. the Health Protection Act (763/1994), or 6. the Foodstuffs Act (23/2006) or of a provision or general order or order concerning an individual case issued on their basis produces, handles, imports or intentionally attempts to import, keeps in his or her possession, stores, transports, keeps for sale, conveys or gives goods or substance, product or object so that the act is conducive to endangering the life or health of another, shall be sentenced, unless a more severe penalty for the act has been provided elsewhere in the law, for a health offence to a fine or to imprisonment for at most six months. (565/2011) (2) Unless a more severe penalty for the act has been provided elsewhere in the law, also a person who intentionally or through gross negligence, in violation of the Product Safety Act or a provision given on its basis or of an order given in general or in an individual case provides, keeps for sale or otherwise in connection with his or her commercial activity provides a consumer service so that the act is conducive to endangering the life or health of another, shall be sentenced for a health offence." Also Section 45 of the Consumer Safety Act can be understood as a kind of penalty if the payment of a conditional fine imposed is ordered by a decision of the Administrative Court. Section 45: Conditional fine, threat against default and threat of suspension of operations The surveillance authority may intensify the effect of an order or prohibition by imposing a conditional fine, or by having measures taken at the expense of the defaulting respondent ('threat against default'), or by imposing a threat of suspension of operations. Provisions on conditional fine, threat against default and threat of suspension of operations are laid down in the Act on Conditional

	Imposition of Fines (1113/1990). The surveillance authority is authorized to reinforce the obligation to provide information referred to in Section 9, the obligation to notify and to provide information referred to in Section 26, the obligation to provide information and present the documents referred to in Section 27, and the obligation to comply with an order referred to in Section 34(2) by imposing a conditional fine. The payment of a conditional fine imposed under paragraph 1 or 2 is ordered by a decision of the Administrative Court.
France	**Art. 17.** − Est puni de l'amende prévue pour les contraventions de la cinquième classe le fait : 1o De fabriquer en vue de la mise sur le marché de l'Union, importer, détenir en vue de la vente ou de la distribution à titre gratuit, mettre en vente, vendre, mettre à disposition sur le marché à titre gratuit ou onéreux des jouets ne respectant pas les obligations prévues aux 2o et 3o de l'article 3 ; 2o De ne pas être en mesure de présenter aux agents chargés du contrôle les documents prévus au chapitre IV. La récidive est réprimée conformément aux dispositions des articles 132-11 et 132-15 du code pénal. Est puni de l'amende prévue pour les contraventions de la troisième classe le fait : 1o De fabriquer en vue de la mise sur le marché de l'Union, importer, détenir en vue de la vente ou de la distribution à titre gratuit, mettre en vente, vendre, mettre à disposition sur le marché à titre gratuit ou onéreux des jouets ne respectant pas l'obligation prévue au 4o de l'article 3; 2o D'apposer sur un jouet, sur son emballage ou sur les documents, notices d'information du fabricant qui l'accompagnent des inscriptions de nature à créer des confusions avec le marquage « CE » ou à en compromettre la visibilité ou la lisibilité ; 3o D'exposer, lors de salons professionnels et expositions, des jouets qui ne respectent pas les dispositions de l'article 6.
Germany	**§ 22 Regulatory offences** Anyone who, contrary to § 4(2) first sentence, also in conjunction with § 6(5) second sentence, deliberately or negligently fails to provide information, fails to provide correct information, fails to provide complete information or fails to provide information on time shall be guilty of a regulatory offence within the meaning of § 19(1)1.b) of the Equipment and Product Safety Act.
Greece	1. Persons who manufacture, import, sell or resell and, in general, place on the market toys which come within the scope of the provisions herein in breach of the said provisions or who obstruct the relevant inspections shall be subject to

	a fine of between EUR 1 000 and EUR 40 000. 2. The fines listed in the table below have been calculated on the basis of the severity of the infringement, taking account of the degree of non-compliance, the risk factor associated with the toy at issue and the number of non-compliant toys placed on the market. **Infringement of provisions of this decision** **Penalties** Infringement of Articles 5, 6, 7, 8 or 10 — Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 1 000 and EUR 40 000 Infringement of Article 11 & Annex II — Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 5 000 and EUR 40 000 Infringement of Article 12 & Annex V — Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 1 000 and EUR 8 000 Infringement of Article 16 & Annex III, Articles 17, 18, 19, 20 & Annex VII, Article 21 & Annex VII or Article 22 & Annex IV, as summarised in Article 42 — Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 1 000 and EUR 40 000 3. In the event of a repeat offence, offenders shall be punished with a fine of at least double the initial fine, capped at EUR 40 000. 4. In the event that the placing of a toy on the market poses a serious risk to the health and safety and protection of consumers/children, in addition to the above, the case file shall be forwarded to the competent prosecuting authorities. 5. The economic operators responsible must: a) allow the authorised officers of the competent services provided for in Article 4 herein entry to manufacturing, sales or storage premises, provide them with any information requested in connection with the manufacture or origin of the toy at issue and facilitate the work of the said inspectors, and b) provide the competent toy-inspection bodies with free samples and, on request, send stamped samples of the toy at issue to a laboratory specified by the competent services provided for in Article 4 herein for testing. The said samples shall be returned on the responsibility of the interested party, once it has been ascertained that they comply with the provisions herein and provided that they were not altered

	during testing, such that they are unsuitable for use. 6. The fine shall be imposed by decision of the Minister for Economic Affairs, Competitiveness and Shipping, at the proposal of the competent authority, once the liable party has been summoned to a hearing in accordance with the provisions of Article 6 of Law 2690/1999 (Government Gazette 45A). The said decision may also ban further placing on the market and sales of the said toys and/or may impose withdrawal thereof from the market. The economic operator shall be responsible for and shall bear the costs of such withdrawal. 7. Any decision issued in accordance with the present article imposing a fine and/or a ban on the placing on the market or sale of a product and/or the withdrawal thereof must be fully reasoned and notified directly to the interested party by registered mail and/or fax. 8. Fines imposed pursuant hereto, the amount of which shall at least cover the costs incurred in ascertaining the unsuitability of the toy, shall be payable within sixty (60) days into special account no. 234218/6, which has been opened at the Bank of Greece in order to cover the costs of all manner of laboratory or other testing of electrical material in circulation, in accordance with decision no 37101/1146/18.04.85 by the Minister for Finance. On expiry of the above deadline, fines shall be assessed and collected in accordance with current provisions on collection of public revenue. 9. The competent authority shall notify the European Commission in accordance with the provisions of Article 40(4). 10. Interested parties may file an appeal with the Minister against the above decision within thirty (30) days of notification thereof.
Hungary	Act CLV of 1997 on consumer protection (hereinafter: Consumer Protection Act) 47. § (1) (a), (b), (c), (d), (e), (f) and (i): ‘47. § (1) If the consumer protection authority finds that the new § 45/A. (1)-(3) Specific consumer protection provisions of the case, all the circumstances (in particular the severity, duration, and recurrence of the infringement and the benefit from it) and proportionality, may: a) order that the situation constituting a violation of law, b) prohibit the continuation of the behaviour constituting an infringement; c) oblige the enterprise to correct any faults or deficiencies by a set date, stipulating that the enterprise of these corrective measures, should inform the consumer protection authority, d) impose conditions until the infringement is terminated or prohibit the sale of goods, or Sale,

	e) the consumer may order life, health and physical integrity dangerous product, withdrawal and recall f) may order the consumer's life, health and physical integrity of the product to be destroyed Consideration of environmental aspects, g) the lawful situation until the infringement period may order the temporary closure of the business concerned, if the consumers' lives, physical integrity and health protection and the prevention of injury to a wide range of consumers is necessary in order to prevent threats, h) the Article 16/A. (1h 3) in the event of a breach of the provisions the infringement may prohibit a period of up to one year from the date of the determination of alcoholic beverages and the tobacco and sexual product, those provisions may, in the case of repeated infringements of the business involved in the infringement for a period of not more than thirty days and, in the case of temporary closure i) consumer protection fine (hereinafter Impose fines). The Consumer Protection Act. Section 47/C. (5) (a) and (b): "The consumer protection authority shall impose fines if appropriate, a) the consumer protection authority of a final decision finding an infringement is provided for the undertaking to give the expiry of the closing date, or within six months following the expiry of the period of the undertaking, where the infringement has been committed on the same site, repeated infringements of the same legal provision, (b) the life and health of consumers, endangers or affects a wide range of consumers, and..." The safety of goods and services and the relating market surveillance procedure 79/1998. (IV. 29.) 6. § (1): 'Where the market surveillance authorities establish the course of the market surveillance process, that a product does not meet the requirements, they are entitled to (a) the danger arising from the use of the product, information on alerts (b) impose comprehensive information, so that the threat inherent in the use of the product in time and appropriate means, if necessary, the radio and television broadcasts or in the press consumers (c) its placing on the market and its advertising and to limit or prohibit the

	measures necessary to enforce the ban, (d) the withdrawal of products already placed on the market and information to the effect in point (b) as set out, (e) order recall of the product — if appropriate, in cooperation with the producers and distributors to recall the product from consideration of environmental aspects and destruction and control their implementation.”
Ireland	**Penalties** 49. (1) A person guilty of an offence under Regulation 48 shall be liable— (a) on summary conviction, to a class A fine or imprisonment for a term not exceeding 6 months or both, or (b) on conviction on indictment, to a fine not exceeding €500,000 or imprisonment for a term not exceeding 2 years or both. (2) (a) Where a person is convicted of an offence under these Regulations in proceedings brought by the Agency, the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the Agency the costs and expenses, measured by the court, incurred by the Agency in relation to the investigation, detection and prosecution of the offence, including the costs and expenses incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of authorised officers, employees, consultants and advisers engaged by the Agency. (b) An order for costs and expenses under subparagraph (a) is in addition to and not instead of any fine or penalty the court may impose. Offences by bodies corporate 50. Where an offence under these Regulations has been committed by a body corporate and is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a person being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person, as well as the body corporate, commits an offence and shall be liable to be proceeded against and punished as if he or she had committed the first-mentioned offence.
Italy	**ARTICLE 31 (Penalties)** 1. Unless the fact constitutes a more serious offence, a manufacturer or importer placing on the market products in breach of Article 3(1) and Article 5(2) shall be punishable by a term of imprisonment of up to one

	year and by a fine from EUR 10 000 to EUR 50 000. 2. Unless the fact constitutes a more serious offence, a manufacturer or importer failing to comply with the measures issued under Article 30(2) shall be punishable by a term of imprisonment from six months to one year and by a fine from EUR 10 000 to EUR 50 000. 3. Unless the fact constitutes an offence, a manufacturer or importer placing on the market a toy not provided with the technical documentation referred to in Annex IV to this Decree shall receive an administrative penalty from EUR 2 500 to EUR 40 000. 4. Unless the fact constitutes an offence, a manufacturer or importer placing on the market a toy not provided with the CE marking shall receive an administrative penalty from EUR 2 500 to EUR 30 000. 5. Unless the fact constitutes an offence, the administrative penalty under paragraph 4 of this Article shall also apply to a manufacturer or importer placing on the market a toy not provided with the warnings referred to in Article 10 of this Decree. 6. Unless the fact constitutes an offence, a manufacturer or importer failing to comply with the prohibition issued under Article 30(6) shall receive an administrative penalty from EUR 2 500 to EUR 10 000. 7. Unless the fact constitutes an offence, a manufacturer or importer placing on the market a toy not provided with the CE marking or the warnings under Article 10 of this Decree shall receive an administrative penalty from EUR 1 500 to EUR 10 000. 8. Unless the fact constitutes an offence, a manufacturer or importer failing to comply with its obligations under Article 8 of this Decree shall receive an administrative penalty from EUR 2 500 to EUR 10 000. 9. Unless the fact constitutes an offence, the administrative penalty under paragraph 8 of this Article shall also apply to any authorised representative failing to comply with his/her obligations under Article 4(3) of this Decree. 10. The administrative penalties referred to in this Article shall be issued by the Chamber of Commerce, Industry, Craft and Agriculture having territorial competence.
Latvia	Supplying an unsafe product can result in a fine of up to LVL 5,000 for each offence, and/or a term of imprisonment of up to three months. (http://www.ptac.gov.lv/page/265&mode=print - Consumer Rights Protection Centre).

Lithuania	Law No IX-1702 of the Republic of Lithuania amending the Administrative Infringements Code (Official Gazette 2003, No 74-3421) Article 50. Amendment of Article 163(13) Article 163(13) shall be amended to read as follows: "Article 163(13). Sales of Goods that Are Unmarked in the Statutory Procedure in the Domestic Market and Providing Incorrect Information about Goods Sales of goods that are unmarked in the statutory procedure in the domestic market of the Republic of Lithuania – shall result in a warning or fine for natural persons pursuing individual activities from LTL 20 up to LTL 100, a fine for corporate employees from LTL 100 up to LTL 500 and a fine for officers from LTL 500 up to LTL 1 000. The same actions committed by a person who has already been imposed an administrative penalty for the infringement referred to in paragraph 1 of this Article – shall result in a fine from LTL 50 up to LTL 200 for natural persons pursuing individual activities, from LTL 200 up to LTL 1 000 for corporate employees and from LTL 1 000 up to LTL 2 000 for officers. Provision of incorrect information on a label of goods – shall result in a warning or fine for natural persons pursuing individual activities from LTL 20 up to LTL 100, a fine for corporate employees from LTL 100 up to LTL 500 and a fine for officers from LTL 500 up to LTL 1 000. The same actions committed by a person who has already been imposed an administrative penalty for the infringement referred to in paragraph 3 of this Article – shall result in a fine from LTL 50 up to LTL 200 for natural persons pursuing individual activities, from LTL 200 up to LTL 1 000 for corporate employees and from LTL 1 000 up to LTL 2 000 for officers." Law No IX-1988 of the Republic of Lithuania amending Articles 1, 3, 4, 7, 8, 9, 10, 11, 13, 14, 15, 16, 16, 19, 21, 23, 24, 25, the title of Chapter Four of the Law on Product Safety and adding an Annex to the Law (Official Gazette 2004, No 25-757) Article 17. Amendment of Article 23 In paragraphs 1, 2, 3, 4, 5, 6, 7 of Article 23 all the words 'unsafe' shall be replaced by the word 'dangerous' and this Article shall read as follows: 'Article 23. Fines for infringements of this Law 1. The producer or distributor who has placed dangerous products on the market shall be fined from LTL 500 to 5 000. 2. The producer or distributor who has placed dangerous products on the

	market following the order to discontinue their sale shall be fined from LTL 3 000 to 15 000. 3. The supplier of a service who has provided or is providing dangerous services shall be fined from LTL 500 to 2 500. 4. The supplier of a service who has provided or keeps providing a dangerous service following the order to discontinue it shall be fined from LTL 2 000 to 10 000. 5. The persons indicated in Article 22 of this Law who fail to comply with the requirements of the Board or the control authorities to withdraw dangerous products from the market or to destroy them shall be fined from LTL 5 000 to 20 000. 6. If the person referred to in Article 22 of this Law placed dangerous products on the market which have caused a health impairment to the consumer shall be fined from LTL 5 000 to 40 000. 7. If the person referred to in Article 22 of this Law placed dangerous products on the market which have caused the consumer's death shall be fined from LTL 20 000 to 80 000. 8. Imposition of fines does not exempt from the duty to compensate damages caused to consumers.' There is no need to transpose and implement this article of the Directive.
Luxembourg	Art. 18. – Dispositions pénales dans le cadre de la surveillance du marché (http://www.ilnas.public.lu/fr/legislation/ilnas/ilnas/loi-ilnas.pdf) (1) Est punie d'une amende de 251 euros à 25.000 euros et d'une peine d'emprisonnement de 8 jours à un an ou d'une de ces peines seulement, toute personne qui a mis sur le marché ou qui a mis à disposition sur le marché un produit dont il sait ou dont il aurait dû savoir que celui-ci n'est pas conforme aux prescriptions de la présente loi ou aux dispositions légales ou réglementaires transposant les directives visées par la présente loi. (2) Est punie des mêmes peines, le maximum de l'amende prévue étant porté à 125.000 euros, toute personne qui ne s'est pas conformée aux décisions prises en application de l'article 17. (3)Est puni d'une amende de 25 euros à 250 euros, le distributeur qui a mis à disposition sur le marché un produit qui n'est pas conforme aux prescriptions de la présente loi ou aux dispositions légales et réglementaires transposant les directives visées par la présente loi. La confiscation du produit peut être ordonnée. (4)Est puni des peines prévues au paragraphe 1er, le distributeur qui a commis

	de nouveau la contravention spécifiée au paragraphe 3 avant l'expiration d'un délai d'un an à partir du jour où une précédente condamnation du chef d'une telle contravention ou d'un des délits spécifiés aux paragraphes 1er et 2 du présent article sera devenue irrévocable.
Malta	PART IV PROCEEDINGS (Product Safety Act V of 2001, as amended by Legal Notice 426 of 2007 and Act XXIX of 2007) Proceedings. 30. Proceedings in relation to any offence under this Act may only be instituted at the instance of the Director, who may conduct the prosecution before the Court. Prescription. 31. Criminal actions for offences under this Act shall be prescribed by the lapse of two years. Fines. 32. (1) A person found guilty of an offence under article 23 shall, on conviction, be liable to a fine (multa) of not less than four hundred and sixty-five euro and eighty-seven cents (465.87) and not exceeding two thousand and three hundred and twenty-nine euro and thirty-seven cents (2,329.37), or to imprisonment for a term not exceeding six months or to both such fine and imprisonment. (2) A person found guilty of any other offence under this Act shall be liable, on conviction, to a fine (multa) of not less than one thousand and one hundred and sixty-four euro and sixty-nine cents (1,164.69) but not exceeding eleven thousand and six hundred and f o r t y - s i x euro and e ighty-seven cents (11,646.87) or to imprisonment for a term not exceeding three years or to both such fine and imprisonment. (3) A person found guilty of a second or subsequent offence shall, on conviction, be liable to a fine (multa) of not less than one thousand and seven hundred and forty-seven euro and three cents (1,747.03) but not exceeding twenty-three thousand and two hundred and ninety-three euro and seventy-three cents (23,293.73) or to imprisonment not exceeding four years or to both such fine and imprisonment. (4) The Court may, upon conviction for any offence committed under this Act, with the exception of offences committed under article 23, if it feels that circumstances so warrant, additionally order the suspension or cancellation of any licence or licences issued in favour of the person charged or in respect of the premises involved in the proceedings. (5) Without prejudice to the generality of the foregoing, any person convicted in relation to an offence under articles 26 or 29 shall additionally be liable to

	the additional fine (multa) of not more than four hundred and sixty-five euro and eighty-seven cents (465.87) for each day that a notice or undertaking has not been complied with. Reimbursement to the Director. 33. Where a person has been convicted of an offence under this Act, the Court shall order that person to reimburse to the Director, within such period as it shall stipulate, any costs incurred in connection with the proceedings instituted against him. Such costs shall include expenses incurred in the seizure, lifting, detention, testing, analysis, inspection and examination of products, or samples thereof, involved in the said proceedings. Right to appeal. 34. The Attorney General shall have the right to appeal from any judgement given in proceedings instituted under this Act or in connection with regulations made thereunder.

Netherlands	Description of the infringement		Fine	Per category
	C-30	Toys (Commodities Act) Decree 2011	I	II
	C-30.1.1	Article 2(1) [It shall be forbidden to manufacture or trade in toys which do not satisfy the provisions of this Decree] in conjunction with Article 3(1) [When designing and manufacturing toys and placing them on the market, manufacturers shall comply with the provisions of: a. Article 4; b. Article 9; c. Article 10; d. Article 11; e. Article 15; f. Article 18; g. Article 21(3) and (4); and h. Annex II to Directive 2009/48/EC.]	€ 525	€ 1050
	C-30.1.2	Article 2(1) [It shall be forbidden to manufacture or trade in toys which do not satisfy the provisions of this Decree] in conjunction with Article 4(1) [A manufacturer who appoints an authorised representative shall comply with and ensure compliance with Article 5 of Directive 2009/48/EC]	€ 525	€ 1050
	C-30.1.3	Article 2(1) [It shall be forbidden to manufacture or trade in toys which do not satisfy the provisions of this Decree] in	€ 525	€ 1050

		conjunction with Article 4(2) [The authorised representative referred to in paragraph 1 shall comply with Articles 5(3) and 9 of Directive 2009/48/EC]		
	C-30.1.4	Article 2(1) [It shall be forbidden to manufacture or trade in toys which do not satisfy the provisions of this Decree] in conjunction with Article 5(1) [When placing toys on the market, importers shall satisfy the requirements of: a. Article 6; b. Article 8; and c.Article 9; of Directive 2009/48/EC]	€ 525	€ 1050
	C-30.1.5	Article 2(1) [It shall be forbidden to manufacture or trade in toys which do not satisfy the provisions of this Decree] in conjunction with Article 6 [When making toys available on the market, distributors shall comply with the provisions of: a. Article 7; b.Article 8; and c. Article 9; of Directive 2009/48/EC]	€ 525	€ 1050
	C-30.2.1	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 3(1) [When designing and manufacturing toys and placing them on the market, manufacturers shall comply with the provisions of: a. Article 4; b. Article 9; c. Article 10; d. Article 11; e. Article 15; f. Article 18; g. Article 21(3) and (4); and h. Annex II to Directive 2009/48/EC]	€ 525	€ 1050
	C-30.2.2	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 3(2) [Instructions and safety information referred to in Article 4(7) of Directive 2009/48/EC shall be written in the Dutch	€ 525	€ 1050

		language at least]		
	C-30.2.3	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 3(3) [The EC declaration of conformity referred to in Article 15(2) of Directive 2009/48/EC shall be written in Dutch or English at least]	€ 525	€ 1050
	C-30.2.4	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 5(1) [When placing toys on the market, importers shall satisfy the requirements of: a. Article 6; b. Article 8; and c. Article 9; of Directive 2009/48/EC]	€ 525	€ 1050
	C-30.2.5	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 5(2) [Instructions and safety information as referred to in Article 6(4) of Directive 2009/48/EC shall be written in the Dutch language at least]	€ 525	€ 1050
	C-30.2.6	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 6 [When making toys available on the market, distributors shall comply with the provisions of: a. Article 7; b. Article 8; and	€ 525	€ 1050

		c. Article 9; of Directive 2009/48/EC]		
	C-30.2.7	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 7(1) [Warnings and safety information concerning toys shall be in accordance with Article 11(1) and (2) of Directive 2009/48/EC]	€ 525	€ 1050
	C-30.2.8	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 7(2) [The warnings and safety information referred to in paragraph 1 shall be written in the Dutch language at least]	€ 525	€ 1050
	C-30.2.9	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 9(1) [In accordance with Article 16(1) and (2) and Article 17 of Directive 2009/48/EC, toys which are made available on the market shall be provided with the CE marking]	€ 525	€ 1050
	C-30.3.1	Article 2(3) [It shall be forbidden to bring toys into the territory of the Netherlands other than in accordance with the provisions of this Decree] in conjunction with Article 5(1) [When placing toys on the market, importers shall satisfy the requirements of: a. Article 6; b. Article 8; and c. Article 9; of Directive 2009/48/EC]	€ 525	€ 1050
Poland	**Chapter 7 criminal Liability (Law on Conformity Assessment) – Google**			

	translate Article 45: Anyone who is on the market or puts into service the product inconsistent with the essential requirements is subject to a fine. Article 46: Anyone who puts the conformity marking on the product, which does not meet the basic or detailed requirements, or for which the manufacturer or his authorized representative issued a declaration of conformity, is subject to a fine. Article 47: Anyone who puts on the product a sign similar to a conformity marking, which could mislead the user, the consumer or distributor of the product, is subject to a fine. Article 47a: Anyone who is on the market or puts into service the product under the label of conformity and without such marking is subject to a fine. Article 47b: Anyone who puts the conformity marking on the product, which is not subject to the labelling or marketed such a device, is subject to a fine. Article 47c: Anyone who, being obliged to store the control, destroys, removes or prevents the security from the examination of the sample, is subject to a fine.
Portugal	**CHAPTER VII Supervision and system of penalties** **Article 35 Power of supervision** 1. The market surveillance and control of toys which enter the Community market in compliance with this Decree-law shall be governed be the provisions of Chapter III of Decree-law No 23/2011 of 11 February 2011 implementing in national law Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008. 2. The Directorate General for Consumers shall be responsible for supervision in respect of the provisions of the preceding paragraph. **Article 36 Offences** 1. The following shall constitute offences punishable by a fine of EUR 1 000 to EUR 2 500 in the case of a natural person and EUR 3 000 to EUR 20 000 in the case of a legal person: (a) infringement of the obligations of economic operators provided for in Article 5(5) and (6), Article 8(5) and (7), Article 9(2) and Article 10(2) to (7); (b) infringement of the information obligation provided for in Article 12; (c) infringement of the obligations relating to technical documentation provided for in Article 24(2) and (3). 2. The following shall constitute offences punishable by a fine of EUR 1 500 to EUR 3 740.98 in the case of a natural person and EUR 5 000 to EUR 44

	891.81 in the case of a legal person: (a) infringement of the obligations of economic operators provided for in Article 5(2), (3) and (7) to (10), Article 6(1) and (2), Article 8(2) to (4), (6), (8) and (9), and Article 9(1) and (3); (b) infringement of the essential safety requirements provided for in Article 13(1) and (2); (c) infringement of the obligations relating to warnings provided for in Articles 14, 15 and 16; (d) infringement of the requirements relating to the EC declaration of conformity provided for in Article 18; (e) infringement of the rules and conditions for affixing the EC marking provided for in Article 20; (f) infringement of the obligation to carry out the safety assessment provided for in Article 21; (g) failure to comply with the conformity assessment procedures provided for in Article 22(1); (h) failure to comply with the technical documentation requirements provided for in Article 24(1); (i) failure to comply with the rules relating to advertising provided for in Article 34(1) and (3). 3. The offences provided for Article 19(2)(a) and (b) of this Decree-law shall apply to the provisions of Article 6 of Decree-law No 23/2011 of 11 February 2011 implementing in national law Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008. 4. Negligence and attempt shall be punishable, the minimum and maximum amounts of the applicable fines being reduced by half. **Article 37 Supplementary penalties** Where the seriousness of the offence and the fault of the perpetrator so justify, the competent authority may, together with the fine, order the imposition of the supplementary penalties provided for under the general system for offences. **Article 38 Power to impose penalties** 1. The ASAE and the Directorate General for Consumers shall be responsible for bringing offence proceedings in connection with unlawful advertising. 2. The Comissão de Aplicação de Coimas em Matéria Económica e de Publicidade (Commission for the Application of Economic and Advertising Fines) (CACMEP) shall be responsible for imposing the fines and supplementary penalties provided for in this Decree-law. **Article 39 Distribution of the proceeds of fines** 1. The proceeds of the fines shall be distributed as follows: (a) 15% to the body which drew up the notice of infringement; (b) 15% to the body which carried out the investigation;

	(c) 10% to the decision-making body; (d) 60% to the State. 2. The distribution of the proceeds of the fines referred to in Article 36(3) shall be governed by Article 10 of Decree-law No 23/2011 of 11 February 2011 implementing in national law Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008.
Romania	**Article 48 Sanctions** (1) Breach of this decision leads to heritage status, disciplinary, administrative or criminal case of the culprits. (2) The contravention and is punishable as follows: a) Failure to art. 4-7 with a fine of 4,000 to 7,500 lei and, if necessary, withdrawal from the market and / or recalled from consumers or prohibiting the placing on the market and / or the availability of non-compliant toys on the market; b) Failure to art. 10 and 11, with a fine of 6,500 to 10,000 lei and, if necessary, withdrawal from the market and / or recalled from consumers or prohibiting the placing on the market and / or the availability of non-compliant toys on the market; c) Failure to art. 15-17, a fine of 1,500 to 5,000 lei and, if necessary, withdrawal from the market and / or recalled from consumers or prohibiting the placing on the market and / or the availability of non-compliant toys on the market; d) Failure to art. 9, a fine of 2,000 to 6,000 lei, if necessary, withdrawal from the market and / or recalled from consumers or prohibiting the placing on the market and / or the availability of non-compliant toys on the market, to provide the required identification data. (3) Establishing offense and applying sanctions are made by representatives of the National Authority for Consumer Protection. (4) The contraventions provided in paragraph (2) Applicant them to the Government Ordinance no. 2/2001 on the legal regime of contraventions, approved with amendments and completions by Law no. 180/2002, with subsequent modifications,. (5) The Ministry of Economy, Trade and Business Environment notify the Commission without delay of any subsequent paragraph.
Slovakia	(1) The Authority Office attributes to the manufacturer, importer, authorized representative or distributor a fine of a) 1,500 to 50,000 euros if they breach the obligation of § 4 paragraph. 1 point. a) and k), § 6 par. 1 point. b), § 6 par. 2 point. c), § 7. 1 point. d) or § 7. 2 point. b) b) 500 to 30,000 euros if they breach the obligation of § 4 paragraph. 1 point.

	b) to f) , I), j) , l) to n) and p) , § 5 section . 2, § 6 par. 1 point. a), c) and d), § 6 par. 2 point. a) to d) , g) , I) and j) , § 7 . 1 point. a) to c), § 7. 2 point. a), c) to f), § 8, § 10 or § 16. 11 c) 200 to 15,000 euros if they breach the obligation of §4. 1 point g) , h) and o) , § 6 par 2 point e) and h) or § 12 (2) The Office shall impose a fine of 150 to 35,000 euros to a person who a) unlawfully acting beyond the activities listed in notification, b) illegally issues, alters or falsifies a document for the purposes of conformity assessment. (3) The Office shall impose a fine of 100 to 10,000 euros to the person who breached the duty. (4) The upper limit of the fine rates shall be increased or doubled if the manufacturer, importer, acting representative or distributor repeatedly violate the same obligation, for breach of which had already been fined by the authorities within 12 months from the date of the first decision . (5) The specifications of the fines should take into particular account the severity, the duration, the consequences of the offense and the repeated breach of obligations under this Act. (6) The fines go to the state budget. (7) A fine may be imposed within one year from the date that the office authority or the supervision office found a violation of obligations under this Act, and not later than three years from the date that the violation obligation occurred.
Slovenia	**Article 42 (Offences)** (1) A fine between EUR 3 000 to 40 000 shall be issued to a legal entity concerning its pursuit of activities as a manufacturer, importer or representative in the Republic of Slovenia where: - it does not perform obligations in accordance with Article 15 of this Decree; - it does not perform tasks under Article 16(3) of this Decree; - it does not perform obligations in accordance with Article 17 of this Decree; - upon the request of the ZIRS it does not provide identification information of economic operators in accordance with Article 20 of this Decree; - marks toys contrary to the general rules for EC marking or on placing the

	EC marking in accordance with Articles 9 and 10 of this Decree; - it does not perform safety assessment in accordance with Article 11 of this Decree; (2) A fine of EUR 2 000 to 15 000 shall be issued to an independent entrepreneur or an individual independently pursuing an activity who concerning the performance of activities as a manufacturer, importer or authorised representative in the Republic of Slovenia has committed an offence listed in the preceding Paragraph. (3) A fine of EUR 1 200 to 4 000 shall be issued to a responsible person of a legal person or independent entrepreneur who as a manufacturer, importer or representative in the Republic of Slovenia commits an offence referred to in Paragraph 1 of this Article. (4) A fine of EUR 1 200 to 3 000 shall be issued to a legal person as a distributer for an offence where: - it does not perform obligations in accordance with Article 17 of this Decree; - upon the request of the ZIRS it does not provide identification information of economic operators in accordance with Article 20 of this Decree. (5) A fine of EUR 800 to 3 000 shall be issued to an independent entrepreneur or individual independently pursuing an activity who as a distributer commits the offence referred to in the preceding Paragraph. (6) A fine of EUR 200 to 400 shall be issued to a responsible person of a legal person or independent entrepreneur who as a distributor of the product commits an offence referred to in Paragraph 4 of this Article.
Spain	**Article 47. Rules governing penalties** 1. The rules governing the offences and penalties for infringement of this Royal Decree shall be those established in Legislative Royal Decree No 1/2007 of 16 November 2007, approving the consolidated text of the General Law for the Protection of Consumers and Users and other supplementing legislation, and the regional implementing provisions. 2. Offences shall be categorised as minor, serious or very serious. Insofar as this Royal Decree is concerned: a) minor infringements shall be: formal labelling deficiencies which do not affect the safety conditions of the toy; formal deficiencies in the EC marking. b) serious infringements shall be: deficiencies in the labelling of the toy which affect safety, and deficiencies relating to warnings, instructions for use or

	recommendations for the appropriate age of children; absence of the identifying particulars of the person responsible for placing the toy on the market; using the EC marking incorrectly; failing to provide the documentation referred to in Annexes III and IV to the Royal Decree, at the request of the authorities. c) very serious infringements shall be: failure to comply with the safety requirements referred to in Article 11 of and Annex II to the Royal Decree. 3. The infringements referred to shall be penalised in accordance with the types and levels of penalties established in Articles 51 and 52 of Legislative Royal Decree No 1/2007 of 16 November 2007. 4. The authorities competent to determine and impose the corresponding penalties shall be the authorities established under Article 3 of this Royal Decree. Where the power to impose penalties lies with the State, the competent authority shall be the Ministry for Health, Social Policy and Equality, through the National Consumer Institute.
Sweden	In Swedish legislation, article 51 of the Toy Safety Directive is transposed through sections 28 and 32 of the Swedish Act on the safety of toys (lagen [2011:579] om leksakers säkerhet). According to section 28, an order or prohibition from a market surveillance authority required in an individual case to ensure compliance with the Act on the safety of toys, or with regulations made in accordance with the Act, shall be made subject to a default fine ("vite" in Swedish), unless it is deemed unnecessary for special reasons. Section 32 prescribes sanction charges ("sanktionsavgift" in Swedish) for economic operators if they intentionally or by neglect fail to comply with certain obligations laid down in the Act on the safety of toys and regulations made in accordance with the Act.
United Kingdom	Offences may result in fines of up to £5,000, or a maximum prison term of six months, or both. Where a supplier does not comply with a request to have toys tested within a reasonable time the penalties are a term of imprisonment up to three months or a fine of up to £5,000. (found in https://www.gov.uk/toy-manufacturers-and-their-responsibilities)

3.16. Penalties for non-compliance with the legislation on pyrotechnic articles

Country	National transpositions of Article 45 of Directive 2013/29/EU
Austria	(1) Unless forms a behaviour to constitute a subject to the jurisdiction of the ordinary courts offense, commits an administrative offense who violates this

	federal law, regulations or decisions issued pursuant to this Federal Law. He is in the event of an infringement 1. the provisions of the second main piece with a fine of up to € 10 000 or imprisonment for up to six weeks 2. the use prohibition according to § 39 para. 2 with a fine not exceeding € 4,360 or imprisonment for up to four weeks 3. other provisions with a fine not exceeding € 3,600 or imprisonment for up to three weeks to punish. (2) The attempt is punishable.
Belgium	The sanctions are laid down in the basic law, i.e. The 'Code de droit économique' (http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2013022819&table_name=loi) Rule XV.102. Section 1. Is punishable by a penalty of level 2, those who infringe Article IX.9. § 2. Is punishable by a penalty of level 3: 1° those placing on the market products which they know or ought to know, on the basis of European standards or Belgian do not have the guarantees referred to in Article XI.2 concerning safety and health protection; 2° those in breach of Article IX.8; Those who violate the articles 3° IX.4, IX.5, IX.6 and IX.7 or a decree adopted pursuant to Articles IX. 4, § § 1 to 3, IX.5, § § 1 and 2; 4° which do not respond to warnings to Rule XV.31. 5° those committing infringements of the rules of the European Union which concern matters under Book IX of the regulatory power of the King. [Article IX.9: For products intended for consumers, labelling and information required by this book and its implementing decrees, instructions for use and the guarantee shall at least be expressed in a language which is comprehensible to the average consumer, in view of the linguistic region in which the products or services are placed on the market. This obligation also applies to other products, unless orders adopted under Article IX.4 and IX.5 provides for

	derogation conditions.] The sanctions referred to in Article XV.102 are the following: Art. XV.69. The provisions of Book I of the Criminal Code, including Chapter VII and Article 85, shall apply to infringements covered by the present Code subject to the application of the specific provisions mentioned below. Art. XV.70. Breaches of this Code shall be punishable by a penalty ranging from level 1 to level 6. • the level-1 penalty shall consist of a fine of EUR 26 to EUR 5,000. • the level-2 penalty shall consist of a fine of EUR 26 to EUR 10,000. • the level-3 penalty shall consist of a fine of EUR 26 to EUR 25,000. • the level-4 penalty shall consist of a fine of EUR 26 to EUR 50,000. • the level-5 penalty shall consist of a fine of EUR 250 to EUR 100,000 and imprisonment of one month to one year or one of these penalties only. • the level-6 penalty shall consist of a fine of EUR 500 to EUR 100,000 and imprisonment of one to five years, or one of these penalties only. Art. XV.71. When the facts as submitted to the Court are the subject of an injunction, it may not qualify for adjudication in the criminal proceedings only after a decision res judicata was made in relation to the injunction. Art. XV.72. In the event of a repeated infringement within five years of a conviction res judicata in respect of the same infringement, the maximum fines and imprisonment is credited in duplicate. Art. XV.73. Companies and associations having legal personality shall be held civilly liable for damages, fines, convictions, confiscations, refunds and any pecuniary sanctions imposed for breaches of this Code against their bodies or its agents. The same is true of the members of all trade associations without legal

	personality, where the infringement was committed by a partner, manager or employee on a transaction falling within the scope of the Association's activities. The shareholder liable is, however, personally bound up to the limit of the amounts of money or securities that it has withdrawn from the operation. These companies, associations and members may be summoned directly before the criminal court by the public prosecutor or plaintiff. Art. XV.74. Upon expiry of a period of ten days from delivery, the Registrar of the Court or the Court must be free of charge to the Minister, by ordinary letter or electronically, a judgment applying a provision of this book.
Bulgaria	Chapter Six ADMINISTRATIVE PENAL PROVISIONS (Bulgarian Law on Technical Requirements to Products) Art. 50. (amended — SG No 93 of 2002, SG No 45 of 2005, SG No 86 of 2007) any person that violates the provisions of Articles 3 or 4 shall be punishable by a fine of BGN 1000 to 5000 or a financial penalty of BGN 5000 to BGN 15 000. Art. 51. (amended — SG No 93 of 2002, SG No 86 of 2007) a person who draws up and/or used a declaration of compliance with content which does not comply with the content defined in the Regulations referred to in Articles 7 and/or the implementing measures referred to in Article 26a or with new approach Directives shall be punishable by a fine of BGN 300 to 1000 or a financial penalty of BGN 1000 to 5000 if the act is not an offence. Article 51a. (New — SG No 93 of 2002, amended in SG No 45 of 2005) any person who places on the market and/or puts into service products with conformity marking in breach of the Regulation referred to in Article 24 shall be punishable by a fine of BGN 300 to 800 or a financial penalty of BGN 500 to BGN 1000. Article 51b. (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, supplemented in SG No 86 of 2007) any person who places on the market and/or puts into service products with conformity marking and supplementary marking or declaration of conformity without having assessed their compliance with the essential requirements laid down in the Regulations referred to in Articles 7 and/or with the eco-design requirements laid down in implementing measures under Article 26a, shall be liable to a fine of BGN 3000 to 8000 or a financial penalty of BGN 5000 to BGN 10 000. Article 51c. (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, supplemented in SG No 86 of 2007) any person who places on the market and/or puts into service products without marking, without

	additional markings or without declaration of conformity, when requested, under the provisions of Article 7 and/or with the eco-design requirements laid down in implementing measures under Article 26a, shall be liable to a fine of BGN 500 to 800 or a financial penalty of BGN 1500 to BGN 3000. Article 51d. (New — SG No 86 of 2007, amended in SG No 38 of 2011) any person who places on the market and/or puts into service products marked contrary to the requirements of Regulation (EC) No 106/2008 of the European Parliament and of the Council of 15 January 2008 on a Community programme for labelling the energy efficiency of office equipment (OJ L 39/1 of 13 February 2008) shall be punishable by a fine of BGN 3000 to 8000 or a financial penalty of BGN 5000 to BGN 10 000. Art. 52. (amended — SG No 93 of 2002, SG No 45 of 2005, SG No 86 of 2007) any person that fails to fulfil its obligations under Articles 25 or 26, paragraph 1 or 2 shall be punishable by a fine of BGN 500 to 1000 or a financial penalty of BGN 5000 to BGN 10 000. Article 52a. (New — SG No 93 of 2002, amended in SG No 45 of 2005, SG No 86 of 2007) any person who places on the market and/or puts into service products without indicated on them the name and/or its head office or without instruction and/or instruction for use in Bulgarian shall be punishable by a fine of BGN 200 to 500 or a financial penalty of BGN 500 to BGN 2000. Article 52b. (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, amended in SG No 86 of 2007) a trader who makes products without conformity marking or without additional marking, when such marking is required in the Regulations referred to in Articles 7 and/or the implementing measures referred to in Article 26a, shall be liable to a fine or penalty payment of BGN 250-1000 Article 52c. (New — SG No 93 of 2002, amended in SG No 45 of 2005, amended and supplemented in SG No 86 of 2007) a trader who makes products without declaration of conformity, when requested, under the provisions of Article 7 and/or implementing measures under Article 26a, shall be liable to a fine or penalty payment of BGN 250-1000 Article 52d. (New — SG No 93 of 2002, amended in SG No 45 of 2005, SG No 86 of 2007) a trader who makes products without indication of name or address of management to the person who places on the market and/or put into service is punishable by a fine or penalty payment of BGN 250-1000 Article 52e. (New — SG No 93 of 2002, amended in SG No 45 of 2005, SG No 86 of 2007) a trader who makes products without instruction and/or instruction for use in Bulgarian, shall be liable to a fine or penalty payment of BGN 250-1000 Article 52f. (New — SG No 86 of 2007, amended in SG No 38 of 2011) a

	trader who makes products marked contrary to the requirements of Regulation (EC) No 106/2008 of the European Parliament and of the Council of 15 January 2008 on a Community programme for labelling the energy efficiency of office equipment, shall be punishable by a fine of BGN 250 or confiscation of property worth BGN 1000. Art. 53. (amended — SG No 93 of 2002, supplemented in SG No 45 of 2005, amended in SG No 86 of 2007, SG No 38 of 2011) for non-compliance or infringement of the compulsory rules referred to in Article 30a, paragraph 1, 2, 4 and 5 and Art. 30c, paragraph 1 shall be fined BGN 300 to 1000 or a financial penalty of BGN 1000 to BGN 5000. Article 53a. (New — SG No 86 of 2007) for other infringements of the provisions of Article 7 and/or implementing measures under Article 26a shall be punishable by a fine of BGN 300 to 1000 or a financial penalty of BGN 1000 to BGN 5000. Art. 54. Article 219. (1) (Amended — SG. — SG No 93 of 2002, SG No 45 of 2005, SG No 95 of 2005, amended and supplemented in SG No 86 of 2007) Statements establishing infringements under Articles 50, 51, 51a to 51d, 52, 52a to 52f, 53, 53a and 56 shall be drawn up by officials designated by the President of the State Agency for Metrological and Technical Surveillance. (2) (supplemented, — SG No 45 of 2005, amended in SG No 95 of 2005) the penalty decrees shall be issued by the State Agency for Metrological and Technical Surveillance or officials authorised by him. (3) (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, repealed in SG No 77 of 2012, in force since 9.10.2012). Art. 55. (1) (amended and supplemented. — SG No 93 of 2002) in breach of the provisions of Articles 36, 44, 46 paragraph 1, 1, 6 and 7 or paragraph 2 and of the coercive administrative measure referred to in Article 49, paragraph 1, natural persons are liable to a fine of BGL 500-10 000, and legal persons and sole traders, financial penalty in the same order. (2) (supplemented, — SG No 93 of 2002) for other breaches of Chapter Five of the law and its implementing regulations, the penalty shall be a fine or penalty payment of BGN 100 to BGN 2000. Art. 56. (Supplemented — SG No 86 of 2007) that prevents or does not provide the documents referred to in Art. 30 g (1) (4 market surveillance authorities and technical surveillance authorities to perform their duties is punishable by a fine of BGN 200 to 2000. Art. 57. Where breaches of this Law or its implementing regulations are committed by those serving equipment with increased risk, infringers may be deprived from the acquired competence for a period of one month to two

	years. Art. 58. (1) (supplemented, — SG No 45 of 2005) the infringements chapter 5 of law and its implementing provisions and infringements under Article 56 shall be established by an official report drawn up by the staff of the Directorate-General for Inspection for government technical supervision". Article 219. (2) (Amended — SG. — SG No 95 of 2005) the penalty decrees shall be issued by the State Agency for Metrological and Technical Surveillance or officials authorised by him. (3) (New — SG No 93 of 2002, repealed in SG No 77 of 2012, in force since 9.10.2012). Article 58a. (New — SG No 45 of 2005) (1) (amended, — SG No 86 of 2007) for the breach is ascertained in accordance with Article 14a or 14b be penalised by a financial penalty of BGN 600. (2) (New — SG No 86 of 2007) in the event of a repeated infringement under paragraph 1 shall be liable to a penalty or a fine of BGN 1000. Article 219. (3) (Amended — SG. — SG No 95 of 2005, former subparagraph 2, No 86 of 2007, amended in SG No 66 of 2013, in force as of 26.07.2013, SG No 66 of 2013, in force as of 26.07.2013) Statements establishing infringements under paragraphs 1 shall be drawn up by determined by the President of the State Agency for Metrological and Technical Supervision of the Minister of Investment Design, officials of the relevant administration. Penalty enactments shall be issued by the State Agency for Metrological and Technical Supervision of the Minister of investment design. Art. 59. The procedure for establishing infringements, issuing, appealing and implementing penalty enactments shall be as set out in the Administrative Infringements and Penalties Act. Article 59a. (New — SG No 86 of 2007) (1) Where the infringer does not arrive to drafting the Act on administrative violation by the control authorities, the act shall be sent immediately for service by the municipality or mayoralty of the registered office of the legal person or sole proprietor. They are obliged to notify the infringer with communication with acknowledgement of deposited Act and within 14 days from the date of receipt to be served. No show of the infringer this statement should be signed by an authorised officer of the municipality or mayoralty and will be forfeited. Upon return of the Act within two months is issued and shall enter into force from the date of issue. (2) The penal orders indicate that the fine or financial penalty imposed, as well as the costs for taking and testing of samples of products shall be payable to the bank account of the State Agency for Metrological and Technical

	Surveillance and serve as a formal reminder after their entry into force. (3) Where the infringer is not found at the address indicated in the service of infringement notices, or has left the country, or has indicated address only abroad, an order will be forfeited. It shall be considered effective two months as of its issue. (4) (Repealed. — SG No 38 of 2012, in force since 1.07.2012).
Croatia	1) A fine in the amount of 40,000 to 100,000 kunas shall be imposed on a legal person if: 1. In the production, transport, use, storage, and handling explosive substances do not take measures to protect the life and health of people, their property and the environment (Article 5, paragraph 1) 2. Do not bring the general act, does not draw up a plan of treatment or fails to comply with the plan and with the regulations (Article 5, paragraph 2 and 3) 3. Do not know all the people in her performing activities with respect to explosive substances with the measures specified in the bylaws or does not enable them to act in the event of an accident (Article 5, paragraph 4) 4. Do not provide a permanent physical or technical protection of facilities that provide services in production, transport and storage of explosive substances (Article 5, paragraph 5) 5. the loss or theft of explosives does not inform the nearest police station (Article 5, paragraph 7) 6. placed on the market and use of explosive substances for which no authorization was granted marketing authorization (Article 6) 7. perform professional tasks in the conformity assessment procedure without authority (Article 8), 8. let explosive substances by persons who do not meet the requirements for handling explosive substances (Article 11, paragraph 1) 9. start production of explosives without the approval of the Ministry and continues to perform production and the Ministry of her decision revoked approval for the production of explosives (Article 14, paragraph 1 and Article 17, paragraph 1) 10. produces explosives at the site without the permission of the Ministry (Article 16, paragraph 1) 11. explore new types of explosive materials without the authorization of the

	Ministry (Article 18) 12. deals with traffic of explosives without a permit from the Ministry (Article 21, paragraph 1) 13. if he sold explosives legal entity or tradesman without purchasing a license (Article 21, paragraph 3) 14. procure explosives without the permission of the police department (Article 22, paragraph 1) 15. running of public fireworks without the approval of the Ministry (Article 31, paragraph 2) 16. perform tasks blasting without the approval of the Ministry (Article 34, paragraph 1) 17. in the performance of mining does not take security measures to protect the life and health of people, their property and the environment (Article 35, paragraph 1) 18. running loud cracking without the permission of the Ministry (Article 41, paragraph 1) 19. improper and unprofessional destruction of explosive substances endangering the lives and health of people, their property and the environment (Article 43, paragraph 2) 20. without the approval of the Ministry or the police department set up a portable tank in a place where performs blasting (article 44, paragraph 3). (2) For the offenses referred to in paragraph 1 of this Article shall be punished with a fine of 5000 to 10,000 kuna and responsible persons in the legal person. (3) For the offenses referred to in paragraph 1 of this Article shall be punished with a fine of 40,000 to 100,000 kuna craftsman or other natural person. (4) For the offenses referred to in paragraph 1 of this Article made in the Magistrates Court will return with a fine legal entity or tradesman imposed a protective measure of prohibition of activity for up to a year. Article 53rd (1) A fine in the amount of 20,000 to 40,000 kunas shall be imposed on a legal person if: 1st Explosive Substances by persons who are not professionally trained but not controlled by trained personnel, or if not previously familiar with the hazards

	and safe method of work (Article 12, paragraph 2) 2. within eight days to notify the Ministry of the start or termination of approved activities with explosive substances or on status changes (Article 13) Third within eight days from the finality of the decision to revoke the authorization for the production of explosives does not submit to the Ministry all the records that must be governed by this Law (Article 17, paragraph 2) 4. Put on the market, transport or use of explosives that are not packaged in the original packaging tested and marked in the manner determined by the regulations on the transport of dangerous goods (Article 20, paragraph 1) and / or if the packaging does not contain the information referred to in Article 20, paragraph 2 of this Act, 5. Within eight days from the finality of the decision on the withdrawal of marketing authorizations of explosives does not submit to the Ministry all the records that must be governed by this Law (Article 21, paragraph 4) 6. procurement of explosive substances in quantities greater than currently available storage capacity (Article 23, paragraph 1) 7. sells explosives and not stay permit or authorization does not specify sales volumes of explosive substances (Article 24, paragraph 1) 8. at the latest 24 hours before the start of the use of explosives does not notify the local competent police department, where she used explosives outside the area police department that issued the approval for the acquisition (Article 24, paragraph 3) 9. Do not return unused explosive materials in the original wrapper in a warehouse or container or destroyed according to the manufacturer's instructions and destroys them so that endangers the life, health and safety of people and material goods and the environment (Article 25) 10. Use purchased explosive substances contrary to the provisions of Article 26, paragraph 1 of this Act, 11. holding larger amounts of pyrotechnic devices for entertainment class I and II. of prescribed in stores, kiosks, warehouses or other containers or mobile stores or sale of pyrotechnic devices for entertainment class I, contrary to the provisions of this Act (Article 29 and Article 30, paragraph 2), or if pyrotechnic articles holds in store windows (Article 30 . paragraph 3) 12. sale of pyrotechnical devices for entertainment class II. outside the approved store or stores of weapons and ammunition, selling these assets in the period from 2 January to 1 December and this means sales to persons under 18 years of age (Article 30, paragraph 1)

	13. within eight days from the finality of the decision to revoke the authorization to perform the public fireworks do not submit to the Ministry all the records that must be governed by this Law (Article 31, paragraph 5); 14. running public fireworks without the approval of the runtime issued by the police department or if you performed a public fireworks display fireworks that are not approved or do not comply with the prescribed conditions (Article 32, paragraphs 1, 2 and 3) 15. within eight days from the finality of the decision to revoke the authorization for the performance of mining does not submit to the Ministry all the records that must be governed by this Law (Article 34, paragraph 5) 16. does not make any plan for mining or if you allow the use of explosives contrary blasting plan (Article 35, paragraph 2) 17. perform blasting in a populated area or in the vicinity of the settlement of a previously not inform the competent police department or to inform the public through local mass media or legal persons that manage communal infrastructure (Article 35, paragraph 3) 18. business overhead blasting, blasting in demining, special mining or underground mining is done by persons who do not have permission for mining or for a particular type of mining (Article 36, 37 and 38) 19. Following the preparation of mining or ancillary tasks performed by a person who does not meet the prescribed conditions (Article 40 paragraph 1 and 2) 20. within eight days from the finality of the decision to revoke the authorization to perform loud shooting does not submit to the Ministry all the records that must be governed by this Law (Article 41, paragraph 4) 21. loud cracking performs more operators who are not capable of handling explosive substances (Article 42, paragraph 1) 22. without the permission of the police department running out shooting in a place where gather a larger number of persons (Article 42, paragraph 3) 23. unused explosive substances for which there are no conditions for storage is not returned to the supplier or destroyed or fails to report to the police department that issued the approval for the acquisition (Article 43, paragraph 1) 24. destroys explosives and does not inform the competent police department or if you through local media not inform the local population in cases when it is foreseen the emergence of strong detonations (Article 43, paragraph 3 and 4)

	25. does not keep proper registers (Article 46, paragraph 2 and 3) 26 does not implement the Inspector's decision (Article 50, paragraph 1 5, 6 and 7) 27. not keep registers referred to in Article 46, paragraph 2 of ten years and registers referred to in Article 46, paragraph 3 five years, 28. inspectors prevents the performance of the inspection supervision or does not provide the necessary data and information (Article 50, paragraph 3) 29.acts contrary to the security measures laid down in the regulations that the Minister of the Interior passes under the authority of this Act. (2) For the offenses referred to in paragraph 1 of this Article shall be punished with a fine of 4000 to 8000 kuna and responsible persons in the legal person. (3) For the offenses referred to in paragraph 1 of this Article shall be punished with a fine of 20,000 to 40,000 kunas craftsman or other natural person. (4) For the offenses referred to in paragraph 1 of this Article made in the Magistrates Court will return with a fine legal entity or tradesman imposed a protective measure of prohibition of activity for up to six months.
Cyprus	Any person who in any way - a) possesses, sells or attempts to sell or acquire pyrotechnic article in violation of the provisions of these Regulations b) affixes or has affixed to pyrotechnic any false marking or labelling or c) falsifies any documents or certificates are provided for in these Regulations commits an offense and, on conviction, is liable to imprisonment not exceeding five (5) years or to a fine not exceeding seventeen thousand euros (17,000 €) or to both such penalties.
Czech Republic	(8) An administrative offense shall be fined up a) 5,000,000 CZK, for an administrative offense under paragraph 1 point. b), c) or r), pursuant to paragraph 2 point. g) pursuant to paragraph 3. d) or to paragraph 4. and), b) 1,000,000 CZK, for an administrative offense under paragraph 1 point. d), i), j), s) and t) c) 500,000 CZK, for an administrative offense under paragraph 1 point. a), e), g), h), k), l), o), p) or q) pursuant to paragraph 2. b) i) j) k) l) m) n) o) or p),

	pursuant to paragraph 3. e), f), g), h), j) or k), pursuant to paragraph 4. b) or c) pursuant to paragraph 5. a), d) or f), d) 100 000 CZK, for an administrative offense under paragraph 1 point. f), m) or n), pursuant to paragraph 2 point. a), c), e), f) or h), according to paragraph 3 point. a), c) or i) or paragraph 5 point. b), c), e) or g) e) 50 000 CZK, for an administrative offense under paragraph 2 point. d) pursuant to paragraph 3. b) pursuant to paragraph 6 or paragraph 7.
Denmark	Penalty that: 1) contrary to § 6 paragraph. 1, § 7, paragraph. 1 pt. 1, 2 or 3, § 8 or § 9, no. 1, 2 or 3, making fireworks or other pyrotechnic articles available on the market 2) brings fireworks covered by § 10 paragraph. 1, no. 1-8 on the market or otherwise make available on the market, 3) fails to store documentation in accordance with § 20, 4) violates the prohibition issued pursuant to § 32 paragraph. 1 5) under leaves to comply with orders issued pursuant to § 32 paragraph. 2, on the withdrawal, recall or destruction of articles or 6) fails to comply with orders issued pursuant to § 32 paragraph. 3, to eliminate improper CE marking. PCS. 2. The penalty may, in aggravating circumstances, increase to imprisonment for up to 2 years if the infringement was committed intentionally or through gross negligence when the violation is: 1) caused significant damage to persons, property or the environment or the risk thereof, or 2) achieved or intended financial gain for himself or others, including savings. PCS. 3. If improper use of CE marking see. § 21 paragraph. 5 or § 22 paragraph. 1 is intentional or due to gross negligence and if the violation is achieved or was intended to achieve financial gain for himself or others, punished the CE marking to a fine, unless more severe punishment is prescribed under other legislation. PCS. 4. There can be imposed on companies. (Legal persons) under the rules of the Penal Code Chapter 5.
Estonia	Penalty payment rates: Failure to comply with the appropriate state official exercising supervision may apply substitutive enforcement or Substitute Enforcement and Penalty Payment Penalty Payment Act. The maximum

	penalty payment is generally 640 euros, the explosives sector operator for 2600 euros. Explosives and pyrotechnic products storage and use of non-compliance [RT I 2010, 31, 158- entered into force. 01.10.2010] (1) of the explosive or pyrotechnic product use or storage of non-compliance, as well as explosive or pyrotechnic product use the restrictions imposed for non-compliance - is punishable by a fine of up to 300 fine units. [RT I 2010, 31, 158- entered into force. 01.10.2010] (2) The same act, if committed by a legal person - is punishable by a fine of up to 3,200 euros. The use of explosive substances store and plants (1) explosive substances store or plants for the operation of the operating license is required - is punishable by a fine of up to 300 fine units. (2) The same act, if committed by a legal person - is punishable by a fine of up to 3,200 euros. Violation of requirements: (1) The project concerned the blasting for carrying out the blasting project is required - is punishable by a fine of up to 300 fine units. (2) The same act, if committed by a legal person - is punishable by a fine of up to 3,200 euros. For the non-compliance of the pyrotechnic article to Estonia for the Technical Surveillance Authority without prior notice, if such, notification is required, as well as explosive substances into the authorization to Estonia for a fine not exceeding 200 penalty units. [RT I, 07.12.2014, 1 entered into force. 01/01/2015] (2) The same act, if committed by a legal person - is punishable by a fine of up to 2,000 euros. [RT I 2010, 22, 108- entered into force. 01.01.2011] Failure to comply with the appropriate state official exercising supervision may apply substitutive enforcement or Substitute Enforcement and Penalty Payment Penalty Payment Act. The maximum penalty payment is generally 640 euros, the explosives sector operator for 2600 euros.
Finland	In addition to the penalty provisions of § 125 chemicals safety law the provisions of Chapter 44. § 11 Penal Code (FFS 39/1889) on penalties for violations of the rules on explosives goods are applied in the landscape. Although the provisions of Chapter 44. § 12 of the Criminal Code The penalty for careless handling of a dangerous chemicals or explosive or such product

	referred to in Chapter 5. Chemical Safety Act shall apply in the province. The penalty for the explosive offense of the Criminal Code provides for Chapter 44, § 11. Anyone who wilfully or negligently violates the obligation laid down in,: § 5 of this Act § 7-12: the manufacturer laid down in obligations, § 13: the importer provided for in obligations, § 14: distributor stipulated in obligations § 42-44, or by virtue of prohibition or order issued, shall be sentenced, unless the act is provided elsewhere more severe punishment, pyrotechnic articles for breaching the provisions of a fine. Administrative coercive measures: The Authority may reinforce a prohibition under this Act or a warrant under penalty of fine or commissioned by, or cessation, such as a periodic penalty payment on the law (1113/1990) provides. Violation of the Explosives Legislation: Anyone who wilfully or negligently contrary to this Act or pursuant to a provision violates 1) the operator 7 to 20, 26 or a 133, § general duties laid down in, 2) 23, 37, 58, 58 a or 58 b § authorization requirement laid down in this Act or the storage area provided for in, 3), 23, 24, 63, 79, 81, 91, 93, 94, 97, 101, 133 or § 134: 33 § reporting obligations laid down in, 4), 28, 30-32, 41-44 or 62 §: accidents laid down in the containment and prevention of obligation, or 98 §: set out in the notification of accidents, 5) § 46-49: the manufacture of the product referred to in, import or marketing of the obligation laid down in Chapter 5, or similar explosives on the 67-69 or The obligation laid down in, 6) 71 §: a § 69 regarding the use of fireworks obligations laid down in, 93 §: 91 § laid down in the quality control obligation in the manufacture and importation of fireworks to the operator responsible for the set obligations, or 94 or 94 a § provided the fireworks show organizer responsibilities and obligations, 7) 73 § concerning the import of explosives authorization requirement laid down in 74 § of the transfer of the obligation laid down in, 75 § transit of the obligation laid down in 77 § of the labelling obligation laid down in, for the use of 78 § provided for in the obligation, for the supply of 82, a 82, 83 or 83 a § the obligation laid down in, § 84 for the holding of the obligation laid down in 86 § of accounts: the obligation laid down in or on the disposal of § 88-90: the obligation laid down in, 8) § 38: audit obligation laid down in, § 53: installation laid down in or maintenance obligation, § 54: audit provided for in, repair or decommissioning obligation, § 55: in the installation, maintenance or operation of the inspection requirement laid down in § 103 or together provided the performance of the inspection tasks obliged, 9), 29, 39, 56, 61, 65, 81, 93, 94 or 112 § the appointment of the person responsible for the obligation or the person in charge of 29, 39, 56, 61, 65, 81 or 95 provided for in § Journal the obligations laid down, 10), 35 or 36 § concerning the storage of dangerous chemicals on or in storage 87 §: the obligation laid down in, 11), 25, 34, 36, 37, 55, 59, 63 66 § of the obligations laid down in or explosives storage , 70, 73, 79, 81, 91, 93, 94, 97 or 100 §: condition or restriction imposed under or 79, 81, 91 or 97 §: the prohibition imposed under 12) 83 §:

	the prohibition issued under or 92 §: order issued under or prohibition, 13), 106, 109 or § 111 of the prohibition imposed under or 105-108 or 110 § the obligation imposed under or 14) 117 or § 121 of the disclosure obligation laid down in shall be sentenced, unless a more severe penalty is provided for violation of the provisions of the explosive to a fine.
France	Is punishable by a fine for 5th class offenses fact of: - Hold or knowingly use a product not equipped conformity marking as provided for in Articles 4 and 5 or not provided with labelling in accordance with the provisions of Article 25; - Affix the conformity marking in violation of Article 22; - Present a public or use a pyrotechnic article at exhibitions, trade fairs and demonstrations for the marketing, without apparent and legible mark meeting the requirements defined by order of the Minister responsible for industrial safety; - Use a product made for research, development and testing without apparent and legible mark meeting the requirements defined by order of the Minister responsible for industrial safety; - Introduce several requests for conformity assessment with several organizations under the first paragraph of Article 15 for the same product; - Carry out handling operations, as defined in paragraph 5 of Article 28 or use products of categories 4, T2 and P2 mentioned in Article 13 without a training certificate or the authorization provided for in Article 28.
Germany	Penalties and fines rules § 39 Administrative offenses (1) An administrative offense who wilfully or negligently 1. contrary to § 3, paragraph 3 a note, correctly, completely or not there on time, 2. contrary to § 3, paragraph 4 an instruction manual does not, not correctly, completely, not in the prescribed manner or time, 3. contrary to § 6 paragraph 1 sentence 1 number 2 a name or contact address not do so correctly, fully or not timely install, 4. contrary to § 6 paragraph 4 sentence 1 the competent market surveillance authority does not do so correctly, complete or not informed in good time, 5. contrary to § 7 paragraph 1 in conjunction with Article 30 paragraph 5

	sentence 1 of the Regulation (EC) no. 765/2008 the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing (EEC) No. 339/93 (OJ. L 218, 13.8.2008, p 30) a marking, a Mark or inscription on a product installs, 6. contrary to § 7 paragraph 2 makes a product available on the market, 7. an ordinance pursuant to a) § 8 paragraph 1 sentence 2 No. 1 or No. 3 or § 34 paragraph 1 point 2, 4 or number 5 or b) § 8 paragraph 1 sentence 2 number 2 or § 34 paragraph 1 point 1 or an enforceable order based on such statutory ordinance to the extent that Ordinance for a specific offense to this fine provision refers, 8. an enforceable order pursuant 1 sentence 1 or sentence 2 a) § 11 paragraph, § 26 paragraph 2 sentence 2 No. 1 or No. 3 or § 37 paragraph 7 Sentence 2 contravenes or b) § 26 paragraph 2 sentence 2 No. 2, 4, 6 to 8 or 9 or paragraph 4 sentence 1 fails to comply, 9. contrary to § 22 paragraph 2 sentence 2 or paragraph 4 uses a called there signs or advertise it, 10. contrary to § 22 paragraph 3 a requirement of the plant number 1, 2, 3, 4, 7, 8, sentence 1, number 9, sentence 2 or Set 3 or number 10 is not observed, 11. contrary to § 22 paragraph 5 sentence 2 a test is not, not correctly, completely or on time documented, 12. contrary to § 28 paragraph 4 sentence 1 a measure does not condone or a market surveillance authority or does not support a proxy, 13. contrary to § 28 paragraph 4 sentence 2 fails to provide information, not correctly, completely or on time granted 14. contrary to § 36 sentence 1 makes a plant not or not timely available, a test is not allows a worker or a tool not or does not provide in time a claim does not, not correctly, completely or on time or makes a document does not or not timely submits 15. contrary to § 38 paragraph 1 sentence 2 in connection with § 22 paragraph 2 sentence 6 of the OSH Act a Measure does not tolerate,

	16. a directly applicable provision in acts of the European Community or the European Union infringes that a substance in a) point 8 letter b or b) the numbers 1 to 6, 8 letter a or the numbers 11 to 13 designated commandment or prohibition is in line, as far as an ordinance pursuant to paragraph 3 for a certain offense to this fine provision refers, or 17. a directly applicable provision in acts of the European Community or the European Union or an enforceable order based on such provision contravenes the content corresponds to a system of which the in a) number 7 letter a or b) number 7 letter b those provisions authorize, insofar an ordinance pursuant to paragraph 3 for a given fine offense to this fine provision refers. (2) The offense may in the cases of paragraph 1, paragraph 7 letter a, number 8 letter b, Number 9, 16 point a and point 17 letter a with a fine not exceeding one hundred thousand euros, in the other cases by a fine of up to ten thousand Euro will be punished. (3) The Federal Government is authorized, as far as the enforcement of acts of the European Community or the European Union is required by ordinance without the consent of Federal designate the offenses as an administrative offense under paragraph 1, point 16 and 17 can be punished. § 40 Penal provisions A prison sentence of up to one year or a fine is imposed on anyone who a in § 39 paragraph 1 point 7 Letter a, number 8 letter b, number 9, 16 letter a or number 17 letter a designated repeated intentional act persistently or life by such an intentional act or compromised health of another or foreign property of significant value.
Greece	1. Imposition of fines and the categorization of infringements. Any economic operator who in the capacity of the manufacturer, the authorized representative, the importer or distributor makes available on the Greek market of pyrotechnic articles falling within the scope of this in contravention of the provisions or impair control thereof, be punished by the competent authority market surveillance by a fine of 2,000 up to 50,000 euros, depending on the severity / gravity of the infringement and non-compliance in accordance with the categories in the following table. Regarding the amount of the fine takes into account the extent of non-compliance, risk and category of pyrotechnics, the status of the economic operator (manufacturer, importer, distributor) and the size of the company, the conditions under which it was committed or continues committed to the contrary, the volume of the available on the market of pyrotechnic articles, the specificities of the findings and their implications for public health and safety, any corrective actions and the subsequent compliance of the economic operator and preventing the control from the company's side and the degree of

	cooperation of the test with the IACs and competent service. These fines are per non-compliant product. If they committed simultaneously cross difference in offenses falling into the above categories A to C, the sum of duty fine cannot exceed the ceiling of 5,000 euros for all offenses falling covered only in A, 30,000 for all violations falling only in B and 50,000 for all infringements fall only in C. When committed violations that fall into more than one of the above categories A to C should only maximum level provided for the fine category. The fines imposed in category D individual for each offense separately. In any case the total fine for all breaches of the table above may not exceed EUR 50,000 per non-compliant type Pyrotechnic. In case of repetition offenders punished fined twice the original to a maximum of 50,000 per non-compliant pyrotechnic article. These fines imposed by reasoned decision of the head of the competent authority. The fine levied ensures and agree to the applicable provisions on public revenue, credited to the Special Account for Ministry of Development Agency Code: 35/110, OEM: 84 583, No. 234218/6 Bank of Greece IBAN GR 8601000230000000002312186 - who established and functions for similar purposes of supervision and control of electro-technical products - cash basis lists drawn up and sent by the authority to tax office the debtor, with restore this service a copy of the summary state attestation tax filled with the relevant certification practice. Said decision allowed the exercise reasoned appeal to the General Secretary Industry-General of the Ministry of Economy, Growth Development and Tourism within thirty (30) days from the notification to the person concerned, in accordance with legislation. *Table with fines (from 2.000 euros up to 50000 euros)*
Hungary	Administrative service fee for the procedure (1) issuing the license rate if a) the application of conformity assessment certification order is directed to authorize 270 970 forint, b) the application of conformity assessment aimed at checking the order of licensing of 270 970 forint (2) entitling the conformity assessment certification and conformity assessment checks to be authorized to carry out In case the procedure for 316 700 forint administrative service fee shall be paid. (3) The administrative service fee shall be paid to the National simultaneously with the submission of the application Police Hungarian State Treasury account number 10023002-01451715-00000000. administrative service fee (4) of paragraph (1) and (2) of the National Police includes revenue. (5) The administrative service fee with respect a) 1990 XCIII to charging on fees. § 28. Law (Duties in the future.) (2) available, b) rectification in the event of non-payment of fees in respect of ITV. 73 / A. § paragraph (1) available, c) the reimbursement of fees on ITV. (1) and (2), § 79, and ITV. f) g) of § 80 paragraph (1) available should be used.

Ireland	34. (1) A person who contravenes these Regulations (other than Part 4) commits an offence and is liable— (a) on summary conviction, to a class A fine, or (b) on conviction on indictment, to a fine not exceeding €50,000. (2) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent or connivance of, or to be attributable to any wilful neglect on the part of, any person, being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person, as well as the body corporate, commits an offence and shall be liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence. (3) Where the affairs of a body corporate are managed by its members, paragraph (1) applies in relation to the acts and defaults of a member in connection with his or her functions of management as if he or she were a director or manager of the body corporate. (4) An offence under these Regulations may be prosecuted summarily by the market surveillance authority. (5) Where a person is convicted of an offence under these Regulations, the court may order the forfeiture to the market surveillance authority of any pyrotechnic article to which the offence relates. (6) Where an order is made under paragraph (5), the market surveillance authority may for the purpose of giving effect to it seize and detain the pyrotechnic article where it has not already been seized under this Regulation. (7) If a person is convicted of an offence under these Regulations the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the prosecutor the costs and expenses, measured by the court, reasonably incurred by the prosecutor in relation to the investigation, detection and prosecution of the offence, including costs incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of employees, consultants and advisers.
Italy	Art. 33. Discipline sanctions 1. Unless the act constitutes a more serious crime, anyone who sells fireworks or other pyrotechnic products under fourteen years shall be punished by imprisonment from three months to one year and a fine of 2,000 euro to 20,000 euro. 2. Unless the act constitutes a more serious offense, anyone selling or delivery of fireworks and pyrotechnics F2 category of categories TI and PI under the age of eighteen or category F3 fireworks in violation of the obligations of

	identification and registration provided for in Article 55 of the text of public safety laws, approved by Royal decree 18 June 1931 n. 773, or in contravention of the legal authorization, it shall be punished with imprisonment from six months to two years and a fine of 20,000 euro to 200,000 euro. 3. Unless the act constitutes a more serious offense, anyone selling or delivery of fireworks of category F4 and professional pyrotechnics of T2 and P2 categories to persons and requirements referred to in 'Article 5, paragraph 2, or in violation of obligations of identification and registration provided or the requirements of the police licenses it shall be punished with imprisonment from six months to three years and a fine of 30,000 euro to 300,000 euro. 1. Unless the act constitutes a more serious offense, the violation of the prohibition laid down in 'Article 5, paragraph 8, shall be punished by imprisonment from one year to three years and a fine of 15,000 euro to 150,000 euro. 2. A police licenses for the production, trade, import and export, the products referred to in this Decree, as well as authorization to carry out the procedures for assessing the conformity of pyrotechnic articles referred to in Article 20, paragraph 1, they cannot be con-ceded, or if granted, may not be renewed, the organization lacking the requirements of Article 43 of the consolidated public safety laws, approved by Royal decree 18 June 1931 n. 773. 3. For violations referred to in this Article, with regard to police license holders referred to in paragraph 5, as well as the police license holders for the transport, storage, possession, and disposal of the products referred to in this decree, may be ordered police authorization suspended in accordance with Article 10 of the consolidated version of the laws on public order. In the most serious cases, or in case of relapse, it may be, also, ordered the revocation. 4. Unless the act constitutes a crime, failure to notify the prefect of Article 14 involves the application of administrative fine of 500 euro to 3,000 euro. 5. Unless the act constitutes a crime, the total omission regulations for affixing the labels on fireworks, still held, under this decree, involves the application of administrative fine of 200 euro to 700 euro for each piece labelled or not for each package is still intact, if the individual parts are not labelled in the same content. 6. Unless the act constitutes a crime, the penalty referred to in paragraph 6 applies also against anyone who holds, for its placing on the market, a product, or, if applicable, its smallest piece of packaging, which does not bear anyway: a) the 'CE-type' or a reference to the recognition under Article 53 of the consolidated text of public safety laws, approved by Royal Decree 18 June

	1931 n. 773; b) a reference to the award decision and the classification of the Ministry in-internal, if any; c) complete instructions for use, warnings and instructions for safe transport, as well as the expiration date, if any, and the year of production, written in Italian, in clear, easily readable; d) precise and unambiguous guidance on the essential elements for the identification of the manufacturer, importer, distributor and to trace the product, including the indication in grams of the NEC (net explosive content). 7. Against the entity that holds, for the placing on the market, a product on which were omitted, even partially, indications provided by law, other than those referred to in paragraph 8, applies an administrative sanction from 20 euro to 60 euro for each piece partially labelled. 8. Unless the act constitutes a crime, a violation of the prohibition of Article 19, paragraph 6, involves the application of administrative fine of 200 euro to 700 euro for each piece.
Latvia	Article 23. Responsibility for the pyrotechnic movement rules violation: For this Law and other statutory pyrotechnic movement rules of persons prosecuted in accordance with the law. Supplying an unsafe product can result in a fine of up to LVL 5,000 for each offence, and/or a term of imprisonment of up to three months. (http://www.ptac.gov.lv/en/content/product-safety-0)
Lithuania	Amendment of the Administrative Code (2014. 16 October. No. XII-1236) Non-admission or otherwise or the Weaponry Fund of the Republic of Lithuania under the Lithuanian Ministry of Internal Affairs officials to companies active in the manufacturing of weapons, their parts, ammunition, explosives, pyrotechnic products, businesses in the sex trade in explosives, weapons, explosives, weapons and ammunition for the repair of the processing of their documents, false information or concealment of documents, these officials also constitutes a legitimate requirements shall entail a fine on the managers of undertakings from seventy two and one hundred and forty four euros. The same acts committed by a person who has already received an administrative penalty for the infringements referred to in the first paragraph of this Article — shall attract a fine of between one hundred and forty four up to two hundred eighty nine euro.” Civil pyrotechnic means the production, import, export, transit, import, export, storage, trade, destruction, accounting of irregularity shall attract a fine of between fifty seven and one hundred and fifteen euros. The same acts

	committed by a person on whom an administrative penalty has already been imposed in respect of the infringement referred to in the first paragraph of this Article shall be subject to a fine from one hundred to two hundred forty four Euro and eighty nine civilian pyrotechnic devices, with or without confiscation. Civilian pyrotechnic devices whose placing on the market, storage, sale or use of which is restricted, making available on the market, possession, sale or use of non-respect of the restrictions shall attract a fine of eighty six and two hundred thirty one euro with the measures in question. Civilian pyrotechnic devices whose placing on the market, storage, sale or use is prohibited, the making available on the market, possession, sale or use of shall be subject to a fine from one hundred to two hundred forty four Euro and eighty nine of the confiscation. The same acts committed by a person who has already received an administrative penalty for the infringements referred to in the first and the second paragraph shall attract a fine of two hundred and eighty nine to five hundred seventy nine euros to the measures in question. The use of civil pyrotechnic means, in violation of the established procedure for the acquisition of shall attract a warning or a fine of between fourteen to twenty eight euro with or without confiscation of pyrotechnic devices. The same acts committed by a person on whom an administrative penalty has already been imposed in respect of the infringement referred to in the first paragraph of this Article shall attract a fine of between fifty seven euros and twenty eight civilian pyrotechnic devices, with or without confiscation. The first paragraph of this Article for an infringement committed from fourteen to sixteen years — shall attract a warning or a fine of parents or guardians (rūpintojams) from fourteen to twenty eight euro civilian pyrotechnic devices, with or without confiscation
Luxembourg	Art. 37. Sanctions: (1) shall apply administrative measures in the context of market surveillance referred to in Article 13 of the Law of 4 July 2014 reorganizing ILNAS. (2) The application of the administrative fines provided for in Article 17 of the Act of July 4, 2014 reorganizing ILNAS. (3) Criminal penalties are those laid down in Articles 18 and 19 of the Act of July 4, 2014 reorganizing ILNAS.
Malta	(1) The penalties applicable for the infringement of any of the provisions of these regulations shall be those provided for in Part IV of the Product Safety Act. Provided that, where it constitutes an offence punishable with a higher punishment under any other law, the higher punishment laid down in that law shall apply.

	(2) The necessary measures allowing the detainment of consignments of pyrotechnic articles that fail to comply with the provisions of these regulations shall be those under the Product Safety Act and the Ordinance. Product Safety Act – Part IV Fines. Amended by: L.N. 426 of 2007. 32. (1) A person found guilty of an offence under article 23 shall, on conviction, be liable to a fine (multa) of not less than four hundred and sixty-five euro and eighty-seven cents (465.87) and not exceeding two thousand and three hundred and twenty-nine euro and thirty-seven cents (2,329.37), or to imprisonment for a term not exceeding six months or to both such fine and imprisonment. (2) A person found guilty of any other offence under this Act shall be liable, on conviction, to a fine (multa) of not less than one thousand and one hundred and sixty-four euro and sixty-nine cents (1,164.69) but not exceeding eleven thousand and six hundred and f o r t y - six euro and eighty-seven cents (11,646.87) or to imprisonment for a term not exceeding three years or to both such fine and imprisonment. (3) A person found guilty of a second or subsequent offence shall, on conviction, be liable to a fine (multa) of not less than one thousand and seven hundred and forty-seven euro and three cents (1,747.03) but not exceeding twenty-three thousand and two hundred and ninety-three euro and seventy-three cents (23,293.73) or to imprisonment not exceeding four years or to both such fine and imprisonment. (4) The Court may, upon conviction for any offence committed under this Act, with the exception of offences committed under article 23, if it feels that circumstances so warrant, additionally order the suspension or cancellation of any licence or licences issued in favour of the person charged or in respect of the premises involved in the proceedings. (5) Without prejudice to the generality of the foregoing, any person convicted in relation to an offence under articles 26 or 29 shall additionally be liable to the additional fine (multa) of not more than four hundred and sixty-five euro and eighty-seven cents (465.87) for each day that a notice or undertaking has not been complied with.
Netherlands	Economic Offences Act Title II. Of penalties and measures Article 5 Unless otherwise provided by law, may in respect of economic offenses to impose no other arrangements are made with the purpose of punishment or disciplinary measure than the penalties and measures in accordance with this

	law. Article 6 1 He who commits an economic offense, shall be punished: 1 °. in the case of crime, as far as an economic offense referred to in Article 1, under 1 or in Article 1a, under 1, with imprisonment not exceeding six years, community service or a fine of the fifth category; 2 °. in case of another crime with imprisonment not exceeding two years, community service or a fine of the fourth category; 3 °. if he commit the offense referred to under 2 ° has made a habit of imprisonment not exceeding four years, community service or a fine of the fifth category; 4 °. in case of violation, as far as an economic offense referred to in Article 1, under 1 or in Article 1a, under 1, with imprisonment not exceeding one year, community service or a fine of the fourth category; 5 °. in the case of any other offense, with imprisonment not exceeding six months, community service or a fine of the fourth category. If the value of the goods with which or with respect to which the economic offense was committed, or wholly or partly obtained by means of the economic offense, exceeds the fourth of the maximum of the fine that in the cases under 1 to 5 ° may be imposed, may, without prejudice to Article 23, paragraph, of the Criminal Code, be fined in the next higher category. 2 Moreover, the additional penalties may, under Article 7, and the measures mentioned in Article 8 imposed, without prejudice to the imposition, in the next cases previously considered, the measures provided elsewhere in law. 3 Notwithstanding the provisions in the first and second paragraph it is that a provision laid down in Article 15, second paragraph, of the Distribution Act, violates punished with imprisonment not exceeding two months or a fine of the first category. 4 Notwithstanding the provisions of paragraph he who violates a regulation laid down by or under Articles 2 and 3, first paragraph, of the Chemical Weapons Convention, Article 3, first and second paragraph of the Law precursors explosives, or articles 2, first and third paragraphs 3 and 4 of the biological weapons Convention, shall be punished with imprisonment not exceeding eight years or a fine of the fifth category, if the offense was intentionally committed with a terrorist intent as provided Article 83a of the Penal Code, or with the objective of preparing or facilitating a terrorist crime under Article 83 of the Code.

	Article 7 The additional penalties are: a. deprivation of the rights mentioned in Article 28, first paragraph, under 1 °, 2 °, 4 ° and 5 ° of the Criminal Code, for a time, the term of imprisonment of at least six months and at most six years exceeding, or in the case of conviction to fines as the sole principal punishment for a period of at least six months and a maximum of six years; b. [Red: expired;] c. total or partial closure of the undertaking of the offender, which the economic offense was committed, for a period not exceeding one year; d. forfeiture of the objects referred to in Article 33a of the Penal Code; e. confiscation of property belonging to the company of the convicted person, in which the economic offense was committed, to the extent that they are similar to and related to keeping the offense related to those mentioned in Article 33a of the Penal Code; f. total or partial withdrawal of certain rights or full or partial denial of certain benefits, the rights or benefits the offender or may be granted in connection with his undertaking by the government, for a period not exceeding two years; g. publication of the court decision. Article 8 Measures include: A. The measures provided for in Title IIA of the First Book of the Penal Code; b. receivership of the company of the offender, which the economic offense was committed, in the case of crime for a period not exceeding three years and in case of violation for a period not exceeding two years; c. imposing the obligation to provision of what is left illegally, negation of what has been done illegally and provision of services to the make up of the foregoing, all at the expense of the convicted person, as far as the court decides otherwise. Article 9 The measures set out in Article 8, b and c, can together with penalties to be imposed by other measures.

	Article 10 1 The ruling, in which an additional penalty or a measure, as stated in Article 8, is imposed shall, so far as necessary, all the details and consequences arranged as needed, including in receivership appointing one or more administrators. By imposing an additional penalty as stated in Article 7, c, can also be ordered that the convicted him by the government on behalf of his company provided modest surrenders; sells his company stocks under supervision; and cooperates in identifying those stocks. 2 Subject to the provisions of Article 577b of the Code of Criminal Procedure, the court which imposed the additional sentence or order, after receipt of an application by the public prosecutor or at the request of the offender in subsequent decision still lay down rules as referred to above, then or in the lead already given regime change or add any relevant supplementary scheme. The proceedings take place in camera; the ruling is made in public. The decision is supported by reasons; it is not subject to any appeal. 3 We reserve before, giving detailed rules for implementing this article. Article 11 If the court does not decide otherwise, a receiver appointed under the preceding Article or Article 29, the same rights and obligations as the administrator referred to in section 409 of Book 1 of the Civil Code, and to any other person without his authorization perform any act of management in the company. 2 The decision under administration by the clerk of the court at first instance that the given decision, published in the Dutch Government Gazette and in one or more by the court to appoint newspapers. The decision receivership is registered in the commercial register pursuant to the provisions under the Trade Register Act 2007. Article 12 [repealed on 01-05-1983] Article 13 1 The right to carry out confiscation does not expire by the death of the condemned. 2 The measure referred to in Article 8 b lapses by the death of the condemned. Article 14 The implementation of an order for the payment of costs, other than that of publication of the judgment made on the manner of implementation exhilarating conviction to a fine, provided that is applied no substitute

	imprisonment. Article 15 [repealed on 01-09-1976]
Poland	Art. 88. The manufacturer or importer or installer that the market or puts into service nonconforming product requirements, is subject to a fine of up to 100 000 zł. Art. 89. The manufacturer or importer or installer that the market or puts into service the product under CE marking, and in the case of measuring instruments also additional labelling or distributor who provides the market a product without this marking is subject to a fine of up to 20 000 zł. Art. 90. 1. The manufacturer or the installer of the product on the market or put into use, which does not comply obligations attaching to the product prepared in a clear, understandable and comprehensible form, in Polish: 1) instruction or 2) information regarding the safety or 3) a copy of the declaration of conformity or label - Subject to a fine of up to 10 000 zł. 2. The manufacturer or installer of the product on the market or put into use, which does not fulfil the obligations in relation to the attachment to the product: 1) information enabling their identification, made in Polish or 2) information allowing identification of the product - Subject to a fine of up to 10 000 zł. Art. 91. The importer of the product on the market or put into use, which does not fulfil the obligations in terms of: 1) ensure that attach to a product made in a clear, understandable and comprehensible form, in Polish: a) instructions or b) information regarding the safety or c) the label, or 2) ensure that attach to the product information to enable identification of the

	product or 3) placed on the product information that will enable him to be identified, prepared in Polish or 4) ensure connection to the product, if applicable, a copy of the declaration of conformity and other documents - Subject to a fine of up to 10 000 zł. Art. 92. The manufacturer or installer that fails to prepare and keep the technical documentation product, the declaration of compliance and documentation necessary to demonstrate the conformity of the product, be fined up to 10 000 zł. Art. 93. The importer who fails to store a copy of the declaration of conformity or the obligation to ensure share market supervisory authority of the technical documentation shall be subject to a fine of up to 10 000 zł. Art. 94. An authorized representative who does not fulfil the obligations in respect of: 1) keep the technical documentation, declaration of conformity and documentation necessary to demonstrate compliance or 2) granting authority to the market surveillance information and documentation in Polish to show product compliance with the requirements of - Subject to a fine of up to 10 000 zł. Art. 95. The operator and entrepreneur who is a user of the product, which prevents or hinders authority to carry out market surveillance checks referred to in Article. 64 paragraph. 1, Art. 82 paragraph. 4 or art. 84 para. 8, subject to a fine of up to 30 000 zł. Art. 96. Controlled who: 1) destroy the control sample, or 2) remove it from the security, or 3) prevents the examination of this sample, or 4) keep it in breach of the conditions laid down in Article. 72 paragraph. 4 - Subject to a fine of up to 30 000 zł. Art. 97. 1. Fines referred to in Article. 88-94, impose, by decision, the market

	surveillance authority lead the procedure referred to in Article. 76 paragraph. 1 or art. 85 paragraph. 1. 2. The fines referred to in Article. 95 and Art. 96, impose, by decision, the market surveillance authority lead control and, in the case of checks by market surveillance authority referred to in Article. 58 paragraph. 2, point 2, district labour inspector. 3. When determining the amount of fines, the market surveillance authority shall take into account in particular: 1) the degree and circumstances of the breach of the Act; 2) the number of non-conforming with the requirements placed on the market, put into use or made available on the market; 3) prior violation of the law; 4) cooperation with the regulatory authority conducting an investigation, referred to in art. 76 paragraph. 1 or art. 85 paragraph. 1 in particular to contribute to the rapid and efficient conduct of the proceedings. 4. The market surveillance authority withdraws from imposing a financial penalty if the trader, punishable, He presented evidence of the execution of the provisions referred to in Article. 82 paragraph. 1. Art. 98. 1. The deadline for payment of the penalty payment is 30 days from the day when the decision becomes final. 2. The fine shall be paid into the bank account market surveillance authority, which it imposed. 3. Do not initiated proceedings on the imposition of a fine, if the date of the offense, which referred to in Article. 88-96, 3 years have elapsed from the end of the year in which the act was committed. 4. Financial penalties shall not be collected after 3 years from the date of the final decision to impose a penalty. 5. Funds from fines shall constitute the revenue of the state budget. 6. fines, not covered in the law, the provisions of Section III of the Act of 29 August 1997. - Tax Ordinance. 7. Fines are subject to execution under the provisions on administrative enforcement proceedings in the field execution of financial obligations

Portugal	1 - It is punishable administrative offense, to a fine from € 1,850 to € 3,740 if the offender is a natural person and € 5,550 to € 44,890 if the offender is legal person: a) Violation of the age limit for availability, provided for in paragraphs 1 to 3 of Article 7; b) Breach of the obligations of economic operators provided for in Articles 8, 9, 10, 11, 12, 13, 14 and 15; c) Violation of the requirements for the EU statement compliance provided for in Article 18; d) Violation of the rules and conditions for affixing CE marking and other markings provided for in Article 20; e) Violation of the rules pertaining to subsidiaries and subcontractors of notified bodies, provided in Article 26; f) Breach of the proper discharge of official duties of the notified bodies referred to in Article 27; g) Violation of the obligation of bodies notified under paragraph 1 of Article 28; h) Violation of rules for the accreditation of people with expertise and available beyond established limits, provided for in specific regulations. 2 - The use of pyrotechnic articles violation the provisions contained in the respective labels or technical standard governing such use, particularly on the location, use or failure the minimum distances required security, is administrative offense punishable with a fine of: a) From € 125 to € 875, in the case of fireworks F1 category; b) € 250 to € 1,750, in the case of category F2; c) € 500 to € 3,500, in the case of category F3; d) From € 1,500 to € 3,740, in the case of F4 category; e) € 250 to € 1,750, in the case of articles Pyrotechnics T1 category; f) € 1500-3740, in the case of articles Pyrotechnics T2 category; category P1; h) From € 1,500 to € 3,740, in the case of articles Pyrotechnics category P2. 3 - If a more severe penalty does not punish such violations, possession,

	transport and storage of pyrotechnic articles in breach of the provisions contained in regulations to this ordinance, it is administrative offense punishable by a fine of: a) From € 125 to € 875, in the case of fireworks F1 category; b) € 250 to € 1,750, in the case of category F2; c) € 500 to € 3,500, in the case of category F3; d) From € 1,500 to € 3,740, in the case of the F4 category; e) € 250 to € 1,750, in the case of articles Pyrotechnics T1 category; f) From € 250 to € 1,750, in the case of articles Pyrotechnics category P1. 4 - At offenses provided for in Article 19 apply –If provisions of Article 6 of the Decree-Law No. 23/2011, February 11, implementing the national legal system Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008. 5 - Negligence is punishable, and the minimum limits and maximum fines halved. 6 - The attempt is punishable by the fine for administrative offense consummated, mitigated.
Romania	(1) In as follows: a) non-compliance with art. 10 para. (1), Art. 20, art. 22 and art. 57; b) Violation of art. 16; c) Violation of art. 24, art. 25, art. 26, art. 27 para. (1), Art. 28; d) Violation of art. 39-47; e) Violation of art. 49-52; f) Violation of art. 59; g) Violation of art. 62-65; h) Violation of art. 29 para. (1), Art. 30; i) non-compliance with art. 54-55.

	(2) The provisions of par. (1) shall be sanctioned as follows: a) those referred to a) with a fine of 8.000 to 10.000 lei, withdrawal from the market and prohibit the making available on the market; b) those in point b) a fine from 2,000 lei to 3,000 lei and confiscation of pyrotechnic articles; c) those in point c), f) and g), a fine of 4,000 lei 8,000 lei and prohibition to provide marketing or marketing; d) those referred to d), h), i), with a fine of 2,000 lei 4,000 lei and prohibition to provide marketing or marketing; e) those in point e) with a fine from 500 lei to 1,000 lei and prohibition to make available on the market of pyrotechnic articles without marking of conformity or incorrect marking. (3) The contraventions and penalties are as follows: a) by the authorized staff of the Labour Inspection, for the offenses referred to in para. (1) a) and c) -i); b) the officers and agents of the Romanian Police, for offenses in para. (1) b).
Slovakia	The supervisory authority, the manufacturer, importer or distributor fine for breach of the obligations set in this Government Regulation under special regulations. (§ 32 of Act no. 264/1999 Coll. § 24 Act no. 250/2007 Coll. consumer protection and the amendment of the Slovak National Council. 372/1990 Coll. on offenses as amended, as amended.) § 32 of Act no. 264/1999 - Fines (1) The surveillance body shall inflict a fine of up to a 5 000 000. - Slovak Crowns (SKK) on anyone who: a) has used the conformity mark or certificate or declaration of conformity illegally or deceptively, b) has placed on the market or distributed determined product without declaration of conformity under § 10 sub-paragraph 4, without certificate of conformity or without the prescribed marking of products with the Slovak conformity mark under § 17 sub-paragraph 3, or has placed the product on the market without authority. c) has failed to comply with the decision on protective measure.

	(2) The Office shall, based on an initiative from outside or on its own findings, inflict a fine of up to 1 000 000. - Slovak Crowns on anyone who without authority: a) has used on the document the denomination "STN", b) has duplicated or distributed a Slovak technical standard, c) has declared himself as an authorised body, d) has issued a certificate. (3) The Ministry of Economy shall, based on an initiative or on its own findings, inflict a fine of up to 1 000. - Slovak Crowns on anyone who has declared himself without authority as an accreditation body or an body for which accreditation certificate has been issued, or failed to return the accreditation certificate (§ 27 sub-paragraph 5). (4) In case of repeated unlawful action there can be inflicted a fine under sub-paragraphs 1 -3 up to the double of inflicted fine. (5) In the process of the infliction of fines there shall be taken into account the price of the product, seriousness, way, duration and consequences of the unlawful action. (6) The fine may be inflicted within one year from the date the body authorised for infliction of fines has learned about the breach of duty, but not later than three years from the date on which such breach of duty has occurred. (7) The fine shall be payable within 30 days from the date of maturity of the decision on the infliction of the fine. (8) The money received from fines is the income of the state budget. §23 act no. 250/2007 Offences (1) Anyone who harms consumer rights by having acted in breach of this Act or separate consumer protection regulations26) is deemed to have committed a offence. (2) A fine up to the amount of SKK 10,000 may be imposed for the offence referred to in paragraph 1. (3) A general regulation on offences shall apply to offences under this Act and related proceedings.27) (4) Revenues from the fines imposed by a municipal authority for committed

	offences constitute revenues of the municipal budget. §24 act no. 250/2007 Sanctions (1) Where the obligations laid down in this Act or in European Community consumer protection laws28) are breached, the supervisory authority shall fine the producer, trader, importer or supplier or the person referred to in §26 up to SKK2,000,000; where the breach recurs within 12 months the authority shall impose a fine up to SKK5,000,000. (2) The supervisory authority shall impose a fine up to SKK10,000,000 upon the producer, trader, importer, supplier or the person referred to in §26 who had produced, sold, imported or supplied a product whose defect caused damage to life or health. The identical fine shall be imposed upon anyone who caused such damage by defective delivery of a service. The fine may not be imposed upon persons who demonstrate that they could not have avoided such damage despite having exerted all effort which could reasonably be expected. (3) A disciplinary fine up to SKK50,000 shall be imposed by the supervisory authority upon the producer, trader, importer and supplier or the person referred to in §26 who mars, thwarts or otherwise hinders the performance of supervisory activities or who, as the case might be, fails to meet the binding instruction referred to in §20(3)(h); the fine may be imposed repeatedly. (4) The fine referred to in paragraph 1 shall not be imposed where a fine under a separate regulation was imposed, or if the fine referred to in paragraph 2 may be imposed. (5) When determining the amount of the fine, an account shall be taken of the nature of the unlawful conduct, gravity of the breach of an obligation and the method and consequences of the breach. (6) Revenues from the fines imposed pursuant to paragraph 1 through 3 constitute revenues of the state budget. (7) The fine may be imposed within one year from the day when the supervisory authority ascertained the breach of an obligation under this Act, however no later than within three years for fines set out in paragraphs 1 and 3 and, for fines set out in paragraph 3, no later than within ten years from the day on which such breach occurred.
Slovenia	8. PENALTY PROVISIONS Article 46 (1) A fine of 5,000 to 50,000 euros shall be imposed on a legal person:

	1. In performing transport explosives or pyrotechnic articles as well as the implementation of fireworks does not ensure the security of persons and property, fire protection, and does not carry out any other measures specified in the regulations issued under this Act (first paragraph of Article 6); 2. carry out the production or transport explosives or pyrotechnic articles without the permission of the Ministry or the competent authority (the first paragraph of Article 9); 3. to change the activity does not obtain a new license (fourth paragraph of Article 9); 4. manufactured, sold or stored explosives or pyrotechnic articles in premises which are not properly constructed or equipped or not secured against access by unauthorized persons (first and third paragraphs of Article 14); 5. preparing explosives on site without specialized equipment or permission of the Ministry (Article 16); 6. allow the explosives destroys a person who is not qualified (first paragraph of Article 19); 7. In case of destruction of explosives, acts contrary to the manufacturer's instructions or destroys explosives in places where this is not allowed in the destruction of not ensuring the safety not destroys or unstable explosive individually (Article 19); 8. research for the development of new types of explosives does not provide the technical and safety measures (first paragraph of Article 20); 9. act contrary to the obligations of the manufacturer, importer or distributor (20a, Article 20.b and 20.c); 10 placed explosives or pyrotechnic articles which do not have the CE marking or has incorrectly CE-marked or do not meet safety requirements (first paragraph of Article 21); 11 placed explosives or pyrotechnic pre-notification ministry or the ministry before it issues a certificate of notification (second paragraph of Article 21); 12 on the market, download or use of explosives that are not in original packaging or it does not contain all the prescribed data (Article 23); 13 in the market of pyrotechnic articles that are not properly labelled or label does not contain all the prescribed data (Article 24); 14. purchases or transfers of explosives or pyrotechnic articles without the appropriate permit (first paragraph of Article 26);

	15. The use of explosives in contradiction with the purposes or in other places, as set out in the authorization for the purchase and transfer (first paragraph of Article 28); 16 in the implementation of fireworks is not implemented security measures listed in the study or carry fireworks without a study (second paragraph of Article 28); 17 performs transmission to the European Union, import, export or transit of explosives or pyrotechnic articles or ammunition without the permission of the ministry or does not comply with specific safety measures specified in the license (first and third paragraphs of Article 31); 18 types of pyrotechnic articles not in the appropriate category depending on the purpose level of hazard and the level of noise (Article 33); 19. enable the purchase of pyrotechnic articles in categories F3, F4, P2 and T2 to a person who does not have the appropriate license or purchase batteries from category F3 to 1000 g net weight of explosive substances and fountains from category F3 to 750 g net weight of explosives in a single physical product a person who is not yet 18 years old or selling fireworks of category F2 and F3, where an explosion (third and fifth paragraphs of Article 35); 20 individuals selling other pyrotechnic articles of category P1 for vehicles, including airbags and belt tensioners, unless they are mounted on the vehicle or detachable part of the vehicle (eighth paragraph of Article 35); 21. Despite the order of the inspector of the withdrawal or recall of an explosive or pyrotechnic product continues to allow its availability on the market (Article 37.a and 37.b); 22. Despite the order of the inspector makes an explosive or pyrotechnic product on the market, which represents a risk to the health or safety of persons or property or the environment (Article 37.c). (2) A fine of EUR 2,000 to EUR 20,000 shall be imposed on an entrepreneur who commits an offense referred to in the preceding paragraph. (3) A fine of 400 to 4,000 euros for an offense from the first paragraph of this Article shall be imposed on the responsible person of the legal entity or entrepreneur. (4) For the offenses referred to in Articles 1, 2, 4, 5, 7, 8, 9, 10, 11, 13, 14, 15 and 16 of the first paragraph of this Article imposed a side sanction the withdrawal of explosives or fireworks. Side sanction shall be imposed even if the products are not owned by the perpetrator. Article 47

	(1) A fine of 3,000 to 15,000 euros shall be imposed on a legal person: 1. does not prepare a management plan in case of accident or other incident (the second paragraph of Article 6); 2. fails to inform people that it engaged in individual work with explosives or pyrotechnic articles with the measures laid down in the general rules and specific plan (third paragraph of Article 6); 3. the loss or theft of explosives or pyrotechnic not informed immediately or within 12 hours of the nearest police station (sixth paragraph of Article 6); 4. do not take into account the additional permit conditions (second paragraph of Article 9); 5. Within eight days does not inform the competent authority or the ministry of the status change, the change in the responsible person or the cessation of activities (third paragraph of Article 9); 6. authorized to carry out the production or transport explosives or pyrotechnic articles a person who does not satisfy the personal conditions (Article 10); 7. not immediately return unused explosives or returned to the seller refuses to accept explosives (fourth paragraph of Article 19); 8. exhibits at fairs or exhibitions or presentations perform for the marketing of pyrotechnic products, which are not adequately labelled or carry out a presentation for marketing without the permission of the competent authority (third and fourth paragraphs of Article 24); 9. Within eight days after the expiration does not return the permission to purchase and transfer of explosives or pyrotechnic products in the Republic of Slovenia (second paragraph of Article 26); 10 not ensure that the authorization for the purchase and transfer of explosives or pyrotechnic products in the Republic of Slovenia during the transport in addition to explosives or pyrotechnic articles (third paragraph of Article 26); 11 sold gunpowder, primers or tubes with primers person who has a valid arms license and a certificate for charging ammunition for its own purposes or sell the black powder to a person who is not authorized by the competent authority (Article 30); 12 not ensure that the authorization for the transfer, import, export or transit throughout transport in addition to explosives, pyrotechnic articles or ammunition (fourth paragraph of Article 31); 13. does not consider age limits for selling pyrotechnic articles (first paragraph

	of Article 35); 14 sell fireworks F1 category, where an explosion outside the allowable time (sixth paragraph of Article 35); 15. does not keep prescribed records are not kept in the prescribed manner, information is not held by the prescribed time does not allow access, inspect and search the data or not allow access to the records outside normal working hours (Article 45); 16. The placing on the market of pyrotechnic articles which have been withdrawn consent to the instructions for the safe use or pyrotechnic articles, which have a temporary certificate of notification or within the prescribed period is not harmonized indications of pyrotechnic articles which are intended for sale or sold within this period contrary to Article 35 (Article 51). (2) A fine of 1,000 to 3,000 euros shall be imposed on an entrepreneur who commits an offense referred to in the preceding paragraph. (3) A fine of 400 to 1,500 euros for an offense from the first paragraph of this Article shall be imposed on the responsible person of the legal entity or entrepreneur. Article 48 (1) A fine of 400 to 1,200 shall be imposed on an individual or natural person who: 1. carry out individual work with explosives or pyrotechnic articles or carry fireworks and the work is not carried out measures for each type of work set out in this Act and regulations issued pursuant to this Law (paragraph 4 of Article 6); 2. is engaged in research for the development of new types of explosives or experimenting with making the already known types of explosives (second paragraph of Article 20); 3. The driver on the officer's request does not indicate authorization for the purchase and transfer of explosives or pyrotechnic articles (third paragraph of Article 26); 4. possession of gunpowder, primers or tubes with primers without a valid arms license and a certificate for charging ammunition for their own use or possession of black powder without the permission of the competent authority (Article 30); 5. driver to a police officer or request does not indicate transfer license in the European Union, import, export or transit (fourth paragraph of Article 31);

	6. sale, purchase, possession or use of fireworks which are intended only for legal persons or entrepreneurs who have the appropriate license or fireworks of category F2 and F3, where an explosion, or be permitted to use the battery from category F3 to 1000 g net mass of explosive substances and fountains from category F3 to 750 g net weight of explosives in a single product a natural person who is not yet 18 years old (third and fifth paragraphs of Article 35); 7. uses fireworks F1 category, where an explosion in places where their use is prohibited or used outside of the allowed time (seventh paragraph of Article 35); 8. The sale, possession or use other pyrotechnic articles of category P1 for vehicles, including airbags and belt tensioners, unless they are mounted on the vehicle or detachable part of the vehicle (eighth paragraph of Article 35); 9. uses fireworks as opposed to the manufacturer's instructions and do not take into account the general prohibition (ninth and tenth paragraphs of Article 35). (2) For the offenses referred to in Articles 2, 4, 6, 7, 8 and 9 of the preceding paragraph shall be taken as secondary sanction of deprivation of explosives, pyrotechnic articles and parts of ammunition. Side sanction shall be imposed even if the products are not owned by the perpetrator. Article 49 (Responsibility for deciding on minor offenses) (1) In deciding on minor offenses from 46, 47 and 48 of this Act is responsible inspectorate. To decide on the offenses referred to in Articles 13, 14 and 16 of the first paragraph of Article 46, 3, 8, 10 and 11 of the first paragraph of Article 47 and the offenses referred to in Article 48 of this Law is also in charge of the police. To decide on the offenses referred to in point 16 of Article 46 and 11 of Article 47 of this Law is also in charge of the customs service. To decide on the offenses referred to in Articles 1, 2, 3 and 4 of Article 46 and 1, 2, 3, 4 and 5 of Article 47 of this Law is also responsible trade inspectorate. (2) The authorities referred to in the preceding paragraph may impose fines for offenses under criminal provisions within the range prescribed by this Act.
Spain	Article 195. Minor offenses. The following behaviours are considered minor offenses: 1. The omission or failure in security measures for the custody of the documents relating to regulated materials, when leading to their loss or theft. 2. The omission of the duty to report to the Weapons and Explosives loss or

	theft of documents relating to controlled substances. 3. The omission of the obligation to submit to the Administration the parties and other documents relating to the matters covered in the fields of industrial or public safety. 4. The omission of data communications is required to refer to the Administration, relating to the matters covered in the fields of industrial or public safety. 5. Irregularities in completing the required books and records relating to controlled substances. 6. Disobedience and / or lack of consideration of the mandates of the competent authority or its agents provided they comply with current regulations in the course of the mission legally entrusted with respect to the regulated materials. 7. All those behaviours which, although not qualified as very serious or serious violations constitute breaches of obligations or requirements or violation of the prohibitions contained in this regulation and its complementary technical instructions, the Organic Law 4/2015, of 30 March protection of public safety, the Law 21/1992 of 16 July, of Industry, or other special laws. 8. Failure to comply with the requirements for associates Administration and notified in the field of industrial safety agencies Article 196. Grave breaches. The following behaviours are considered serious offenses: 1. The manufacture, storage, sale, distribution, purchase or sale, possession or use of controlled substances, in violation of applicable regulations, lacking the documentation and the necessary authorizations or who exceeds the authorized limits. 2. The manufacture, storage, sale, distribution and use of controlled substances, in greater quantity than authorized. 3. The omission or failure in the adoption or effectiveness of the measures or mandatory public safety precautions in the manufacture, storage, distribution, circulation, trade, possession or use of regulated materials. 4. The omission or failure in the adoption or effectiveness of industrial safety measures in the manufacture, storage, possession or use of controlled substances, when involving danger or serious damage to people, flora, fauna, property or the environment.

	5. The movement or transport of controlled materials, without meeting the requirements for documentation, or public safety measures regarding industrial safety measures when, in the latter case, such failure behave danger or harm to persons , flora, fauna, property or the environment. 6. The claim or provision of false information or circumstances to justify unauthorized commercial transactions or obtain authorizations or documentation relating to controlled substances. 7. The refusal of access to the competent authorities or their agents or hindering the exercise of inspections or regulatory controls in workshops, transportation, warehouses and other facilities relating to regulated materials. 8. The resistance or impedance to provide the information required by the government, when there were legal or regulatory obligation to respond to such a request for information. 9. The start or performance of any activity relating to matters governed without proper authorization. 10. The opening or operation of any establishment, or the start or performance of any activity relating to matters regulated without adopting mandatory security measures, or when they are insufficient. 11. The lack of books or records that are required with respect to regulated materials. 12. The use of any other marking that may lead to confusion with the CE marking to pyrotechnic articles. 13. Repeated failure to comply with the requirements set for associates Administration and notified in the field of industrial safety agencies. Article 197. Very serious offenses. The following behaviours are considered very serious infringements: 1. The acts described in paragraphs 1 and 4 of the previous article, if, as a result of them very serious damage is caused. 2. The acts described in paragraphs 3 and 5 of the previous article, if, as a result of which the loss or theft of controlled substances occurs. 3. The illicit use of CE marking, when the same result a serious injury or a serious and imminent danger to people, flora, fauna, property or the environment arises. 4. The improper execution by the notified of the actions entrusted body and continue to certify once the withdrawal notification when such conduct is a

	serious injury or a serious and imminent danger to persons arising, flora, fauna, property or the environment. 5. Failure to comply with the requirements for notified bodies, when the same result a serious injury or a serious and imminent danger for people, flora, fauna, property or the environment arises. Article 198. Inspection and sanctions. 1. Inspection. a) For the development of the inspection function, Functional Areas of Industry and Energy of delegations or sub-delegations of Government, may establish mechanisms for collaboration with bodies or authorities with competence and responsibilities in the workplace as well as in the fields public security and safety. b) Staff Functional Area Industry and Energy to perform the inspection task has in the exercise of their functions the character of public authority. c) The inspection activity was documented by minutes that will be equipped with presumption of certainty regarding the facts reflected in them that have been found by the inspector, notwithstanding evidence to the contrary. In the case of inspections workshops and warehouses of finished products ready content model will be adjusted in the ITC number 24. 2. Penalties. a) The conduct classified as minor breaches in paragraphs 1, 2, 5, and 6 of Article 195 shall be punished with fine from 100 euros to 600 euros. The conduct described as a minor offense in paragraph 8 of Article 195 shall be punished by a fine of up to 3,005.06 euros. The acts described as minor offenses in paragraphs 3, 4, and 7 of Article 195 shall be punished with fine from 100 euros to 600 euros or up to 3,005.06 euros as they relate to issues of public safety or industrial safety respectively. b) The acts described as grave breaches in paragraphs 1, 2, 3, 6, 11 and 12 of Article 196 shall be punished with fine from 601 euros to 30,000 euros. The acts described as grave breaches in paragraphs 4 and 13 of Article 196 shall be punished with fine from EUR 3,005.07 to 90,151.81 euros. The acts described as grave breaches in paragraphs 5, 7, 8, 9 and 10 of Article 196 shall be punished with fine from 601 euros to 30,000 euros or a fine from EUR 3,005.07 to 90,151.81 euros as they relate to aspects of citizen or industrial, security respectively. Moreover, the acts described in paragraphs 1, 2 and 12 of Article 196 shall be punished with the seizure of all the seized material or any material that excess

	amount, if any, of the authorized amount. In turn, the conduct described in paragraph 13 of Article 196 shall also be punished with the temporary withdrawal of the authorization of up to one year. The conduct described in paragraph 1 of Article 196 shall entail, where appropriate, closure of the establishment where the offense occurs for a period not exceeding six months. The acts described in paragraphs 3 and 10 of Article 196 entail the closure of the establishment where the infringement occurred until such security measures are established or existing anomalies are corrected. c) The conduct classified as very serious infringements in paragraph 3 of Article 197 shall be punished with fine from 30,001 euros to 600,000 euros. Behaviours classified as very serious infringements in paragraphs 4 and 5 of Article 197 shall be punished with fine from 90,151.82 to 601,012.10 euros. Behaviours classified as very serious infringements in paragraphs 1 and 2 of Article 197 shall be punished with fine from 30,001 euros to 600,000 euros or a fine from 90,151.82 to 601,012.10 euros as they relate to issues of public safety or security Industrial respectively. On the other hand, the conduct described in paragraph 1 of Article 197 shall be punished, where appropriate, with the closure of the establishment where the infringement for a period of six months and one day to two years to occur. Similarly, the conduct described in paragraph 2 of Article 197 shall be punished, where appropriate, with the closure of the establishment where the offense or carrier occurs for a period of six months and one day to two years, provided that the amount stolen or lost, the mode or subtraction authors cause alarm. In turn, the conduct described in paragraph 3 of Article 197 shall be punished, where appropriate, with the seizure of equipment. The conduct described in paragraph 5 of Article 197 shall also be punished, where appropriate, with the suspension of activity or closure of the establishment for a maximum period of five years. d) To determine the amount and graduation of sanctions and basis of the principle of proportionality, the following circumstances are taken into account: i. The importance of damage or deterioration caused. ii. The degree of participation and benefit gained. iii. The economic capacity of the offender.

	iv. The intent in the commission of the offense. v. The intent, guilt and recidivism. e) The material seized will be destroyed if its use constituted a safety hazard. The sanctioning body shall, in any event, determine the final destination to be given to the seized material. The expenses resulting from intervention operations, storage, transportation and destruction shall be to the infringer. Article 199. Prescription of offenses. 1. The administrative offenses referred to in the preceding articles relating to public safety aspects expire after six months, a year or two years if committed, as are mild, serious or very serious, respectively. 2. The administrative offenses referred to in the preceding articles relating to industrial safety aspects prescribed a year, three years or five years if committed, as are mild, serious or very serious, respectively. Article 200. Prescription of sanctions. 1. Penalties imposed for offenses relating to public safety issues classified as very serious lapse after three years, those imposed for serious violations after two years, and those imposed for minor infractions per year, calculated from the day following one in which becomes final in administrative resolution for which the penalty is imposed. Interrupt prescription initiation, with knowledge of the subject, the execution procedure, returning to the period of time if it is paralyzed for more than a month for reasons not attributable to the offender cause. 2. The penalties prescribed a year, three years or five years, depending on the respective infringements relating to industrial safety aspects have been classified as minor, serious or very serious, respectively, calculated from the day following that that becomes final in administrative resolution for which the penalty is imposed.
Sweden	Liquidated damages and the threat of performance: The supervisory authority may attach to a prohibition or injunction as issued under this law with a fine or with the threat that the neglected measure is carried out at the defaulter's expense. Penalty provisions: Provisions on penalties for breaches of explosives found in Chapter 44. § 11 of the Criminal Code. Anyone who wilfully or negligently violates the obligation under § 5 of this Act, the manufacturer's obligation under § 7-12, the importer's obligations under § 13, the distributor's obligations under § 14 or a prohibition or injunction issued pursuant to § 42-44

	shall, unless more severe penalty is provided elsewhere in the law, for violation of the provisions of pyrotechnics sentenced to a fine.
United Kingdom	1) A person guilty of an offence under regulation 62 in respect of a category F1 firework, a category F2 firework, or a category F3 firework is liable on summary conviction— (a) in England and Wales, to a fine or imprisonment for a term not exceeding 3 months or to both; (b) in Scotland or Northern Ireland, to a fine not exceeding level 5 on the standard scale or imprisonment for a term not exceeding 3 months or to both. (2) A person guilty of an offence under regulation 62 in respect of a pyrotechnic article to which paragraph (1) does not apply is liable— (a) on summary conviction— (i) in England and Wales, to a fine or imprisonment for a term not exceeding 3 months or to both; (ii) in Scotland or Northern Ireland, to a fine not exceeding the statutory maximum or imprisonment for a term not exceeding 3 months or to both; (b) on conviction on indictment, to a fine or imprisonment for a term not exceeding 2 years or to both.

3.17. Case study on application of sanctions in the toys sector

Case Study: *An informal inquiry in the field of toys safety showed that 26 Member States as well as Iceland and Norway reported to have the possibility of imposing economic sanctions. 24 Member States, Iceland and Norway reported to also have the possibility of imposing other than economic sanctions. In particular:*

1. *Economic sanctions – BG, BE, CZ, DK, EE, IE, EL, ES, FR, HR, IT, CY, LV, LT, LU, MT, NL, AT, PL, PT, RO, SI, SK, FI, SE,UK, IS,NO*

2. *Imprisonment – EE, IE, EL, IT, CY, LV, LU, MT, NL, SI, UK,IS, NO*

3. *Seizure or destruction of the product – BG, CZ, DK, EE, IE, EL, ES, FR, HR, IT, CY, LV, LU, NL, AT, PT, RO, FI, SE, UK,IS, NO*

4. *Publication of the fines imposed or of the judgment –BE, IE, EL, ES, CY, NL, AT, SK, UK,IS*

5. *Temporary or permanent disqualification from the practice of industrial or commercial activities, including stopping production –BE, ES, FR, HR, LV, LU, MT, NL, AT, RO, SE, IS*

6.	*Others: Measures on the product (withdrawal) BE, BG, EL, FR, FI + Community service: LV*

However despite this apparently broad range of available tools an analysis of overall sanctions (voluntary corrective action, compulsory restrictive measures, penalties) actually imposed in the toys sector between 2010 and 2013 shows that following inspections with finding of non-compliance on average the EU authorities were able to impose some sanction in two-thirds of cases at most, as illustrated by the following table.[240]

Table 13-3: Follow up to inspections in the toys sector: percentage of cases of non-compliance where measures and/or penalties were applied in the 2010-2013 period

BE	n.a.
BG	37
CZ	37
DK	68
DE	n.a.
EE	100
IE	100
EL	52
ES	n.a.
FR	29
HR	n.a.
IT	n.a.
CY	46
LV	86
LT	n.a.
LU	71
HU	98

240 This average is based on data provided by 17 Member States. Notably, it excludes Germany, Spain, Lithuania and the Netherlands for which no information on investigations in the toys sectors is provided. It also excludes the UK, Belgium, Poland, Slovenia, Croatia, Italy and Austria whose data are incomplete or contained inconsistencies so that the share of self-initiated investigations could not be calculated. The average probably overestimates the number of inspections with a follow-up, as in some case both corrective action and sanctions were imposed in a given inspection, so the figures worked out by the Commission involve some double counting.

MT	52
NL	n.a.
AT	n.a.
PL	n.a.
PT	75
RO	100
SI	n.a.
SK	14
FI	69
SE	36
UK	n.a.

EUROPEAN
COMMISSION

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PART 4/4

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council

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{SWD(2017) 469 final} - {SWD(2017) 470 final}

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ANNEX 14: BACKGROUND INFORMATION ON OBJECTIVE 4 – PROMOTING COMPLIANCE

1. COMPLIANCE AND MIXES OF REGULATORY STRATEGIES[1]

Compliance-oriented regulation is often aimed at providing incentives and encouragement for voluntary compliance and nurturing the ability of enterprises to secure compliance through self-regulation, internal management systems, and market mechanisms where possible, rather than automatically using punishment for violations of the rules in the first instance. When organisations do fail to comply, a compliance-oriented regulatory approach will attempt to *restore* compliance rather than revert immediately to a purely punishment-oriented approach.

Restorative justice must always be backed up by the possibility of more punitive sanctions. This gives regulators the option of responding to non-compliant enterprises that demonstrate bad faith in the restorative justice process with more punitive sanctions. It is also important that enterprises know that "softer" enforcement strategies such as restorative justice will be followed by harsher strategies such as fines and license suspensions, if non-compliance persists. Indeed the evidence shows that persuasive and compliance-oriented enforcement methods are more likely to work where they are backed up by the possibility of more severe methods. The central principle here is that a regulator should have available a range of enforcement mechanisms in order to be responsive to the particular type of non-compliance it faces in any individual situation. A regulator can start with persuasive or restorative strategies and then move to more punitive strategies if voluntary compliance fails. If the application of punitive sanctions succeeds in bringing about compliance then the regulator can respond by reverting to a trusting demeanour, rather than building resistance by being overly punitive. If the initial round of punitive sanctions does not bring about compliance, then the regulator can respond by invoking harsher sanctions. The wider the range of strategies (from restorative to punitive) available to the regulator, the more successful this type of responsive, "tit-for-tat" enforcement is likely to be.

This principle has been demonstrated in the idea of a pyramid of enforcement strategies (see below). The pyramid is a schematic representation of the idea that instead of using the most drastic regulatory strategies first, regulators should trade on the goodwill of those they are regulating. Regulators should encourage those regulated to comply voluntarily, using more drastic regulatory measures only when that fails and reverting to a trusting demeanour when these strategies achieve their goal: "Compliance is optimised by regulation that is contingent, co-operative, tough and forgiving." In this model prioritising restorative, compliance-oriented means of regulation in time ensures that co-operative, voluntary measures are used more frequently without compromising the possibility of using harsher measures where necessary. In the pyramid illustrated, license suspension and revocation are at the top of the pyramid because they represent the complete closing down of a business, as compared with a criminal financial penalty or the jailing of a particular executive. Each regulatory regime would, however, design its own pyramid of sanctions. For example corporate probation (where a company is put on "probation" until it is adequately in compliance) might be included, or criminal penalties might be considered harsher than license revocation. This concept does not suggest that the direct use of punitive sanctions as part of a tit-for-tat enforcement strategy should be excluded.

1 OECD\ (2000), pp. 41-42 and 73-76.

Source: Ayres, I. & Braithwaite, J. (1992), *Responsive Regulation: Transcending the Deregulation Debate*, Oxford University Press, New York, p. 35.

Summary of scholarly literature on regulatory compliance

[…] The developments in research on deterrence and compliance have led to a more holistic, pragmatic, and outcome-oriented approach to regulatory research: many contemporary regulation scholars are *pragmatic* in the sense that they use empirical evidence about what is likely to work, rather than being guided purely by ideological positions about what form of regulation is most desirable. Scholarly interest has turned towards research that evaluates alternatives to traditional "command-and-control strategies" that relied on a simple theory of deterrence. In particular this research takes a more *holistic* approach towards regulation and examines the effectiveness of mixes of regulatory strategies that will utilise the complexity and variety of motivations underlying compliance. This type of research is also extending beyond looking at regulatory enforcement strategies to the impacts on compliance of total regulatory design. The result is a more *outcome-oriented* approach to the study of regulatory compliance. The emphasis is on the substantive policy objectives of the regulation, and whether the regulatory policy instruments chosen are capable of accomplishing those objectives, not on compliance with rules that may or may not be effective at achieving the desired result.

The most influential theory of the optimal mix of regulatory strategies is Ayres and Braithwaite's (1992) pyramid of enforcement strategies. In their book, *Responsive Regulation*, Ayres and Braithwaite demonstrate why this pyramid of regulatory strategies is an effective and efficient approach to accomplishing compliance with policy objectives on the basis of empirical psychological and sociological evidence, as well as economic and political modelling and game theory. The pyramid is a schematic representation of the idea that instead of using their most drastic regulatory strategies first, regulators should trade on the goodwill of those they are regulating, encouraging them to comply voluntarily, using more drastic regulatory measures only when that fails and reverting to a trusting demeanour when these strategies achieve their goal: "Compliance is optimised by regulation that is contingently co-operative, tough and forgiving" (Ayres & Braithwaite, 1992, p. 51). In this model prioritising restorative, compliance-oriented means of regulation in time ensures that co-operative, voluntary measures are used more frequently without compromising the possibility of using harsher measures where necessary. […]

An impressive array of research supports Ayres and Braithwaite's basic premise that it is more effective to maximise self-regulatory possibilities for business by using less coercive, more dialogic methods of regulation first and more coercive measures only when less coercive means fail. Braithwaite's own research programme with various co-authors has demonstrated and evaluated the relevance of the pyramid as an explanatory heuristic in a variety of substantive regulatory arenas including coal mine safety, pharmaceutical safety, and nursing home regulation (*e.g.* Braithwaite, 1984, 1985; Grabosky & Braithwaite, 1986; Braithwaite & Makkai, 1991, 1994). A number of other researchers have also found the pyramid useful as a descriptive tool to explain where regulation is successful at accomplishing compliance, and as a normative theory for how compliance could be improved: for example Rees (1988, 1994) on occupational health and safety regulation and nuclear power industry self-regulation, Gunningham (1994) on environmental regulation, Parker (1997, 1999*a*, 1999*b*) on regulation of the legal profession, competition and consumer protection law, and anti-discrimination law, Hopkins (1995; see generally 1994, p. 432) on occupational health and safety, and Haines (1997) on safety in the construction industry.

Other researchers have discovered complementary explanations of the interdependence of co-operative and punitive regulation in accomplishing compliance. Burby and Paterson (1993); see also Honneland (1998), for example, compare co-operative enforcement with sanction-oriented enforcement for improving compliance with North Carolina state environmental regulation. In their study compliance-oriented regulatory design in the form of performance standards were more effectively enforced by co-operative strategies that were in turn backed up by potential application of deterrent sanctions than by the application of deterrent sanctions alone.

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2. COMPLIANCE ASSISTANCE ORGANISED AT EUROPEAN LEVEL[2]

2.1. Product Contact Points under Regulation (EC) 764/2008

The Regulation[3] aims to guarantee the free movement of goods in the internal market, in the absence of harmonised rules. It lays down procedures to be followed by Member States when denying market access to a product lawfully marketed in a Member State. Another goal is to increase awareness of the mutual recognition principle, which allows for products lawfully marketed in another Member State to be sold in other Member States, despite the fact that this product complies with different national technical rules, ensuring legal certainty for national authorities and businesses and improving administrative cooperation between national authorities.

As the application of the mutual recognition principle is not automatic, certain national technical regulations may prevail. Economic operators may wish to know about the applicable national rules before entering a market. The Regulation contains the obligation for Member States to establish national Product Contact Points ("PCPs"). These provide, upon request, information on the national technical rules applicable to a specific product, the contact details of the competent authorities in charge of supervising the implementation of the technical rules in question and remedies available in case of dispute between the economic operator and the competent authority. The scope of the PCPs is limited to the non-harmonised sector[4]. They therefore qualify as "assistance services".

The Regulation contains a limited number of quality criteria, mostly voluntary. The only "hard" criterion is that PCPs should reply to requests within 15 working days of receiving them. According to a recital, PCPs should be adequately equipped and resourced, and are encouraged to make the information available online and in other Community languages. The provision of information in the scope of the Regulation should be free of charge. For additional information PCPs may charge proportionate fees. The list of PCPs can be found on

2 For further detailed info, please consult SWD(2017)213 final = Evaluation of existing (regulatory and non-regulatory) framework of relevance to the Single Digital Gateway

3 Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC

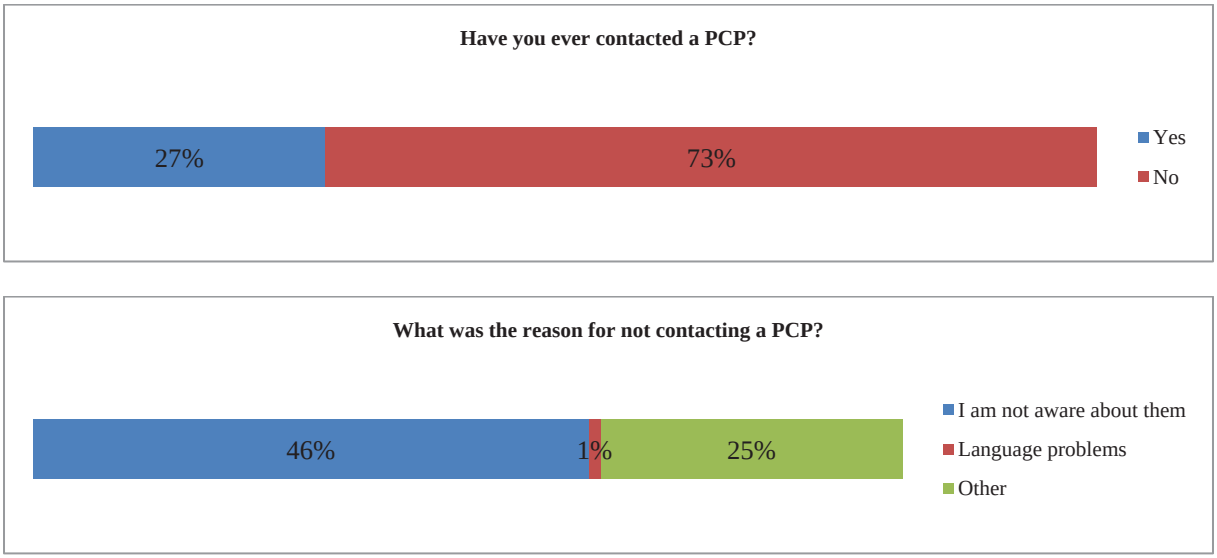
4 As opposed to the (EU) harmonised sector, for which the PCPs are not responsible.

https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/contacts-list/.

PCPs have been established in all EU Member States. Their list was initially published in the OJ[5] and is regularly updated and available online on the Commission's website[6]. The Regulation left the set-up of PCPs to the discretion of Member States, thus, their organisation and function vary significantly. Most Member States have a single PCP, responsible for all inquiries related to non-harmonised products. In a few Member States[7], the PCP is split between a general one and a construction products specific one. Other Member States[8] have PCPs in 6-7 different ministries. In almost all Member States, the PCP (or the co-ordinator, where there are several PCPs) is located within the ministry responsible for industry/business and the internal market, often as part of a group or team dealing with internal market policy. Only in Slovenia the PCP is located in an independent institute (the Slovenian Institute for Standardisation). A few PCPs handle queries (or part of queries) themselves. In Malta, the PCP is responsible for all communication with companies. However, this setup is unique to Malta (and difficult, if not impossible, to handle in a larger Member State), and in most cases queries from economic operators are passed on to the responsible ministry, department or directorate or, occasionally, the relevant local authority. In Italy, there is an appointed PCP, however, economic operators must contact the relevant ministry in charge of their product and receive their answer from this authority – without the PCP being involved. The way replies are being provided to economic operators also varies from one Member State to another. Very often, the responsible authority replies directly to the company making the query. Thus, the PCP has little insight on the outcome of the queries. Sometimes, national authorities provide answers to companies via the PCP.

It should be noted that most of the businesses replying to the 2016 public consultation declared that they have never contacted a PCP in order to obtain information about the applicable national rules and the mutual recognition principle, mostly because they are not aware about them.

Figure 14-1: Public consultation on mutual recognition - 2016



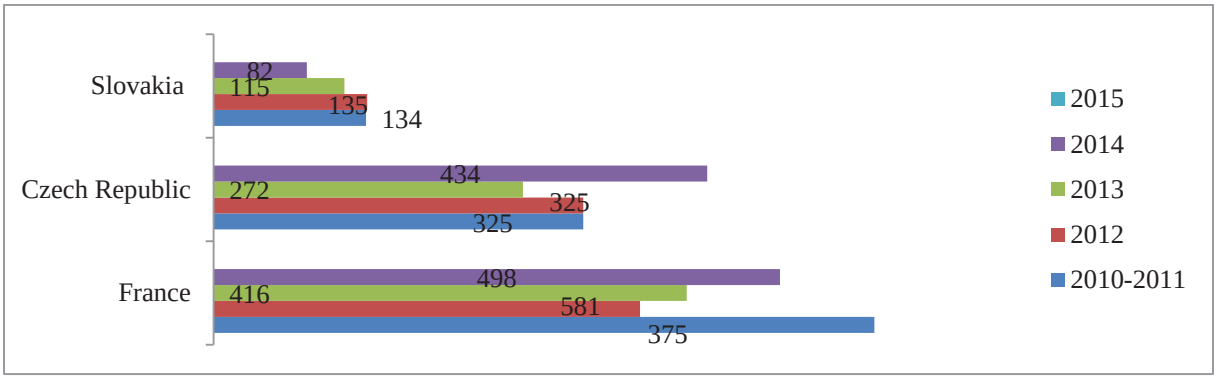
5 OJ C 185 of 7.08.2009, p. 6-12
6 https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/contacts-list_en
7 Estonia, Latvia and Poland
8 Romania, Portugal and the Netherlands

In the period between 2009 and 2015, the Product Contact Points received **8024** questions from economic operators.

2010-2011[9]	2012	2013	2014	2015
1402	1439	1826	1793	1564

The PCPs that were most contacted are France and the Czech Republic, followed by Slovakia.

Figure 14-2: Most contacted PCPs



However, the number of questions indicated above is only indicative and does not constitute an accurate picture of all questions received or treated by the PCPs. This is because not all Member States are indicating in their annual reports the number of questions received and treated by the PCPs. In 2010-2011, 2012 and 2014, 17 Member States indicated the number of questions received by the PCPs. 19 Member States supplied this information in 2013 and 16 Member States supplied this information in 2015. Also, with regard to the number of questions received, it is not certain that the number indicated covers questions related to mutual recognition only. Some Member States are reporting those questions related to mutual recognition only, while others are reporting all questions received, even when outside the remit of the PCPs. A few Member States[10] conducted national survey on the usefulness of the PCPs, and the results show that economic operators are globally satisfied with the services provided by the network, which are considered as useful.

The evaluation of mutual recognition in the area of goods indicates that, in general, the main issues underlined by economic operators in relation to PCPs are the long delays for receiving an answer, the quality of the answer or even the absence of it. These issues are also highlighted by the Member States in their annual reports. Some Member States indicated that the 15 days deadline set out by the Regulation is difficult to meet, although most of the time respected. According to the information submitted in the annual reports, these delays are caused by the wide range of products (or aspects of) falling under the scope of mutual recognition as well as the increasing number of applicable national rules, which makes it difficult to easily identify the responsible persons having the necessary expertise. The decentralisation of certain Member States administration and the fact that most often the necessary competences are distributed between different ministries add to these difficulties. Very often, the PCPs have to send the inquiry to the local responsible officer. Last but not least, language issues, especially when technical language is involved, add further delays and contributes to the sometimes low quality of the answers provided. Some good practices were

9 The reporting in annual since 2012
10 See annual reports from SE 2015, DE and FR 2013

also highlighted by Member States in their annual reports as regards the functioning of PCPs. Slovakia for example indicated that an expert network was put in place to support the work of the PCP. Furthermore, the PCP is located in the same department dealing with Directive (EU) 2015/1534, thus aware of all national regulations notified to the Commission and subject to the application of the mutual recognition principle.

Overall, the PCPs network is considered by Member States in their annual reports as a useful tool, having the potential to help economic operators in obtaining information about the applicable national rules and the mutual recognition principle. Member States consider however that it needs to be further strengthened. In their annual reports, they call on enhancing administrative cooperation, and integrating the PCPs into a wider network, in order for them to gain in expertise and to reply more efficiently to the inquiries they received. This view is also shared by businesses, as 58% of the respondents indicated in the 2016 public consultation that PCPs are a useful tool, despite the fact that only 7% of them considered their experience with PCPs as satisfactory.

National authorities incurred costs related to implementing their obligation to establish PCP (putting them in place and having them functioning on an annual basis). Most of the time, the PCP has been integrated in an already existing department dealing with internal market issues. Based on the annual reports[11], one person in average is fulfilling the task of PCP. This is the case for example in France, Sweden, Ireland, Greece, the Netherlands, Bulgaria and Poland. In cases where the function of PCP is available in several ministries, such as in Romania or Portugal, several persons (5-8) have PCP related tasks among their portfolio. Estimates of labour costs for PCPs can be made by taking into account the costs of Full Time Equivalents (FTEs) necessary to perform the required tasks every year. As detailed information on the salary costs of administrative staff employed PCP are not available, an estimate has be made based on the Eurostat data (period 2010-2011) on the gross annual salaries for employees in national public administrations, as shown in the table below:

Table 14-1: Gross annual salaries for employees in the public administration Eurostat

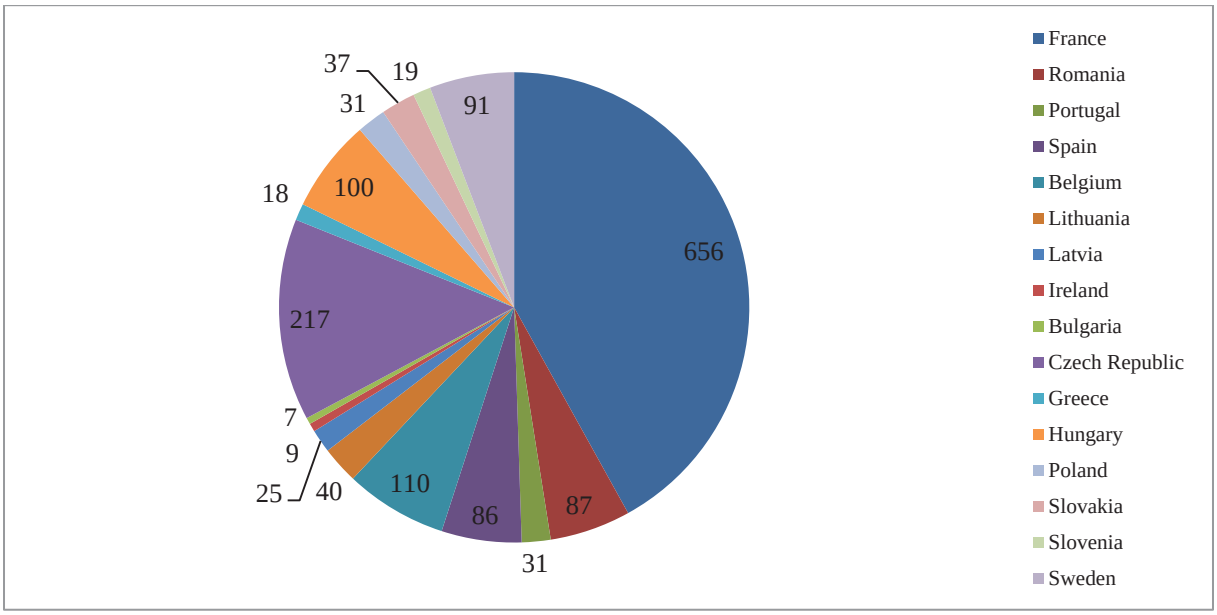
GEO/TIME	N of staff	2010	2011
Belgium	1	40124	40921
Czech Republic	5[12]	12786	12850
Denmark	2	*Information not available*	
Germany	2	*Information not available*	
Estonia	1	11541	11944
Ireland	1	*Information not available*	
Greece	2	*Information not available*	
Spain	0.5	29541	29069
France	1	*Information not available*	
Netherlands	1	46988	47450
Portugal	8	*Information not available*	
Romania	8	7675	7417
Slovakia	0.5	11648	11060
Sweden	1	38954	41963

PCPs reply to inquiries from economic operators within the limits set out by the Regulation, and the necessity, very often, to communicate in English. Most Member States (25)[13] have online portals providing information on the role of PCPs and mutual recognition. 18 Member

11 See annex 7
12 For all issues related to internal market information, so we can assume that one person fulfils the tasks of PCP
13 See "Screening Report on Member States Product Contact Points and Product Contact Points for Construction", Ecorys, 2016

States provide this information (sometimes partially) in English. The availability of online information generates costs related to creating the website and keeping it up-to-date; however, these are easily counterbalanced by the potential reduction of the number of "basic" inquiries PCPs would have to deal with in the absence of such online information. The number of inquiries received by PCPs varies from one Member State to another. Some Member States (France, Czech Republic, Belgium, Hungary and Sweden) registered a high number of requests, while other very little. For example, in 2015, out of the 22 annual reports received, **16 only indicate the number of inquiries received**. The number of questions received amounted to **1645**. The most active Member States are France, Czech Republic and Belgium, followed closely by Hungary and Sweden.

Figure 14-3: PCPs activity 2015



The fact that some PCPs receive a higher number of inquiries can be explained by the fact that these are big attractive and / or more difficult markets, or that promotion of PCPs has been more efficient. The low numbers registered in certain Member States can be also explained by the fact that requests are not properly registered and monitored, or reported to the Commission. For example, some Member States are indicating in their annual reports an increase of the number of inquiries received by the PCPs, while the actual number of these inquiries was never communicated.[14]

2.2. Product Contact Points for Construction under Regulation 305/2011

The aim of the Construction Products Regulation[15] (CPR) is to facilitate the free movement of construction products.

Member States had to set up Product Contact Points for Construction ("PCPCs") that should provide information on technical rules for construction products, contact details of authorities and information on remedies at the request of the economic operator. They cover the

14 For a full overview of the number of inquiries received by the PCPs see annex 7
15 Regulation 305/2011

harmonised and non-harmonised sector. They qualify as "assistance services" for the purposes of the Single Digital Gateway, as they offer a personalised service. A website with information is voluntary.

The quality provisions for the PCPCs have been modelled on those applying to the PCPs under the Mutual Recognition Regulation (MRR) that was adopted three years earlier. For example, the 15 working-day deadline also applies to requests made to the PCPCs. However, many of the voluntary quality recommendations of the MRR have been weakened or dropped. The only quality criterion that the CPR contains and the MRR doesn't is that information shall be provided using "transparent and easily understandable terms".

No information is available on whether PCPCs are recording the enquiries (and replies sent) in a database.

2.3. Your Europe

The "Your Europe" (YE) portal has been created under the IDABC initiative[16] and was first launched in 2005. The 2013 Commission Communication on an "Action Plan for boosting Your Europe in cooperation with the Member States" was positively welcomed by both the EP and the Council.

The portal is part of the inter-institutional "Europa" website[17] and contains practical and user-friendly information, in 23 languages, for citizens and businesses on rights and opportunities in the Single Market. The portal is divided into a Citizens section and a Business section.

As it is essential for people to find out about EU rights and how to exercise them in a particular country, Your Europe is a joint project of the Commission and the Member States. Visitors find EU level information provided by the Commission as well as the respective national information and implementation provided by the Member States through an Editorial Board, if not already collected through other expert groups/networks. Your Europe is divided up into topical sections that present EU-level content (EU rights) and national content, including through links to Member States' pages.

Your Europe also links to relevant assistance and problem-solving services (Your Europe Advice, Europe Direct, SOLVIT, EEC-Net, Enterprise Europe Network, etc.), other EU portals (e.g. e-justice, Euraxess, EURES), Commission websites, national contact and enforcement bodies, relevant forms and to relevant EU law and a few e-procedures (European Professional Card, Online Dispute Resolution).

As part of the Europa platform of the Commission, Your Europe respects the corporate "Information Providers Guide"[18], i.e. the Europa-specific quality standards on content (definition, drafting, SEO, …) and design (structure, layout, usability, accessibility, …). Your Europe is a multilingual portal covering currently 23 languages[19] for the EU-level content. Information is provided in plain language, avoiding legal and administrative jargon. The portal is adapted for use through mobile devices and complies with corporate standards for web accessibility.

16 Decision 2004/387/EC of the European Parliament and of the Council of 21 April 2004 on interoperable delivery of pan-European eGovernment services to public administrations, businesses and citizens (IDABC).
17 http://europa.eu/youreurope
18 http://ec.europa.eu/ipg/index_en.htm
19 All official EU languages but Irish, the business sections also covers Norwegian.

2.4. Your Europe Advice

"Your Europe Advice" (YEA)[20] is a Europe-wide service funded and supported by the Commission that offers citizens and businesses tailored information and advice on their EU rights (mainly internal market rights), free of charge and in all 24 EU languages. The service is outsourced to an external contractor that manages a network of about 65 legal experts with EU law background and expertise and experience in national law and administration in all Member States. YEA is mentioned in the Your Europe Action Plan of 2013. The objective of YEA is to provide a fast, high-quality, personalised legal advice service to citizens and businesses free of charge.

YEA is intended to be an extension of the practical information provided on the Your Europe portal. The Your Europe portal offers a link to YEA whenever citizens need personalised and specialised advice. In their replies YEA advice experts also signpost to other information and advice services, including, but not limited to, the Scadplus website, EURES, ECC Net and other EU and national level information services. YEA has a mandate to respond to enquiries submitted by EU or EEA citizens or their family members who are entitled to benefit from EU rights.

Citizens and businesses receive comprehensive advice within one week and are directed or "signposted", when appropriate, to the authority or other body (local, national or European) best placed to solve their problem. The contract with the contractor specifies the speed of replies to enquiries (within 72 hours), and how the deadlines are calculated. Deadline compliance is monitored by the contractor and the Commission. A large number of quality criteria apply to the replies. Some refer to substance, such as relevance, accuracy, completeness, legal reference and sign-posting, where possible. Others refer to style, e.g. the requirement for the replies to be polite, personalized and tailor-made; in clear, simple, non-technical and non-legalistic terms and easily understandable for "normal" citizens without legal knowledge. The legal experts must also live up to quality criteria as regards their qualification, experience and communication skills.

Apart from its core activity – provision of legal advice to citizens – the service has a number of other functions. Among these is the provision of feedback about the cases and the problems experienced by EU citizens in the various Member States through quarterly feedback reports to the Commission. Enquiries are analysed and regular reports are sent to the Commission. These reports provide an up-to-date picture of where obstacles to exercising EU rights persist. The YEA database with more than 200 000 real life cases constitutes a wealth of information which can be exploited by Commission services for policy shaping or impact assessments.

2.5. Enterprise Europe Network (EEN)

The Enterprise Europe Network was launched in February 2008 by the European Commission. It is co-financed under COSME (Competitiveness of Small and Medium-sized Enterprises) — an EU funding programme designed to encourage the competitiveness of European enterprises. According to the EEN call for proposals the Network is established "to contribute to the objectives of the COSME programme by facilitating access to European and international markets for European SMEs and by providing growth-oriented integrated business and innovation support services that help strengthen the competitiveness and sustainability of European Enterprises." The Enterprise Europe Network is the world's largest

20 http://europa.eu/youreurope/advice/about_en.htm

support network for small and medium sized businesses (SMEs) with international ambitions. It has 3,000 experts across 600 member organisations in more than 60 countries. Member organisations include chambers of commerce and industry, technology centres, and research institutes. The Commission Executive Agency for Small and Medium-Sized Enterprises (EASME) implements the Network for the Commission.

The Network helps SMEs innovate and grow internationally. It provides international business expertise with local knowledge in three areas: partnership services[21], innovation support and advisory services. Only the latter are of relevance to the Single Digital Gateway. Advisory services include practical and customised advice on doing business in another country and national legal requirements applying to the marketing of goods and the provision of services, advice on intellectual property and information and advice on EU law and standards and the Internal Market more generally. SMEs can contact domestic EEN partners, which get in touch with relevant EEN partners in the target country and receive information and advice from them.

The EEN also signposts to other suitable providers of SME-oriented services. This is called the "no wrong door" principle.

The performance of the network is monitored through "Key Performance Indicators". Performance is defined as growth in turnover and employment of SMEs. More specific guidelines apply to advisory services, as specified in the EEN's "Achievement Guidelines on Advisory Services Outcomes" of June 2015. As a starting-point, the network partner should agree an "advisory plan" with the client. This plan should be a short and clear document defining the actions to address the gaps and needs, identify other service providers where relevant, and schedule the actions. All provided services need to be documented in the Customer Relations Management or internal documentation. This could cover emails exchange and documentation forwarded to the client, client confirmation on the advisory plan implementation, etc.

All achievements must be reported on in the achievement report, to be submitted to EASME's Achievements Database in the Network IT Platform. The achievements report has to contain a short section on the advice given and the advisory plan, how the plan was implemented and what initial and longer-term impacts on the client are expected. The documentation of outputs is to be kept at the premises of the Network partners and should be available to EASME or auditors upon request. Quality checks are performed regularly to verify the quality and eligibility of registered achievement reports. The Network will assess the impact of the implemented advisory plan through the impact assessment procedure of the Network. The EASME Project Adviser in charge of partner reporting can perform in-depth evaluations of achievements and can put achievement reports on hold or reject them.

Enterprise Europe Network partners make use of the SME Feedback database to record problems or cases faced by SMEs in the internal market Some broad headings are provided[22] to facilitate the analysis, and businesses are asked to quantify the loss of time and loss of income (additional costs) caused by the problem. Businesses can also provide details on how the problem could be solved. European Commission officials can check the database.

21 The Network manages Europe’s largest database of business cooperation opportunities.

22 Lack of detail in the text of the European legislation/programme, national requirements in a cross border activity avoid correct functioning of the Internal Market, severe difficulties to find European information needed to carry out the activity, the wording of the European legislation/programme or the procedure negatively affects in particular SMEs, and wrong interpretation at national level of a European text, other.

2.6. Evaluation

An evaluation of these instruments was performed in the context of the creation of the 'Single Digital Gateway'[23]. The focuses on a number of elements that are particularly important for businesses and citizens with respect to their rights and obligations concerning the Single Market: information, assistance and problem-solving services, online procedures, quality criteria for such services, (online) findability and visibility of services, as well as one element that is important for the Commission as guardian of the Single Market, namely the collection of case feedback to inform policy making. It does not consider other elements or functionalities of the instruments. The evaluation aims at analysing how these services are performing together, and to what extent they are reaching the objectives to deliver to businesses and citizens the information, assistance and procedures they need in relation with their EU rights and obligations. In turn, this contributes to a better functioning Single Market, increased cross-border activities, more competition, jobs and growth.

Centralised helpdesk service at EU level, building on Your Europe Advice service

To assist business with compliance information, the option of a centralised *helpdesk service* was considered. This option would however be less effective for SMEs, in particular if no regular awareness campaigns were to be launched, but which would also raise costs. The relative distance from the target audience would entail that its efficiency could be quite questionable, especially in combination with the Single Digital Gateway.

Besides the Single Digital Gateway, the extension of the 'Your Europe Advice' (YEA) service would involve annual costs of about EUR 1.8 million for all areas. Adding regular awareness raising would total such an option to EUR 2 million/year. The direct and indirect costs of YEA per reply correspond to other comparable possibilities citizens have to get the same level of advice (e.g. ask a lawyer; send a question to the European Commission or a national administration). The estimated cost of the Europe Direct Call Centres is EUR 88.26 per hour. However, these hourly cost would increase when specific technical and legal expertise with respect to EU product legislation would have to be hired. The experts in YEA would have to have a good grasp of the technicalities of EU product legislation and the cover all EU languages, especially when the target audience might ask fairly technical questions. At the same time, they would have to be familiar with the national transpositions and implementations of Union harmonisation legislation and developments in national product markets. It may be very challenging to find available experts who would meet these criteria and who together would be able to cover product legislation in all Member States at a reasonable cost. This option was therefore not further examine in this impact assessment.

3. COMPLIANCE SCHEMES

3.1. Abbreviations

AR	Awareness Raising
AdCo	Administrative Cooperation Groups

23 SWD(2017)213 final - Evaluation of existing (regulatory and non-regulatory) framework of relevance to the Single Digital Gateway

BSI	The British Standards Institution
CA	Compliance Assistance
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CS	Compliance Schemes
EC	European Commission
EEA	European Economic Area
EU	European Union
IMP-MSG	Internal Market for Products - Market Surveillance Group
MS	Market Surveillance
MSAs	Market Surveillance Authorities
NCP	National Contact Point for Market Surveillance
SME	Small and Medium Sized Enterprises
TA	Trade Association

3.2. Definitions

Awareness raising	Campaigns designed to heighten the widespread awareness of economic operators to the requirements of the legislation that governs the product sectors in which they operate and to direct them to sources of information and practical assistance.
Compliance assistance	Assistance provided by public authorities to support economic operators by helping them understand and comply with the rules. They are aimed at economic operators who want to comply but lack the competence or resources; most often SME's.
Compliance schemes	Schemes developed by Member States establishing criteria which,

	when fully followed by an economic operator, would provide a reinforced presumption that the economic operator is following all applicable rules regarding the safety and compliance of the products intended to be placed on the market in the EU. The "earned recognition" would be taken into consideration by MSAs when setting enforcement priorities and carrying out risk assessment to determine inspection frequency or scope.
Earned recognition	Recognised and approved activities and procedures undertaken by economic operators to ensure compliance with EU legislation that are taken into consideration by MSA as part of their risk-based inspection programmes.
Practices	Awareness campaigns, compliance assistance initiatives or compliance schemes

3.3. Introduction

Market surveillance authorities in EEA countries have the duty to check compliance with EU directives and regulations. They must deal with rogue operators but also with economic operators who are willing and able to comply with the rules and those willing to comply, but unknowingly breaking the rules because they lack sufficient knowledge. There are increasing pressures on the Market Surveillance Authorities to rethink their approach to how they seek to enforce EU legislation with both large national and international economic operators and small and medium enterprises (SMEs). Increasingly, the modernising regulation agenda is likely to drive agencies towards modernising their approach to enforcement practices.

MSAs in twenty Member States provided information concerning the compliance practices that they use; three provided quite limited information and eight did not provide details of any practices at all. This limited and disappointing response allowed the study to identify and analyse 56 specific compliance practices across all product categories. The analysis produced a total of 27 compliance practices that had some particular merit and these were further reduced to produce 14 "best practice" schemes based upon the information received.

The breakdown of the 14 compliance practices identified as "best practice" is as follows:

- Awareness raising: 4 "best practices" examples;
- Compliance assistance: 6 "best practices" examples;
- Compliance schemes: 4 "best practices" examples.

The compliance practices are not rated in any order of importance or preference as they all have strengths and weaknesses that are important if their usage is being considered in a

specific set of circumstances and in relation to specific product sectors. Issues such as cost, resources and opportunity costs need to be considered.

Whilst it is not possible to be definitive about the total number, scope, quality, cost or usage of the practices that are in operation across all MSA in Member States, the picture that has emerged is that Awareness Raising and Compliance Assistance are much more common than Compliance Schemes but that many Member States may not use any such schemes at all.

The usage of the identified compliance practices appears to be evenly spread across most of the Member States. The result also indicates that the usage of compliance practices does not appear to be related to the length of time that a country has been a member of the European Union and shows that no Member State reported a significantly greater number of compliance practices than the rest. Equally there is no evidence that suggests that specific Member States have adopted a policy stance upon the usage of compliance practices that has determined that MSAs should engage in their operation.

There is a degree of uniformity in that some product sectors feature prominently in all three categories of compliance practices. As the number of practices identified is small and some product categories cover a wide range of products, it is very difficult to be precise about which product sectors attract compliance practices. However, the split of compliance practices appears to relate slightly more towards consumer products rather than professional products. Mass produced products such as toys, electrical products, pre-packaged items and personal protective equipment, as well as machinery that covers both types of products, all featured strongly in the practices identified whilst large pieces of specialised equipment such as non-road machinery did not feature at all. It is surprising that practices aimed at the manufacturers and importers of products covered by the General Product Safety Directive (2001/95/EC) did not feature more highly, in view of the relative lack of harmonised standards for such products.

The practices employed by MSAs do not always sit exactly within the EU chosen definitions as they often have features that cross these boundaries. Many Compliance Assistance protocols have the flexibility to extend into Awareness Raising when there is a change in legislation or a major example of non-compliance is discovered. They can also have elements of a Compliance Scheme if economic operators use the compliance advice provided and then can provide evidence of systems or activities that would reduce their risk assessment scores for inspection frequency or scope based upon their improved likelihood of compliance through an earned recognition protocol.

It was very difficult to assign a specific cost to the compliance practices when they are embedded in the normal market surveillance protocols of the MSA and not budgeted separately. Very few practices were developed with key performance indicators and performance measurement procedures in place. This in turn made it very difficult to determine the effectiveness or cost efficiency of the practices.

The report concludes with a number of recommendations that that should serve as a toolkit for improving compliance practices and to encourage a greater use of them by MSAs.

3.4. Results

The initial collation of information from the survey sought to establish the full range of product sectors covered by Awareness Raising, Compliance Assistance practices and

Compliance Schemes. Initially each practice was counted as a separate practice under every product sector that it covered. However, as many of the practices reported by MSAs covered a range of product sectors, this recording format appeared to indicate a much larger number of separate practices in operation than is the case. Based upon the further information received from MSAs and additional research by members of the study team, practices that cover a range of product sectors were defined as single compliance practices if they operated under a common set of principles by the same MSAs irrespective of how many product groups are covered.

Based upon this accounting procedure, the results of the survey can be summarised as follows:

- 56 specific compliance practices across all product categories have been identified;
- 13 specific practices[24] were classified as Awareness Raising Campaigns;
- 22 specific practices were classified as Compliance Assistance;
- 9 practices were classified as Compliance Schemes;
- 7 practices were classified as joint Awareness Raising Campaigns and Compliance Assistance;
- 2 practices were classified as joint Compliance Assistance and Compliance Schemes;
- 3 practices were classified as covering aspects of all three practices. [AR/CA/CS]; and
- The practices have been in operation for between 1 and 15 years.

This initial information was then analysed and based upon how well it met the study criteria, further enquiries were made by the experts of the Study Team and a larger data file was created based upon the information gained to answer the questions posed in the "questionnaire".

This detailed analysis took account of the selection criteria as set out in the terms of reference for Task 1 and Task 2 and looked for evidence of their effectiveness as specified.

Details of each Member States response; the categories of practices operated by MSA's in those Member States, classification of the practice, the product sectors involved in each practice are provided in Table 14-2.

Further analysis of the survey results was undertaken to determine which product sectors featured most heavily across all three types of compliance practice and in each separate practice category. This information is given in Tables 14-3 & 14-4 and the product sectors are identified by the numbering as set out in the reference document contained in Annex.

24 Irrespective of the number of product groups covered – similarly for all practices

Table 14-2: Information of practices provided by MSAs in Member States25

COUNTRY	AR	CA	CS	Details
Austria	×	×	✔	1. Compliance scheme **[CS]** – Products: (30)[26] *Very limited information obtained*
Belgium	×	✔	✔	1. Yearly inspection campaign [**CA/CS**] - Products - (1, 2, 21, 22, 24, 25, 30) 2. Self-checking guides for fertilizers to be used by economic operators [**CA**] - Products: (30)
Bulgaria	✔	✔	×	1. Awareness Raising [**AR**] – Products: (22B) 2. Compliance Assistance [**CA**] – Products: (22B)
Croatia	✔	×	×	1. Awareness Raising [**AR**] – Products: (2,3,22 & 32)
Cyprus	✔	✔	✔	1. Ensuring the Safety of Toys [**AR & CA**]– Products: (3) 2. Market Surveillance of Medical Devices [**AR/CA/CS**] – Products: (1) 3. Labour Inspection Awareness Campaigns and Compliance Assistance Initiatives [**AR &CA**] - Products:(4, 7, 9, 10, 12, 13) 4. Import control protocol [**CS**] – Products: (14 & 15)
Czech Republic	-	-	-	No information of practices received

25 As this table is based upon voluntary responses from Member States an **X** in any column should not be interpreted that relevant practices are not in operation.
26 () Product category as set out in Annex

COUNTRY	AR	CA	CS	Details
Denmark	✔	×	×	1. Good Communication – a catalogue of best practice [**AR**] – (*All* = All product sectors*)
Estonia	✔	✔	✔	1. Pyrotechnic Awareness Campaigns [**AR**] – (14) 2. EEE Awareness Campaigns [**AR**] - Products: (18,20,21,23) 3. EEE Compliance Assistance [**CA]** - Products: (18,20,21,23) 4. EEE Compliance Scheme [**CS**] - Products: (18,20,21,23) 5. Metrology Awareness Campaigns [**AR**] – (17) 6. Metrology Compliance Assistance [**CA**] – (17) 7. Metrology Compliance Scheme [**CS**] – (17)
Finland	×	✔	×	1. EEE Compliance Assistance [**CA**] – Products:(13, 18, 20, 21, 23) 2. Lifts Safety Campaign[27] [**AR**] – Products: (10) 3. Toy safety Campaign[28] [**AR**] – Products: (3)
France	✔	✔	✔	1. Initial market release of products [**CS**] - Products: (3, 4, 5, 9, 13, 14, 17) 2. Awareness campaigns – [**AR**] - Products: (3, 4, 5, 9, 13, 14, 17)

27 Aimed at lift owners and lift users
28 Aimed at children

COUNTRY	AR	CA	CS	Details
				3. Compliance Assistance – [**CA**] - Products: (3, 4, 5, 9, 13, 14, 17) Compliance Scheme – [**CS**] - Products: (3, 4, 5, 9, 13, 14, 17)
Germany	-	-	-	General information provided but no details of specific practices
Greece	✔	✔	✔	1. Control of Chemicals other than REACH – [**AR/CA/CS**] Products: (22B) – *very limited information obtained*
Hungary	-	-	-	No information of practices received
Iceland	×	×	×	Practices not used in product sectors 5, 13, 18, 20, 21, 23 and no information received for the rest
Ireland	✔	✔	✔	1. MS protocol [**CA**] – Product: (14) 2. Training scheme [**CA**] – Product: (23) 3. MS protocols [**AR/CA] –** Products: (4, 9, 10, 17, 18, 22)
Italy	-	-	-	No information of practices received
Latvia	✔	✔	×	1. Medical Devices advice [**CA**] - Products: (1) 2. Cosmetics advice [**CA**] – Products: (2) 3. Chemical Substances advice [**CA**] –Products: (22 A/B) 4. Biocides advice [**CA**] – Product: (32)

COUNTRY	AR	CA	CS	Details
				5. Be smart–build safe campaign [**AR/CA**]–Products (5) 6. Consultation protocol [**CA**] – (*All**)
Liechtenstein	-	-	-	No information of practices received
Lithuania	✔	✔	✔	1. Legal metrology supervision [**AR/CA**]– Products: (17) 2. Pyrotechnics supervision [**CA/CS**] – Products: (14)
Luxembourg	✔	✔	✔	1. Accredited quality management system [**AR/CA/CS**] Covers MS of 25 of the 33 product categories including (3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 15, 17, 18, 19, 20, 22A 23, 25, 31, 32, 33)
Malta	-	-	-	No information of practices received
Netherlands	✔	✔	✔	1. MS protocols [**CS**] – Products: (*All**) 2. MS scheme [**CA**] – Products: (18, 19) 3. MS scheme [**AR**] – Products: (17, 18, 19)
Norway	✔	×	×	1. MS protocols [**AR**] – Product: (5)
Poland	✔	×	×	1. MS awareness campaign [**AR**] – Product: (5) *Very limited information obtained*
Portugal	✔	✔	×	1. Regulatory & Scientific Advice Office [**AR/CA**] – (1, 2)

COUNTRY	AR	CA	CS	Details
Romania	-	-	-	No information of practices received
Slovakia	×	✔	×	1. MS Information activities [**CA**] – Product: (2)
Slovenia	×	✔	✔	1. MS protocols [**CS**] – Products: (17)
Spain	×	✔	×	1. MS protocols [**CA**] – Products: (3, 4, 5, 20, 21, 22, 31, 33)
Sweden	✔	✔	×	1. MS protocols [**AR/CA**] – Products: (4, 7, 9, 13) 2. Sectoral agreements [**CA**] – Products: (*All**) 3. MSP proactive activities [**AR**] – Products: (*All**) 4. Information brochure [**CA**] – Products: (4) 5. Educational package [**CA**] – Products: (3)
UK	✔	✔	✔	1. Primary Authority [**CS**] – Products: (*All**) 2. Home Authority [**CA**] – Products: (*All**) 3. MS activity [**AR**] – Products: (5) 4. Regulatory information [**CA**]: Product (15, 22A, 32) 5. Trader Advice [**CA**] – (*All**)

Table 14-3: Number of Practices in operation by product sector29

NUMBER OF PRACTICES IN EACH CATEGORY OF COMPLIANCE PRACTICE AND IN TOTAL FOR EACH PRODUCT SECTOR																		
Product sectors	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**
AR[30]	2	2	5	5	4	1	3	1	5	4	1	1	4	3	1	0	6	4	2
CA[31]	4	4	4	7	6	1	3	1	5	3	1	1	5	4	2	0	5	5	2
CS[32]	2	1	3	3	3	1	1	1	4	1	1	0	3	5	2	0	5	2	1
Totals	**8**	**7**	**12**	**15**	**13**	**3**	**7**	**3**	**14**	**8**	**3**	**2**	**12**	**12**	**5**	**0**	**16**	**11**	**5**

Product sectors	**20**	**21**	**22**	**22A**	**22B**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**Total**	**ALL**[33]
AR	2	0	2	1	2	2	0	1	0	0	0	0	0	1	2	1	0	**68**	2
CA	4	3	4	2	2	4	1	2	0	0	0	0	2	2	3	2	0	**94**	2
CS	2	1	1	1	1	2	1	2	0	0	0	0	2	1	1	1	0	**55**	2
Totals	**8**	**4**	**7**	**4**	**5**	**8**	**2**	**5**	**0**	**0**	**0**	**0**	**4**	**4**	**6**	**4**	**0**	**217**	**6**

Table 14-4: Practices in order of usage by product sector

29 Annex Reference List of Product Sectors as per the project ToR
30 AR = Awareness raising
31 CA = Compliance assistance
32 CS = Compliance scheme
33 ALL = Practices that cover all product sectors

THE PRACTICES FOR EACH CATEGORY OF COMPLIANCE PRACTICE AND IN TOTAL FOR EACH PRODUCT SECTOR SHOWN IN ORDER OF USAGE BY MARKET SURVEILLANCE AUTHORITIES																			
Product sectors	**17**	**4**	**9**	**5**	**13**	**14**	**3**	**18**	**1**	**20**	**23**	**10**	**7**	**2**	**22**	**32**	**15**	**19**	**25**
AR	6	5	5	4	4	3	5	4	2	2	2	4	3	2	2	2	1	2	1
CA	5	7	5	6	5	4	4	5	4	4	4	3	3	4	4	3	2	2	2
CS	5	3	4	3	3	5	3	2	2	2	2	1	1	1	1	1	2	1	2
Totals	**16**	**15**	**14**	**13**	**12**	**12**	**12**	**11**	**8**	**8**	**8**	**8**	**7**	**7**	**7**	**6**	**5**	**5**	**5**

Product sectors	**22B**	**21**	**22A**	**30**	**31**	**33**	**6**	**8**	**11**	**12**	**24**	**16**	**26**	**27**	**28**	**29**	**34**		
AR	2	0	1	0	1	1	1	1	1	1	0	0	0	0	0	0	0		
CA	2	3	2	2	2	2	1	1	1	1	1	0	0	0	0	0	0		
CS	1	1	1	2	1	1	1	1	1	0	1	0	0	0	0	0	0		
Totals	**5**	**4**	**4**	**4**	**4**	**4**	**3**	**3**	**3**	**2**	**2**	**0**	**0**	**0**	**0**	**0**	**0**		

3.5. Conclusions of the Survey

The Study was charged to ascertain whether MSAs typically or exceptionally use compliance schemes, provide compliance assistance or resort to awareness raising when enforcing the relevant legislation.

As the response to the survey was voluntary and as replies were only received from a minority of MSAs in each Member States, the results of the survey cannot necessarily be taken as an absolute statement of the current usage of compliance practices by MSAs across the European Union. In addition, MSAs did not provide answers to all the questions posed by the study.

Whilst it is not possible to be definitive about the total number, scope, quality, cost or usage of the practices that are in operation across all MSA in Member States, it is very clear that many MSA's did not feel compelled to confirm or deny that they operate such practices as an intrinsic feature of their market surveillance procedures. The picture that has emerged from the survey results is that Awareness Raising and Compliance Assistance are more common than Compliance Schemes but that many Member States may not use any such schemes at all.

This view is supported by the responses of Member States as reported in 2014 in meetings with the Commission, amongst others due to considerations of costs and administrative burden:

> *The majority of the delegates at a meeting of the Expert Group on the Internal Market - Market Surveillance Group on 19 May 2014 informed the European Commission that **they do not run such schemes**. But they do perform horizontal checks at manufacturer and importer level. The current practice takes into account good compliance records, and quality systems in place to define the economic operator's risk profile and decide if he will be checked. However, market surveillance authorities were generally opposed to formalising this current practice and to restricting their options for checking all businesses and products.*[34]
>
> *They were concerned that such practices could be seen as providing an ex-ante approval of products. Questions were also raised regarding the possibility for the economic operator to take advantage of the compliance scheme and use it as publicity.* [35]
>
> *The national market surveillance authorities of the EEA EFTA States **did not, for the time being, see a value added by introducing such schemes**, mainly due to the administrative burdens demanded by operating them. And **were not aware of any relevant schemes** at national level in the EEA EFTA States.*[36]

Having contacted over 500 separate MSAs that are responsible for 34 product sectors in each Member State and only being provided with detailed information on 56 practices, the conclusion that can be drawn from the study is that many MSA's have not greatly changed their position since May 2014.

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34 Summary of the Minutes of the Meeting of The Expert Group on the Internal Market for Products – Market Surveillance Group Monday 19 May 2014

35 Ibid

36 European Economic Area Standing Committee of the EFTA States, Ref: 14-131336, Rev.1 18 July 2014 Subcommittee I On The Free Movement Of Goods EEA EFTA - Compliance Schemes Operated By MSAS

If it is accepted that Member States and their MSAs would normally respond positively to a request for information from a Directorate General and would be keen to detail successful market surveillance initiatives, then a reasonable conclusion is that compliance practices are not being widely used across all product sectors by many MSAs. However, another possibility that is supported by some of the responses to the questionnaire is that the operation of such practices is now so firmly embedded within the general market surveillance protocol that they are no longer perceived as a separate or independent practice. This explanation would apply more specifically to Compliance Assistance and to a lesser degree, Awareness Raising.

The usage of this relatively small number of identified compliance practices appears to be evenly spread across most of the Member States, even if the countries that did not respond are not considered to have adopted any compliance practice. The result indicates that the usage of compliance practices does not appear to be related to the length of time that a country has been a member of the European Union while also showing that no Member State reported a significantly greater number of compliance practices than the rest. There also appeared to no discernible difference in the usage of compliance practices between large and small countries. Equally there is no evidence that suggests that specific Member States have adopted a policy stance upon the usage of compliance practices that has determined that MSAs should engage in their operation. Usage of compliance practices could be considered to be more dependent upon the policies and strategies of individual MSAs and quite independent of the member country.

From the information provided to the Study Team through the survey it was found that:

- Almost half of all the practices identified were applicable to a range of product sectors:
    - 52% of practices related to a single product sector [29 practices];
    - 34% of practices related to a range of product sectors – these included between 2 & 25 separate product sectors [19 practices];
    - 14% of practices were applicable across all product sectors [8 practices];
- The product sectors where these practices were mostly in operation are:
    - Measuring instruments, non-automatic weighing machines, pre-packaged products and units of measurement;
    - Personal protective equipment;
    - Machinery;
    - Construction products;
    - Equipment and protective systems intended for use in potentially explosive atmospheres;
    - Pyrotechnics;
    - Toys; and

- Electrical products (EMC & LVD),

- The product sectors where specific practices do not appear to be in use:
  - Appliances burning gaseous fuels;
  - Recreational craft;
  - Marine equipment;
  - Motor vehicles and tractors;
  - Non-road mobile machinery; and
  - Crystal glass.

- The product sectors where awareness raising features most often:
  - Measuring instruments, non-automatic weighing machines, pre-packaged products and units of measurement;
  - Personal protective equipment;
  - Machinery;
  - Construction products;
  - Toys;
  - Lifts:
  - Explosives for civil use; and
  - Electrical Equipment under EMC

- The product sectors where compliance assistance features most often:
  - Personal protective equipment;
  - Construction products;
  - Machinery;
  - ATEX[37]
  - Measuring instruments, non-automatic weighing machines, pre-packaged products and units of measurement; and
  - Electrical Equipment under EMC

- The product sectors where compliance schemes feature most often:

37 ATEX = Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres.

- Pyrotechnics;
- Measuring instruments, non-automatic weighing machines, pre-packaged products and units of measurement; and
- Personal protective equipment.

There is a degree of uniformity in that some product sectors feature prominently in all three categories of compliance practices. The split of compliance practices appears to relate slightly more towards consumer products rather than professional products except that ATEX equipment, a non-consumer product category features quite prominently, whilst crystal glass, a consumer product, does not feature at all; and of those product sectors that do feature prominently, a number contain both consumer and professional products (e.g. machinery and construction products). Mass produced products such as toys, electrical products, pre-packaged items, and personal protective equipment all featured strongly in the practices identified whilst large pieces of specialised equipment such as non-road machinery did not feature at all. It is accepted that compliance practices may not be as relevant in every product group, if, for instance, products are subject to type approval and obligatory surveillance by a third party through the relevant conformity assessment procedure, e.g. the automotive industry or gas appliances.

Whilst the study focused primarily on EU harmonised product legislation, in view of the relative lack of harmonised standards for products covered by the General Product Safety Directive (2001/95/EC), it is surprising that practices aimed at the manufacturers and importers of such products did not feature more highly.

The practices employed by MSAs do not always sit exactly within the EU chosen definitions as they often have features that cross these boundaries. Many Compliance Assistance protocols have the flexibility to extend into Awareness Raising when there is a change in legislation or a major example of non-compliance is discovered. They can also have elements of a Compliance Scheme if economic operators use the compliance advice provided and then can provide evidence of systems or activities that would reduce their risk assessment scores for inspection frequency or scope based upon their improved likelihood of compliance through an earned recognition protocol. It is often very difficult to assign a specific cost to the compliance practices when they are embedded in the normal market surveillance protocols of the MSA and not budgeted separately.

3.6. Feedback from businesses and trade associations

The study team sought to conduct interviews with twenty large scale economic operators and industry associations that have made use of compliance practices or have members operating within the relevant product sectors to gain their opinions upon the use and benefits of these practices. The choice of business stakeholders also sought to provide a balanced representation of businesses' typology (large business vs SMEs; manufacturers, importers and distributors) and geographical origin within the EEA.

This task was originally part of Task 1.1 but at the Kick-off meeting it was agreed that this task would provide better information if it was conducted after the “10 best practice” schemes, had been identified. This change of timeframe allowed the study team to obtain specific industry feedback upon the types of practices identified and the comments received

have been incorporated in the development of the recommendations that form part of this report.

It proved difficult to arrange interviews with some trade associations due to the appropriate personal not being available or the association requiring time to consult is membership or to draft a formal response. It was particularly difficult to gain a comprehensive response from economic operators regarding compliance schemes as so few member countries appear to have adopted such practices. However, it was possible to discuss compliance practices in general with nine trade associations and with three economic operators. To compensate for the lack of response from trade associations, the study team have researched public statements made by trade associations on the topic of compliance and MSA support and specific cases studies.

Feedback from trade associations and economic operators included:

Positive comments:

1 Trade associations are generally in favour of compliance initiatives.

2 They favour the concept of recognition in cases where all legal requirements were being complied with – earned recognition or recognition as an 'approved' economic operator, leading to less pressure directed at such economic operators.

3 They support a risk based approach as this would allow more pressure to be directed towards those who did not comply.

4 They support practices that have a single point of contact for approach.

Less positive comments included:

1 Many Trade Associations are not aware of examples of compliance practices, suggesting that not many schemes are in use.

2 They indicate that there is only low level of activity happening with any of these schemes.

3 They feel that more awareness raising should be initiated by market surveillance authorities to encourage greater compliance and to publicise those practices in operation.

4 Too many MSAs are only reactive in their approach to compliance assistance.

5 There needs to be greater harmonisation between MSA's on such matters as risk assessment which is currently too subjective.

6 Although no specific pitfalls were highlighted, concern was raised that in regards to non-harmonised product groups, a single compliance scheme might not be appropriate for all compliant products.

7 Concern was also expressed as to whether the MSAs would have the resources and expertise to keep up to date with regular legislation amendments and an extensive product range.

8 A view was expressed that in respect of Regulation 1223/2009 there would be no added benefit to having regulators develop compliance schemes as it would require resources to develop, maintain and update both from the regulatory authorities involved and from the trade association in consulting over their content. Such a procedure would delay informing manufacturers regarding changes and updates to the Regulation or its practical interpretation.

Issues raised:

1. Trade Associations feel that they should have input to MS testing programmes through national market surveillance programmes and EU MS programmes (WELMEC) so that suggestions from industry can be included in these programmes.

2. Awareness campaigns could include an annual conference open to both regulators and industry which is organised by the regulator and/or the trade association.

3. The incentive of earned recognition could encourage more trade associations to develop Codes of Practices for their members but this is not always possible due to the current state of the regulatory market.

4. There can be a disincentive to engage with MSAs because cheap imports from countries such as China which do not comply with legal requirements are not being controlled as little or no enforcement now takes place due to cutbacks.

5. They are concerned about a lack of budget to undertake enforcement and the difficulties with controlling the online marketplace.

6. Inconsistencies with enforcement, some MSA's being tougher than others.

7. Little or no account is taken of the history of the business and the risk posed and the extra steps the legitimate industry takes to get things right such as extra sampling and the wish for this to be recognised and distinguished from the industry 'bad guys'.

8. Inconsistencies between MSA's on failure rates and results of failures from Notified bodies which raises issues on such matters as adequacy of controls imposed by member states on Notified bodies.

9. For boilers, third party compliance verification has been helpful as an additional tool for compliance assessment in the interest of authorities, consumers and industry.

Trade Associations and economic operators providing feedback:

- Association of European Heating (EHI)
- European Fireworks Association
- Toy Industries of Europe (TIE)
- UK Weighing Federation
- Agricultural Engineers Association

- Cosmetics, Toiletries and Perfumery Association (CTPA)
- British Constructional Steelwork Association Ltd (BCSA)
- British Safety Industry Federation (BSIF)
- British Candlemakers Federation
- IKEA (UK and Ireland)
- Wm Morrison Supermarkets PLC (UK)
- SIA "Pipelife Latvia" (Latvia)

Specific comments:

Latvian business

- The modern approach to market surveillance is much better. A fast response to requests for information and the help provided by the MSA is appreciated by businesses.
- Training seminars are helpful in reducing misunderstandings but they need to be widely publicised in order to reach as many economic operators as possible

Previously published Market Surveillance Best Practice Case Studies

"The European Partnership for Energy and the Environment (EPEE), the voice of the manufacturers of heating and cooling equipment in Europe, is committed to improving market surveillance implementation, which is often fragmented and insufficiently resourced throughout the EU Member States. Without proper enforcement, legislation will not reach its full potential and the market will be further distorted at the expense of the environment, consumers and industry. Sharing knowledge on projects and policies is key for better market surveillance in Europe. Within this context, this guide offers some best practices from national market surveillance authorities of EU Member States on how to navigate current challenges and obstacles. EPEE has focused particularly on the EU Eco-design legislation."[38]

- **Finnish Safety and Chemicals Agency (TUKES)**, Finland's market surveillance authority, has provided several insights for other Member States on how to deal with market surveillance. Since 1992, TUKES has been active on safety related legislation. From their experiences, the following best practices have been identified.
  - **A holistic, integrated approach to market surveillance**

    TUKES provides information on eco design through its telephone hotline and FAQ page and online forum. The agency reports a further need to communicate basic eco design information with small and medium sized enterprises (SMEs) that are among the first to be impacted by EU eco design legislation.
  - **Regional Initiatives on market surveillance:**

38 Market Surveillance Best Practice Case Studies – The European Partnership for Energy and the Environment (EPEE)

Finland is a member of the Nordic Forum, a regionally-focused platform for sharing information and providing assistance on market surveillance among Denmark, Finland, Iceland, Sweden and Norway. The Nordic Forum meets three to four times each year to discuss these issues.

- **Greater EU market surveillance cooperation on non-safety issues for products:** TUKES has prioritised the creation of an EU-wide database dedicated to market surveillance on non-safety related issues, on which Member States do not have an organized system or initiative to share information within the EU.

Previously published views of Industry[39]

- In the UK the National Audit Office (NAO), the Better Regulation Executive (BRE) and the Better Regulation Delivery Office (BRDO), both from the Department for Business, Innovation and Skills (BIS) and Department for Environment, Food and Rural Affairs (Defra) commissioned a survey to determine businesses' views on the extent of the burden of regulation, both in general and in specific regulatory areas. The survey, conducted by Jigsaw Research in February and March 2014, comprised 2,500 20-minute telephone interviews with senior business decision-makers.

  - Some key findings:

    - 91% of businesses use some form of external support when complying with the one specific law type that they were asked questions about. This support includes using websites (54%), seeking help from advisors/agents (51%), trade associations/business organisations (46%), friends/peers (43%) and inspectors (38%).

    - Medium and large sized companies (50+ employees) are more likely to seek external support from websites and advisors. Micro and small companies (less than 50 employees) are more likely to seek external support from friends and peers.

    - 46% make use of trade associations or business organisations and 43% talk to friends, family, other contacts or peers.

    - Around two-fifths (38%) use inspectors from the local council or regulatory bodies to help their business in complying.

    - Half (50%) use external agents because of a lack of clarity in the legal requirement for regulatory compliance, and two-fifths (40%) do so because of insufficient advice from regulators.

    - Sole employee businesses are least likely to seek more/specialist knowledge (possibly due to a lack of perceived need) and small to medium companies more so (possibly due to fewer internal specialists when compared with large businesses).

    - Small businesses are more likely to use a number of sources to help with compliance for one specific law type. 62% use government websites

39 Business Perceptions Survey 2014

(compared with 54% of all businesses) while 62% use external advisers/agents (compared with 51% of all businesses).

- ❖ Just under a half of businesses (49%) agree that 'good regulatory advice helps make confident investment decisions'.

- ❖ Approaching six in ten (59%) agree that finding information about which regulations apply is a burden and just over half (53%) feel this applies to finding guidance and advice explaining what you have to do to comply.

Previously published comments of Trade Associations

- ➢ "The European machinery industry, represented by CECE, CECIMO, CEMA, FEM and EUROMAP, warmly welcomes the proposal for a Regulation on market surveillance from the Commission, as it reflects many of the suggestions that our industry has made during the past months. - "Trade Associations should be taken on board to cooperate with the Authorities of the Member States to set up technical procedures for the inspection of the machines".

- ➢ "Improving information from authorities to businesses: Dissemination of information to the various stakeholders is a key part of effective market surveillance. Ensure that the existing system contains the information on results of market surveillance that is relevant for businesses."

  -The Association of Swedish Engineering Industry (Teknikföretagen) and the Swedish Trade Federation (Svensk Handel) - Stockholm, September 2009.

Orgalime answer to the Commission questionnaire on "Internal Market for Goods – Enforcement and Compliance"

Question B2.4. What is your opinion on the following approaches by national authorities to reduce the level of non-compliant products on the market?

1. National authorities should focus exclusively on enforcement and leave it entirely up to the businesses to ensure compliance by developing their own approaches. → **not effective**

2. In addition to enforcement national authorities should also provide information on product requirements. → **effective**

3. In addition to enforcement national authorities should also provide support to businesses through guidance on how to interpret product requirements**.** → **effective**

4. In addition to enforcement national authorities should also allow businesses to enter into agreements with authorities to receive binding advice from them on how to interpret product requirements in specific situations. → **not effective**

We would like to emphasize that information should be made available first and foremost at local level, in a tailored manner for each sector. While such information needs to be updated and co- ordinated centrally, a single multilingual portal is not the best way to ensure greater awareness of SMEs. We should also promote the role of national trade associations.

Comments about UK Primary Authority

- **Large International business: "**The Company signed up to the Primary Authority scheme in the UK, there being no similar scheme in Ireland. They find this scheme works for them well and are positive about the outcomes it provides for the company, but the expense of it is constantly reviewed and questioned as to whether it is still value for money, especially where regulators are fully stretched on other priorities, but this appears to be the only potential pitfall".

- **Large UK business:** "Primary authority has provided us with sound advice from a regulatory perspective but more so on a practical level to improve safety standards for our circa 8500 staff and circa 430,000 members."

- **UK trade association with 160 members:**

    - "Primary Authority partnerships are built on trust, and have resulted in a much better understanding and working relationship between MSAs and industry".

    - "Because the MSA has confidence that members of the trade association [TA] are compliant, they can focus their resources more effectively on areas of market surveillance where non-compliance is more likely to be found".

    - "The co-ordinated primary authority partnership serves as a conduit for shared intelligence about non-compliant businesses and this is very helpful to MSA in targeting their resources effectively".

Comments from a primary authority evaluation in 2013 re business benefits:

- A reduction in the amount of time businesses spend on regulatory activities;
- Improvements in relationships with regulators;
- Improved intelligence about regulatory matters;
- Improvements in the consistency of regulatory advice and guidance;
- Access to advice, both Primary Authority Advice and other non- statutory advice;
- Support for staff development;
- Advice on planned or future developments;
- Support for addressing "incoming" regulatory issues from enforcing authorities;
- Advice on standardising policies, procedures, systems and documentation.

Overall summary of view of industry

Trade Associations represent the economic operators who seek to comply with the law and therefore are generally supportive of compliance practices. They are concerned about ease of access to guidance, accuracy and consistency of advice and demands upon their resources. However, they are also seeking protection for unfair competition from the easy availability of non-compliant products or activities. They are often keen to work closely with the

enforcement authorities so that the experience, views and needs of their members are considered in the planning and development stages of compliance practices. Trade associations are often a major source of advice and guidance for their members and would not see any advantage if the MSAs merely duplicated their efforts.

The feedback received from the trade associations consulted when added to the previously published comments from industry and the results of research publically available gives a clear indication that compliance practices are welcomed and supported by economic operators if they are well designed, appropriately resourced, backed by relevant expertise and are efficient and effective. However, these is a concern that the development and operation of compliance practices might divert resources from delivering a scale of inspection that provides compliant economic operators with the protection and assurance of a "level playing field" and rewards the investment of resources into compliance systems and best practices.

As consistent market surveillance practices universally applied across all EU member countries still appear to be some way off, part of an ideal solution could provide a mechanism for economic operators to seek advice from a single point of contact on an EU wide basis that is recognised, acknowledged and respected by all other EU MSA's in a consistent manner. Perhaps it can never be achieved, or is a long-term aspiration. There would also need to be some form of dispute resolution process between MSA's but either way, this sort of approach utilising a single point of contact appears to be favoured by industry.

3.7. Further analysis of identified compliance practices

The study team reviewed the 56 compliance practices that had been detailed through the survey, applied the benchmark criteria and sought to identify specific elements essential for their success that included:

a. cost-efficient compared with more classical styles of enforcement;

b. more suitable for a range of market/product sectors; and

c. easily replicated in other Member States.

Visits were made to interview the Market Surveillance Authorities operating the compliance practices that appeared to meet some of the benchmark criteria and offered elements of good practices and transferability. It was not always possible to arrange interviews with all the MSAs that we wished to interview due to a lack of availability of personnel from the MSA. When interview were not possible, further details were obtained through exchanges of e-mails.

In total interviews were conducted with MSAs in 13 member countries. The countries visited were:

- Belgium
- Croatia
- Cyprus
- Denmark
- Eire
- Finland
- France
- Latvia
- Luxembourg
- Netherlands
- Slovenia
- Sweden
- United Kingdom

❖ Detailed information was obtained by e-mail from Portugal and Spain.

This consultation produced a total of 27 compliance practices that had particular merit and these were further reduced to produce 14 "best practice" schemes. The 13 compliance practices that did not make the final 14 are detailed in Section 27 of this report. The breakdown of the 27 compliance practices into 14 identified as "best practice" is as follows:

- Awareness raising: a total of 10 practices including 4 "best practices" examples;
- Compliance assistance: a total of 12 practices including 6 "best practices" examples;
- Compliance schemes: a total of 5 practices including 4 "best practices" examples.

The compliance practices are not listed in any order of importance or preference as they all have strengths and weaknesses that are important if their usage is being considered in a specific set of circumstances and in relation to specific product sectors. Issues such as cost, resources and opportunity costs need to be considered. The list is followed by a detailed analysis of each practice.

3.8. The List of "Best Practice" Schemes

COMPLIANCE SCHEMES

- **UNITED KINGDOM - BEIS: Primary Authority/CTSI: Home Authority [CS1]**
- **FRANCE - DGCCRF: Market Surveillance protocol - Supply chain supervision [CS2]**

- **NETHERLAND - NVWA: Market Surveillance – Regulatory protocols [CS3**
- **LUXEMBURG - ILNAS - SURVEILLANCE DU MARCHÉ: MS Quality Management System [CS4]**

COMPLIANCE ASSISTANCE

- **PORTUGAL - INFARMED I.P: Regulatory and Scientific Advice Office & Guide [CA1]**
- **NETHERLANDS - AGENTSCHAPTELECOM: Market Surveillance Protocols [CA2]**
- **CYPRUS - CCPS: Ensuring the Safety of Toys [CA3]**
- **SWEDEN - SWEDISH CONSUMER AGENCY: PPE Compliance brochure [CA4]**
- **SPAIN - SOIVRE INSPECTION SERVICE: Market Surveillance protocol [CA5]**
- **SWEDEN - SWEDISH CONSUMER AGENCY: Web based information [CA6]**

AWARENESS RAISING

- **CYPRUS - LABOUR INSPECTION: Market Surveillance protocols [AR1]**
- **LATVIA - CRPC: BE SMART – Build Safe Campaign [AR2]**
- **DENMARK - DANISH MS COMMITTEE - Good Communication [AR3]**
- **IRELAND - DEPARTMENT OF JOBS, ENTERPRISE AND INNOVATION - Market Surveillance protocols [AR4]**

3.9. Good Practice

GOOD PRACTICE FOR GENERAL AWARENESS RAISING – *[See section 27]*

- **FINLAND – PIKI'S ROOM**

OTHER EXAMPLES OF GOOD PRACTICE – *[SEE SECTION 26]*

- **BUSINESS AWARENESS RAISING INITIATIVES**
- **PROOF OF AGE SCHEMES**
- **FOOD HYGIENE RATING SCHEME**
- **BUSINESS COMPANION**
- **COMPLIANCE ADVICE CENTRES**

3.10. Compliance Schemes

TITLE: *CS1 -* **Market Surveillance protocol - Primary & Home Authority**

OPERATOR: **DEPARTMENT FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY**

COUNTRY: **United Kingdom**

DETAILS: Primary Authority [PA][40] is a statutory scheme, established in the UK by the Regulatory Enforcement and Sanctions Act 2008, that came into operation in 2009 and allows economic operators to be involved in their own regulation. The scheme enables them to form a statutory partnership with one MSA, which then provides them with robust and reliable assured advice and requires all other local regulators to consider this advice when carrying out inspections or addressing non-compliance.

Through Primary Authority, Economic Operators and MSAs can develop better working relationships that are based on trust. One of the main purposes is to ensure that consistent advice on compliance can be given to and received by businesses across whole trading sectors and can provided through trade associations in conjunction with the PA MSA.

Economic operators receiving and following assured advice from their primary authority can be confident that they are compliant.

An inspection plan for all sites operated by an economic operator can be produced by its primary authority to improve the effectiveness of visits by local regulators, avoid repeated checks, and enable better sharing of information. Other inspection bodies must follow the requirements of the plan, unless the primary authority is notified in advance and has agreed to an alternative course of action.

COMMENT: A scheme designed to provide economic operators with a single point of contact and consistency of advice when they are responsible to multiple MSAs all enforcing within the same product sectors. A unique element is the financial arrangement between the MSA and the economic operator that allows the MSA to recover the costs of providing guidance. This will probably require legislative approval in Member Countries before it could be replicated. This scheme is run along aside a non-regulatory, free scheme called "Home Authority" operated by the MSAs themselves based upon a model developed by the professional association for Market Surveillance Inspectors. (CTSI)[41]

ASSESSMENT:

1. **Effectiveness**

   - Design: To ensure that local enforcement is consistent at a national level and sufficiently flexible to address local circumstances. It allows an eligible Economic Operator to form a legally recognised partnership with a single local MSA in relation to regulatory compliance. This MSA is then known as its 'primary authority' (PA).

40 https://www.gov.uk/government/publications/primary-authority-overview
41 Chartered Trading Standards Institute

- Evidence of results: Numbers of EO agreeing PA partnerships has increased from 6 joining in 2009 to 9,370 in 2016. As of 12th October, there are 15,733 EOs involved in 16,849 PA agreements with 180 MSAs. Very few PA partnerships have been discontinued since the commencement of the scheme.

  An Independent Review of Primary Authority in 2013 concluded that EOs were deriving a wide range of benefits from Primary Authority including a reduction in the amount of time EOs spent on regulatory activities. The large number of EOs involved and countless thousands of pieces of advice issued are a very positive indicator as there has only been two challenges to Primary Authority Advice resulting in formal determinations.

- Costs: The resourcing of each partnership is a matter for the EO & MSA concerned. The design and launch cost were covered by the Ministry. The total budget is not known because the operational costs are shared between several sources.

- Duration: 7 years

- Coverage: **National** - through local MSAs across all product sectors

- Meets product harmonisation principles: Easier for EOs to be compliant, by removing uncertainties and eliminating the possibility of MSAs providing inconsistent or conflicting advice. The availability of a single point of contact at a PA to deal with a major issue such as a product recall has many benefits for the EO, including a consistent approach, shared knowledge and expertise.

2. **Cost-efficiency:** EO's can tailor the terms of their PA agreement to meet their own needs and cost benefits. The partnership agreements provide MSAs with the ability to fund their advice provision. Co-ordinated planning between MSAs with a designated lead MSA can reduce both scope and frequency of inspection and sampling and avoid duplication.

3. **Specific elements:**

   - Eligible economic operators can be local, regional or national.

   - Statutory scheme to provide robust and reliable assured advice to Economic Operators;

   - Terms and conditions set in Primary Authority Handbook[42] [159 pages]

   - Voluntary engagement with MSAs by individual EO's who can decide what level of support they require;

   - Resourcing of partnerships is a matter for the parties concerned

   - Advice given by PA must be respected by all other MSA's who may have an overlapping interest in the EO.

42 www.gov.uk/government/publications/primary-authority-handbook

- A PA can recover its costs from the EO - but charging is not mandatory[43]

4. **Ease of replication:** May conflict with legislation or anti-corruption initiatives that prohibit government departments and their staff from receiving recompense for advice and assistance provided during their official duties. Would need legislation in most/all member countries.

   This type of practice may work best in member countries that operate market surveillance at both national and regional or local level through independent MSAs and municipal bodies as the practice aims to provided consistency of advice and enforcement whilst avoiding uncertainty and duplication. It would also require an identified need of the national and regional EOs and an indication of their willingness to meet the PA costs.

5. **Earned recognition/impact upon inspection:** An inspection plan for an EO can be produced by its PA to improve the effectiveness of visits by local regulators, avoid repeated checks, and enable better sharing of information. All other MSA's must follow the requirements of a PA plan, unless the PA is notified in advance and has agreed to an alternative course of action. The 2013 review of PA conclude that it had a positive impact upon enforcement activity.

TITLE: ***CS2*** **- Market Surveillance protocol - Supply chain supervision –**

"Contrôle de la première mise sur le marché" [CPMM]

OPERATOR: DIRECTION GÉNÉRALE DE LA CONCURRENCE, DE LA CONSOMMATION ET DE LA RÉPRESSION DES FRAUDES (DGCCRF)[44]

COUNTRY: France

DETAILS: MS Inspection of the main operators placing products on the French market to assess their ability to respect all applicable product legislation and identify those with efficient internal checking procedures. The practice was devised as a cost-efficient and time-efficient inspection method for the operators responsible for most of the products being placed on the market, before they are dispatched in the retail shops. The targeted operators are subjected to initial CPMM inspection and regular follow-up inspections. Specific indicators determine the frequency of inspections and risk-rating system of EOs is included in the scheme, with inspection frequency being reduced if the risk level of the EO is reduced. EOs with a good CPMM control history and known to have appropriate procedures in place are more readily left in full control of recall operations when these situations arise. CPMM can be translated into 'Initial market release control' and covers both food and non-food products when covered by sector-specific regulations e.g.: products with the CE marking (LVD, Toys, REACH). The sector-specific regulation can also be a national regulation: e.g.: in France, some GPSD products are also covered by national regulations: bicycles, child-care articles or leather products.

43 See **Annex E** for a full explanation of cost recovery
44 www.economie.gouv.fr/dgccrf

Key elements designed to make CPMM effective and efficient:

- Ensure proper coverage of economic operators
- Objective risk rating system
- Qualified inspectors
- Result assessment?
- What is the acceptable cost?

COMMENT: A market surveillance approach focused upon the head of the supply chain to prevent non-compliant products from entering the market. The procedures adopted present economic operators with the ability to reduce their inspection frequency if they can demonstrate that they have systems and procedures in place to ensure complaint products.

The CPMM controls are only one constituent of the market surveillance activity, along with control programs targeting specific products and reactive controls following safety alerts and consumer complaints.

ASSESSMENT:

1. **Effectiveness**

   - Design: To ensure the compliance of regulated products by a focus upon the head of the supply chain achieved through risk-based inspection of the main EO's placing product on the market to assess their ability to comply with all applicable product legislation. Practice aimed at EOs placing regulated products on the market with a yearly turn-over > 2 million euros.

   - Evidence of results: The effect is claimed to be similar to market surveillance, but targeting the operators placing on the market ensures better coverage (multiplier effect).

   - Costs: Budget comes from the main yearly MSA operation budget and was never individualized. But human resources for the CPMM scheme to function at national level is estimated around 18 FTE.

   - Duration: 10 years in current form.

   - Coverage: **National** - All product sectors if regulated (3,4,5,9,13,14,17) and covering EU and national regulations.

   - Meets product harmonisation principles: provides a risk-based approach to market surveillance that encourages EO to set up effective compliance measures.

2. **Cost-efficiency**: The practice was devised as a cost-efficient and time-efficient inspection method to cover the operators responsible for most of the products being placed on the market, before they are dispatched to the retail shops. Controls upstream in the distribution chain are the most cost efficient and ensure the widest coverage.

3. **Specific elements**:

1. There is a national list of economic operators subject to the CPMM control scheme, but the eligibility assessment of an operator is made at the regional level (following harmonized national criteria).

2. Economic operators included in CPMM include those:

- place a product on the national market (manufacturers, importers … but also introducers)
- Dealing in products that have to comply with sector-specific regulations (European + National)
- Companies of significant importance
    i. Size: revenues around 2 million euros (approx.); or
    ii. Product distribution: nationwide

- The *Code de la consummation* provides a legal basis for the controls and procedures are set in several internal control policy documents covering programming, preparing, realizing, follow-up and training.

3. Each company has an ID file that details:

- If the company is subject to the CPMM scheme
- When the last inspection took place & next CPMM control is scheduled
- The lastest risk rating

- A detailed risk-based inspection policy provides a strong incentive for companies to take steps to prevent non-compliant products from entering the market.

4. CPMM offers the opportunity of a wide-spectrum inspection covering an assessment of the company's capacity to comply with applicable law; an assessment of the company's capacity to handle a crisis situation; and its product checks;

- The EO risk-approach of the CPMM does not go into too many details when it comes to product categories of the operator (An EO dealing with both low-risk products and high-risk products will mainly be considered as dealing with high-risk products)
- The CPMM scheme ensures that all operators in the target group are inspected with an appropriate frequency.
- The scheme was expanded from producers to importers and/or distributors placing a product on the market
- CPMM is a mandatory inspection: operators cannot choose to be part or not scheme.

- There is no contract between operators and the MSA.

- It is not an audit nor a consultancy service: no fee is paid.

4. **Ease of replication**: The practice can be transferred if MSAs have the power to conduct preventive inspections during which inspectors can have access to all company premises, documents and information relating to product compliance.

5. **Earned recognition/impact upon inspection**: Inspection frequency is reduced as the risk profile of an EO diminishes. However, EOs do not "engage with the scheme" as it is up to DGCCRF to decide whether an operator should be included in this control scheme. Companies with a good CPMM control history and known to have appropriate procedures in place are more readily left in full control of recall operations if these situations arise.

TITLE: ***CS3 -*** **Market Surveillance protocols**

OPERATOR: **NEDERLANDSE VOEDING AND WAREN AUTORITEIT [NVWA]**

NETHERLANDS FOOD AND CONSUMER PRODUCT SAFETY AUTHORITY[45]

COUNTRY: Netherlands

DETAILS: A Market Surveillance system based upon documented procedures, risk assessment, process audits and planned sampling. This process allows the MSA to group economic operators into defined categories that have specific inspection criteria. The reasoning behind this practice is that it will encourage economic operators to improve their in-house quality procedures and raise their category rating. The revision of the General Product Safety Directive in 2001 was the trigger for the adoption of a more system approach market surveillance.

"Operators that make a demonstrable effort to improve compliance are eligible for reduced surveillance. Under certain circumstances agreements can be concluded with such businesses laying down a regime of reduced supervision and constant effort to improve compliance on the part of the operator. The market surveillance authority and the company see each other as partners with respect to assurance of product compliance."[46]

COMMENT: A well organised, focused and comprehensive approach to market surveillance that offers benefits to economic operators to demonstrate their desire and ability to comply with the legislative requirements. The approach is in accordance with the Hampton[47] principles of better regulation with a core policy of "soft where possible, hard where necessary".

45 https://english.**nvwa**.nl
46 Netherlands - National Product Market Surveillance Plan for 2015–2016
47 2005 Hampton Report

ASSESSMENT:

1. **Effectiveness**:

   - Design: Market surveillance protocol focusing as much as possible with the front end of the commercial chain - producers, importers and distributors. Proactive market surveillance is risk-based and seeks to influence the behaviour of operators in such a way as to encourage compliance with the law.

   - Evidence of results: No investigation of reduction in dangerous products but an impression has been formed that number of safe products is increasing. An external consultancy company conducted a study economic operators' experience of the system surveillance approach.

   - Costs: No specific budget – part of general MS budget.

   - Duration: 7 years of functional audits

   - Coverage: **National** – Most product sectors are covered but not those dealing in professional use machinery, vehicles or recreational crafts. Large scale producers and importers are targeted.

   - Meets product harmonisation principles: MS protocols designed to ensure that EO only put safe products on market and comply with relevant legislation. New GPSD (2001) was the trigger for more system audit approach market surveillance.

2. **Cost-efficiency**: The auditing is conducted as part of inspection programmes. Costs are higher but advantage is claimed to be higher effectiveness.

3. **Specific elements**:

   - Written procedures to implement the objectives

   - "Auditing" on the basis of risk assessment of the economic operators compliance procedures and product sampling.

   - Audit points are Inspection results, knowledge of legislation, etc**.**

   - EOs get encouraged to adopt a more pro-active approach to product safety (e.g. by installing a product quality system)

   - At least one contact with the EO each year.

   - Change of earlier approaches: much more preparation is needed, deep knowledge of standards, requirements. At least 4 working days per inspection (2 days preparation, 1 day site, 1 day reporting).

   - Use of social media (twitter and apps) to contact stakeholders and keep in touch with them about the market surveillance and the products involved.

   - More traditional forms of consultation and coordination also take place through periodic meetings with stakeholders.

- These consultations are generally organised within sectors.

- Stakeholders may be economic operators or consumers, as well as NGOs and knowledge organisations such as universities.

4. **Ease of replication**: Can be applied by other MSAs if staff have systems analysis qualifications, experience or training.

5. **Earned recognition/impact upon inspection**: EOs that make a demonstrable effort to improve compliance are eligible for reduced surveillance.

TITLE: ***CS4 -*** **MS Quality Management System**

OPERATOR: ILNAS - SURVEILLANCE DU MARCHÉ - MINISTRY OF ECONOMY

COUNTRY: Luxembourg

DETAILS: The Market Surveillance departments in Luxembourg were previously scattered over the country. In 2008, by the creation of ILNAS[48], the competences had been regrouped to harmonise their operations and to put them together in one place. An ISO 9001 Quality Management System [QMS] complete with electronic database, quality policy, quality manual, documented procedures and programmed working was introduction of to deliver an improved inspection regime and to seek ensure client satisfaction. MS activity is enhanced through creating a QMS that integrates the legal requirements and an internal structure. Activities are revised every year in accordance with the ISO 9001 requirements. The overall intention was to design and introduce an operational system capable of meeting national and EI requirements.

COMMENT: Accurate and readily accessible information about the inspection history of economic operators, the products they trade and the systems that they use is the prerequisite of accurate EO risk assessment and the development of an information-led inspection programme that recognises and benefits those who have the means and desire to comply.

ASSESSMENT:

1. **Effectiveness**:

   - Design: A management tool based upon an electronic database of historical inspection information operating within a Quality Management System. This allows a more sophisticated inspection regime to be adopted and based upon accurate and accessible information.

   - Evidence of results: KPIs & annual audit. Increase in RAPEX/ICSMS notifications and participation in ADCO/Prosafe. Credibility amongst stakeholders improved.

48 https://portail-qualite.public.lu/fr/index.html

- Costs: Development of the QMS over 2 years period and the internal electronic database included:
    - 500 person days (2 staff in QMS and 1 staff in software for the database)
    - 5,000 euro: Audit cost
    - 5,000 euro: IT equipment
    - 15,000 euro: extension of existing ILNAS database of ILNAS
    - 5,000 euro: staff training
- Duration: Database 2011, QMS Since 2013.
- Coverage: **National** Wide range of products {3-11, 13-15, 17-20, 23, 25, 31, 33}
- Meets product harmonisation principles. Better data & quick access to it – Improves decision making - More consistent approach by MSAs.

2. **Cost-efficiency**: Clear benefits over time but costs are front-loaded and can involve high initial resource depending upon starting position. Claims of improved efficiency – too soon for definitive evidence but there has been recognition of improved market surveillance and enhanced credibility.

3. **Specific elements**:
    - Classification of risk rating used for economic operators
    - Transparency of operation through documented strategies and procedures
    - Key performance indicators are in place that cover:
        i. Rate of closed files of imported products;
        ii. Rate of closed files of products found on the field (shops, distributors, manufacturers);
        iii. Number of field inspections;
        iv. Number of national/European campaigns per category;
        v. Number of information campaigns;
        vi. Number of complaints by external stakeholders.
    - Quick transfer of information to database – contains economic operator's data plus MS inspection and sampling data
    - Accurate and upto date information provides for good decision making and supports an effective market surveillance regime
    - Good collaboration with Customs Service

- Information provided to EOs via website, factsheets for 25 product sectors & a quarterly newsletter plus specific product alerts

- This approach complements and has parallels with product safety compliance where conformity assessment modules require manufacturers to apply quality assurance systems. It is relevant to all products under 765/2008 and provides "best practice" to help MSA's meet the needs and approval of all stakeholders.

4. **Ease of replication**: Could be implemented by all MSAs if budgets allow.

5. **Earned recognition/impact upon inspection**: EOs are classified through risk assessment - Too soon to measure impact upon inspection demands.

3.11. Compliance Assistance

TITLE: ***CA1 -*** **Regulatory and Scientific Advice Office & Guide**

OPERATOR: **NATIONAL AUTHORITY OF MEDICINES AND HEALTH PRODUCTS,**

COUNTRY: **Portugal**

DETAILS: THE GUIDE FOR REGULATORY AND SCIENTIFIC ADVICE (RSA**)** provides information regarding legal requirements applicable to Cosmetic Products and Medical Devices to economic operators through an advice office and training sessions**.** The Regulatory and Scientific Advice Office (GARC), provided by Infarmed[49], has the competence to advise on issues arising with the preparation of documentation for:

- clinical trial, marketing authorisation, submission of variations, renewals or other subjects related to medicines for human use;

- EC marking or complementary procedures;

- notification or registration of medical devices and cosmetic products;

- licensing and good practices procedures;

GARC's final goal is that applications are submitted in accordance with current regulatory and scientific requirements thus allowing for a quicker validation and assessment.

COMMENT: Advice can be sought during initial development stages of medical devices and cosmetic products (pre-submission) and during post-marketing. The guidance will be regularly updated to reflect the scientific and regulatory evolution, in accordance with new legislation and applicable guidelines. It will also mirror the experience gained in the process.

49 www.**infarmed**.pt

ASSESSMENT:

1. **Effectiveness**:

   - Design: Expert advice for EOs to enable them to achieve compliance by building it into their products from conception to production. Advice is also available on the procedures necessary to be completed before a product is placed on the market.

   - Evidence of results: None provided but as because of the services available it is believed that fewer non-compliant products will be placed on the market

   - Costs: No information provide but fees are only charged for medicines

   - Duration: Since 2008

   - Coverage: **National** - Medical devices and cosmetics [Product sectors 1 & 2]

   - Meets product harmonisation principles: By making it easier and more straightforward for EOs to be compliant and helping them to build in compliance.

2. **Cost-efficiency:** Less time should be taken up by MSAs in inspecting cosmetic products and medical devices on the market and this time could be used for other priority market surveillance work.

3. **Specific elements**:

   - For cosmetics, information is provided in respect of the:

     - regulatory framework for cosmetic products in Portugal
     - steps to be taken to place a cosmetic product on the market
     - steps to be taken to import cosmetic products
     - requirements needed by a technician
     - cost of marketing cosmetic products in Portugal
     - requirements for manufacturing cosmetic products in Portugal.

   - For medical devices:

     - Several training sessions per year regarding legal requirements
     - information regarding medical devices placed on the market;
     - Preparation of documentation for:
       - clinical studies;
       - EC marking or complementary procedures;

- notification or registration of medical devices and cosmetic products;
- licensing and good practices procedures
- Information on technical files and product registration

➢ INFARMED, I.P., will not provide advice whenever the same advice has been requested to EMA's Scientific Advice Working Party (SAWP).

➢ The advice provided by INFARMED, I.P., will only refer to questions to which no clear answer can be found on national regulation or in national or European guidelines, including European and Portuguese Pharmacopoeias.

4. **Ease of replication**: Further detailed information would need to be established.

5. **Earned recognition/impact upon inspection**: No information provided.

TITLE: ***CA2 -*** **Market Surveillance protocols**

OPERATOR: **AGENTSCHAPTELECOM**[50]

COUNTRY: **Netherlands**

DETAILS: The MSA works between the economic operators and the Notified Body to provide high quality information upon the application of legislation, the appropriate means of compliance & relevant risk assessment strategies and procedures. The website provides Guidelines for equipment providing relevant background information, documents and forms as well as access to the relevant laws and regulations on the marketing of electrical appliances. Specific information about the R & TTE and EMC Directive is provided. Major objective is to make inspections more effective.

COMMENT: Good example of co-operation between the MSA and a Notified Body to provide consistent and comprehensive information to economic operators.

ASSESSMENT:

1. **Effectiveness**

➢ Design: Assistance in understanding the application of legislation especially for EO associations to produce more effective market surveillance

➢ Evidence of results: Objectives not formulated, no quality manual, specific indicators are still in development.

➢ Costs: Budget cannot be defined. MS system is budgeted as a single entity.

➢ Duration: Since 2010

50 https://www.agentschaptelecom.nl

- Coverage: **National** - Compliance assistance (related to directives 18, 19), awareness (Dutch "voorlichting" for 17, 18, 19)

- Meets product harmonisation principles: Harmonisation of methods for compliance

2. **Cost-efficiency**: More effective MS should be cost effective.

3. **Specific elements**: Providing good information to EOs for them to better formulate the risk analysis of their products. Information is provided through a website and through trade associations in the relevant product sectors.

4. **Ease of replication**: Depends upon the degree of co-operation between the MSAs and Notified Bodies.

5. **Earned recognition/impact upon inspection**: None - reduction in inspections.

TITLE: ***CA3*** **- Ensuring the Safety of Toys**

OPERATOR: **COMPETITION AND CONSUMER PROTECTION SERVICE**[51]

COUNTRY: Cyprus

DETAILS: Expert knowledge and guidance on toy safety is provided for Market Surveillance inspectors through an internal single point of contact that also informs the inspection planning process and oversees the targeted sampling that is co-ordinated with EU joint actions.

Due to the size of the economy within which the MSA operates it has been possible to perform effective toy safety surveillance by allocating the responsibility to one senior manager who influences and oversees toy safety inspection outcomes across all inspection activities. Implementation has been based on need and takes account of the risks nationally posed by this product sector compared to other product sectors perceived to be of lower risk.

Key to its success is that the person tasked with the responsibility is up to date with all matters concerning toys and toy safety, including enforcement requirements, complaints statistics, accident trends and known problem areas. The position within the organisation held by the post-holder is at an appropriate management level for this approach to be effective. The post-holder has the necessary delegated power to oversee and inform all the inspection planning process and to tailor it to suit the organisational needs. This oversite by a single person includes the development of sampling programmes and participation in EU joint actions which provides sampling opportunities that would otherwise be unavailable or hard to secure.

COMMENT: A considered approach to compliance assistance to ensure that consistent and accurate information is provided to economic operators and underpins the inspection planning and sampling activities. In addition, the practice also seeks to align activities with EU joint actions. Prioritising toy safety activities and allocating specific responsibility has been an effective way of increasing effectiveness of inspections and targeted sampling. It has also led

51 http://www.mcit.gov.cy/mcit/cyco/cyconsumer.nsf/page22_en/page22_en?OpenDocument

to a higher profile being given to the issue of unsafe toys found on the market and interactions with key stakeholders.

Such an approach provides MSA's, with a valuable expertise resource which can be utilised to inform, train and coach the inspectorate, to educate and inform economic operators and through the media and dedicated proactive enforcement, to inform citizens.

This approach has the potential to be successfully implemented in larger member states where organisation of MSA responsibilities is performed at a regional or local level. However, it is important that attention is given to effective co-ordination and cooperation and to the analysis of both risk (product and EO) and the appropriate level of resources required for effective service delivery.

ASSESSMENT:

1. **Effectiveness**

   - Design: To make better use of limited resources by providing staff with a designated source of information regarding specific product sectors.

   - Evidence of results: Increase in non-compliant products being withdrawn from the market. Injuries currently not being monitored.

   - Costs: Included with overall service budget

   - Duration: 2 years

   - Coverage: Safety of toys and all child care products covered by GPSD

   - Meets product harmonisation principles: Raised inspection levels from a previous low level and provides accurate and consistent information to EO's through fully informed and more confident staff. Now there is effective coordination of activities, standard forms and documents, increase in visibility, increase in both quality and number of inspections, and establishment of a sampling programme.

2. **Cost-efficiency**: Better use of inspection resource - Increase inspection of targeted products.

3. **Specific elements**: Single person responsibility to oversee the service delivery on a day to day basis including overseeing sampling, Prosafe joint actions, RAPEX, Information is also utilised to guide inspection programmes and for visibility opportunities with key stakeholders.

4. **Ease of replication**: Could work within any product sector given staff with high level of product specific knowledge and experience. Lower risk products with less indications of general non-compliance may not warrant such an approach.

5. **Earned recognition/impact upon inspection**: None - currently no risk rating of premises.

TITLE: *CA4 -* **PPE Compliance brochure**

OPERATOR: **SWEDISH CONSUMER AGENCY**

COUNTRY: **Sweden**

DETAILS: Provision of technical assistance through a product sector specific publication. The objective is to meet the needs of the various economic operators dealing with PPE on the Swedish market. Many of these economic operators deal with a wide spectrum of products and do not fully understand the specific requirements of the PPE directive. The brochure entitled "Almost everything you need to know about PPE" gathers together into a single publication useful information upon the directive reuirements for economic operators.

COMMENT: Focused information provided in a durable format that should result in more well educated economic operators placing compliant products on the market. This type of approach to compliance guidance is resource and quality demanding as the legal and safety requirements often varies from time to time resulting in the given information needing to be updated in time.

ASSESSMENT:

1. **Effectiveness**

   - Design: An information source available both as a printed brochure and as electronic document to download. The main objective was to enable economic operators with easy access for accurate and quality assured information about PPE in a single place.

   - Evidence of results: The brochure has been available for almost a year and will be evaluated later.

   - Costs: The brochure was produced within the normal service delivery which is provided through Governmental funding

   - Duration: Since 2015

   - Coverage: **National** - All economic operators trading in PPE

   - Meets product harmonisation principles: National authorities have a duty to inform stake holders about product regulations & rules

2. **Cost-efficiency**: When economic operators call requesting advice, responding is resource and quality demanding. The brochure provides economic operators with option of direct access to vital information regarding product rules and market surveillance. Less internal resources spent on individual communication with economic operators compared with small budget for printing

3. **Specific elements**: The brochure gathers all useful information for economic operators. The title is "Almost everything you need to know about PPE." The objective was to be able to deliver quality assured information in a resource efficient manner.

4. **Ease of replication**: Current practice already in many MSAs/Member States

5. **Earned recognition/impact upon inspection**: No – None

TITLE: ***CA5 -*** **Market Surveillance protocols**

OPERATOR: **SOIVRE INSPECTION SERVICE**

COUNTRY: Spain

DETAILS: SOIVRE Inspection Service has legal base on the border to carry out safety controls on specific products in application of Regulation 765/2008 and specified national legislation. This MSA has sought collaboration by providing importers with technical assistance and co-operation with Spanish Customs Service and other Spanish MSAs to develop mutual understanding. The main objective of the practice is to help importers comply with the requirements of the legislation when they import goods from third countries. Importers can address enquiries to any of the MSA's offices or send an e-mail to get information about controls and applied legislation. In addition, the MSA has conducted public presentations about import and safety requirements.

COMMENT: Close co-operation between MSAs, the Customs Service and economic operators provide the basis to ensure more consistency in the information provided and enforcement actions taken. This type of approach can be very successful when there is a low knowledge base among stakeholders regarding the safety legislations and safety standards.

ASSESSMENT:

1. **Effectiveness**:

   - Design: Control of imported products through information provision to importers to correct any ignorance of essential safety requirements. Importers provided with clear access and contact details if they import these categories of product and need information.

   - Evidence of results: Importers informed about product safety and compliance requirements previously to the import have less non-conformities in their products. There have been no impact studies, but it is assumed an improvement in the safety of the products placed on the market.

   - Costs: There is no additional budget for this practice – no cost analysis

   - Duration: Since 2008

   - Coverage: **National** - Imported toys, personal protective equipment, furniture, timber products, small electrical equipment, textile products and footwear at all border points

   - Meets product harmonisation principles: Control of products from third countries

2. **Cost-efficiency**: A single authority responsible for import control and co-operation with other internal MSAs offers cost and strategic benefits.

3. **Specific elements**: Technical assistance to assist importers comply the legal requirements when importing products through from third countries.

4. **Ease of replication**: Could be easily replicated by MSAs who wish to provide accurate and accessible information relating to importers' obligations and the products they import and have a good working co-operation with the Customs Service.

5. **Earned recognition/impact upon inspection**: No - When inspections identify non-compliant products, importers are included in a specific filter in the risk assessment tool that increases the number of inspections.

TITLE: ***CA6 -*** **Web based information for economic operators**

OPERATOR: **SWEDISH CONSUMER AGENCY**

COUNTRY: Sweden

DETAILS: A web based information provision of the legal requirements for products accessible by economic operators and designed to suit the needs of various kinds of economic operators.

The main objective is to inform economic operators and their respective trade associations about the legal requirements for placing products on the market and to provide guidance about achieving safe products and fair competition on the market. The site contains information not only about product safety but also about consumer rights in general.

COMMENT: This website is designed to be used by economic operators only, consumers and others are directed to other websites. Using a website to inform economic operators ensures easy access and a consistent response as they can always receive an answer and that all economic operators receive the same answer.

ASSESSMENT:

1. **Effectiveness**:

   - Design: Website is designed to be used by economic operators only and input of EOs was sought during development of the site covering both structure and content. The information about rules and advice on how to act is general and can be used by stakeholders in all sectors. Other information is directed to the following sectors: Toys, PPE and the non-harmonised area. The objective was mainly to be able to deliver quality assured information in a resource efficient manner

   - Evidence of results: Too soon for evaluation

- Costs: 1800 person hours & 2,000 euros [20,000SEK] for 10 months' development of content –exclude technical platform & development tools costs. The costs were provided through Government funding

- Duration: Operational since 2015 and intended to operate for many years

- Coverage: All economic operators in general and, in particular, those trading in toys, personal protective equipment (for private use) and non-harmonised products.

- Meets product harmonisation principles: Proactive information provision to deliver quality assured information in a resource efficient manner.

2. **Cost-efficiency**: Economic operators that need information often call for advice. This is resource demanding and a website can provide much of the information, thus freeing up staff resources for other tasks. The quality of the information given is easier to control via a website and provides consistent advice to EOs with direct access 24/7. Less internal resources are spent on individual communication with economic operators but more well educated economic operators on the market.

3. **Specific elements**: Information about this site was provided to larger industry associations. Consumers and others are directed to other websites.

4. **Ease of replication**: Most MSAs operate websites but aspects of the development could be followed by others

5. **Earned recognition/impact upon inspection**: No – None

3.12. Awareness Raising

TITLE: ***AR1*** **- Market Surveillance protocols**

OPERATOR: DEPARTMENT OF LABOUR INSPECTION

COUNTRY: Cyprus

DETAILS: The scheme is based on providing appropriate and timely advice and support to all key stakeholders in areas identified as the cause of high numbers of accidents in the workplace. In addition, the scheme supports stakeholders where there is a change or introduction of new safety legislation. The aim is to provide all the necessary support to ensure that those responsible for the safety of products under the control of the department are fully aware of their duties and responsibilities, so that accidents in the workplace can be minimised. Regular consultation with stakeholders is undertaken to identify where awareness of the relevant safety requirements needs to improve, including issues of concern that have been identified during the practical application of the requirements in the workplace. To complement this work, compliance assistance is provided by means of technical guidance documentation specifically aimed at products presenting a higher risk and requiring a greater understanding by economic operators to implement further safety improvements. The aim is to provide the necessary technical information to secure compliance with legislation that

presents specific technical challenges. In addition, general guidance is provided on the website of the Department.[52]

COMMENT: Covers aspects of both awareness raising and compliance assistance and the awareness events are very valuable for economic operators. They are promoted proactively and seek to provide economic operators with a formal opportunity to ensure that their knowledge of new legal requirements is correct and up to date. Because consultation takes place on a regular basis between the MSA and economic operators this develops good working relations and a shared purpose which can be otherwise difficult to achieve. As the provision of such awareness campaigns is at the request of stakeholders, input and outcomes are higher than would otherwise be achieved.

ASSESSMENT:

1. **Effectiveness**:

   - Design: Targeting key stakeholder groups - aimed at Trade Associations, Employers and Chambers of Commerce. Driven by need to address the high numbers of accidents involving foreign workers

   - Evidence of results: KPIs – number of accidents & numbers of non- compliant products identified. But no formal review yet

   - Costs: No specific budget as cost included in overall budget of department

   - Duration: Since 2014

   - Coverage: Lifts, machinery, pressure equipment, simple pressure vessels, PPE, ATEX, noise emissions- outdoor equipment.

   - Meets product harmonisation principles: Encourages compliance where there may be a lack of understanding by EOs of technical requirements.

2. **Cost-efficiency**: Not measured but claimed to be reasonably effective due to blanket coverage which is possible due to low numbers of EOs

3. **Specific elements**: In advance of changes to legislation, relevant stakeholders are contacted and an awareness event organised on the topic.

4. **Ease of replication**: Possible for all product sectors

5. **Earned recognition/impact upon inspection**: None – Inspection levels have remained constant

52 http://www.mlsi.gov.cy/mlsi/dli/dliup.nsf/pageh6_en/pageh6_en?OpenDocument

TITLE: ***AR2 -*** **Be Smart – Build Safe Campaign**

OPERATOR: **CONSUMER RIGHTS PROTECTION CENTRE**[53]

COUNTRY: Latvia

DETAILS: A campaign to raise awareness of the legislation controlling the safety of construction products, and how to identify safe construction products. Helpful advice and assistance is provided to economic operators. Economic operators and consumers are informed about the importance of purchasing and using only safe construction products. How safe products can be identified and distinguished from potentially unsafe products is also explained. The practice was introduced by CRPC in response to an urgent need for effective action following a major incident that involved the collapse of a supermarket roof in 2013.

COMMENT: When economic operators are unaware about the requirements for construction materials, non-compliant construction products can be incorporated into a building and are then unable to be inspected. This is a good example of how the MSA can be proactive in assisting an industry in improving its compliance within a specific product sector. Subject to translation this practice could be transposed into different countries and the approach is valid across all product sectors. It changes the status of the MSA from just being an enforcement authority to being part of the "solution to the problem".

ASSESSMENT:

1. **Effectiveness:**

   - Design: To inform economic operators (manufacturers and builders) and consumers about the requirements of Regulation 305/2011 and national legislation on construction products. Specific awareness programme aimed at professionals & EOs in the building industry and provided through TV, Radio, Web page, Brochures and Seminars

   - Evidence of results: 9200 viewings on the website, 160 seminar registrations, 2000 leaflets distributed, recorded increase in business contacts.

   - Costs: Part of CPRC's annual budget plus €45,000 to cover advertisements on TV

   - Duration: The practice was introduced and pushed hard in 2015. It is still running - although not as intensely as in the first year.

   - Coverage: National – Construction products and building industry

   - Meets product harmonisation principles: MS surveillance response to accidents and injury information

2. **Cost-efficiency**: Data on the percentage of non-conformances found at construction sites is being collected and the results will be available from the beginning of 2017. Current feedback from businesses has shown that economic operators now have a better understanding of the laws relating to construction products

53 https://www.em.gov.lv/en/sectoral_policy/construction/regulation_of_circulation_of_construction_products/

3. **Specific elements**: A targeted response to major incident involving a structural failure in supermarket in November 2013

4. **Ease of replication**: A good practice example of a comprehensive response to identified non-compliances in a specific product sector

5. **Earned recognition/impact upon inspection**: The results of the practice will be used as part of the CRPC's risk assessment procedure. No immediate reduction in visits but it has reduced the amount of time needed to be spent inspecting reputable businesses because they now have fewer non-compliances needing to be dealt with by CRPC. This enables more businesses in the sector to be inspected by CRPC and results in improved targeting of resources.

TITLE: ***AR3*** **- Good Communication**

OPERATOR: **DANISH MARKET SURVEILLANCE COMMITTEE**

COUNTRY: **Denmark**

DETAILS: An interactive best practice communication catalogue for the use of MSAs across all product sectors. The catalogue contains ideas, examples and practical tools that MSAs can use when developing market surveillance communication activities directed at businesses. The catalogue was developed to assist MSAs that do not have their own separate communication units. When a MSA wants make awareness raising activities, inspiration, checklists and good examples can be found in the best practice catalogue. The catalogue was made with the assistance of external consultants and in close cooperation with MSAs and their needs. Stakeholder organizations and businesses were also involved in the development.

INITIAL COMMENT: Seeks to ensure that awareness campaigns benefit from best practice and are effective. It should make it easier to initiate and develop communication activities, particularly for smaller MSAs.

ASSESSMENT:

1. **Effectiveness**:

   - Design: Practical communication material developed by the market surveillance committee for MSAs across sectors to improve their awareness raising.

   - Evidence of results: Too early to evaluate but at a round-table discussion in the market surveillance committee, there has been overall positive feedback from MSAs regarding the use of the catalogue in practice.

   - Costs: The development of the catalogue had a budget of approximately €40.000

   - Duration: Since 2016.

   - Coverage: **National** - across all product sectors.

- Meets product harmonisation principles: Enables MSAs the means to become better communicators and engage with EOs more effectively.

2. **Cost-efficiency**: Saves individual MSAs from "re-inventing the wheel" and benefits smaller MSAs and those without experience in awareness raining initiatives.

3. **Specific elements**: An interactive best practice communications toolkit of best practice containing ideas, examples and practical tools that MSAs can make use of when developing markets surveillance communication activities directed at businesses.

4. **Ease of replication**: Good practice, easily replicated across Member States.

5. **Earned recognition/impact upon inspection**: No – None.

TITLE: ***AR4 –*** **Market Surveillance protocol**

OPERATOR: **DEPARTMENT OF JOBS, ENTERPRISE AND INNOVATION**

COUNTRY Ireland

DETAILS: The MSA has developed various guidance documents and provides advice regarding Explosives and Pyrotechnics legislation aimed at the explosives and fireworks industry. It also provides guidance regarding the operation of the Department's import licensing system. Website & press releases are used to raise awareness and are targeted at Halloween, the main period for the use of fireworks. Information is issued via the national print media as well as through web sites and social media.

COMMENT: Timely and targeted information is provided for economic operators and is linked with public awareness campaigns covering safety and non-compliance This practice provides a comprehensive approach to safety within a specific product sector. Both guidance for economic operators and information for consumers benefit from the expertise and experience of the MSA staff.

ASSESSMENT:

1. **Effectiveness**:

   - Design: A three track approach to firework safety that includes -

     - Guidance Documents / Advice: To assist importers/economic operators/ professional users understand the requirements of the legislation in so far as it applies to explosives/pyrotechnics and the import licensing procedure.

     - Publicity campaign: To raise awareness that only Category F1 fireworks are legal for sale to the public. All other fireworks can only be part of a display provided by professional users.

- Publicity campaign: To raise awareness among the general public about the safety aspects when using Category F1 fireworks.

- Evidence of results: Hospital inpatients statistics show a decreasing trend over past six years. Evidence of less availability of non-CE marked products.

- Costs: Included with overall ministry budget – specific cost not disclosed.

- Duration: Since 2009

- Coverage: National - Pyrotechnics

- Meets product harmonisation principles: Provides economic operators with regulatory compliance guidance and informs the public – making them better able to use fireworks safely and to report non-compliance.

2. **Cost-efficiency**: Co-ordinated campaigns for economic operators and consumers that can be very cost effective.

3. **Specific elements**: Based upon the national legal background that includes an import licensing system and allows only category F1 fireworks to be legal for sale to the general public. Links guidance to EOs with public safety information.

4. **Ease of replication**: Easily replicated in targeted safety campaigns. In relation to fireworks the national restriction upon the sale of fireworks makes compliance easier to control when the sale and use by consumers is strictly controlled

5. **Earned recognition/impact upon inspection**: None, but as inspection is risk-based, so information of non-compliance activity will result in more enforcement action.

3.13. Legal Requirements and Best Practice for Market Surveillance

A criterion set for the analysis of the compliance practices identified through the study was to determine "if the practices are consistent with the principles underlying EU product harmonisation legislation (notably the so-called New Approach legislation) and market surveillance legislation (Regulation (EC) 765/2008)". EU Member Countries are given considerable discretion under the subsidiarity rules when it comes to determining the nature and detail of their market surveillance activities. In particular, there is very limited requirement upon MSA' in respect of advice and guidance to Economic Operators.

Regulation (EC) 765/2008 has:

- ***Article 19 (2) Second sub paragraph****: (Market surveillance authorities) "shall cooperate with economic operators regarding actions which could prevent or reduce risks caused by products made available by those operators."*

General Product Safety Directive 2001/95/EC has:

- ***(24)*** *The safety of consumers depends to a great extent on the active enforcement of Community product safety requirements. The Member States should, therefore, establish systematic approaches to ensure the effectiveness of market surveillance*

and other enforcement activities and should ensure their openness to the public and interested parties.

However, there is a considerable body of best practice guidance which states:

- ***"Market surveillance authorities** must be organised and equipped to cope with their obligations but the EU legal framework does not prescribe how the Member States are to implement the directives or how the legislation should be enforced. How the requirements in the treaties are to be fulfilled is up to the Member States, since market surveillance is a national responsibility and falls under the principle of subsidiarity.[54]"*

- ***"Market surveillance** does not formally take place during the design and production stages, which is before the manufacturer has taken formal responsibility for the conformity of the products, usually by affixing the CE marking. However, nothing prevents market surveillance authorities and economic operators to collaborate during the design and production phase. Such collaboration may help taking preventive actions and identifying as early as possible safety and conformity issues.[55]"*

- ***"For market surveillance to be efficient**, resources should be concentrated where risks are likely to be higher or non-compliance more frequent, or where a particular interest can be identified.[56]"*

- ***"Better regulation** sets out to ensure**:** regulatory burdens on businesses are kept to a minimum.[57]"*

- ***"Risk assessment –** though widely recognised as fundamental to effectiveness – is not implemented as thoroughly and comprehensively as it should be. Risk assessment should be comprehensive, and should be the basis for all regulators' enforcement programmes. Proper analysis of risk directs regulators' efforts at areas where it is most needed, and should enable them to reduce the administrative burden of regulation, while maintaining or even improving regulatory outcomes. I am therefore recommending that:*

    - *comprehensive risk assessment should be the foundation of all regulators' enforcement programmes;*

    - *there should be no inspections without a reason;*

    - *resources released from unnecessary inspections should be redirected towards advice to improve compliance;"[58]*

3.14. Review of Compliance Practices identified by the Study

Consideration of the various elements that underpin the operation of the compliance practices identified through the study has allowed the Study team to highlight some general similarities

54 EMARS – Best Practice Techniques in Market Surveillance
55 Blue Guide - page 95
56 ibid
57 EU "Better regulation: why and how" - http://ec.europa.eu/info/strategy/better-regulation-why-and-how_en
58 Reducing administrative burdens: effective inspection and enforcement. Philip Hampton - March 2005: The Hampton Review – Final Report

as well as the strengths and weakness that can be used to inform "best practice" considerations for future practices.

General:

- Although only nine member countries provided sufficient evidence that indicated that their MSA's utilised all three types of compliance practices, it could be wrong to conclude that such practices are not a regular feature of many market surveillance enforcement programmes.

- The constituent elements of awareness raising, compliance assistance and compliance schemes are often seen by MSA's as a well organised, focused and comprehensive approach to market surveillance but they do not necessarily recognise the specific terms or consider them as stand-alone activities.

- The difference between awareness raising and compliance assistance often appears to be very minor – awareness raising often centred upon consumers and end users of products.

- A considered approach to awareness raising and compliance assistance ensures that consistent and accurate information is provided to economic operators for them to achieve compliance by building it into their products from design to production and one that underpins the MSA's inspection planning and sampling activities.

- There is a generally agreed approach by MSA's that assistance provided to economic operators and trade associations to assist them in understanding the application of legislation will produce more effective market surveillance.

- Despite a general lack of evidence of effectiveness, a number of MSAs expressed an impression that the number of unsafe products is decreasing as a result of compliance practices.

Strengths:

- Many of the practices have been designed to address specific market surveillance issues such as poor level of economic operators' knowledge in a product sector or as part of a general inspection reform.

- Significant elements include:

    - Availability of detailed and expert knowledge

    - Dependable advice and guidance

    - Targeted information upon specific trades or product sectors

    - Single point of contact

    - Easy access for accurate and quality assured information in a single place.

    - A variety of access points and information channels

- ❖ Information sources available both as a printed documents and as on-line electronic documents available to download.

- ➢ Most compliance practices identified do appear to be easily transferable to other product sectors, MSA's and Member Countries.

Weaknesses:

- ➢ Very few compliance practices where specifically aimed at SME's. Most compliance assistance and awareness raising was designed to have a universal appeal to all economic operators with a rather simplistic "one box fits all" approach.

- ➢ Many compliance practices are of long standing, five years plus, without a comprehensive review of their continuing need and effectiveness.

- ➢ A serious lack of objective evidence of effectiveness:

  - o Objectives not formulated, goals not set;
  - o Assumptions based upon belief/professional experience;
  - o Key Performance Indicators not set;
  - o Performance not measured;
  - o Programmes not reviewed on a regular basis;
  - o Very little evidence of monitoring of accidents and injuries;
  - o Very little evidence of a measured reduction in dangerous products.

- ➢ A belief by some MSA's that risk assessed inspection programming alone can be an incentive for EOs to improve compliance measures.

- ➢ Inspection levels remaining constant despite compliance practices being used.

- ➢ No measurement of opportunity cost of resources being used for compliance practices.

- ➢ The true costs of compliance practices are often hard to quantify as they are accounted for as part of general MS budget.

- ➢ Very little cost/benefit analysis.

- ➢ High cost of campaigns involving TV advertising.

Compliance Schemes:

- ➢ There are legality issues[59] surrounding the implementation of compliance schemes in some Member Countries without changes to the existing national legislation.

59 It has been suggested that national legislation in some countries may restrict the ability of MSAs to "favour" economic operators in respect of reductions in scope, frequency or intensity of inspections. This issues has not been researched as part of the study.

- There can be an issue with the extra income provided by a "primary authority" type scheme becoming a funding dependency should the MSA's general budget be cut due to economic considerations.

- There is an argument that national and multi-national economic operators already have the resources to determine product compliance and such schemes do not benefit SME's sufficiently.

- There may be a need for systems analysis qualifications, experience or training within the MSA for its staff to able to meet the requirements of national and multi-national EOs.

- The need for detailed and effective policies and procedures to safeguard the ability of the MSA to be responsible for the advice given whilst retaining its independent and transparent duty to take enforcement action in appropriate circumstances.

3.15. Compliance Practices identified by other studies

Guidelines for Coordinated and Effective Ecodesign Market Surveillance[60]

In addition to the monitoring, verification and enforcement activities, many MSAs arrange proactive and preventing activities to inform manufacturers and their representatives or importers about the eco-design requirements that are in force or coming into force:

- Most commonly is for the MSAs to hold information meetings, send out newsletters and publish guidelines on how to comply.

- Some MSAs issue brochures, guides and leaflets.

- Some MSAs work in cooperation with other public bodies such as Chambers of Commerce and national agencies to disseminate information about the eco-design requirements of products.

- MSAs can make public announcements beforehand to inform manufacturers and their representatives or importers about planned market surveillance action(s), by e.g. publish their yearly market surveillance programme on their website. The publication of the results of market surveillance activities can be a way of discouraging possible improper behaviour by other economic operators.

- MSAs can also cooperate with national customs authorities in market surveillance of the Ecodesign Directive in order to prevent non-compliant products entering the EU-market.

3.16. Recommendations

The study is charged with providing a set of recommendations that could serve as a toolkit for improving Member States performance in relation to compliance practices. Many of the examples used in this report are based upon activities that have been common place in some MSAs for many years, and in this sense, it is somewhat surprising that more MSAs did not respond and cite these types of activities. The Study Team did not identify any pattern or

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obvious reason to explain why the use of compliance practices and the coverage of product sectors within the compliance practices varied from country to country and from MSA to MSA. As very few of the compliance practices have specific features that would be difficult to replicate and as all countries would benefit from adopting the highlighted practices, the real issues would seem to be resources, both human and financial, a lack of good service management that understands the benefits of a proactive approach, a reluctance to engage in inspection reform and the lack of an EU legal requirement that such practices are mandatory, or indeed supported. Therefore, the following recommendations do not represent new or novel ideas but rely heavily upon tried and tested principles.

Based upon the results of the study survey, interviews with MSA's using compliance practices, interviews with economic operators and trade associations and generally available public information, the Study Team would recommend:

1. Compliance practices should not be considered as special activities additional to the more traditional or "classical" styles of enforcement but rather be integral components of a comprehensive market surveillance regime. To encourage this approach, it is considered important for the relevant EU Directorates General to support a wider definition of market surveillance and to provide clear guidance that compliance practices are an expectation within market surveillance.

2. Compliance practices are best adopted as part of an inspection reform programme based upon a quality management format including enforcement policies, comprehensive databases of economic operators' details, previous inspection and product sampling results, consumer complaints, accident and injury data & statistics that inform a risk-assessed inspection and sampling programme with documented procedures, product examination and sampling and auditing of the economic operator's quality assurance procedures.

3. Compliance practices are best adopted as part of strong co-operative partnerships between the relevant Market Surveillance Authorities in each product sector or sectors and including Customs Services and other law enforcement bodies as appropriate. This approach should contribute to accuracy of advice, consistency of enforcement, reduction of duplication and cost-efficiency.

4. Trade associations can be valuable partners in compliance practices as they aid the distribution of information amongst their members, make access to information concentrated in a single point of contact and can inform the MSA upon the needs and preferences of their members.

5. Compliance practices should encourage economic operators to adopt a more pro-active approach to legal compliance and product safety (e.g. by installing quality management or assurance systems) Wherever possible, there should be an element of "earned recognition" linked to the practices, so that the resources deployed by the economic operator can be justified through reduced inspection scope or frequency.

6. Compliance practices should contain the specific elements that have been identified as essential for the success of compliance practices and which lead to improved compliance with regulation and market surveillance efficiency;

- Compliance practices need to be well designed and developed to maximise efficiency and effectiveness through a co-ordinated approach of all MSA's involved in the selected product sector(s);

- Compliance practices need to meet the basic requirement of encouraging compliance through encouraging and facilitating better understanding of the legal and safety requirements by Economic Operators;

- Compliance practices should not be limited to the product sector of the originating authority if capable of being rolled out across other product sectors with beneficial impact;

- Compliance practices need to include clear, quantifiable and measurable Key Performance Indicators of success that should be set in advance and supported by baseline statistics;

- The performance of compliance practices should be measured and reviewed at defined intervals to determine their efficiency and effectiveness;

- Specific schemes and practices should be full costed if possible, including the measurement of resource usage and opportunity costs. Without a true resource and financial cost of implementation and impact assessment together with post implementation monitoring against accurate pre-implementation compliance rates and accident and injury statistics; an accurate cost-efficiency assessment is very difficult;

- Compliance practices should be designed and developed to meet the researched and clearly identified requirements of the intended economic operators through an awareness of:

    - Needs in different product sectors – *especially those of SMEs*

    - Reactive assistance v proactive assistance – *a researched balance*

    - Suitable access channels

        - Inspection visits – *often preferred by SME's*

        - Hotlines – *can provide easy access but at a cost*

        - Internet – *24/7 information provision*

        - Social media – *Blogs, Twitter, Facebook, YouTube*

        - Product sector – *Separate channels for different product sectors*

        - Industry only - *Separate channels for industry & consumers*

    - Suitable medium for the advice

        - Verbal advice

        - Written advice – fact sheets, leaflets

- Digital downloads
- Interactive

3.17. Other examples of best practice

- **Lessons from other sectors**

  - **Business Awareness Raising**[61]

    - **Develop a unified set of guidelines:**

      Often there is no central information point for business operators to gain an overview of their legal obligations. Such information overviews should combine input from various stakeholders, include relevant legislation and highlight issues of responsibility in the supply chain. The ACCC's Business Guide to Selling Online to Consumers in Australia, is considered to be a good practice in this respect.

    - **Product requirement legislation in understandable terms:**

      Keeping track of new and amended legislation can be complicated and as a result, business operators sometimes violate product requirements unintentionally. Regularly informing operators of the changes to relevant legislation is a useful practice that could again yield benefits by preventing non-compliant and unsafe products from entering the market to begin with. In the case of Estonia, the Consumer Protection Board has implemented this practice effectively; regular updates are sent around on legislation that is relevant to operators.

    - **Interactive information provision:**

      Interactive methods of information provision tend to lead to a more active way of absorbing and remembering information. This is demonstrated in the Dutch case for instance, where the "TradeRouteAsia" website uses e-learning modules and quizzes to involve and test business operators on their knowledge. In a non-digital manner, the seminar series organised in Malta also forms a more interactive, real-life method of providing information.

Business awareness raising		
Estonia	Regular updates for business operators on new relevant legislation	Consumer Protection Board of Estonia & Information Letters
Australia	Centralised information on selling online in a given country	The Australian Competition and Consumer Commission (ACCC) business guide to selling products online to

61 "*Good Practice in Market Surveillance Activities related to Non-Food Consumer Products sold Online" - Authors: Jacqueline Snijders (Panteia), Amber van der Graaf (Panteia) & Mike Coyne (CSES) for Austrian Institute of Economic Research (WIFO).*

		Australian consumers
The Netherlands	Raising business operator awareness on how to import safe goods from Asia	The Dutch Authority (NVWA) - the information and learning website TradeRouteAsia.nl

- **Austrian Institute of Construction Engineering [OIB]**

  The Austrian Institute of Construction Engineering (OIB) is the coordinating platform of the federal states for construction products and construction technology and performs the following tasks:

  - The OIB is a European technical assessment body and national approval body for construction products;
  - It issues the OIB guidelines, in order to enable federal states to harmonise the technical requirements in the building regulations;
  - As market surveillance authority, the OIB ensures that the construction products on the Austrian market fulfil all legal requirements and do not endanger health and safety;
  - As a product contact point, the OIB provides information about the currently valid technical requirements for construction products in Austria.

- **Proof of Age schemes**: joint action between enforcement agencies and economic operators to restrict the supply of age-restricted products through the issue of proof of age cards to those young people who have recently attained the correct age to able to purchase legally. Responsible economic operators can support such schemes and aid compliance across the retail sector. Schemes cover products such as fireworks, knives, alcohol and tobacco that present safety concerns if supplied to young children. These schemes can provide examples of best practices in respect of multiple enforcement agencies cooperating together and working with commerce. [https://www.citizencard.com]

- **Food Hygiene Rating Scheme - Food Standards Agency**: The food hygiene rating or inspection result given to a business reflects the standards of food hygiene found on the date of inspection or visit by the local authority. At the end of the inspection, the business is given one of the six ratings from 0-5. The top rating of '5' means that the business was found to have 'very good' hygiene standards. Economic operators can display stickers at the entrance to their establishments stating the rating given, "scores on the doors". The information provided on businesses is held by FSA on behalf of local authorities and is searchable online by consumers. [https://www.food.gov.uk/business-industry/hygieneratings]

- **Business Companion – CTSI & BEIS:** Free, impartial legal guidance for businesses and individuals that need to know about product safety and consumer protection legislation. The guidance is divided up into 15 broad Quick Guides and

each one contains a number of more detailed In-depth Guides. [www.businesscompanion.org.uk]

- **Compliance Advice Centres – Environmental Protection Agency USA:**

  Compliance advice centres (CAC's) serve different sectors of the US economy and have been developed in partnership with trade associations, academic institutions, environment groups and relevant stakeholders to identify the support needs of economic operators and to develop materials for compliance and performance improvement. The service is web-based and provides a one-stop-shop and user friendly source of advice for SME's. The agency (EPA) is instrumental to their success in providing non-financial support in the form of staff time, expertise, use of facilities and the provision of alerts to new sector specific regulations. [https://www.epa.gov/compliance]

➢ **Adopt, collaborate or sign-post**

- There is much professionally developed compliance guidance prepared in collaboration between enforcement agencies and industry that is already available and perhaps does not need to be duplicated but economic operators would benefit if its content was endorsed and its availability was more widely advertised by a wider range of enforcement and guidance bodies.

- Recommendations and guidance from Administrative Cooperation groups (ADCOs) that support the implementation of EU product legislation is made available on the European Commission's website.

- Other examples would include:

  - Euro Safe Child PRODUCT SAFETY GUIDE [WWW.CHILDSAFETYEUROPE.ORG/PUBLICATIONS/INFO/PRODUCT-SAFETY-GUIDE.PDF]

  - Product Safety Focus Group Joint Guidance with the British Blind and shutter Association (BBSA) on INTERNAL WINDOW BLINDS [HTTPS://BBSA.ORG.UK/TRADE/CHILD-SAFETY-2]

  - CANDLEMAKERS ADVICE SHEET - Joint advice from Trading Standards and the British Candlemakers Federation [www.britishcandles.org/documents]

  - TOY SAFETY – Examples of **a**dvice and guidance that is freely available:

    - TOY SAFETY DIRECTIVE 2009/48/EC - *AN EXPLANATORY GUIDANCE DOCUMENT*

      EUROPEAN COMMISSION, ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

    - GUIDANCE ON TOY SAFETY - *17 GUIDANCE DOCUMENTS*

THE EUROPEAN COMMISSION AND THE EXPERT GROUP ON TOY SAFETY

- TOY SAFETY IN THE EU - *A PRACTICAL GUIDE TO THE LEGAL OBLIGATIONS OF MANUFACTURERS, IMPORTERS AND DISTRIBUTORS*

  TOY INDUSTRIES OF EUROPE (TIE) - *part of an education campaign financed by the European Commission*

- TOY MANUFACTURERS, IMPORTERS AND DISTRIBUTORS: YOUR RESPONSIBILITIES - *HOW TO PRODUCE AND LABEL TOYS FOR CHILDREN TO COMPLY WITH SAFETY AND WARNING REGULATIONS*

  DEPARTMENT FOR BUSINESS, INNOVATION & SKILLS - *UK Ministry*

- INTRODUCTION TO THE TOY SAFETY DIRECTIVE

  BRITISH TOY & HOBBY ASSOCIATION – *UK Trade Association*

- REVISED TOY SAFETY DIRECTIVE 2009/48/EC - *SAFETY UPDATE*

  BRITISH TOY & HOBBY ASSOCIATION– *UK Trade Association*

- EU TOY SAFETY DIRECTIVE 2009/48/EC - *FREQUENTLY ASKED QUESTIONS*

  UL-STR - G*lobal independent safety science company*

- EU TO SAFETY DIRECTIVE 2009/48/EC: *TECHNICAL DOCUMENTATION REQUIREMENTS*

  BUREAU VERITAS - G*lobal provider of Testing, Inspection and Certification (TIC) services*

- HOME TOY PRODUCERS – *BASIC GUIDANCE FOR TRADERS*

  HAMPSHIRE COUNTY COUNCIL - *Web advice from one of UK's 200+ MSA's for toy safety*

➢ **Finally**

Many of the principles and methods of providing advice and guidance to economic operators present in the compliance practices detailed in this study have been practised by market surveillance authorities for many years. Therefore, it is very surprising that more MSA appear not to have already benefitted from these good practices. Just a few examples would include:

- Business advice packs provided during inspection visits. [UK – 1990]
- On-line information. [Latvia – 2004]
- POLISH ENTERPRISE IN THE EUROPEAN UNION - Products subject to conformity

  assessment and CE marking. [Poland – 2005]
- TV/Radio/Poster product safety awareness raising campaign. [Romania – 2006]
- MACHINERY, ELECTRICAL EQUIPMENT, PERSONAL PROTECTIVE EQUIPMENT, CHEMICALS & SIMPLE PRESSURE VESSELS - Market Control in Finland
- [Guidance leaflet - 2008]
- Website "traderouteasia.com". [Netherlands – 2008]
- Product Safety Guide for Business. [Australia – 2012]

3.18. The List of other Practices that were identified for further analysis

The table below presents an overview of the other practices which have been identified as containing elements of good practices but are not included in the "best practice" list. They have been split into the three categories, compliance schemes, compliance assistance and awareness raising. Some practices were categorised into good market surveillance and good awareness raising practices, since they do not fit into the three categories of compliance schemes, compliance assistance and awareness raising practices but may provide useful information.

COMPLIANCE SCHEMES

TITLE	TYPE	TERM	PRODUCT SECTORS[62]	MSA	COUNTRY	No
Regulatory Compliance protocol	CS	10	14, 15	INSPECTOR OF EXPLOSIVES	Cyprus	CS5
DETAILS: *A MS programme designed to ensure that all imports of explosives for civil use are fully compliant with relevant national legislation. This is achieved by control of the whole of the supply chain. Control from the point of entry into the country via customs control and licensing controls over all Economic Operators in the supply chain. Because the control of explosives at all points in the supply chain is strongly regulated this has presented the MSA with the opportunity to intervene at any point within the supply chain to perform compliance checks. All legitimate suppliers are known to the MSA through a licencing regime which*						

62 See Annex for "Reference List of Product Sectors as per the ToR"

eases the task. Any product not found to comply is removed from the market before it reaches the end user. This approach avoids having to remove defective products once they have been sold to the end user which can be particularly challenging. Success is aided by working in cooperation with Customs and the Police.

INITIAL COMMENT: *A well-focused approach to ensuring control of a specific product sector through good information of the economic operators and co-ordination. Tight control of the whole supply chain is aided by the fact the product category is highly regulated.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Covers importation and the whole supply chain*
   - Evidence of results: "*Accident statistics for pyrotechnics are at a low level. No issues with civil explosives"*
   - Costs: *Part of overall budget – no breakdown.*
   - Duration: *Since 2006*
   - Coverage: *Restricted to explosives - product sectors 14 & 15*
   - Meets product harmonisation principles: *Inspection protocol that starts with the importer and includes working in cooperation with other partners*
2. Cost-efficiency: *Control at import and co-operative working should bring operational cost benefits but no figures available.*
3. Specific elements: *Use of licensing, involvement of Police, Customs Service, EO's employees and public. Monitoring of accident statistics*
4. Ease of replication: *May be limited by the licencing element of the scheme. Also, the number of EO's is small in a very specialised product sector.*
5. Earned recognition/impact upon inspection: *No reduction in inspection levels.*

COMPLIANCE ASSISTANCE

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	CA	13	2	PUBLIC HEALTH AUTHORITY	Slovak Republic	CA7

DETAILS: *The Public Health Authority has competence on the territory of the Slovak Republic and is the supreme office for the regional public health authorities. It manages, controls and coordinates them. The execution of state administration carried out by regional public health offices. Information gathered from MS activities, questions from economic operators, consumer complaints and changes in legislation is used to address problems in the market by providing advice and guidance through a series of lectures, workshops and direct advice. This proactive approach has increased the willingness of Economic Operators to seek advice from the MSAs. The measure of success is based upon a reduction in the number of non-compliant products available on the market. A similar programme operates in the Czech Republic. Slovakia cooperates with Czech Republic through the exchange of information and market surveillance activities.*

INITIAL COMMENT: *A comprehensive approach to market surveillance that uses the results of inspection to highlight specific problems and then utilises compliance assistance across a number of access channels to seek to reduce non-compliance. The programme is operated nationally whilst the enforcement is regionally based. This approach should ensure consistency of advice across the market sector*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *To provide information to EOs and monitor the sale of cosmetic products via the internet*
   - Evidence of results: *No performance indicators but overall reduction in the number of non-compliant cosmetic products found during inspection.*
   - Costs: *Covered within overall budget that also includes market surveillance of food products.*
   - Duration: *13 years*
   - Coverage: ***State organisation*** *- Cosmetic products*
   - Meets product harmonisation principles: *Market surveillance provision. Results published in Annual Report of Market Surveillance Programme.*
2. Cost-efficiency: *Unable to measure due to no specific costing or performance*

measurement

3. Specific elements: *Responds to a variety of information inputs, works with Customs Service and Testing Laboratories*

4. Ease of replication: *Yes, a similar programme is being operated in the Czech Republic*

5. Earned recognition/impact upon inspection: *No – Less non-compliance reported*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Industry sectoral agreements	CA	-	3, 4, 31	SWEDISH CONSUMER AGENCY	Sweden	CA8

DETAILS: *IF the Swedish Consumer Agency and the economical operators (sometimes represented by an industry association) agree that an existing standard for certain products (often non-harmonised) does not fully comply with the national regulation and if it is not possible to amend the standard; then an industry sectoral agreement could be signed. This agreement acts to amend the standard and is valid for those economic operators on the national market who signed the agreement.*

INITIAL COMMENT: *Close co-operation between MSA and economic operators to ensure a more consistent approach to agreeing solutions to issues. Since standards have evolved, the activity in this area is less frequent but signing agreements is still a valid tool for compliance assistance.*

FURTHER ASSESSMENT:

1. Effectiveness

   - Design: *Technical assistance for EOs when there is a lack of harmonised standards.*
   - Evidence of results: *No specific indicators are used to monitor performance but instead of being regarded as a threat, the authorities are now more regarded as experts that could be consulted.*
   - Costs: *The negotiating phase is the most time consuming and budget involves travel and accommodation costs*.
   - Duration: *Activity in this area is less frequent now since standards have evolved*.
   - Coverage: ***National*** *– Across Toys, PPE & GPSD*
   - Meets product harmonisation principles: *Encourages the use of standards as the means of compliance*

2. Cost-efficiency: *This activity with agreements is declining in the product safety area*

3. Specific elements: *Industry sectoral agreement signed with trade associations to agree the means of compliance in the absence of harmonised standards.*

4. Ease of replication: *Application is still valid across a range of non-harmonised products but the challenge is that new economic operators can enter the market who are not part of the agreement.*

5. Earned recognition/impact upon inspection: *No – None*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Market Surveillance protocol	CA	8	U	CONSUMER RIGHTS PROTECTION CENTRE	Latvia	CA9

DETAILS*: This practice is a modern approach to market surveillance and operates in accordance with the principle that 'prevention is better than cure'.*

CRPC works with economic operators and provides them with information and support, rather than just leave them to their own devices and only contact them after something goes wrong. CRPC and businesses believe this approach makes a lot of sense.

The practice is to inform economic operators about legal requirements as an integral part of the CRPC's MS activity. The approach seeks to help reputable economic operators to be compliant and enables them to take the necessary corrective actions if necessary. This then enables CRPC to focus resources on non-compliant businesses.

INITIAL COMMENT: *Compliance assistance is provided as an intrinsic part of the market surveillance.*

FURTHER ASSESSMENT:

1. Effectiveness

   - Design: *A MS approach that seeks to help reputable economic operators to be confident that they are compliant and in some cases enables them to take the necessary corrective actions. This enables CRPC to focus resources on non-compliant businesses.*

   - Evidence of results: *Reduction in non-compliances found on inspection – year on year aggregates – no data provided*

   - Costs: *Contained within annual service budget*

   - Duration: *Since 2009*

- Coverage: ***National*** - *All categories of non-food products excluding medical devices and cosmetics*

- Meets product harmonisation principles: *Economic operators need to be aware of the legal regulations – assists compliance*

2. Cost-efficiency: *Because of limited market surveillance resources, and as the number of economic operators is huge, there is a need for an innovative and cost efficient approach to market surveillance.*

3. Specific elements: *This is part of the CRPC's usual MS activity*. *Depending on the product sectors there is collaboration with other regulators such as the State Building Control Agency and with trade associations.*

4. Ease of replication: *Should be part of all MSAs*

5. Earned recognition/impact upon inspection: *Yes - Visits reduced where a large number of economic operators were involved and could be notified and advised as a group.*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	CA/CS	6	1, 2, 21, 22, 24, 25, 30	FEDERAL PUBLIC SERVICE OF HEALTH, FOOD CHAIN SAFETY & ENVIRONMENT (FASFC).	Belgium	CA10

DETAILS: *Market Surveillance procedures that influence inspections through risk assessment and co-ordination with national and regional campaigns. The market surveillance procedures include both active and passive response protocols designed to deal with the range of issues faced and work in co-operation with other inspection units from other federal public services.*

INITIAL COMMENT: *Market Surveillance protocols that combine elements of awareness raising and compliance assistance with procedures for risk assessing economic operators and thus influencing inspection frequency or scope.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *EOs are controlled on short notice (e.g. less than 4 weeks) on proportional basis regarding the EO.*
   - Evidence of results: *None provided although KPIs are claimed to be in place. Number of consumer complaints have increased – suggesting better consumer awareness as opposed to EO awareness.*
   - Costs: *Part of 160,000 Euros operating costs budget for the federal public service – no individual cost*
   - Duration: *Since 2006*
   - Coverage: ***National*** *- Medical devices, Cosmetics, Chemical substances, Other chemicals, Efficiency-hot boilers, Tyre labelling & Fertilisers*
   - Meets product harmonisation principles: *Provides information for EOs via website and uses risk assessment to determine status of EOs.*
2. Cost-efficiency: *No data re impact upon market compliance/safer products*
3. Specific elements: *Risk analysis on basis of public health, environment concerns, specific problems, effectiveness of the action of EOs, Written procedures, co-ordination with regional level activities.*
4. Ease of replication*: Appears designed to meet specific product sector requirements but is a multi-product approach that can be transferred*
5. Earned recognition/impact upon inspection: *No – but successful campaigns did result in a reduction of inspections (e.g. batteries are not controlled anymore because there was a synergy with BEBAT who had organised awareness campaigns)*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	CA	20	17	MINISTRY OF ECONOMY OF THE REPUBLIC OF LITHUANIA, EU INTERNAL MARKET COORDINATION DIVISIONS	Lithuania	CA11

DETAILS: *The practice aims to inform economic operators about the legal requirements pertaining to the product sector as an integral part of the legal metrological supervision activity. The approach covers the market surveillance of measuring instruments assigned to legal metrology, pre-packed products and the instruments for pre-packed products and measuring containers by seeking to share information and organize joint events of consultations and meetings for the economic operators involved.*

INITIAL COMMENT: *Compliance assistance is provided as an intrinsic part market surveillance protocol and was was devised specifically to address the problems of legal metrology.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Market surveillance via inspection visits (4,000 per annum)*
   - Evidence of results: *Decline in the number of violations each year compared to 2014 - 2015 offenses decreased by 24%*
   - Costs: *Included within overall inspection budget*
   - Duration: *Since 1966*
   - Coverage: ***National*** *- Measuring instruments, pre-packed products and measuring containers*
   - Meets product harmonisation principles: *Meets MS obligation with accreditation of competence to carry out tests, calibrations and sampling.*
2. Cost-efficiency: *No data provided other than the reduction in non-compliance and reduced inspection visit duration*
3. Specific elements: *LST EN ISO / IEC 17025: 2005 standard accredited Inspection Measurement and Research Division.*
4. Ease of replication: *This practice is appropriate to legal metrology*
5. Earned recognition/impact upon inspection: *The number of inspections each year has remained the same, but their duration has decreased.*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Training Programme for Authorised Officers	CA	3	23	DEPARTMENT OF COMMUNICATIONS, ENERGY & NATURAL RESOURCES (DCENR)	Ireland	CA12

DETAILS:

The practice was developed as the central core of the planned service delivery arrangements when the inspection process was out-sourced by the department to and external agency and include the following:

1. *Provision of a training programme for authorised officers to ensure those appointed to carry out market surveillance operations understand the provisions of the applicable legislation, their powers under the legislation and best practice in carrying out inspection activities.*

2. *Development and delivery of awareness raising programmes for relevant economic operators and stakeholders*

3. *National inspection programme*

INITIAL COMMENT: *A considered and well managed approach to ensure that all stakeholders receive accurate information delivered according to best practice and that enforcement is both well planned and delivered by well trained staff.*

FURTHER ASSESSMENT:

1. Effectiveness

   - Design: *Provision of training programmes for authorised officers, inspection programme & awareness raising for economic operators*

   - Evidence of results: *Initial small inspection programme over three phases has defined a baseline for compliance and inspection protocols*

   - Costs: *Subject to public tender for outsourcing – Ministry budget.*

   - Duration: *Since 2013 & 2011 respectively*

   - Coverage: ***National*** *– Eco-design & Energy Labelling (Directives 2009/125/EC and 2010/30/EC*

   - Meets product harmonisation principles: *Ensure those appointed to carry out market surveillance operations and those supplying goods understand the provisions of the applicable legislation, their duties/powers under the legislation and best practice in carrying out inspection activities or placing products on the*

market

2. Cost-efficiency: *Better information & enforcement benefits both EO's and consumers*

3. Specific elements: *Enforcement was outsourced. Training was provided for the newly authorised officers employed by the external service provider to ensure compliant and consistent enforcement.*

4. Ease of replication; *Could be useful in Member States where market surveillance enforcement activities are out sourced or provided by other government/regional/local agencies*

5. Earned recognition/impact upon inspection: *No – None*

AWARENESS RAISING

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	AR/CA	12	22B	MINISTRY OF ENVIRONMENT AND WATER	Bulgaria	AR5

DETAILS: *Information is provided to economic operators and certification bodies through an annual workshop that is promoted through the MSA website, e-mail, direct mailing and via relevant NGO's AND as part of the MS protocol through direct contact via telephone, e-mail.*

INITIAL COMMENT: *Covers aspects of both AR & CA and the annual workshop is a very valuable asset as it provides economic operators with a regular opportunity to ensure that their knowledge of their legal requirements is correct and up to date.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Workshops on the bans and restrictions for placing on the market of paints, fluorinated greenhouse gases and ozone depleting substances plus response to direct requests from EOs*
   - Evidence of results: *Reduction in the number of non-compliant chemical products found.*
   - Costs: *Funded for one workshop per year*
   - Duration: *Since membership of EU*
   - Coverage: ***National*** *- 22/B Other chemicals (Paints, Fluorinated greenhouse gases, Ozone Depleting Substances): Directive 2004/42/EC, Regulation (EU) 517/2014, Regulation (EC) 1005/2009*
   - Meets product harmonisation principles: *Awareness raising of legal requirements plus partnership working with Customs Service*
2. Cost-efficiency: *No performance data provided*
3. Specific elements; *Contact with branch Chambers of Commerce & Trade Associations together with direct contact with EOs & Website*
4. Ease of replication: *Yes, for all product sectors in all member states*
5. Earned recognition/impact upon inspection: *Reduced inspection of low-risk EOs*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocols	AR/CA	-	4, 9, 10, 17, 18, 22	DEPARTMENT OF JOBS, ENTERPRISE AND INNOVATION HEALTH AND SAFETY AUTHORITY	Ireland	AR6

DETAILS: *Awareness raising provided to economic operators through website, lectures, articles in e- journals and visits to premises and trade shows. Compliance assistance through answers to individual queries and normal enforcement activities.*

INITIAL COMMENT: *A good example of how the MSA can be proactive in assisting an industry in improving its compliance across a number of product sectors by embedding awareness raising and compliance assistance into its normal market surveillance procedures.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Awareness raising and compliance assistance incorporated as part of market surveillance protocols. Proactive contributions to e-journals and trade shows*
   - Evidence of results: *N/A*
   - Costs: *Contained within service budget*
   - Duration: *N/A*
   - Coverage: ***National*** *- Machinery, Lifts, PPE, PED, TPED, ATEX, REACH + Classification and Labelling, Detergents - some product sectors have the MS enforcement duty split between HSE & CCPC along occupational/recreational lines*
   - Meets product harmonisation principles: *Provides AR/CA within MS activities*
2. Cost-efficiency: *Combination of advice and enforcement across linked enforcement duties can make good use of scarce resources*
3. Specific elements: *Combining a joint enforcement responsibility for market surveillance of machinery with occupational health and safety in the workplace. Seeks to work through trade associations to widen influence. Works well within a very small market.*
4. Ease of replication: *Would expect most MSAs to already replicate most of these activities*
5. Earned recognition/impact upon inspection: *No – None*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	AR	-	5	MINISTRY OF LOCAL GOVERNMENT AND MODERNISATION. NORWEGIAN BUILDING AUTHORITY (NBA) IS A SUBORDINATE AGENCY	Norway	AR7

DETAILS: *Economic operators are targeted through 7-8 campaigns per year informed by regular consultations with professional bodies, notified bodies, technical assessment bodies and the screening of complaints plus risk assessments of products*

INITIAL COMMENT: *Targeted information to economic operators based upon consultation, risk assessment and complaint analysis.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Comprehensive MS protocol in specific product sector*
   - Evidence of results: *No information provided*
   - Costs: *Containing with MS budget that also contains a testing budget*
   - Duration: *Unknown*
   - Coverage: ***Two National networks*** *– covering consumer & industrial construction products*
   - Meets product harmonisation principles: *Wide consultation with professional organisations, Notified Bodies and technical Assessment Bodies to identify products to control, as well as screening the complaints from previous years*
2. Cost-efficiency: *Working closely with Notified Bodies can reduce costs*
3. Specific elements: *Combination of proactive and reactive market surveillance activities, risk assessment and co-operation with 4 Notified Bodies and Customs Service.*
4. Ease of replication: *A member state's solution to its local situation that would not necessarily be helpful to others although it does contain some MS good practice.*
5. Earned recognition/impact upon inspection. *No – None*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	AR	7	14,17,18,20,21,23	TECHNICAL REGULATORY AUTHORITY CONSUMER PROTECTION BOARD	Estonia	AR8

DETAILS: *Manufacturers, importers and distributors are informed of the legal requirements for measuring instruments by information booklets and other PR activities. Decreasing interest for seminar type events probably because majority of the information can be nowadays found quite easily from our homepage and similar internet sources.*

INITIAL COMMENT: *Targeted information to economic operators through a number of access channels across a range of product sectors*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Comprehensive approach to the provision of information to EOs through face to face discussions, training days, information booklets & website.*
   - Evidence of results: *Not known. Main outcome is likely to be an overall rise in the level of knowledge*
   - Costs: *No additional funds – contained within normal MSA budget.*
   - Duration: *Since 2008 – Training days have now ceased except for events for Pyrotechnics every 2 years*
   - Coverage: ***National*** *- LVD, EMC, ROHS, Eco-design applicable products + Measuring Instruments, Non-automatic weighing, Pre-packaged products + Pyrotechnics 2013/29/EC*
   - Meets product harmonisation principles: *Informed EOs are better placed to produce/import compliant products*
2. Cost-efficiency: *Minimum cost approach but no measurement of effectiveness or efficiency. Printed booklets used in areas of little change*
3. Specific elements: *Focused upon on-line access to information + printed booklets for MI distributed during inspection visits – Pyrotechnics booklets mainly aimed at consumers with the training days targeted on importers and retailers.*
4. Ease of replication: *Normal MS activity*
5. Earned recognition/impact upon inspection: *No – None*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	AR		5	EAST AYRSHIRE TRADING STANDARDS SERVICE	United Kingdom	AR9

DETAILS: *An information sharing initiative by the MSA to the economic operators in a specific product sector.*

COMMENT: *Targeted information to economic operators in local area based upon a direct and proactive approach to an identified issue.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Raise awareness amongst business of the legal requirements and provide guidance on the steps to be taken to achieve compliance.*
   - Evidence of results: *61% found to be compliant or actively seeking compliance on first contact - Informal review after year one indicated that some businesses were still slow to comply through lack of understanding of requirements. Project was continued for another year*
   - Costs: *Contained within MS budget*
   - Duration: *2 years*
   - Coverage: *Small number of local business re Construction Products Directive*
   - Meets product harmonisation principles: *Combats EOs lack of knowledge of regulations and consequent failure to comply.*
2. Cost-efficiency: *No information provided*
3. Specific elements: *Information provided to a specific section of a product sector – Steel construction – to meet a local need*
4. Ease of replication: *The project was taken up by a number of MSAs in the West of Scotland – could be replicated to deal any local compliance issue.*
5. Earned recognition/impact upon inspection: *Yes, businesses that responded to the initial letter were not inspected if they were able to send documentary proof of compliance.*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	AR	2	2,3,22,32	Ministry of Health, Department for Objects of Common Use and Noise Protection	Croatia	AR10

DETAILS: *An information provision initiative by the MSA to the economic operators in a specific product sector.*

COMMENT: *Information on toy safety, cosmetics and chemicals made accessible for economic operators via website and e-mail response.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *To inform economic operators of the legal requirements and provide feedback guidance on the steps to be taken to achieve compliance.*
   - Evidence of results: *No indicators set or review conducted*
   - Costs: *Started with EU funding and continued with Chamber of Commerce funding – no amounts detailed*
   - Duration: *2 years*
   - Coverage: *National & local*
   - Meets product harmonisation principles: *Combats EOs lack of knowledge of regulations and consequent failure to comply.*
2. Cost-efficiency: *No information provided*
3. Specific elements: *Information provided to a number of a product sectors – Toys, cosmetics, chemicals, biocides & REACH*
4. Ease of replication: *Would normally be considered by all MSA's*
5. Earned recognition/impact upon inspection: *None*

GOOD MARKET SURVEILLANCE PRACTICE

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	AR,CA	16	17	METROLOGY INSTITUTE OF THE REPUBLIC OF SLOVENIA (MIRS)	Slovenia	MS1

DETAILS: *MS system based upon the systematic monitoring of the level of compliance in specific product sectors through risk assessment and classification of the supervised economic operators based upon inspection results.*

INITIAL COMMENT: *A comprehensive market surveillance system that seeks to risk assess economic operators and classifies them for inspection planning. This should encourage economic operators to improve their procedures and influence to scope or frequency of their inspections.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Increase the effectiveness of the market surveillance/inspection through risk assessment-led inspection*
   - Evidence of results: *The comparison between the supervised fields at the beginning of surveillance/inspection in year 2000 and today*
   - Costs: *Market surveillance budget*
   - Duration: *6 years*
   - Coverage: NATIONAL
   - Meets product harmonisation principles; *Well-designed risk-based market surveillance planning and procedures*
2. Cost-efficiency: *Seeking to develop successful surveillance activities with limited resources*
3. Specific elements: *The basic goal of eliminating non-compliant measuring instruments & pre- package products from the market/ use*
4. Ease of replication: *Should already be part of all market surveillance systems*
5. Earned recognition/impact upon inspection: *Yes – Numbers of inspections reduced*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Market Surveillance of Medical Devices	AR,CA, CS	14	1	CYMDA	Cyprus	MS2

DETAILS: A *comprehensive MS programme including inspections, complaint investigation, sampling, inspection check sheets, seminars, visibility mailing list, patient group feedback and cooperation with customs. This approach to market surveillance uses a wide range of tools available to any MSA and is an example of effective controls being implemented using existing established methods delivered in an appropriate way to match service delivery needs.*

INITIAL COMMENT: *A comprehensive market surveillance system that seeks to utilise a full range of information inputs and which benefits from co-operation with the customs service. This has the potential to encourage importers to improve their procedures and influence to scope or frequency of their inspections. This has the potential to encourage importers to improve their procedures and influence the scope or frequency of the MSA inspections*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Within modest resources, implementing a comprehensive MS programme*
   - Evidence of results*: Increased detection of non-compliant products*
   - Costs: *Budget is part of overall budget of Authority (exact figures not available)*
   - Duration: *Commenced in 2002*
   - Coverage: *Medical devices*
   - Meets product harmonisation principles; *Regular inspection, complaint investigation and product sampling*
2. Cost-efficiency: *No measurable results*
3. Specific elements: *Rolling 3 monthly programme of inspections of manufacturers, importers, distributors, retailers and workplaces*
4. Ease of replication: *Normal Market Surveillance activity – should be implemented in all Member States by all MSAs*
5. Earned recognition/impact upon inspection: *None - No reduction in inspections*

GOOD PRACTICE FOR AWARENESS CAMPAIGNS

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Piki's room	AR	1.5	U	FINNISH SAFETY AND CHEMICALS AGENCY TUKES	Finland	AR GP1

DETAILS: *Children's safety game and TV-programme series for children. Both aimed at 3-5-year-old children to increase their safety awareness and teach them safe ways of behaving. The ultimate goal is to reduce accidents.*

INITIAL COMMENT: *An excellent example of the potential to deliver information to specific audiences through the use of methods and access channels that are favoured by or more suited to the selected audience.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *To increase children's safety awareness and to reduce accidents and injuries caused by unsafe behaviour and misuse of products.*
   - Evidence of results: *Piki's room games are played by approx. 2000 children daily at the hugely popular Pikku Kakkonen website for children*.
   - Costs: *So far 41000 Euros*
   - Duration: *Starting from February 2015, undefined duration. First 3 games were published in February followed by 5 more games in August 2015*
   - Coverage: *National across electrical appliances, personal protective equipment, toys and chemicals.*
   - Meets product harmonisation principles:
2. Cost-efficiency: *Long term plan to change behaviours and reduce accidents and injuries over many years*
3. Specific elements: *It offers children a fun way to learn about safety, avoid patronizing tone and get the message through without even noticing it.*
4. Ease of replication: *Very much transferable, only needs to be translated to the language of the region. It is suitable to all product groups used by consumers, also for consumer services and other types of safe behaviour education.*
5. Earned recognition/impact upon inspection; *N/A*

3.19. Annexes

Reference List of Product Sectors as per the project ToR:

	Product Sectors	Relevant legislation
1	Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	Directives 93/42/EEC, 98/79/EC and 90/385/EEC
2	Cosmetics	Regulation (EC) 1223/2009
3	Toys	Directive 2009/48/EC
4	Personal protective equipment	Directive 89/686/EEC
5	Construction products	Regulation (EU) 305/2011
6	Aerosol dispensers	Directive 75/324/EEC
7	Simple pressure vessels and Pressure equipment	Directives 2009/105/EC and 97/23/EC. Directives 2014/29/EU and 2014/68/EU
8	Transportable pressure equipment	Directive 2010/35/EU
9	Machinery	Directive 2006/42/EC
10	Lifts	Directive 1995/16/EC - Directive 2014/33/EU
11	Cableways	Directive 2000/9/EC
12	Noise emission for outdoor equipment	Directive 2000/14/EC
13	Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	Directive 1994/9/EC - Directive 2014/34/EU
14	Pyrotechnics	Directive 2007/23/EC - Directive 2013/29/EU
15	Explosives for civil uses	Directive 93/15/EEC - Directive 2014/28/EU
16	Appliances burning gaseous fuels	Directive 2009/142/EC
17	Measuring instruments, Non-automatic weighing instruments, Pre-packaged products and Units of measurement	Directives 2004/22/EC and 2009/23/EC - Directives 2014/32/EU and 2014/31/EU; Directive 2007/45/EC, 75/107/EEC and 76/211/EEC; Directive 80/181/EEC
18	Electrical equipment under EMC	Directive 2004/108/EC - Directive 2014/30/EU
19	Radio and telecom equipment under RTTE - RED	Directive 1999/5/EC - Directive 2014/53/EU
20	Electrical appliances and equipment under LVD	Directive 2006/95/EC - Directive 2014/35/EU
21	Electrical and electronic equipment under RoHS and WEEE and batteries	Directives 2011/65/EU, 2002/96/EC and 2006/66/EC
22	A) Chemical substances under REACH and Classification and Labelling Regulations	Regulations (EC) 1907/2006 and 1272/2008/EC
22	B) Other chemicals (Detergents, Paints, Persistent Organic Pollutants, Fluorinated greenhouse gases, Ozone Depleting	Regulation (EC) 648/2004, Directive 2004/42/EC, Regulation (EC) 850/2004, Regulation (EC) 842/2006 and Regulation (EU) 517/2014, Regulation (EC) 1005/2009

	Substances, etc.)	
23	Eco-design and Energy Labelling	Directives 2009/125/EC and 2010/30/EU
24	Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	Directive 1992/42/EEC
25	Tyre labelling	Regulation (EC) 1222/2009
26	Recreational craft	Directive 1994/25/EC - Directive 2013/53/EU
27	Marine equipment	Directive 96/98/EC -Directive 2014/90/EU
28	Motor vehicles and Tractors	Directive 2002/24/EC - Regulation (EU) 168/2013; Directive 2007/46/EC; Directive 2003/37/EC - Regulation (EU) 167/2013
29	Non-road mobile machinery	Directive 97/68/EC
30	Fertilisers	Regulation (EC) 2003/2003
31	Other consumer products under GPSD (optional)	Directive 2001/95/EC
32	Biocides	Regulation (EU) 528/2012
33	Textile and Footwear labelling	Regulation (EC) 1007/2011 and Directive 94/11/EC
34	Crystal glass	Directive 69/493/EEC

Primary Authority – Cost recovery

A key element of Primary Authority is that MSAs acting as primary authorities have the discretion to recover their costs. Section 31 of The Regulatory Enforcement and Sanctions Act 2008 states: *'The primary authority may charge the regulated person such fees as it considers to represent the costs reasonably incurred by it in the exercise of its functions under this Part in relation to the regulated person.'* This makes it very clear that MSAs are not expected to make money out of Primary Authority, but cost recovery allows an MSA to operate a primary authority partnership whilst retaining the ability to provide a proficient and effective market surveillance service. Businesses in primary authority partnerships benefit in lots of ways including having access to assured legal advice provided to them at cost price.

Cost recovery is a concept that has caused much discussion and debate in the UK around the ethics of charging businesses for advice and support:

- Some businesses argued that, as they were already paying business rates and taxes, they should not be charged additionally for the advice services provided by MSAs.

- Some MSAs were concerned that businesses paying for services would be seen to be paying for immunity from prosecution. Furthermore, they were concerned that their own integrity might be questioned, and their reputation for fairness and even-handedness tarnished.

The taxes and business rates (community charges) paid by businesses for market surveillance, are in reality a very small proportion of the overall taxes and business rates that they pay. The

operation of a Primary Authority partnership is over and above the basic service level provided and the cost is not therefore included in these basic charges. The cost has to be accounted for in a different way.

Many businesses in the UK want a higher than basic level of service from their MSAs that will give them assurance that they were compliant, and that would reduce uncertainties caused by inconsistent legal interpretations of the law. This enables them to have a degree of confidence when investing in compliance and helps them to grow their businesses. An important added benefit is because MSAs have confidence that a business in a primary authority partnership with an MSA will have received good, sound advice from their partner MSA and will therefore be compliant. They will have access to see what advice has been given and will therefore need to spend less time on inspecting those businesses.

Most MSAs cannot normally afford to provide such a high level of service out of their normal annual service budget without reducing their capacity to carry out other high priority work. The ability for them to recover their costs is therefore very important for product safety, and for market surveillance in general. This is only true however if the MSA is allowed to retain the costs recovered within their own budget. If the recovered costs are not 'ring fenced' in this way, and are absorbed into other wider budgets, the benefits to product safety and market surveillance generally outlined above would be lost.

4. DIGITAL COMPLIANCE

4.1. Introduction

Many instruments of Union harmonisation legislation oblige the manufacturer or the importer to ensure compliance, to keep documentary evidence of the compliance process. Firstly, many instruments of Union harmonisation legislation oblige the manufacturer to draw up technical documentation containing information to demonstrate the conformity of the product to the applicable requirements. The technical documentation is usually quite voluminous and contains very valuable technical information which could contain essential elements protected by intellectual property rights and the legislation on trade secrets. Therefore, technical documentation or parts of it is often only shared with market surveillance authorities, upon their request, and not with any other actors in the supply chain. The latter include distributors, other intermediaries and possibly conformity assessment bodies. In order to assess the compliance of a product, these actors should rely, partly on the markings on the product but primarily on the EU declaration of conformity. Secondly, these instruments of Union harmonisation legislation also oblige the manufacturer to draw up and sign an EU declaration of conformity before placing a product on the market. By drawing up and signing the EU declaration of conformity, the manufacturer assumes responsibility for the compliance of the product. Where several pieces of Union harmonisation legislation apply to a product, the manufacturer or the authorised representative has to provide a single declaration of conformity in respect of all such Union acts. The EU declaration of conformity must be made available to the surveillance authority upon request. The EU declaration of conformity must be translated into the language or languages required by the Member State in which the product is placed or made available on the market. It should be noted that Union harmonisation legislation relating to machinery, equipment in potentially explosive atmospheres, radio and terminal telecommunication equipment, measuring instruments, recreational craft, lifts, high-speed and conventional rail systems and constituents of the European Air Traffic Management network require products to be accompanied by the EU

declaration of conformity. However, some instruments of Union legislation do neither provide for technical documentation, nor for a declaration of conformity.

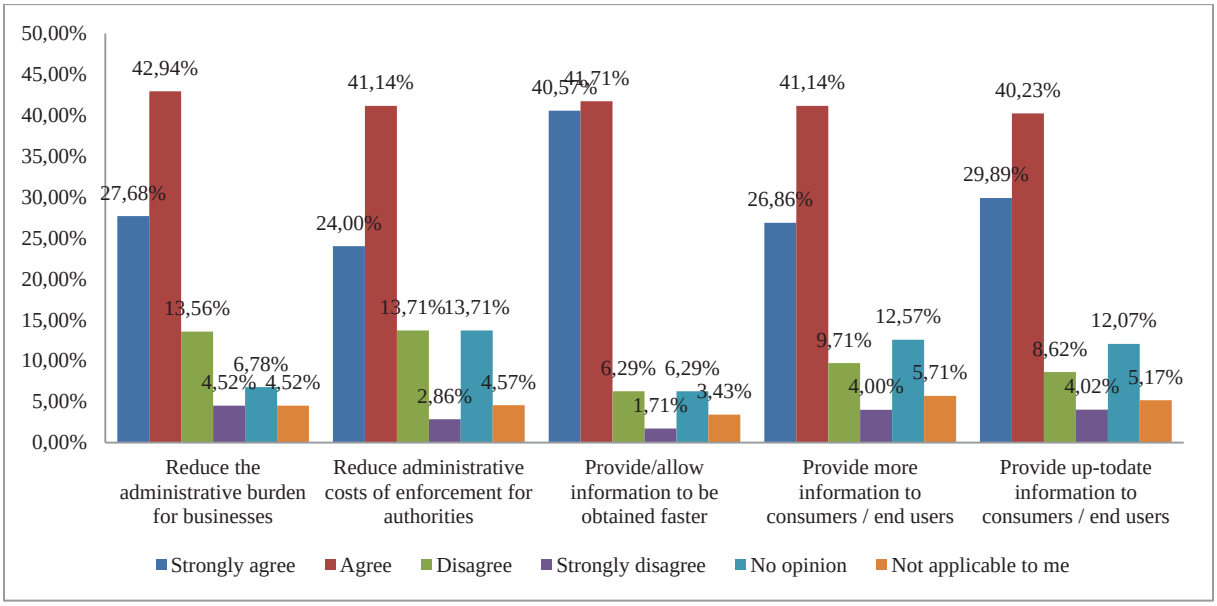
Union legislation that provides for technical documentation and for a declaration of conformity allows market surveillance authorities to request the technical documentation or the declaration of conformity either in paper or in electronic form, as they prefer. Each of both forms of transmission has its own problems of transparency:

- The transmission in paper should not make a major difference for the manufacturer or, as the case may be, the authorised representative, especially to market surveillance authorities, although an electronic transmission might be more efficient. The major drawback of paper is that the declaration of conformity is, in most cases, not readily accessible to other economic operators in the supply chain, for example distributors, except in the cases where the products must be accompanied by the declaration. This might cut them off from important compliance information. In theory, they could ask their suppliers to provide them with a paper copy for all deliveries but this would create a challenging administrative burden for all actors in the supply chain, especially in the light of the obligation for the manufacturer or the authorised representative to continuously update the declaration of conformity. In practice, however, requesting and keeping a paper version of the EU declaration of conformity constitute a fairly important administrative burden for distributors and other intermediaries. Furthermore, where the paper copy was not transmitted by the manufacturer to other economic operators in the supply chain, the latter cannot provide it to the consumer when he or she would seek it.

- Electronic transmission is less easy than it would seem. Firstly, the transmission in electronic form to market surveillance authorities depends essentially upon the latter's willingness to accept electronic documentation. This would then concern scanned versions of signed declarations in paper form. Secondly, the transmission in electronic form to other actors in the supply chain is not a very widespread practice in the EU: only 18% of the respondents of the public consultation always or often publish their declarations of conformity on their site. Thirdly, the electronic signature on declarations of conformity, in accordance with the first eSignatures Directive 1999/93/EC and its replacing Regulation (EU) No 910/2014 on electronic identification and trust services for electronic transactions in the internal market (eIDAS Regulation), seems to be rarely used, notwithstanding the fundamental legal rule that all electronic signatures and verification services must be admissible as evidence in legal proceedings. Fourthly, the electronic seals introduced by eIDAS cannot be used for EU declarations of conformity which require the name and the function of the natural person who signs on behalf of the manufacturer or his authorised representative. Electronic seals are similar to electronic signatures but only available to legal persons such as corporate entities in order to minimize the importance of the “authorized signer” for a particular entity. The electronic seal is associated with that entity and any use of that seal is presumed to be binding on that entity.

A large majority of respondents strongly agrees or agrees that a broader use of electronic means to demonstrate compliance would help to reduce the administrative burden for businesses (70.62%), reduce administrative costs of enforcement for authorities (65.14%), provide/allow information to be obtained faster (82.29%), provide more information to

consumers/end users (68.00%) and provide up-to-date information to consumers/end users (70.11%).



In addition, Union product legislation obliges economic operators to inform the national competent authorities of risks to the health, safety and other public interests posed by products they market. Such information must be made available to consumers.

In particular, according to Article 12 of the General Product Safety Directive[63] (GPSD) and Article 22 of Regulation (EC) No 765/2008[64], voluntary measures[65] taken by economic operators against dangerous products (e.g. a company itself recalls a dangerous product it placed on the market) are to be reported to Member States' authorities and, through them, to the Commission and to the other Member States through the RAPEX system. Moreover, according to Article 23 of Regulation (EC) No 765/2008, voluntary measures against harmonised products posing a less than serious risk need to also be reported to Member States authorities and, through them, to the Commission and the other Member States. As regards non-harmonised products posing a less than serious risk, Member States are not requested by the GPSD to report such voluntary measures to the Commission. For any notification in the RAPEX system, the competent authorities of the Member States must take responsibility concerning the information transmitted therein.

This procedure takes necessarily a certain amount of time due to the various steps described in the legal framework. For example, according to the RAPEX Guidelines[66], Member States have 10 days as of the receipt of information on voluntary measures from the economic operator to notify the Commission in the RAPEX system. This time lapse may be necessary

63 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance), OJ L 11/4 of 15.1.2002

64 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 OJ L 218 of 13.08.2008

65 RAPEX also covers compulsory market surveillance measures adopted by competent authorities in respect of dangerous products. Such measures are outside the scope of this analysis since they fall entirely under the responsibility of the Member States as of their initiation.

66 Commission Decision of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive), OJ L 22/1 of 26.1.2010

for national authorities to make their own assessment of the risk at stake, independently of the level of risk alleged by the economic operator. The Commission has, afterwards, 5 days to validate the notification and distribute it to the other Member States. Notifications sent in languages other than English, also need to be translated. The publication of the notification on the Commission's RAPEX website after its validation can take in practice several days. Consequently, publication of a voluntary measure (e.g. a recall of a passenger car due to safety issues of the airbags) happens weeks after the measure was taken. Thus, RAPEX, which serves a central point of reference in terms of measures against dangerous products in the EU, and even beyond, cannot be a "just in time" system in passing the information about risks posed by products in such cases to consumers and businesses.

Moreover, notice by the economic operators of such voluntary measures will not necessarily reach all consumers that bought the product.

4.2. Existing Technologies

This section is built on *G. Baldini et al.; Enforcers and brand owners' empowerment in the fight against counterfeiting* (updated version of Baldini G. and Cano Pons E., Enforcers and brand owners' empowerment in the fight against counterfeiting, EUR 28400 EN, doi:10.2760/135671) and was adapted for enforcement of Union harmonisation legislation.

Different techniques have been proposed to fight against counterfeiting. These techniques include identification and authentication technologies, processes to control supply chains and technologies to track and trace products. A technique can be based on various tools and equipment. In this report, we will pay special attention to the use of the smartphone and other portable devices as tools to empower law enforcers and . The same techniques could be used for the purpose of compliance: the analysed techniques can also be an important element in supporting Due Diligence practices and Supply Chain Integrity, because the different categories of users can authenticate goods in different parts of the supply chain and report the presence of non-compliance.

Definitions

This section provides the operating context and definitions of key terms used in this report.

- Empowerment: For the aim of this section, the term empowerment indicates the act of enabling law enforcers (e.g. customs and market surveillance authorities) and manufacturers through techniques on the basis of available information, visual inspection and validation through tools 'readily' available. The term 'readily' refers to techniques and tools that are widely available on the market and do not need sophisticated technological solutions and systems or complex training.

- Users: While in literature and elsewhere, empowerment is associated with the concept of the 'consumer' in its widest sense (to encompass private citizens, enforcers and businesses purchasing products), in this report, law enforcement authorities, manufacturers and enterprises — including small to medium-sized enterprises (SMEs) — are all considered as users. Enterprises cannot implement sophisticated or expensive controls for the goods provided by the supplier, such as forensic labs or responsible supply chain management while retailers and distributors may want to check that the received products comply with the law.

Techniques

Two main categories of 'readily' available techniques based on different tools or equipment have been identified.

1. The first category is represented by the modern smartphone (or similar device, such as a tablet). The modern smartphone is equipped with a high-resolution camera (e.g. 5 megapixels and above), support for different standards for wireless connectivity, a powerful processor able to support the implementation of sophisticated algorithms and support for Near Field Communication (NFC) and Radio Frequency Identification (RFID) readers. In addition, the smartphone can be integrated and augmented with a wide range of plug-in devices and tools (e.g. a USB microscope). This category will be the main focus of this report.

2. The second category is represented by the wider domain of portable products (e.g. portable spectrometers), which have already appeared on the market. In many cases, these portable products implement systems that have been available until only recently in forensic labs. An example of this is represented by the category of portable spectrometers. This report will also provide an overview of these systems, without specifying the product or the manufacturer.

In addition to the abovementioned tools, this category also includes low-cost tools, such as readily available chemical reagents or polarised filters.

The focus is on techniques to be used in the 'field', where field is the physical area where the user operates and where the goods are either exposed or in transit. In other words, it refers to physical locations, which are different from forensic labs, where goods that may need to be verified are placed, and that can coincide with the enterprise's premises, the marketplace, the customs area etc. This section does not relate to empowerment techniques for e-commerce as the user does not have physical access to the goods.

Empowerment via Use of a Smartphone

Capabilities of a smartphone

A description of the approach to empowerment via use of a smartphone is presented below.

The centre of the suggested approach would be a smartphone, that is to say, a tool used nowadays by all relevant users. The smartphone acts as a field sensor (to detect optical features, read RFID tags, geolocations etc.), telecommunication gateway (to obtain real-time information on the object or to allow direct interactions between the object and a remote verification system) and notification system (to provide information to the track and trace supply chain system).

Furthermore, the smartphone can be connected to other systems and components, such as the producer's supply chain, the law enforcer's reference database and other systems.

More precisely, nowadays a smartphone (June 2016) has the following capabilities:

1) A high-resolution camera. It is now commonplace to buy a smartphone with a 5 megapixel (MP) camera for under EUR 100 and the trend will continue, so we can envisage that new cameras will have an even higher resolution.

2) Wireless connectivity through different wireless communication standards: Wi-Fi, GSM, Universal Mobile Telecommunications System (UMTS), Long Term Evolution (LTE) and with broadband capacity. This ensures that data can be sent quickly to a remote server (e.g. cloud database) or a remote application.

3) High-performance computing platform. Today's smartphones have similar computational power and capabilities to the older desktop computers, and this trend is likely to continue.

4) Near field communication (NFC) readers to read high-frequency (HF) RFIDs, which both operate at the 13.56 MHz frequency.

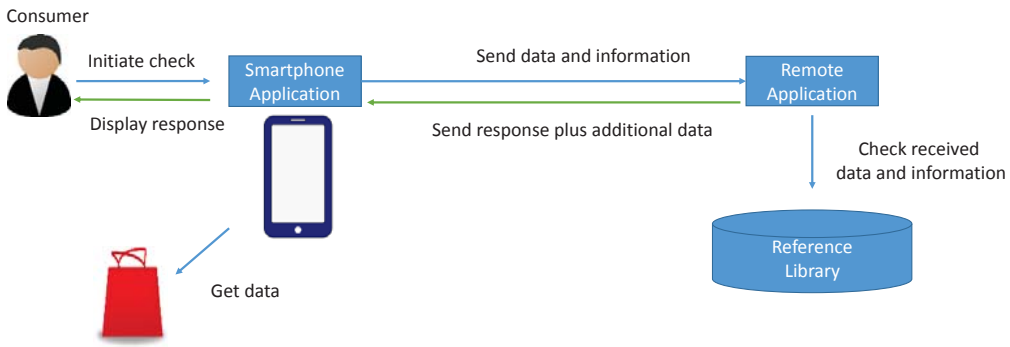
5) Global Navigation Satellite Systems (GNSS), which can record the time and space when goods are being evaluated.

6) Plug-ins of different components through the USB interface. For example, visual augmentation equipment (e.g. USB microscope) or a DVB dongle (e.g. to collect radio frequency emissions) can be added to a smartphone.

7) Installation and activation of applications on a smartphone.

Most of these capabilities were not present in smartphones until recently. The new capabilities mean that it is possible to implement various techniques, which will be described here.

In the context of assessing compliance, the smartphone itself is the component (in the hand of the law enforcement official or the representative of a manufacturer, namely the 'users') of a wider system, which can include an application, a communication protocol, a reference library, a manufacturer database of the product features, or a database linked to the supply chain and other elements. The smartphone is used to collect data (e.g. images, RFIDs) from the goods to be evaluated. This data can be processed in the smartphone itself (e.g. to extract features) to generate additional information from the raw data using an application. The application sends the data and the information to a remote application using wireless connectivity and a specific communication/data protocol. Additional information can also be sent from the smartphone, such as its position if the privacy settings defined by the user allow this. The remote application uses a reference library or a supply chain database to match the data and information received from the smartphone. The matching information and related data (e.g. for which market the product is produced) is then sent back to the smartphone. Then, the application in the smartphone displays this information and data to the user. This generic workflow is represented in the following figure:



The users only see and use the smartphone, but adequate infrastructure must be built to implement the underlying technique. This is described in the following paragraph.

Main components of a smartphone-based approach

Beyond the smartphone, a complete solution must include the following elements.

1) **Smartphone application**. This is the application running on a smartphone, which implements a Graphical User Interface (GUI) to the user to receive requests. The smartphone is connected to the main sensors of the smartphone to collect the required data (e.g. images). The application can also implement specific algorithms to process the data. For example, it could extract statistical features from the retrieved image. The smartphone application is also responsible for sending the data and any additional

information (e.g. features, position or privacy settings) to the remote application using a well-defined communication protocol.

2) **Communication protocol**. This communication protocol is responsible for sending the data and information from the smartphone application to the remote application and sending back the response from the remote application to the smartphone application.

3) **Remote application**. This is the remote application hosted on a remote server, which also uses the communication protocol to exchange data with the smartphone application. The remote application uses the information from a reference library to evaluate whether the received data and information from the smartphone identify the products.

4) **Reference library**. This is the database of the matching information (e.g. track and trace or fingerprinting for product identifications), which can be created by manufacturers or by other organisations that collect the information that identifies valid goods from several manufacturers. The reference library is a generic term, which can include many different types of information, for example, the fingerprinting of goods or the serialisation number of an overt/covert tag. Note that the reference library can also be used to insert additional information useful for the different categories of users.

Specific empowerment techniques

One can distinguish different empowerment techniques based on smartphone information, how the reference library is created and what type of information is stored or collected by the smartphone.

1) **Reference library created by the manufacturer during the manufacturing process**. The reference library is created by the manufacturer itself or by a company working for it and the specific information on the single product is collected and stored in the reference library during the manufacturing phase. In other words, the manufacturing plan of the manufacturer is equipped with systems and devices to collect the unique fingerprinting of the product and/or the package, which is then stored for future use. Note that the fingerprinting information can be in different forms: it can be a serial number represented in the barcode or QR code, it can be a fingerprinting of the product itself on the basis of its physical or chemical properties, or it can be the RFID applied to the product and/or the package. It can also be a serial number embedded in an overt or covert tag. In fact, a combination of these fingerprinting methods can also be used to improve authentication accuracy and resistance to the threat of cloning. In this case, the reference library must store the correlation of the set of data used to identify the package and/or the product uniquely.

2) **Reference library created by a commercial third party, which works with the manufacturer**. In this case, the reference library is created by a third party, which works with the manufacturer to insert its own tags. The tag is applied to the product after the manufacturing process. As a consequence, it is not an intrinsic property of the

product. The difference with the previous case is that a correlation between the tag identifier and the product must be done before the product is distributed on the market. This can increase the risk of cloning or removal of the tag. The advantage is that the manufacturer does not need to invest in technology if it lacks skills, competences or economic capabilities (e.g. because it is a small company with a limited budget), as the commercial third party will perform this activity.

3) **Reference library created by another third party**. In this case, the reference library is created by another party different from the manufacturer, even if it may collaborate with the manufacturer. For example, the third party can be a public body that collects information from different manufacturers with the aim of helping competent authorities detect non-compliant products on the basis of specific features.

Law enforcement authorities in particular might have direct access to information when they have suspicious products in front of them in the course of their front-line activities in customs areas and the marketplace. Through scanning or reading codes or other technologies placed on the product or its packaging, an application may submit the results stored in the reference library. In principle, this functionality might also be extended to external users of the reference library, such as enterprises acting in the supply chain that need to verify the authenticity and details of goods they are dealing with, as well as to private consumers at a point of sale. Through appropriate technical solutions based on interoperability between databases, the reference library might be connected to other similar repositories available on the market (e.g. GS1 database for barcodes); it might also host reference libraries created by manufacturers, in order to integrate the reference library accessible to users.

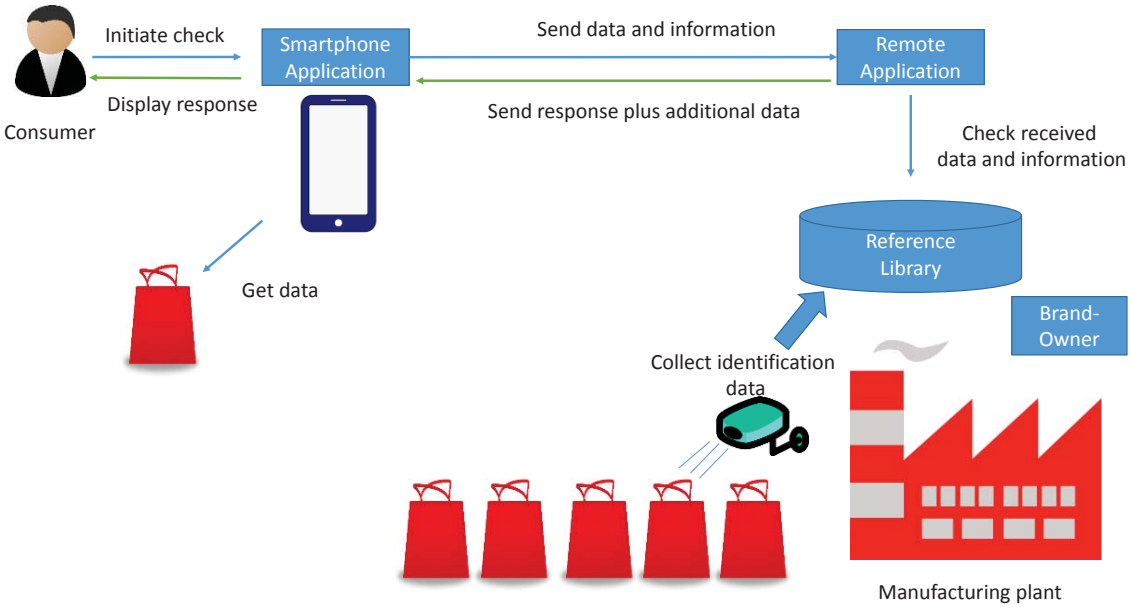
Reference library created by a manufacturer during the manufacturing process

In this case, the manufacturer collects the data to identify the goods in the supply chain or manufacturing process itself. The data can be defined and extracted using different authentication technologies. For example, it can be the specific signature of the paper of a packet of cigarettes (taken with an image) or it can be the identifier of an RFID embedded in the product.

The choice of the serialisation and authentication technology is really dependent on many factors: the type of goods, the impact of the authentication technology in the manufacturing process, the associated costs and so on. For many consumer goods, barcodes, QR codes or simple overt/covert technologies can be used, while more sophisticated and expensive goods can use RFID or more complex authentication technologies.

The goal is to collect and store identification and authentication information, which can be correlated with the data extracted by a smartphone in the field. This means that the data generation and collection process in the manufacturing plant must be designed together with the definition of the application in the smartphone or the related protocol.

A pictorial description of the process is provided below:



Supply chain information, such as the tracking and tracing of data, can also be used for this purpose if the manufacturer so desires. In this case, we must distinguish between closed-loop track and trace supply chains.

- A **closed-loop** supply chain is when the manufacturer, retailer and distributor are the same entity and the tracked goods are controlled by the same business entity (either directly or indirectly).

- An **open-loop** supply chain, meanwhile, is where the tracked goods can be distributed to different business entities, each of them equipped with its own back end. This difference is quite relevant to supporting the empowerment concept because in closed-loop, the ICT infrastructure is not designed to share information on the tracked goods with external entities. In open-loop, the extension to the end user is relatively straightforward and the associated costs are similar to the implementation of an Android application and connected to a remote back-end infrastructure (e.g. a cloud infrastructure).

Another aspect to be considered for the development of an empowerment solution is related to information sharing among the different back-end systems, which store the tracking information on the goods. The back-end systems should be capable of exchanging information with similar data formats. In addition, security and access control solutions should be developed to protect sensitive data, but also to guarantee access to the end users or the empowerment back-end systems, which are responsible for matching the information collected by end users. All these factors contribute to the overall cost of the empowerment solution.

The authentication information can be collected not only on the goods itself but also on the packages, which store the goods in a recursive way. In other words, the packages containing the goods can be authenticated as well. Recursive means that this process can be repeated for the larger packages storing the smaller packages. In this way, the user can trace the goods better.

An example of this technique is CODENTIFY, developed by the Digital Coding & Tracking Association, which represents some of the world's largest manufacturers of tobacco products. CODENTIFY can support:

- tracking and tracing — enabling the electronic monitoring of products as they move through the supply chain and the tracing backwards of their journey history to identify potential points of diversion;

- product authentication — enabling anyone, anytime, anywhere to immediately verify the authenticity of a product using widely available technologies, such as a mobile phone or the internet;

- digital tax verification — enabling governments to verify and control online the volume of products manufactured and so calculate the commensurate amount of excise and other taxes due.

In the pharmaceutical sector, a similar serialisation and tracking system is going to be set up under Commission Delegated Regulation (EU) 2016/161 of 2 October 2015, which was published, after scrutiny by the European Parliament and the Council, on 9 February 2016. The Delegated Regulation, and the new medicine verification system it lays down, will apply as of 9 February 2019.

This new system is based on a unique identifier, defined as a 2-D Data-Matrix code, developed to ISO standards (GS1).

The key data elements are:

- product code (14-digit)

- randomised unique serial number

- expiry date

- batch number

- (national reimbursement number or other national number (where necessary)).

The serialisation is based on a random number. The validity check (i.e. verification) of the serial number will be done at the point of dispensing (e.g. the pharmacist) by using a central cloud system, which stores and updates the status of the tracked pharmaceutical products. The cloud system will be called EMVO — European Medicine Verification Organisation, responsible for the operation of the European hub.

A Swedish pilot project (designed and deployed in 2009/2010) was implemented successfully to high levels of satisfaction from the stakeholders involved (e.g. pharmacists and wholesalers).

A German pilot project securPharm was implemented successfully. Coding is written in the Data Matrix code in accordance with ISO/IEC 16022. After an operating time of more than three years, the securPharm project is well on its way. The stakeholder associations have

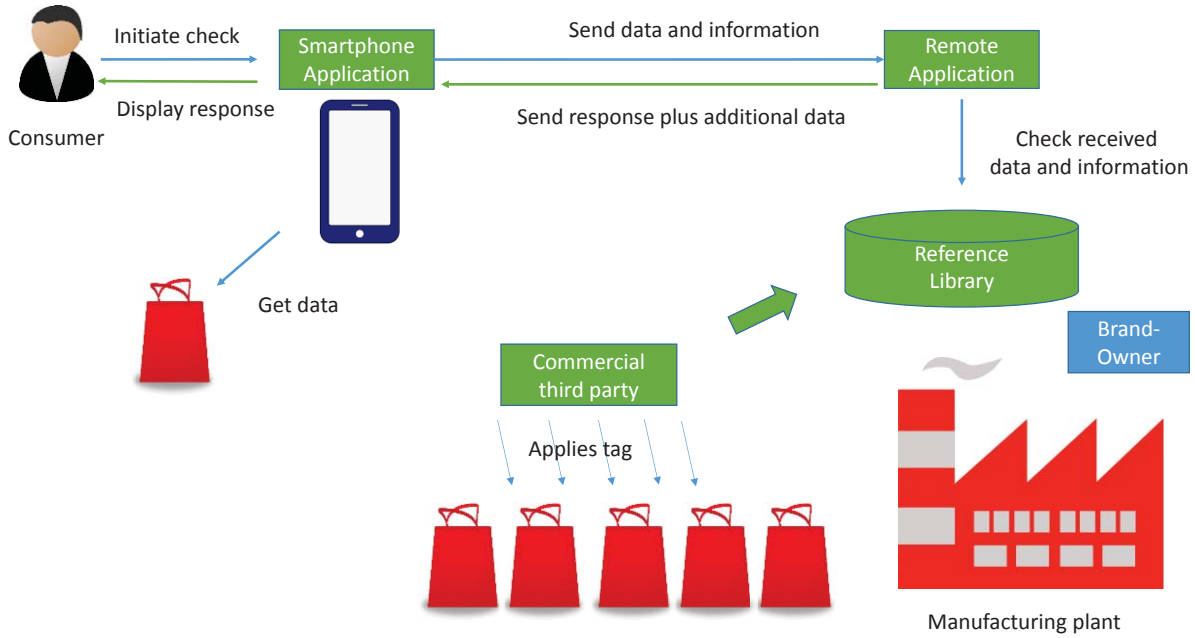
started a system for the verification of pharmaceuticals that meets the requirements of the EU Falsified Medicines Directive and works under real-life conditions.

Another example where the intrinsic features of a product taken during the manufacturing process are used to empower the user is the system developed by the electronics maker NEC. It has developed an authentication system that compares images taken with a smartphone with those in a cloud-based database. Images of the authentic product from the manufacturer would need to be registered beforehand. As described in the report, this can be applied to the retail sector or any other product, which can be identified through augmented visual inspection. NEC stated that the technology is currently in the testing phase and the firm plans to release a commercial version in 2015, but at the time of drafting this report (January 2017), no commercial versions are still available.

Reference library created by a third party working with the manufacturer

In this case, a commercial third party that has developed a technology for authentication or track and trace, works together with the manufacturer to apply identifier tags to the goods during the manufacturing process or after the manufacturing process and prior to distribution. This case is different from the previous one, because the authentication information (e.g. overt tag) is not an intrinsic part of the product but it is applied to it. Note that the identifier tag could be part of the supply chain integrity process and similar considerations of the open and closed supply chain also apply to this case.

The overall workflow is described below. The commercial third party applies its own identification and authentication tags to the goods after they are produced at the manufacturing plant and before distribution to the market. The identification and authentication data is then stored in the reference library. Usually, the commercial third party has also developed a remote application and smartphone application to implement the overall workflow.



This technique is more appropriate for small companies that cannot afford the implementation of more expensive techniques and for the types of product where a tag cannot be inserted during the manufacturing process.

Another advantage of this technique is that the commercial third party, which has developed the technology, can create a single smartphone application, a single communication protocol and a single reference library for different categories of goods and brands, thus facilitating the checks by the user.

Reference library created by a third party other than manufacturers

In this technique, the reference library is created by a third party on the basis of reported information on non-compliant products. For example, a consumer association or law enforcement agency can build a knowledge-based system, which includes a reference library to indicate the most common cases of non-compliance. A user can check the validity of goods by sending relevant authentication data to a remote application linked to a reference library. The response from the remote application will give a probability to the user that the identity of the product is what it claims to be. In a similar approach, the remote application can provide data or digital information (e.g. images) to help the user identify the goods.

The advantage of such reference library is that it can include many different types of goods from different brands and it can process and receive input from many different categories of stakeholders. Another important advantage of implementing the reference library through a public body is that it becomes a central point of contact across Europe and for different private organisations. In this way, the standardisation of the reference library formats and input data processes is easier to achieve. The main disadvantage of this type of option is that the information stored in the reference library may be inaccurate, incomplete or not up to date.

Costs analysis

The costs associated with the design and deployments of technological solutions to empower the smartphone user are structured in the following way:

1) **Design and implementation of the mobile application**. This is the cost of developing a mobile application that can be installed on a smartphone. The application must be designed to interact with the smartphone's sensors, which are needed to collect the requested data, such as images, NFC readings, track and trace information and GNSS position.

2) **Reference library**. This is the cost of developing the reference library, which is used to compare the identification data collected in the field with the database of identification data stored before the goods are distributed on the market. These costs can also be based on different elements: a) the implementation of the means to collect data in the manufacturing or distribution processes, b) the creation of a database to store the reference data, c) the development of the remote application to make available and manage the reference library and d) the publication of the reference library on the web to be accessible by the mobile application. Other associated costs, such as the development of standards or protocols, are described in the other items of this numbered list.

3) **Development of standards**. This is the cost of developing standards for: a) the definition of the protocol between the smartphone and the reference library, b) the format of the data stored in the reference library, c) the serialisation coding to identify the goods in the reference library, d) the back-end systems used to support the supply chain. These should be interoperable and use a similar data format (e.g. based on an OASIS standard).

4) **Open-loop v closed-loop supply chain**. If the empowerment solution has to be built on a closed-loop chain, extensive and costly modifications to the supply chain will be required. This is not the case for an open-loop chain, which is designed to support different entities. As a consequence, one relevant cost can be associated with the integration of the ICT systems used to support the supply chain with the reference library. Note that the integration between the two systems does not need to be complete.

5) **Privacy, security and access control**. This item includes various elements, which address the privacy and security aspects of the empowerment concept. Privacy aspects can be quite important for users. If they are not addressed, citizens could fear that their personal data is at risk when sending data about the goods. In addition, different categories of user (e.g. law enforcers, manufacturers) can have different access to the reference library data. For example, law enforcers can also use data based on covert features rather than on overt features. In addition, access control functions may be required to ensure that only the reference library can be accessed by the web and not other data systems, which store sensitive information.

Authentication technologies

This section briefly describes authentication technologies, which can be used to identify and authenticate the goods in the field against a reference library and which can be supported by the capabilities of the smartphone.

Numeric Identifier/One-dimensional barcode

This was the first technique used to serialise products and, with this information, to track and trace goods in a supply or distribution chain. The first implementation was the Universal Product Code (UPC), which has been a dominant barcode standard in North America since it was established in the 1970s. The UPC has evolved into various versions, for example, UPC-A and UPC-E.

At international level, the Global Trade Item Number (GTIN) is an identification number that may be encoded in UPC-A, UPC-E, EAN-8 and EAN-13 barcodes, as well as other barcodes in the GS1 system.

Numeric identifiers based on barcodes have been used extensively for many years around the world, and they remain the most used track and trace or identification technique.

As extensive literature is available on this technique, we refer the reader to related references.

There are various examples of the smartphone's ability to read and analyse barcodes, therefore this can be considered a very mature technology.

QR codes and other two-dimensional barcodes

The QR (Quick Response) code is a two-dimensional (2-D) barcode.

In comparison to one-dimensional barcodes, the QR code is able to store more information in the same space. QR codes are designed to be read and understood (decoded) by computers, using machine-vision systems consisting of optical laser scanners or cameras and barcode-interpreting software.

Unlike 1-D barcodes, the QR code is a 2-D matrix code that conveys information not by the size and position of bars and spaces in a single (horizontal) dimension, but by the arrangement of its light and dark elements, called 'modules'.

The QR code has a number of advantages in comparison to a one-dimensional barcode. The main advantage is the high-capacity data storage, as a QR code can store hundreds of times more data than a one-dimensional barcode. The QR code is also more robust against curved surfaces or errors due to marks or spots.

There are various examples for the use of the smartphone to read and analyse QR codes, therefore this can be considered a very mature technology.

Physical fingerprint technology on visible spectrum

Physical fingerprints use the specific characteristics of the base material or the packaging. For instance, paper, cardboard, metal and plastic are made up of tiny fibers in random orientations, which are naturally unique in their structure. According to this, every package has its own microscopic structure, its own fingerprint, which cannot be rebuilt and cannot be removed. For authentication to be secure, it is important to use this technology directly on the base material of the smallest packaging available to users; fingerprints of labels, stickers or banderoles will verify the attached strip but not the packaging onto which these are applied. This includes any physical fingerprint technology regardless of the medium (i.e. material) where it is applied: holograms, paper, inks, security threads and regardless of whether it is overt or covert.

For greater security, it is possible to combine a printed unique identifier as the visible element and a physical fingerprint of a package as the invisible element of a security feature. On a mass production line, each package can be scanned and its unique fingerprint can be recorded and linked to its specific unique identifier. When checking, regardless of whether a package is genuine or not, the system compares the physical fingerprint on the base material to the digital fingerprint embedded in (or retrieved from) the unique identifier.

The use of the smartphone to read and analyse physical fingerprint technology is a recent development, but it is supported by an increasing number of companies thanks to the smartphone's higher-resolution camera.

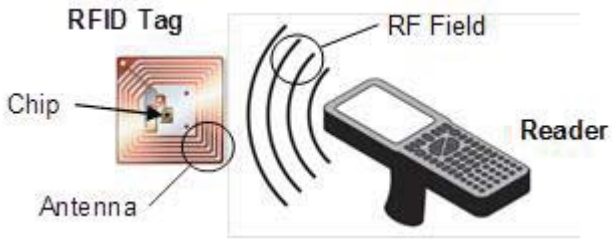
The techniques based on the unique fingerprinting of goods are more accurate and robust against cloning attacks because it is quite difficult for other businesses to reproduce exactly the unique fingerprint of goods. However, it may not be possible to obtain fingerprints of all the different materials using the smartphone features. Furthermore, they could be very

relevant in the context of identifying counterfeited products but they seem much less relevant in the more general context of compliance with EU harmonisation legislation.

Radio Frequency Identifier (RFID)

An RFID tag is basically a device composed of a small chip connected to a coil. The chip is essentially a state machine with a memory, providing limited storage and computational capabilities. To communicate with such devices, an RFID tag reader has to be used. The reader emits a radio frequency (RF) field that by induction through the coil powers the chip. At the same time, the reader itself modulates the field to code commands sent to the chip, which in turn replies to the reader modulating the same field, so establishing a bi-directional communication.

Figure 14-4: Radio Frequency ID



The main purpose of an RFID tag is to memorise data and release it when queried by a reader; usually, at least a unique identifier (ID) is stored in the chip. According to this peculiarity, one of their main applications is item labelling.

RFID tags can be stuck onto or embedded in items to track their position, reading the tags at different places, and to receive information about them easily, storing specific item-data in each applied tag. The information gathered from a tag can also be related to additional item data stored in a back-end system.

A smartphone with an NFC reader can read some types of RFIDs but not all of them, even if various RFID readers connected to USBs are available on the market. Passive RFID tags primarily operate at three frequency ranges:

- low frequency (LF) 125-134 kHz
- high frequency (HF)13.56 MHz
- ultra high frequency (UHF) 856 MHz to 960 MHz.

Near-field communication devices operate at the same frequency (13.56 MHz) as HF RFID readers and tags. The standards and protocols of the NFC format are based on RFID standards outlined in ISO/IEC 14443, and the basis for parts of ISO/IEC 18092.

The RFID can be inserted in the product if the type of product and its material composition allows. For example, an RFID can be inserted in the fabric of a luxury bag, but it is more difficult to insert an RFID in a semi-conductor chip. In other words, RFID technology can be used both by the manufacturer in the manufacturing process or applied to the product in the distribution phase using a tag.

Analysis of the different techniques

The advantage of the barcode or QR code is its cost-effectiveness and simplicity. It can be applied to the material using special inks or as a tag. The clearest disadvantage is that it is clonable, as it is relatively easy to reproduce a barcode or QR code. The threat of cloning can be mitigated through the empowerment solution itself: the smartphone can send the identifier of the barcode or QR code to a remote application attached to the reference library, which can check the presence of duplicated identifiers and duly inform the user.

The advantage of the barcode or QR code and other overt or covert techniques in comparison to the RFID-based technique is the cost of the token itself, even if the cost of RFID has decreased considerably in recent times. Barcode labels cost less than USD 0.02 per label, while RFID tags are at least three times more expensive per tag. The precise cost of RFID tags varies, depending on the underlying RFID technology, but active RFID tags are usually priced between USD 20 and USD 70, whereas passive RFID tags are between USD 0.07 and USD 0.20.

The disadvantages of the barcode and QR code in comparison to RFID are that a direct line of sight is requested between the reader and the code. In addition, the presence of visible light is needed with nothing obstructing the light path between them. RFID tags can be read at a distance; moreover, UHF and BAP RFID can be read at even greater distances and can be scanned much faster.

Regarding the different categories of users, the techniques are mostly clear and easy to understand, even if they can be complemented to increase the security of each specific class. In other words, the empowerment technique can be implemented in such a way that the smartphone provides specific data to the average citizen, and other data to manufacturers, retailers and law enforcers. For example, covert data could be used for manufacturers and law enforcers while only overt data is used for average citizens and retailers.

The analysis of the different techniques is shown in the next table:

Metrics	**Law Enforcers**	**Manufacturers**	**Enterprises (especially SMEs)**
Requested resources	**Barcode and QR code** Low, because a smartphone is already equipped with NFC, a high-resolution camera and communication systems. **RFID** Low, similar to barcode and QR code if the smartphone is equipped with an RFID reader, otherwise High.	**Barcode and QR code** Low, if the solution is based on an extension of an existing **open-loop** track and trace infrastructure. Medium, if the solution is based on an extension of an existing **closed-loop** track and trace infrastructure. High/Very high, if a new track and trace infrastructure must be	**Barcode and QR code** Low, because a smartphone is already equipped with NFC, a high-resolution camera and communication systems. **RFID** Low, similar to barcode and QR code if the smartphone is equipped with an RFID reader, otherwise High.

		created. **RFID** Same considerations as barcode and QR code with the additional cost of RFID components.	
Need for adaptation to organisations and existing processes	**Barcode and QR code** Low, because the checking of the barcode or QR code can be easily automated. **RFID** Medium, because the procedure is very simple for RFID-enabled smartphones, but these specific models must be purchased as they may not be available in the mass consumer market.	**Barcode and QR code** Low, if the solution is based on an extension of an existing **open-loop** track and trace infrastructure. Medium, if the solution is based on an extension of an existing **closed-loop** track and trace infrastructure High/Very high, if a new track and trace infrastructure must be created. **RFID** Same considerations as barcode and QR code with the additional cost of RFID components.	**Barcode and QR code** Low, because the checking of the barcode or QR code can be easily automated. **RFID** Medium, because the procedure is very simple for RFID-enabled smartphones, but these models must be purchased.
Requested level of training	**Barcode and QR code** Low, because the checking of the barcode or QR code can be easily automated. **RFID** Low, because the procedure is very simple for RFID-enabled smartphones.	**Barcode and QR code** Low, because the checking of the barcode or QR code can be easily automated. **RFID** Low, because the procedure is very simple for RFID-enabled smartphones.	**Barcode and QR code** Low, because the checking of the barcode or QR code can be easily automated. **RFID** Low, because the procedure is very simple for RFID-enabled smartphones.
Robustness and adaptability to environmental conditions	**Barcode and QR code** High, because the checking of the barcode or QR code has been	**Barcode and QR code** High, because the checking of the barcode or QR code has been	**Barcode and QR code** High, because the checking of the barcode or QR code has been used for years in many different

	used for years in many different environmental conditions and manufacturers are able to produce environmentally robust tags and labels. **RFID** High, because the RFID is not or is slightly impacted by rain or darkness, as it uses low-frequency radio communication.	used for years in many different environmental conditions and manufacturers are able to produce environmentally robust tags and labels. **RFID** High, because the RFID is not or is slightly impacted by rain or darkness, as it uses low-frequency radio communication.	environmental conditions and manufacturers are able to produce environmentally robust tags and labels. **RFID** High, because the RFID is not or is slightly impacted by rain or darkness, as it uses low-frequency radio communication.
Flexibility to support multiple applications	**General** As described in the rest of the report, it is possible that these techniques may be implemented using different applications and slightly different standards. This is the current situation at the time of writing this report even if current activities, such as the WCO and the IPM Connected program, can mitigate this issue. At least, this is the case for barcode and QR code based techniques. This issue is particularly relevant for law enforcers rather than other types of customers, who have to deal with a specific set of products. **Barcode and QR code** Medium, because there are currently many applications for checking barcode and QR code. Current initiatives, such as IPM Connected, can mitigate this issue (then the Medium level).	**General** The manufacturer will likely use a specific technique and implementation for their products. As a consequence, the multi-use capability will be high because there is a single technique. **Barcode and QR code** High, because there will be only one implementation of the technique. **RFID** High, because there will be only one implementation of the technique. .	**General** An enterprise is usually interested only in a specific set of products. In other words, the multi-use capability is less requested than the law enforcer, but it is still needed for a set of products. As a consequence, a Medium level is suggested for all the techniques. **Barcode and QR code** Medium. **RFID** Medium.

	RFID Low, as similar considerations for barcode and QR code apply, with the difference that as yet, IPM Connected and similar initiatives do not address RFID.		
Upgrade capability	**Barcode and QR code** High, unless the barcode or QR code structure must be changed. **RFID** High, because RFID technology is quite stable, at least for the physical layer.	**Barcode and QR code** High, unless the barcode or QR code structure must be changed. **RFID** High, because RFID technology is quite stable, at least for the physical layer.	**Barcode and QR code** High, unless the barcode or QR code structure must be changed. **RFID** High, because RFID technology is quite stable, at least for the physical layer.
Original set and deployment cost (CAPEX)	**Barcode and QR code** Medium. The smartphone must be purchased but the technology is already implemented. **RFID** Medium/High. A smartphone with an RFID reader must be purchased.	**Barcode and QR code** Medium. The smartphone must be purchased but the technology is already implemented. **RFID** Medium/High. A smartphone with an RFID reader must be purchased.	**Barcode and QR code** Medium. The smartphone must be purchased but the technology is already implemented. **RFID** Medium/High. A smartphone with an RFID reader must be purchased.
Operational Cost (OPEX)	**Barcode and QR code** Low. **RFID** Low.	**Barcode and QR code** Low. **RFID** Low.	**Barcode and QR code** Low. **RFID** Low.
Market and standardisation support	**Barcode and QR code** Medium. While there are many applications on the market, a common standard must still be defined even if there are available	**Barcode and QR code** High. Many manufacturers have built and deployed their own version of the technique.	**Barcode and QR code** Medium. While there are many applications on the market, a common standard must still be defined even if there are available drafts.

	drafts. **RFID** Medium. While there are many applications on the market, a common standard must still be defined even if there are available drafts.	**RFID** Medium/High. Many manufacturers have built and deployed their own version of the technique even if it less deployed than barcode and QR code because of the costs.	**RFID** Medium. While there are many applications on the market, a common standard must still be defined even if there are available drafts.
Interoperability with existing open tools	**General** Law enforcers can use existing activities, such as IPM Connected, to bridge the techniques to ICT systems already deployed. For techniques already deployed, the level of interoperability can be high, while it is low for techniques that have limited deployment in the market. **Barcode and QR code** Medium **RFID** Low/Medium	**General** Manufacturers have usually designed and deployed track and trace solutions to support their production and distribution chain. Then, they have a high degree of interoperability because the techniques used are an evolution of the existing systems. **Barcode and QR code** Very High **RFID** Medium	**General** Enterprises must build up a new system in many cases, even if they already have distribution channels with suppliers. As a consequence, the degree of interoperability is less for the manufacturers but slightly higher for the law enforcers, at least for some techniques. **Barcode and QR code** Medium/High **RFID** Medium

Techniques using smartphones have now reached maturity and they can be both cost-effective and highly accurate in identifying and authenticating a product. These techniques can be applied by the manufacturer as part of the product itself, or they can be applied to the product depending on the feasibility of applying intrinsic features.

With its high-resolution camera and wireless connectivity, the smartphone also has the capability to support the various techniques.

One potential issue is the variety of technical solutions present on the market, which requires a standardisation effort to avoid complex validation procedures by the various categories of users, which may limit the validity of these techniques. For example, a law enforcer may be obliged to use many different smartphone applications for each technique or brand.

Issues and Challenges

Privacy aspects

This section addresses the problem of a consumer's privacy in the context of empowerment. This issue potentially impacts on only consumers, as the other categories will use empowerment techniques as part of their professional duties. By contrast, consumers may be rightfully worried that empowerment techniques could provide a remote application with their personal data when checking products.

Privacy aspects can be addressed easily, using the two privacy protection techniques that follow in the design of the application on the smartphone.

1. Application of anonymisation technology, before sending data to the remote application to check if goods comply. The term 'anonymisation' refers to the process to render the data sent to the remote application 'anonymous' as regards the consumer's identity. For example, the smartphone user's identity, or other identifying data (e.g. location), is removed from the set of transmitted data.

2. Use of informed consent. In this instance, the consumer accepts that the transmitted data contains personal information through informed consent, which is registered electronically on the smartphone and sent together with the application data.

More sophisticated Privacy Enhancing Technologies (PET) can be used to protect the privacy rights of citizens, but these technologies come at a cost. Furthermore, the economics related to the deployment of PET or more sophisticated forms of informed consent can undoubtedly be an obstacle to the deployment of empowerment techniques.

Market fragmentation

There are many empowerment technologies on the market. Such technologies can use the smartphone, which is today a consumer mass market device (and whose cost will decrease even further in the future), or other devices that are either simpler or more sophisticated.

One significant issue is the variety of techniques in the different domains and sectors, which can become a hurdle for the users that belong to the professional categories, such as law enforcers and retailers or distributors.

While manufacturers work in their specific sectors and may adopt only one or two empowerment techniques, law enforcers have to evaluate many different types of goods in their daily activities. The availability of many different empowerment techniques and applications may become a hindrance rather than an effective supporting tool, because law enforcers will have to use a separate technique for different types of goods and even different types of brands. It is easy to imagine that such an approach is impractical and may have a negative impact on the deployment of empowerment techniques in the law enforcer community and in other categories as well (e.g. retailers and distributors). Consumers citizen can also be adversely affected by the availability of empowerment techniques, but for this category, the adoption of these techniques is on a voluntary basis rather than required by their professional activities. Thus, it can be less relevant.

Actions must be taken to support law enforcers and retailers or distributors to overcome these issues. Various approaches are possible.

1) A common standard for identification and authentication is defined for brands belonging to the same sector or across different sectors. Then, applications are developed on the basis of this standard in such a way that a single application is able to evaluate goods of different brands in a specific sector. While this is not an easy task, there are already standardisation efforts in place, which can be a valid basis for further development (REF).

2) Foster a collaborative cooperation from law enforcement authorities, EU institutions, and industry associations to use a common reference library in the EU, so that convergence efforts are concentrated in one single library. If accompanied by (a) developments intended to enable law enforcers and manufacturers to use smartphones to access the information contained in the database securely; and (b) a standardisation process at EU level.

Training

The empowerment techniques presented in this section do require some basic level of training. Training and knowledge on how to use each empowerment technique are important elements in their successful deployment, as a lack of training can reduce accuracy in identifying goods. A lack of accuracy and the consequent frustration from users when using the techniques could lead very quickly to a complete rejection of the empowerment technique. Training should be provided by the companies (e.g. manufacturers) or technological implementers of the technique.

The operational effort needed to develop training practices for empowerment solutions can be considerable and it is preferable that the empowerment techniques develop automatic support mechanisms. For example, a wizard or an automated sequence of steps is implemented to guide the user in the proper acquisition of a product's data.

4.3. Data carrier technologies and architectures

4.3.1. General technologies for automatic identification (AutoID)

Automatic identification (also commonly referred to as "auto-ID") refers to the methods of automatically (i.e. without human involvement) identifying objects and determining their belonging to a certain type or class of objects or their individual identity that differs from all other objects. In addition, it often includes automatically collecting data about them ("automatic data capture").

Objects may include people, animals, goods and products in transit. Automatic identification of objects may use a characteristic or unique property of the object itself (like e.g. the voice or fingerprint of a human being) or of an affixed coding device (e.g. a label or tag), which encodes the object related data. The identification device is normally connected to a data processing or computer system for further processing and manipulation of the object data.

Technologies typically considered as part of auto-ID include barcodes, Radio Frequency Identification (RFID), smart cards, magnetic stripes, machine vision, biometrics, touch memory, optical character recognition (OCR), and voice recognition[67].

In recent years automatic identification procedures (Auto-ID) have been introduced in many service industries, purchasing and distribution logistics, industry, manufacturing companies and material flow systems.

Optical systems (Barcode and Data Matrix)

A **barcode** is a machine-readable, optical representation of data formed by combinations of high and low reflectance regions on the surface of an object according to a predetermined, geometrical pattern. Barcodes are read by optical laser scanning, i.e. by the different reflection of a laser beam from the dark (low reflectance) bars and light (high reflectance) gaps. Barcode scanners and interpretive software have become available on many devices including desktop printers and smartphones.

Barcodes may be distinguished according to the geometry of the optical data representation[68]: A linear or **one-dimensional (1D) barcode** is a binary code comprising a field or sequence of lines (bars) and gaps arranged in a parallel configuration. The data is represented by the varying widths and spacing within the sequence of wide and narrow bars and gaps and can be interpreted numerically and alphanumerically.

Most barcode systems identify only class of products, not individual items. The most widely used barcode is the EAN-13 (International Article Number, formerly named European Article Number) code. The EAN-13 uses 13 digits to code a combined country identifier, company identifier and item (or object) type number as well as a check digit. The UPC (Universal Product Code) from the USA represents a subset of the EAN code, and is therefore compatible with it. Other barcode systems in common use are Code Codabar, which is used for medical applications as well as fields with high safety requirements, Code 2/5 interleaved, Code 39 and GS1-128 (formerly named UCC/EAN-128).

Two-dimensional (2D) barcodes use geometric patterns in two dimensions, like e.g. rectangles, dots, or hexagons, to code information, so it can represent more data per unit area. A Data Matrix code is a two-dimensional matrix barcode consisting of dark and light "cells", little squares arranged in either a square or rectangular pattern that represent bits. The information to be encoded can be text or numeric data (see Figure 14-5). Compared to one-dimensional barcodes, they can represent more data per unit area. Usual data sizes range from a few bytes up to 1556 bytes. They need a scanning device capable of simultaneous reading in a vertical and a horizontal direction.

Figure 14-5: Illustration of ECC200 Data Matrix code

67 Agarwal, V.: Assessing the benefits of Auto-ID Technology in the Consumer Goods Industry. Cambridge University Auto-ID Centre Report, 2001. URL: http://cocoa.ethz.ch/downloads/2014/06/None_CAM-WH-003.pdf, Access: 2015/10/19.

68 Kato, H.; Tan, K.; Chai, D. (2010): Barcodes for Mobile Devices. Cambridge University Press, Cambridge a.o.

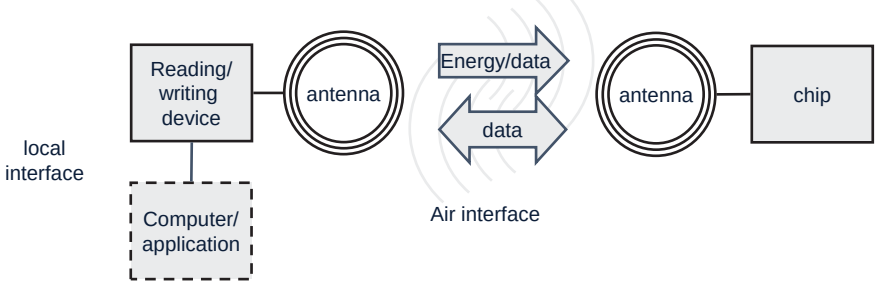
Radiofrequency-based systems (passive RFID in HF and UHF band)

In Radio Frequency Identification (RFID), an object is identified via an attached electronic device (Transponder, or tag) that uses radio frequency or magnetic field variations to communicate to a reading device.

First, transponders contain an integrated circuit or an electronic microchip for storage of data and processing data and modulating and demodulating a radio-frequency (RF) signal, collecting DC power from the incident reader signal. The tag information is stored in a non-volatile memory. Second, they contain a coupling element, such as a coiled antenna, used to communicate via radio frequency waves by receiving and transmitting the signals. The data capacities of RFID transponders range from a few bytes to several kilobytes. In addition, 1-bit transponders are used in electronic article surveillance, e.g. to protect goods in shops. Depending on their power supply, transponders may be either active or passive. Passive transponders obtain all their power from the interrogation signal of the reader. Conversely, active transponders incorporate a battery or a solar cell, which supplies all or part of the power for the operation of a microchip.

The reading device (transceiver, interrogator or reader), which may be a read or write/read device., consists of a radio frequency module, a control unit, and a coupling element to interrogate electronic tags via radio frequency waves for information stored on them. The readers can communicate their received data to the data processing subsystem via a fitted interface. Readers emit an interrogation signal, which forms an interrogation zone within which the transponders may be read. The size and geometry of the interrogation zone is a function of the transceiver and transponder characteristics. The general system configuration is presented in the following Figure 14-6:

Figure 14-6: General system configuration of RFID



Numerous different RFID systems and RFID transponders systems are available on the market. The technical parameters of these systems are often optimised for specific fields of application, e.g. industrial automation or access control. The technical requirements of different fields of application however often partially overlap, making clear distinction between different systems difficult at times.

One of the most important characteristic of an RFID system is its operating frequency, which is the frequency at which the reader transmits. The transmission frequency of the transponder is in most cases the same as the transmission frequency of the reader (load modulation, backscatter). However, the transponder's 'transmitting power' may be set several powers of ten lower than that of the reader. The different transmission frequencies are classified into the three basic ranges, LF (low frequency, 30–300 kHz), HF (high frequency)/RF radio frequency (3–30MHz) and UHF (ultra-high frequency, 300MHz–3 GHz)/microwave (>3 GHz). According to range RFID systems can be subdivided into close-coupling (0–1 cm), remote-coupling (0–1 m), and long-range (>1m) systems. Passive RFID transponders can be read at small to medium distances and active RFID tags at small to large distances. For more information on each range class, see Table 14-5:

Range class	Frequency range	Operating frequencies	Range	Data speed	Basic characteristics regulations
low frequency (LF)	30–300 kHz	0–135 kHz	~ 10 cm	Low	
high frequency / radio frequency (HF / RF)	3–30MHz	13.56 MHz	10 cm - 1 m	Low to moderate	most common frequency
ultra-high frequency (UHF)	300MHz–3 GHz	433 MHz	1-100 m	moderate	Active transponders
		865-868MHz in Europe 915MHz in the US	up to 6m	Moderate to high	ISM band Backscatter systems
microwave	>3 GHz	2.45 GHz 5.8 GHz 24.125 GHz	~ 100-300 m	high	

Table 14-5: RFID operating frequency classes

RFID transponders can be classified according to their possibility of writing data to the transponder. In non-writable transponders, the transponder's data record, usually a simple (serial) number, is incorporated when the chip is manufactured and cannot be altered thereafter.

In writable transponders, the reader device can write data to the transponder. Three main procedures are used to store the data: in passive RFID systems **EEPROMs** (electrically erasable programmable read-only memory) are dominant. Data stored in an EEPROM is retained for several years without a power supply. The energy required for writing to or reading from a transponder using EEPROM technology is transmitted by inductive coupling. The guaranteed number of write access operations to a memory address is typically around 105 cycles.

FRAMs (ferromagnetic random access memory) have recently been used in isolated cases. The read power consumption of FRAMs is lower than that of EEPROMs by a factor of 100 and the writing time is 1000 times lower. Over 1010 write cycles have been being achieved.

Particularly in active microwave systems, **SRAMs** (static random access memory) are used for data storage as well. They allow very rapid write cycles. However, data retention requires

an uninterruptible power supply from an auxiliary battery, as SRAM memory cells require a constant power supply to retain stored data. Therefore, transponders using this memory technology always have their own battery. Data transmission between reader and transponder employs either inductive coupling or the backscatter procedure (microwave). SRAM memory can be reprogrammed any number of times with high write speeds. However, the integral battery limits the temperature range of this transponder to 0–60 ◦C.

Further identification systems

Optical character recognition (OCR) uses special fonts with stylized characters so that they can be read automatically by machines. One application example is the registration of cheques in banking, where personal data, such as name and account number, is printed on the bottom line of a cheque in OCR type.

Advantages of OCR systems are the high density of information and the possibility of reading data visually. However, OCR systems have failed to become more universally applied because of their high price and the complicated readers that they require in comparison with other ID procedures.

In the context of identification systems, **biometrics** refers to all procedures that identify people by comparing unmistakable and individual physical characteristics. In practice, these are fingerprinting and hand printing procedures, voice identification and retina (or iris) identification. Voice identification converts the words spoken by an individual human being into a computer linked microphone to into digital signals, which are evaluated by the identification software in order to check the speech characteristics of the speaker for correspondence to an existing reference pattern. Biometrics is mostly suited to identifying human beings.

A **smart card** is an electronic data storage system, possibly with additional computing capacity (microprocessor card), which is normally incorporated into a plastic card the size of a credit card. Smart card systems are similar in characteristics and often considered a subclass of RFID systems. Their main difference from other RFID systems however is their small reading range due to contact based reading. Smart cards are placed in a reader, which makes a galvanic connection to the contact surfaces of the smart card using contact springs. Like a passive RFID transponder, the smart card is supplied with energy and a clock pulse from the reader via the contact surfaces. Data transfer between the reader and the card takes place using a bidirectional serial interface (I/O port). It is possible to differentiate between two basic types of smart card based upon their internal functionality: the memory card and the microprocessor card. In memory cards the memory is accessed using a sequential logic (state machine). Microprocessor cards contain a microprocessor connected to a segmented memory.

4.3.2. AutoID technologies

4.3.2.1. Comparison of the basic capabilities

The AutoID technologies differ in their basic characteristics, which makes them more suitable or less suitable for the intended purpose of providing unique identification of maritime

equipment. A comparison of the basic capabilities of the different auto-ID technologies, as included in Table 14-6, shows the particular suitability of either barcode or RFID technologies:

System parameters	1D Barcode	2D Barcode	OCR	Biometry	Voice recognition	Smart card	RFID systems
typical data quantity (bytes)	1–100	10-~5 k	1–100	–	–	16–64 k	16–64 k
data density	medium	medium	Low	High	High	Very high	Very high
machine readability	Good	Good	Good	Expensive	Expensive	Good	Good
readability by people	Limited	Limited	Simple	Difficult	Simple	Impossible	Impossible
influence of dirt/damp	high	high	Very high	–	–	Possible (contacts)	No influence
influence of (optical) covering	Total failure	Total failure	Total failure	Possible	–	–	No influence
influence of direction and position	Low	Low	Low	–	–	Unidirectional	No influence
degradation/wear	Limited	Limited	Limited	–	–	Contacts	No influence
purchase cost/reading electronics	Very low	Very low	Medium	Very high	Very high	Low	Medium
operating costs (e.g. printer)	Low	Low	Low	None	None	Medium (contacts)	None
unauthorized copying/modification	Slight	Slight	Slight	Impossible	Possible* (audio tape)	Impossible	Impossible
reading speed (including handling of data carrier)	Low ~4 s	Low ~4 s	Low ~3 s	Very low >5–10 s	Very low >5 s	Low ~4 s	Very fast ~0.5 s
maximum distance between data carrier and reader	0–50 cm	0–50 cm	<1 cm Scanner	Direct contact**	0–50 cm	Direct contact	HF. 0-1 m, UHF: 0–12m, 0-100 m (microwave, active systems)

* The danger of 'replay' can be reduced by selecting the text to be spoken using a random generator, because the text that must be spoken is not known in advance. ** This only applies for fingerprint ID. In the case of retina or iris evaluation direct contact is not necessary or possible.

Table 14-6: Comparison of different RFID systems showing their advantages and disadvantages[69]

Depending on their power supply, transponders may be either active or passive. Considering RFID systems, active transponders need to incorporate a battery or a solar cell, which supplies all or part of the power for the operation of a microchip, and need regular replacement (in case of battery) or at least regular check (in case of solar cells). Microwave systems have a significantly higher range than inductive systems, typically 2–15 m. However, in contrast to inductive systems, microwave systems require an additional backup battery. The transmission power of the reader is generally insufficient to supply enough power for the operation of the transponder.

4.3.2.2.Passive UHF-RFID

An Active Reader Passive Tag RFID system has an active reader, which transmits interrogator signals and also receives authentication replies from passive tags.

The required range of an application is dependent upon several factors:

69 Finkenzeller, K. (2010): RFID Handbook - Fundamentals and Applications in Contactless Smart Cards, Radio Frequency Identification and Near-Field Communication. Third Edition, Giesecke & Devrient GmbH, Munich, Germany, p. 7. Summary assessment (last line) added by authors of this report.

– The positional accuracy of the transponder.

– The minimum distance between several transponders in practical operation.

– The speed of the transponder in the interrogation zone of the reader.

Passive UHF-RFID transponders are produced and used in many different varieties, differing in many important properties. Some different properties of such transponders are listed in Table 14-7.

Aspect	**Options**
protection classes	IP66: Dust tight, Powerful water jets IP67: Dust tight, Immersion up to 1 m IP68: Dust tight, Immersion beyond 1 m IP69K: Dust tight, Powerful high temperature water jets
temperature resistance	Operating temperature: - 50°C up to 100°C Storage temperature: up to 240°C for 30s
materials	polyamide PVC PPS + epoxy PVC, OEM stainless steel fiberglass FR4 copper/polyimide (CU/PI) silicon poly-oxymethylene glass acrylonitrile butadiene styrene (abs) aluminium and polymer polypropylene
designs	disk disk sticker tag disk with hole disk with 2 holes screw dry inlay wet inlay smart card rod smart label glass rod key fob coin tag half lens form
dimensions	L/⌀: 2,6mm-126mm, H: 0,5mm-22mm L/⌀: 3,15mm, W: 13,3mm

Aspect	Options
mounting	self-adhesive magnetic screws or rivets zip-ties wire sticky foam
environment	readable in wet environments shock resistant resistant against chemicals screwable in metal

Table 14-7: alternative characteristics of transponders

Transponders with different properties may be chosen for different products o applications within the tagging of maritime equipment.

Transponders must be resistant against different environmental conditions. These conditions may be challenging or even haphazard. Protection Classification societies standardize against which environmental properties a transponder is safeguarded, so they will not destroy it or hinder its functional performance. More information on different tag protection Classification societies and the kind of protection they offer is provided in Table 14-8:

Protection classes			
IP66	Dust tight	Powerful water jets	can be installed in Ex zones 1, 2, 21 and 22
IP67	Dust tight	Immersion up to 1 m	suited for outdoor use can be used in Ex zones 0, 1, 2, 20, 21 and 22
IP68	Dust tight	Immersion beyond 1 m	suited for outdoor use
IP69K	Dust tight	Powerful high temperature water jets	suited for outdoor use

Table 14-8: Tag protection classes

Transponders belonging to different protection classes may be needed for different applications within the tagging of maritime equipment.

Standards

Relevant standards for UHF-RFID transponders have been issued by International Organization Standards (ISO) and the International Electrotechnical Committee (IEC).

(a) ISO/IEC 18000 is an international standard that describes a series of diverse RFID technologies, each using a unique frequency range. The standard consists of several different parts, under the general title Information technology — Radio frequency identification for item management. The various parts of ISO/IEC 18000 describe air interface communication at different frequencies in order to be able to utilize the

different physical behaviours. The various parts of ISO/IEC 18000 are developed by ISO/IEC JTC1 SC31, "Automatic Data Capture Techniques". The most important parts of this report are the following:

(b) ISO/IEC 18000 Part 1: Reference architecture and definition of parameters to be standardized.

(c) ISO/IEC 18000 Part 6: Parameters for air interface communications at 860 MHz to 960 MHz.

(d) ISO/IEC 18046 defines performance test methods.

(e) ISO/IEC 18047 in its corresponding parts conformance test methods for the various parts of ISO/IEC 18000.

Appropriate Carrier

The primary function of the transponder's carrier and housing is to ensure cohesion of the various components, such as antenna and chip. However, the use of certain materials may also protect against external influences and increase, for example, insulation from metal influences. In addition, the housing may consciously enlarge the transponder to achieve, for example, better capacities for assembly. The antenna is the largest transponder component and determines its size. Different transponder carrier forms are listed in the below table:

Carrier form	**description**
disks and coins	The transponder is housed in a round (ABS) injection moulded housing; Alternatively polystyrol or even epoxy resin may be used to achieve a wider operating temperature range. The diameter of disks/coins is ranging from a few millimetres to 10 cm. Usually contains a hole for a fastening screw in the centre.
glass housing	Used for identification of animals or further processing into other construction formats. Glass tubes contain a microchip mounted upon a carrier (PCB) and a chip capacitor to smooth the supply current obtained. The transponder coil incorporates wire of 0.03mm thickness wound onto a ferrite core. The internal components are embedded in a soft adhesive to achieve mechanical stability. Length of glass tubes normally in range 12–32mm
plastic housing	For applications involving particularly high mechanical demands. Plastic housings can easily be integrated into other products. Greater functional range than glass housings; ability to accept larger microchips and greater tolerance to mechanical vibrations.

Carrier form	description
inductively coupled transponders in metal surfaces	The transponder coil is wound in a ferrite pot core. The transponder chip is mounted on the reverse of the ferrite pot core and contacted with the transponder coil. In order to obtain sufficient mechanical stability, vibration and heat tolerance, transponder chip and ferrite pot core are cast into a PPS shell using epoxy resin.
smart labels	Paper-thin transponder format. The transponder coil is applied to a plastic foil of just 0.1mm thickness by screen printing or etching. The foil is often laminated using a layer of paper and its back is coated with adhesive. Smart labels are thin and flexible enough to be stuck to luggage, packages and goods of all types. They are normally supplied in the form of self-adhesive stickers on an endless roll.
coil-on-chip	Integration of the coil onto the chip is made possible by a special micro galvanic process that can take place on a normal CMOS wafer. The coil is placed directly onto the isolator of the silicon chip. Extreme miniaturisation of transponders is possible using coil-on-chip technology. The size of the entire transponder is just 3 x 3mm. The transponders are frequently embedded in a plastic shell and are among the smallest RFID transponders available.

Possible dimensions

The approximate dimensions of the different transponder carrier forms are compared in in the below table:

Carrier form	Dimensions (diameter x height or length x width x height)
disks and coins	diameter of disks/coins: few mm - 1 0 cm height of disks/coins: few mm – 1 cm
glass housing	length of glass tubes: 12–32mm diameter of glass tubes: 1-5 mm
plastic housing	Length, width: e.g. 12 x 6 mm Height: 3 mm

Carrier form	Dimensions (diameter x height or length x width x height)
inductively coupled transponders in metal surfaces	diameter of disks/coins: few mm height of disks/coins: less than 1 mm
smart labels	Length, width: a few cm each thickness of plastic foil: ~ 0.1mm
coil-on-chip	Length, width: ~3 x 3mm thickness of plastic foil: ~ 0.1mm

Permanent mounting options

Transponders of normal sizes can be mounted in several permanent or removable ways. The mounting options applicable to RFID transponders are compared in in the below table.

method	conditions	benefits
gluing	clean prepared surface	fast, cheap
riveting	sufficient area for receiving the transponder and the ability to bore holes	removal difficult
screws	sufficient area for receiving the transponder to the bore and the possibility of Holes and optionally introduction of threads must be given	easy disassembly removal impossible without tools
hooking	sufficient surface for receiving the transponder and the possibility for attachment appropriate holder must be given	flexible use multiple use of transponders
inserting	sufficient surface for receiving the transponder and the possibility for attachment a tab must be added	flexible use multiple use of transponders
magnetic fixing	sufficient space for accommodating the transponder as well as a magnetic Substrate must be added	flexible use multiple use of transponders

With respect to the durable lifelong usage of transponders on the product, a later implementation guideline could request for permanent mounting options.

Scenarios of counterfeiting

- Attacks on RFID transponders (cf. Figure 14-7) can occur due to the following reasons:[70]

70 Finkenzeller, K. (2010): RFID Handbook - Fundamentals and Applications in Contactless Smart Cards, Radio Frequency Identification and Near-Field Communication. Third Edition, Giesecke & Devrient GmbH, Munich, Germany, p. 215.

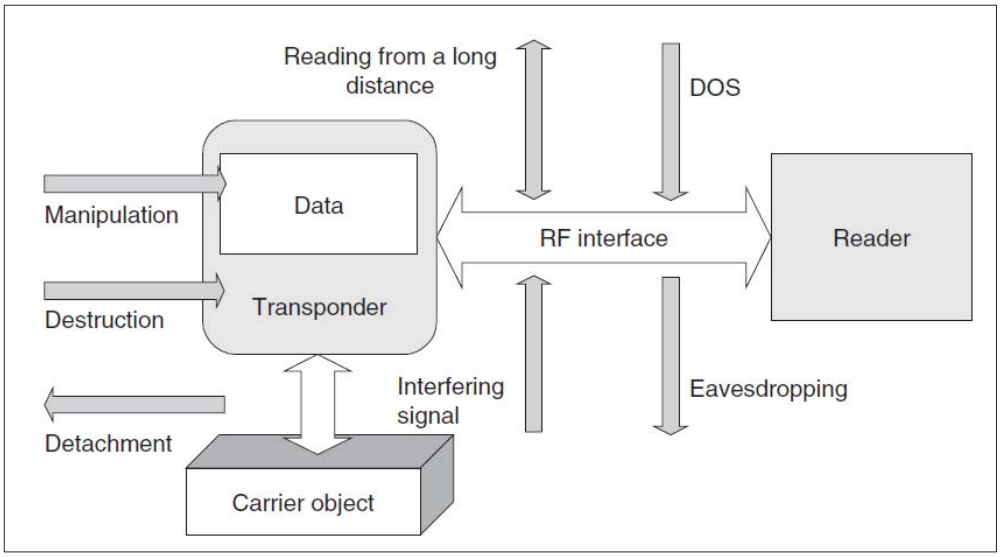
- Spying out: The attacker tries to get unauthorized access to information and data of the active and passive file.

- Deception: The attacker tries to feed incorrect information into the RFID system in order to deceive the active party, i.e. the RFID system operator, or the passive party, i.e. the user of the RFID system.

- Denial of service: This kind of attack affects the availability of functions of the RFID system.

- Protection of privacy: The attacker considers the RFID system to be a threat to her privacy and tries to protect herself with attacks on the RFID system.

Figure 14-7: Some attack options on RFID systems[71]



Often transponders are physically accessible to attackers and can be attacked by varying methods or with varying objectives. Potential attacks and countermeasures are listed in Table 14-9:

Type of attack	Description	Countermeasures
mechanical or chemical **destruction**	The antenna can be easily severed or cut off, for instance. The chip can be easily snapped or smashed.	protected or resistant carrier and mounting
skimming	Removal of a transponder in order to clone and/or modify data.	non-removable mounting of transponders
cloning of read-only transponders	The attacker can replace the PROM containing a	Protection by Cryptographic Measures:

71 Rikcha (2004): Risiken und Chancen des Einsatzes von RFID-Systemen, Studie des Bundesamtes für Sicherheit in der Informationstechnik in Zusammenarbeit mit dem Institut für Zukunftsstudien und Technologiebewertung (IZT) und der Eidgenössischen Materialprüfungs- und Forschungsanstalt (EMPA),November

Type of attack	Description	Countermeasures
	read-only transponder's serial number with a multi-programmable memory (EPROM) and program this serial number into the transponder clone. The transponder clone can send the serial number previously read out from the genuine transponder and thus pretend the presence of this genuine transponder to the reader. The reader is not able to determine whether the currently received serial number was sent by a genuine transponder or a transponder clone. The attacker does not have to have physical access to the transponder, but only needs to use a suitable reader in order to enter the read range of the transponder to be cloned, without being detected.	• Mutual Symmetrical Authentication between reader and transponder via three-pass mutual authentication, in which both participants in the communication check the other party's knowledge of a secret cryptologic key. • Authentication using Derived Keys: Each transponder is secured with a different cryptologic key. A key is calculated using a cryptologic algorithm based on the serial number of the transponder and a master key, and the transponder is thus initialised. Each transponder thus receives a key linked to its own ID number and the master key. Encrypted Data Transfer: During the writing or re-writing process, the transmission data (plain text) is transformed into cipher data (cipher text) using a secret key and a cryptographic algorithm. Without knowing the encryption algorithm and the secret key K a potential attacker is unable to interpret the recorded data. It is not possible to recreate the transmission data from the cipher data.
cloning re-writable transponders	If the memory sections of a transponder can be read or written without any restrictions, i.e. without requiring a password or key, an attacker can manipulate stored data for his personal advantage or produce copies of the attacked transponder by reading data and copying them to other transponders. Cloning of transponders can be efficiently prevented by using authentication and encrypted data transmission.	
eavesdropping	As RFID systems communicate with electromagnetic waves, systems can be generally intercepted with very basic means and the data replayed in order to imitate a genuine data carrier ('replay and fraud').	

Table 14-9: Potential attacks on RFID transponders and countermeasures

4.3.2.3.Data Matrix

Two-dimensional (2D) barcodes use geometric patterns in two dimensions, like e.g. rectangles, dots, or hexagons, to code information, so it can represent more data per unit area. The most relevant matrix barcodes are Aztec, Data Matrix, QR-Code and PDF 417, ECC200 and GS1 Data Matrix. An overview of different two-dimensional barcodes (or matrix barcodes) is given in Table 14-10:

2d barcode	**Example symbol**	**Most relevant standard(s)**	**Description/comments**
Aztec		ISO/IEC 24778:2008	Potential to use less space than other matrix barcodes as no surrounding blank "quiet zone" required
Data Matrix		ISO/IEC 16022:2006— Data Matrix bar code symbology specification	ability to encode fifty characters in a symbol readable at 2 or 3 mm² code can be read with only a 20% contrast ratio highly scalable (300 micro meters (laser etched) to 1 meter square)
QR-Code		ISO/IEC 18004	developed by Toyota subsidiary Denso Wave Can encode music, images, URLs, emails most frequently used type to scan with smartphones
PDF 417		ISO 15438	stacked linear barcode

Table 14-10: Overview of different two-dimensional barcodes

Aztec Code is a type of 2D barcode that was published by AIM, Inc. in 1997 and is public domain. Aztec code has the potential to save space, as it does not require a surrounding blank "quiet zone". The symbol is built on a square grid with a bulls-eye pattern at its centre for locating the code. Data is encoded in concentric square rings around the bulls-eye pattern. The central bulls-eye is 9×9 or 13×13 pixels, and one row of pixels around that encodes basic coding parameters, producing a "core" of 11×11 or 15×15 squares. Data is added in "layers", each one containing two rings of pixels, giving total sizes of 15×15, 19×19, 23×23, etc.

The corners of the core include orientation marks, allowing the code to be read if rotated or reflected. Decoding begins at the corner with three black pixels, and proceeds clockwise to the corners with two, one, and zero black pixels. The variable pixels in the central core encode the size, so it is not necessary to mark the boundary of the code with a blank "quiet zone", although some bar code readers require one.

Additional capabilities that differentiate ECC 200 symbols from the earlier standards include inverse reading symbols (light images on a dark background), a specification of the character set (via Extended Channel Interpretations), rectangular symbols and structured append (linking of up to 16 symbols to encode larger amounts of data).

QR-Code (Quick Response Code) was developed by Denso Wave in 1994. QR-Code is a quadratic matrix code including three corner marks, which can be read even if up to 30% of the mark has been destroyed. QR-Code's (177x177 elements, with error correction level „L") allows to code up to 2953 Byte or 4296 ASCII signs (with 7 Bit per sign).

PDF417 is a stacked linear barcode symbol format used in a variety of applications, primarily transport, identification cards, and inventory management. PDF stands for Portable Data File. The 417 signifies that each pattern in the code consists of 4 bars and spaces, and that each pattern is 17 units long. A symbol consists of 3 to 90 rows, each of which is like a small linear bar code. Each row includes a quiet zone (a mandatory minimum amount of white space before the bar code begins), a start pattern which identifies the format as PDF417 and a "row left" codeword containing information about the row (such as the row number and error correction level). These are followed by 1-30 data codewords: Codewords are a group of bars and spaces representing one or more numbers, letters, or other symbols. The row ends with a "row right" codeword with more information about the row, a stop pattern and another quiet zone.

PDF417 uses a base 929 encoding. Each codeword represents a number between 0 and 928 inclusive. The code words are represented by patterns of dark (bar) and light (space) regions. Each of these patterns contains four bars and four spaces (where the 4 in the name comes from). The total width is 17 times the width of the narrowest allowed vertical bar (the X dimension); this is where the 17 in the name comes from. Each pattern starts with a bar and ends with a space. All rows are of the same width; each row has the same number of code words. Of the 929 available codewords, 900 are used for data, and 29 for special functions. Three different encoding schemes are defined and can be mixed as necessary within a single symbol:

- Text: each codeword represents one or two characters.
- Byte: each group of 5 codewords represents 6 bytes.
- Numeric: groups of up to 15 codewords represent as many as 44 decimal digits.

GS1 Data Matrix is a two-dimensional (2D) matrix barcode which may be printed as a square or rectangular symbol made up of individual dots, cells or squares. This representation is an ordered grid of dark and light dots bordered by a finder pattern. The finder pattern is partly used to specify the orientation and structure of the symbol. The data is encoded using a series of dark or light dots based upon a pre-determined size. The size of these dots is known as the X-dimension.

ECC 200 is the newest version of Data Matrix and uses Reed-Solomon codes for error and erasure recovery. ECC stands for Error Checking and Correcting. ECC 200 allows the routine reconstruction of the entire encoded data string when the symbol has sustained 30% damage, assuming the matrix can still be accurately located. Data Matrix has an error rate of less than 1 in 10 million characters scanned.

Symbols have an even number of rows and an even number of columns. Most of the symbols are square with sizes from 10×10 to 144×144. Some symbols however are rectangular with sizes from 8×18 to 16×48 (even values only). All symbols utilizing the ECC 200 error

correction can be recognized by the upper right corner module being the same as the background colour (binary 0).

Standards

A comprehensive set of matrix barcode related standards has been issued by following standardization bodies the American National Standards Institute (ANSI), International Organization Standards (ISO) and the International Electrotechnical Committee (IEC).

The most relevant standards for Data Matrix barcodes are listed in Table 14-11:

standard	**Topic, description**
ANSI MH10.8.6	Bar Codes and Two-Dimensional (2D) Symbols for Product Packaging
ANSI X12.3	Data Element Dictionary
ISO/IEC 16022:2006	Data Matrix bar code symbology specification
ISO/IEC 15415	Information Technology – Automatic Identification and Data Capture Techniques – Bar Code Print Quality Test Specification – Two-Dimensional Symbols (2-D Print Quality Standard)
ISO/IEC 15416	Information Technology – Automatic Identification and Data Capture Techniques - Bar Code Print Quality Test Specification – Linear Symbols
ISO/IEC 15418:2009	Information Technology - Automatic Identification and Data Capture Techniques - Symbol Data Format Semantics (GS1 Application Identifiers and ASC MH10 Data Identifiers and maintenance)
ISO/IEC 15424:2008	Information Technology - Automatic Identification and Data Capture Techniques - Data Carrier Identifiers (including Symbology Identifiers) [IDs for distinguishing different bar code types]
ISO/IEC 15434:2006	Information Technology – Automatic Identification and Data Capture Techniques - Syntax for high-capacity ADC media (format of data transferred from scanner to software, etc.)
ISO/IEC 15438	Information Technology - Automatic Identification and Data Capture Techniques - Bar Code Symbology Specification – PDF417
ISO/IEC 15459	Information Technology - Automatic Identification and Data Capture Techniques - Unique Identifiers
ISO/IEC 16022:2006	Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification
ISO/IEC 16388	Information Technology - Automatic Identification and Data Capture Techniques - Bar Code Symbology Specification – Code 39
MHIA MH10.8.1	Linear Bar Code and Two-Dimensional Symbols Used in Shipping, Receiving, and Transport Applications
MHIA MH10.8.2	Data Application Identifier Standard

standard	Topic, description
GS1 Data Matrix Guideline	Overview and technical introduction to the use of GS1 Data Matrix. Release 2.2.1, Ratified, July 2015

Table 14-11: relevant standards for Data Matrix barcode

Appropriate Carrier and placement of the mark

In the most general terms, it is required that a Data Matrix applied to an object fulfils the following minimal conditions[72]:

- It remains readable throughout the object's normal life cycle.
- It withstands all environmental conditions to which the object will be exposed under normal operating conditions.
- It does not damage or detriment the functional performance, reliability, or durability of the object.

These minimal conditions should guide the selection of appropriate carriers for the Data Matrix barcodes. In terms of the carrier of the mark, the most important distinction is between non-intrusive marking and intrusive marking.

Non-intrusive marking methods add material to the surface of the item. These material additions can be applied either directly, e.g. by stenciling, laser bonding, or direct ink jet, or indirectly in form of a label or data plate. An intrusive marking method either deforms or removes material from the surface of the item. Methods include dot peening, stamping, abrading, scribing, or etching.

Generally, non-intrusive marking methods should be applied, unless intrusive marking is specifically authorized by quality assurance, safety, and engineering competencies of the relevant program. Often, labelling will be the easiest and cheapest method to implement. However, to determine the best marking solution for a specific type of equipment, many factors about the item to be marked should be considered. These include the function the item has to fulfil and the environment in which the item is stored or operated, the available marking area, material type, colour and mechanical properties of the material (like hardness, surface roughness/finish or surface thickness).

Preliminary advice regarding the data carrier will be included in the preliminary conclusions on data readers.

Placement of the Mark: Where the mark is placed on the item strongly influences the mark's durability and usefulness. Therefore, when determining where to place the mark, many

72 Compare for the analogous minimal requirements set up by: Department of the Navy: Item Unique Identification (Iuid) Marking Guide: Applying Data Matrix Identification Symbols to Legacy Parts.

aspects should be considered. Some useful general advice for placement of marks may be given as follows[73]:

- Apply marks in protected areas, when possible.
- Apply marks on flat areas when possible.
- The mark should be readable when the marked item is in-service.
- The mark should be readable when the marked item is stowed.
- Multiple identical marks can be applied to the same item.

Unless directed to the contrary by the technical authority, marks/labels should not be placed on the following item parts or surfaces:

- On components or pieces authorized to be replaced during field maintenance.
- Over vents and/or air intakes.
- Over other information.
- Covering windows, view ports, access ports, or fastener holes.
- Over seams between separable pieces of the item.
- In direct air streams (for example, leading edge of wings, helicopter rotors, exposed portions of turbine blades, and so forth).
- On sealing surfaces.
- On wearing surfaces.
- Near high heat sources.
- Over lenses, optics, or sensors.
- On surfaces with dimensional tolerance requirements.
- On precision cleaned parts in hermetically sealed packaging.

Other placement considerations become important in specialized circumstances, such as when marking curved, rough, or shiny surfaces or marking items that are sensitive to electrostatic discharge. Many placement considerations stem from a technical understanding of how 2D barcode readers (scanners) decode symbols as well as understanding efforts taken to maximize the reliability of decoding the Data Matrix. For information about mark placement on curved, rough, or irregularly shaped items.

73 Compare for the analogous advice for placement of marks in: Department of the Navy: Item Unique Identification (Iuid) Marking Guide: Applying Data Matrix Identification Symbols to Legacy Parts.

Scenarios of counterfeiting

Barcodes (in particular two-dimensional barcodes), when applied as labels, can be destroyed or detached from the object to be identified. When using labels, in contrast to direct part marking, the obstacles for reproducing unauthorized pirated copies of products are low, because counterfeiting of tags is simple.

The reading process itself can be seen as relatively unattractive for attacks. However, using backend IT systems for providing further information and making validation of possible codes and their conformity to the predefined code scheme could be of interest.

5. "IMPACTS DIGITAL COMPLIANCE OPTIONS"[74]

5.1. Introduction

This document is the final report for the evaluation of impact of the "Internal Market for Goods – Digital Compliance".

5.1.1. Study objectives

The main purpose of the study is to provide input for the Impact Assessment (IA) accompanying a new Enforcement and Compliance initiative with respect to the internal market for products.

The study aims to achieve this objective by collecting economic data, quantifying benefits/costs and measuring the possible impact of the preliminary options identified by the Commission. Qualitative information will be used to offer a comprehensive understanding of the potential impacts of the different policy options.

5.1.2. Overview of the tasks carried out

The table below provides an update on each of the tasks to be carried out as part of this contract and its current status.

Table 14-12: List of tasks carried out

Phase	Activity	Notes
Task 0 Inception phase	Task 0.1: Internal kick-off	
	Task 0.2: Kick-off meeting	
	Task 0.3: Scoping interviews	
	Task 0.4: EU Literature review	
	Task 0.5: Stakeholder identification	
	Task 0.6: Development of a conceptual impact model	Approved with inception report

74 Study, VVA, draft final report, April 2017.

	Task 0.7: Fine-tuning of the proposed methodology and drafting of inception report	Approved with inception report
	Task 0.8: Approval of the Inception Report	
Task 1 Data collection	Task 1.1: Literature review at the national level	Data collection in parallel with interviews of national stakeholders
	Task 1.2: On-line survey	Market surveillance authorities have either been interviewed or filled in the survey; 66 Notified Bodies have been contacted to fill in the questionnaire in writing. 10 notified bodies took part in the survey.
	Task 1.3: In-depth interviews at the national level	68 interviews completed
	Task 1.4: CATI survey	More than 1700 company interviews completed.
	Task 1.5: Interim Report	Approved
Task 2 Data analysis	Task 2.1 Creation of a single database for analysis	Updated with complete data
	Task 2.2 Cost–Benefit Analysis	
	Task 2.3 Competitiveness Analysis	
Task 3 Reporting	Task 3.1: Develop the baseline scenario	Updated with complete data
	Task 3.2: Conduct the assessment of potential option	Updated with complete data
	Task 3.4: Draft Final report & Final Report	Second revision completed
	Inception meeting	
	Interim meeting	
	Final meeting	

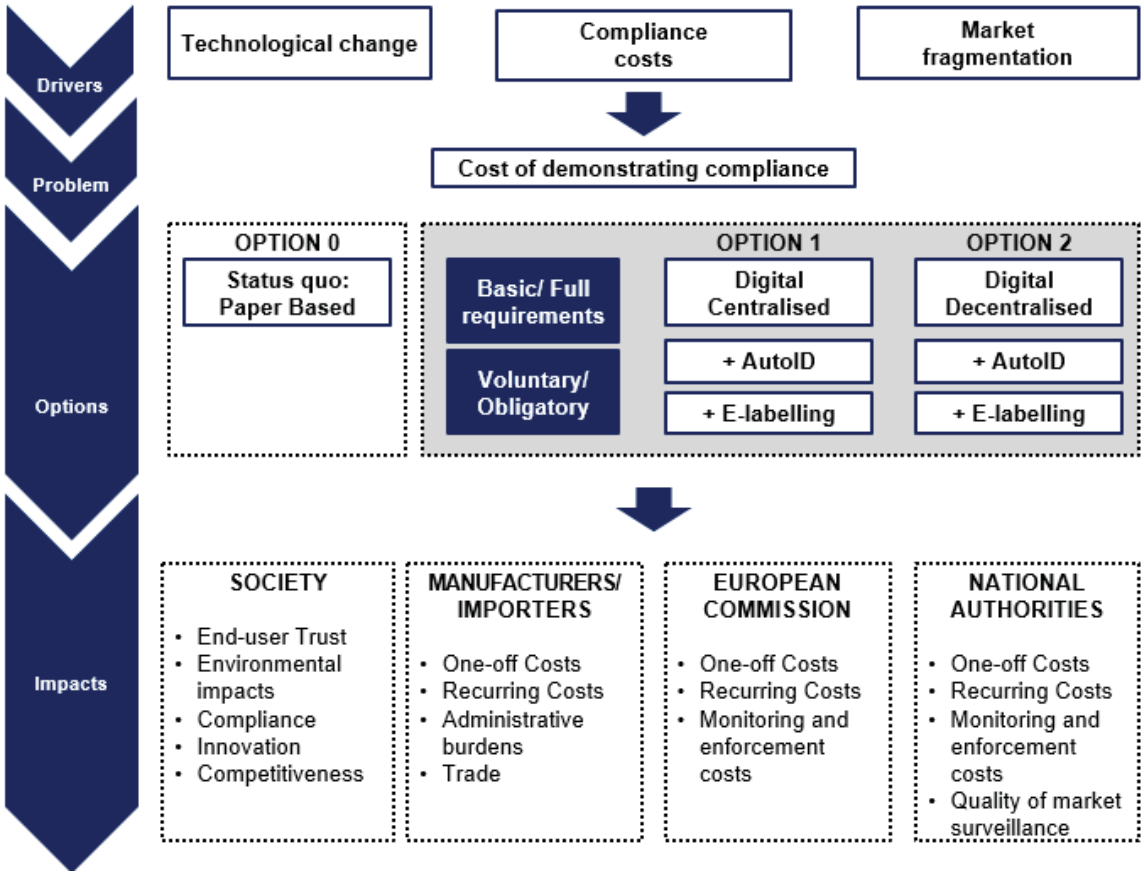
5.2. Methodological framework

5.2.1. Overall impact assessment framework

The figure below presents the conceptual impact assessment framework for this study which focuses on the costs of demonstrating compliance as the main problem to be tackled by the envisaged initiative. For instance, the cost of demonstrating compliance could include administrative burden for answering requests from market surveillance authorities regarding documents needed to demonstrate compliance; displaying (or publishing) the compliance information; updating compliance information for existing products; complying with different compliance procedures across Member States; IT costs; or general labour cost. It should be

emphasised that the costs referred to in this study do not include the actual compliance costs (e.g. product testing, etc). The study focuses instead on the cost of *demonstrating* that a product is compliant.

Figure 14-8: Impact assessment framework



As the figure indicates, the proposed digital compliance initiative aims to address three main problems:

1. Technological and product change;
2. The emergence of differences across countries and sectors in terms of compliance procedures; and
3. The need to reduce compliance costs.

First of all, products have become more complex and incorporate a greater variety of technologies while the product cycles become shorter. There is a clear need to respond effectively to the rapidly evolving needs of industry, society, consumers and other stakeholders. The initiative aims to provide manufacturers with other mechanisms rather than the current paper-based procedure, in order to demonstrate product compliance with the applicable legislation.

Second, there are already (and there are likely to be further) differences in compliance systems across the Single Market, both across countries and across sectors. Even though the participation by relevant stakeholders has improved, it could still be more effective.

Finally, there is a need to reduce costs associated with product compliance processes in line with the EU's Better Regulation objectives. Taking this into consideration, the absence of a Europe-wide and cross-sector mechanism which allows the provision of compliance information electronically could possibly lead to the unilateral development of national systems in the Member States.

This, in turn, could raise the problem of system incompatibility or information asymmetry and therefore encourage fragmentation of the internal market and affect its proper functioning because:

- There are cases where different sectoral legislative acts apply to a specific product;

- Businesses and authorities have to deal with multiple systems at the same time;

A variety of systems will not improve the ability of businesses to comply with EU legislation, on the contrary will create an additional burden and confusion.

Sections 5.3, 5.4 and 5.5 of this report provide an assessment of the costs and benefits of the current (baseline) situation and the policy options that have been put forward to tackle the above problems. Section 5.6 summarises the key findings and conclusions and Section 5.7 sets out recommendations on the basis of these conclusions.

5.2.2. Methodological approach

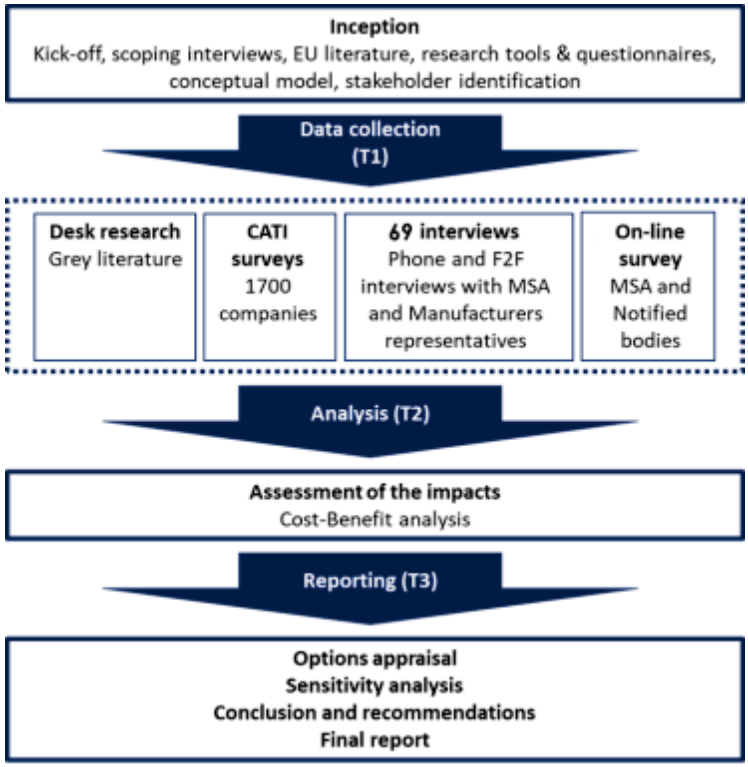
The figure below details the overall methodological approach. Subsequent sub-sections define the methodology used for the data collection in greater detail. The study was divided into three phases: Data collection, Analysis and Reporting:

- Data collection consisted of a combination of desk research, CATI interviews with companies affected by the proposed initiative and a targeted interview programme and online survey with MSAs, Notified Bodies and industry representatives.

- Analysis consisted of the assessment of impacts in a cost benefit model both for the current situation (Baseline) as well as for each of the proposed potential initiatives.

- Finally, reporting included the appraisal of each of the options under consideration, a sensitivity analysis, the development of conclusions and recommendations and the drafting of the present final report.

Figure 14-9: Methodological approach



5.2.2.1. Literature review at national level

The main objective of the literature review was to identify all national information related to **digital compliance schemes at national levels** and the **costs and benefits of demonstrating compliance for businesses and surveillance authorities** under a paper-based and/or digital compliance system.

Other relevant information within the scope of the review included:

- Trends and evolution of manufacturer problems in demonstrating compliance with technical product documentation and EU Declaration of Conformity;
- Trends and evolution of importer problems in demonstrating compliance with technical product documentation and EU Declaration of Conformity;
- Recent developments in improving market surveillance using digital means;
- Trends and evolution in Automatic ID technology and its applications;
- Trends and evolution in E-labelling technology and its applications;
- Cross-border issues in the demonstration of compliance.

The literature review involved the collection of statistics, economic and other literature and studies at national level relevant for the assessment; including complaints data, enforcement decisions and information efforts. A list of references is included in Annex 7.1.

The information gathered served as an input to fine-tuning interview questionnaire and surveys. Mapping country specificities also improved the analysis and interpretation of data gathered in other tasks. The literature review was carried out in preparation and together with interviews and CATI survey.

5.2.2.2. In-depth interviews

In order to build upon and complement the literature review, the research team conducted an interview programme with market surveillance authorities and sector representatives.

69 in-depth interviews were conducted, of which 19 with national market surveillance authorities and 50 with sector representatives and companies. The list of interviewed stakeholders is provided in Annex 7.2.

The **purpose of the interviews** was to gather qualitative and quantitative insights on experiences with the legislation within the scope of the study. To ensure that all relevant issues are covered and that the data collected is comparable, semi-structured interviews were carried out. This type of interviews enables the interviewer to have the flexibility to focus on specific points where the interviewee has particular knowledge.

To facilitate the interview process, **interview guides** (Annex 7.3) were sent to interviewees ahead of the interview to give them the possibility to prepare. As there are two types of respondents, the questions differ slightly to address costs and benefits borne by each stakeholder type. The interview guide includes a section introducing the study and explaining its specificities. Among the information presented to interviewees, the interview guide includes a description of what is meant by digitally demonstrating compliance, an overview of the policy options and the scope of the study (which excludes conformity assessment and CE marking).

A **guidance note** was prepared for the data collection team in order to align interviewers with the objectives of the study, the policy options under consideration and the type of stakeholders interviewed. This was complemented by a **briefing session**, during which the methodology and the approach of the study was discussed with the data collection team.

Interviews were **conducted by phone and face-to-face.** When requested, interviews notes were validated by interviewees. All interviews were stored in a shared folder for subsequent analysis. Interviews were collected simultaneously with the running of the online survey and the CATI survey.

5.2.2.3. Online survey

In addition to the in-depth interviews, the research team launched an online survey targeting public organisations such as notified bodies and market surveillance authorities that could not be reached through the interview programme. The survey questionnaire can be found in Annex 7.4. As the annex illustrates, the foreseen survey questions are simplified versions of the questions in the interview programme. A total of 11 authorities completed the survey, of

which 10 Notified bodies and 1 MSA. The survey data were combined with the data from in-depth interviews and used to determine the costs and benefits of each policy option.

5.2.2.4. CATI survey

The CATI survey was used to **gather quantitative information from individual businesses.** The data gathered were used to carry out the CBA and the CATI survey questionnaire is presented in Annex 7.5

More than **1700 company interviews** were completed in the relevant NACE sectors (Annex 7.7) across the 28 Member States, ensuring geographical coverage and robustness of the analysis.

The CATI company used the Standard Industrial Classification (SIC) codes to identify relevant industries. The conversion table used to convert SIC to NACE codes is provided in Annex 7.8. The two systems do not always match perfectly. As a result, for each NACE code in scope we used data from the best fitting SIC code(s). Sometimes, more than one NACE code fits the same SIC code. In those cases, each interview was counted once for every NACE code that fits the SIC code. After this adjustment, the 1700 interviews constituted a database of 3482 rows. The final database ensures the coverage of businesses of different type and size.

As displayed in the figure below, 90% of respondents are manufacturers, 25% are distributors and 24% importers. The total adds up to more than 100% because a significant number of companies fall into more than one category.

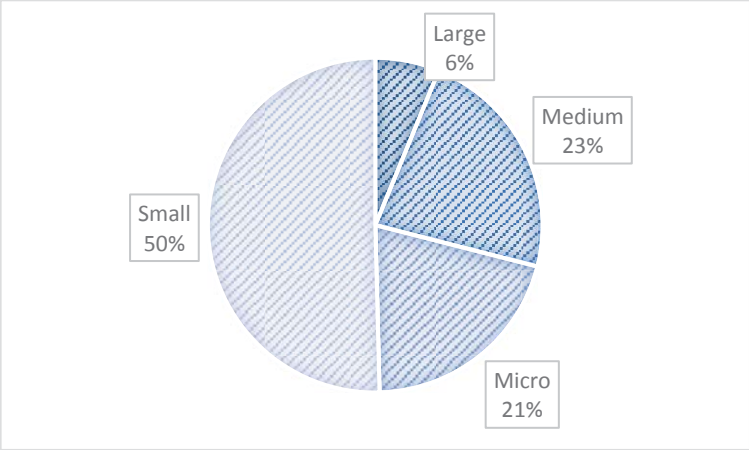
Figure 14-10: Share of responses, by company type

Source: CATI survey

In terms of company size, 94% of the companies interviewed for the CATI are SMEs:

- 21% are micro enterprises (with less than 10 persons employed);
- 50% are small enterprises (with 10-49 persons employed);
- 23% are medium enterprises (with 50-249 persons employed);
- 6% Large companies (with more than 250 persons employed).

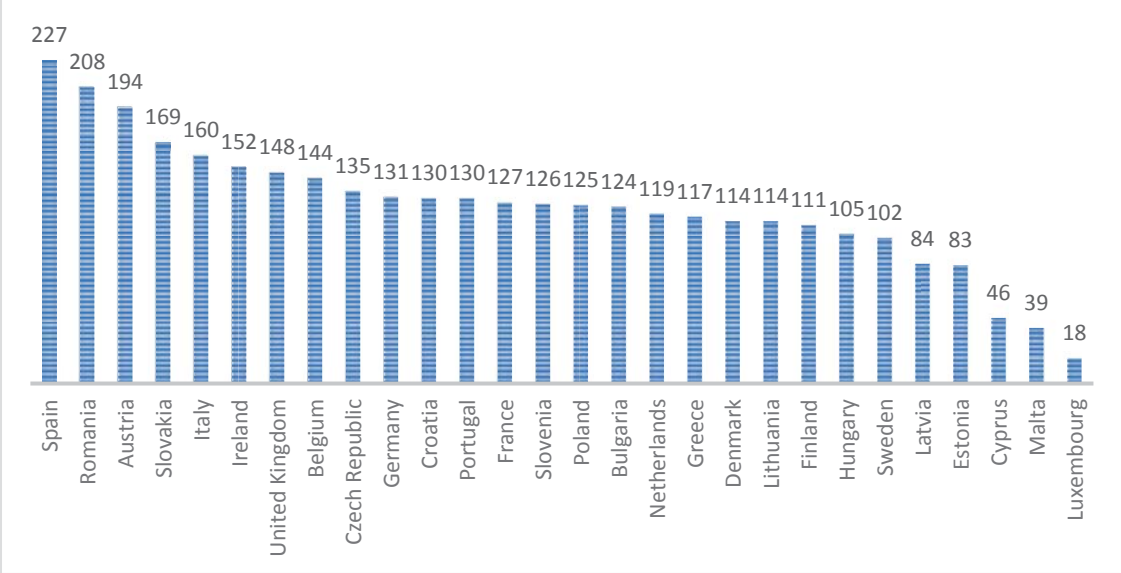
Figure 14-11: Number of responses by company size



Source: CATI survey

The figure below summarizes the geographical coverage after adjusting for NACE code. Interviews have been collected across all 28 MS, ensuring full geographical coverage.

Figure 14-12: Number of responses by country



Source: CATI survey

Further, although sector coverage was agreed with the Commission during the inception phase of the study, it is nevertheless possible that not all companies in the relevant NACE sectors are within the scope of the study. Hence, the survey also included questions for companies to self-report whether they produce any of the documents required for demonstrating compliance. This allowed the team to:

- Compute the share of companies in the relevant sectors for this study that indicate that they demonstrate compliance

- Estimate the total population of enterprises in the EU that demonstrate compliance

- Estimate total costs / benefits at EU level (once combined with interview results)

The CATI survey was carried out over the course of 60 days. An initial fine-tuning phase was performed together with the CATI company to ensure the quality of the questionnaire, a high response rate and a detailed planning of the timeframe.

5.2.3. Structure of the cost benefit analysis

The main analytical tool in this present study is a cost-benefit analysis. The cost benefit analysis shows:

The current costs (and benefits) of the paper based system (see Section 5.3)

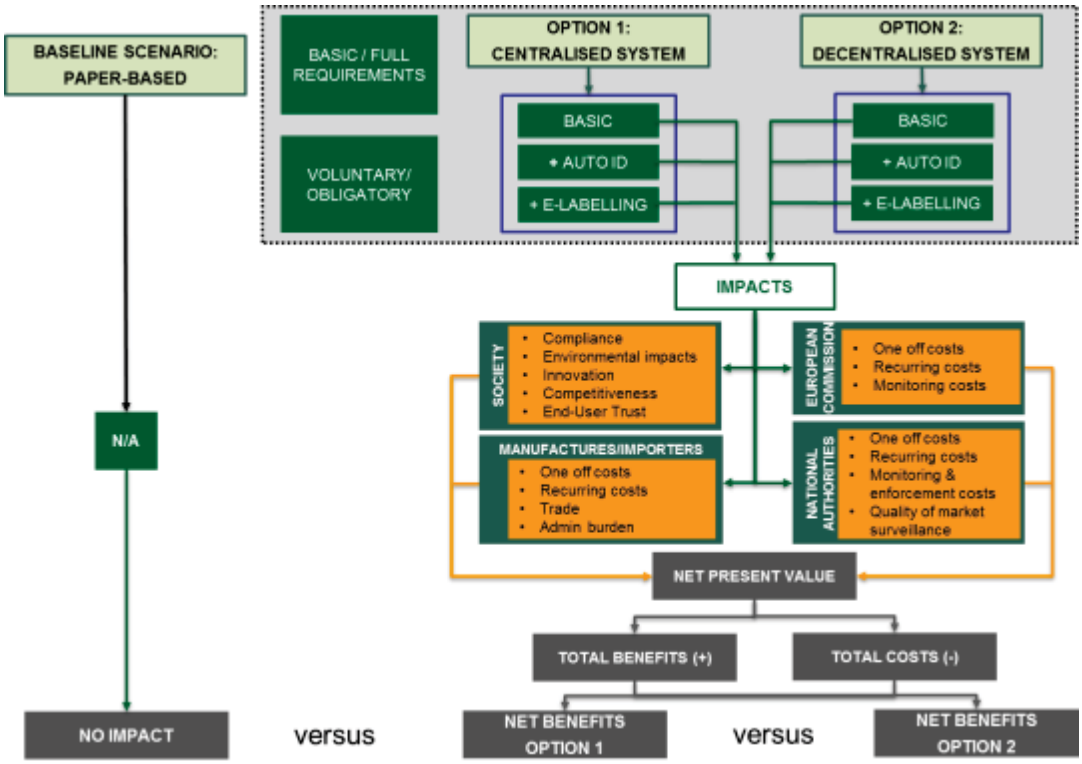
- The projected cost (and benefits) for each of the options and sub-options (see Sections 5.4 and 5.5)

- A sensitivity analysis which indicates how robust the options appraisal is to variations in the underlying parameters of the analysis.

The cost-benefit analysis in this report is based on the results of interviews with enterprises, their representatives and market surveillance authorities as well as the CATI survey described above. The CATI interviews cover all sectors listed in Annex 7.6, a breakdown of CATI responses by country and sector is in Annex 7.7. The results of the CATI survey are weighted by sector to achieve a more representative picture of the European enterprise population.

Where no quantitative data are available the analysis juxtaposes quantitative results with qualitative elements to arrive at a comprehensive picture of the merits of the different options. The figure below provides the final structure for the cost-benefit model.

Figure 14-13: Structure of the cost-benefit model



Note: Impacts in italics will be quantified if possible – otherwise they will be included in the qualitative analysis

The comparison of the options is based on the "net present value" for each of the options (where sufficient quantitative data are available):

$$NPV = \sum_{t=0}^{T} \frac{(B_t - C_t)}{(1+r)^t}$$

Where:

B_t = benefits in Euros received in year *t*, (where available)

C_t = costs in Euros received in year *t* (where available)

r = discount rate

The "paper based" scenario (option 0) constitutes the baseline against which the impacts of the two options are assessed.

5.3. Description and assessment of the baseline

5.3.1. Description of the baseline

Generally, **when a product is placed on the market the manufacturer is obliged to take all measures necessary to ensure that the manufacturing process assures compliance of the products**[75].

Manufacturers have to demonstrate compliance of their products through two main sets of documents:

1. **The technical product documentation** Under Union harmonisation legislation the manufacturer is obliged to draw up a technical documentation which shall contain information that demonstrates the products complies with the requirements. Moreover, the technical documentation has to be available as soon as the product is placed on the market, regardless of its geographical origin or location. One more important aspect is that the technical documentation has to be kept for 10 years starting from the date of the product's placement on the market. Exceptions can be made only if there is applicable Union harmonisation legislation which provides expressly for a different duration.

   The contents of the technical documentation are laid down, in each EU harmonisation act, in accordance with the products concerned. Also, the documentation must include a description of the product and of the way in which it is intended to be used. This must cover the design, manufacture and operation of the product. The documentation must contain the details considered necessary, from a technical point of view, for demonstrating the conformity of the product with essential requirements of Union harmonisation law.

   Frequently, the technical documentation has to contain also an "adequate analysis and assessment of the risk(s)". This consists in the identification of all the possible risks of the product and the determination of the essential requirements applicable. Furthermore, if there are cases where a product has been redesigned and conformity has been reassesed, the technical documentation must provide all versions of the product (this must include the description of the changes, how the various versions of the product can be identified and on the different conformity assessments).

2. **The EU Declaration of Conformity**. The manufacturer or the authorised representative established within the Union must also devise and sign an EU Declaration of Conformity. The EU Declaration of Conformity must contain all relevant information to identify the Union harmonisation legislation according to which it is issued, as well as all relevant information concerning the manufacturer, the authorised representative, the Notified Body (if applicable), the product, and where appropriate a reference to harmonised standards or other technical specifications. Only a single declaration of conformity is required where a product is covered by several pieces of Union harmonisation legislation requiring an EU Declaration of Conformity.

3. **Manufacturers have to meet and fullfil the traceability requirements of the products**. This is done by indicating the name, registered trade name or registered trade mark and the address at which they can be contacted. This information must be displayed on the product, on its packaging or in a document which accompanies the

75 See COM Notice (2016) 1958 final "The 'Blue Guide' on the implementation of EU product rules 2016" of 05/04/2016, section 3.1, p 28-31 on ec.europa.eu/DocsRoom/documents/12661/attachments/1/.../pdf

product. The address must indicate a contact point for the manufacturer. Likewise, importers have to indicate their name, registered trade name or registered trade mark and the address at which they can be contacted, on the product or, where that is not possible, on its packaging or in a document accompanying the product. On top of this, manufacturers must also make sure that their product bears a type, batch, serial or model number or other element allowing their identification (if the nature or size doesn't allow it, it must be provided on the packaging or in a document accompanying the product).

If there is a grounded request, the manufacturer must provide the competent national authority with all the information and documentation needed to demonstrate the conformity of the product. This must be done in a language accessible for the authority. Moreover, if the products placed on the market present any risk, the manufacturer must cooperate with the authority to address this risk. Manufacturers must also identify any economic operator to whom they have supplied the product if the market surveillance authorities request it. They must be able to present this information for a period of 10 years after they have supplied the product.

5.3.2. Interview results regarding the baseline

Results of interviews with market surveillance authorities (MSAs) and manufacturer associations, found that different Member States (MS), have different ways of dealing with market surveillance. For instance:

1. Market surveillance can be a national (ex. Slovenia) or a regional (ex. Germany) level competence.

2. MSAs can be organised along industry sectors (i.e. more than one authority dealing with market surveillance, but with different sector competencies) or they can be more centralised.

3. MSAs have different approaches to market surveillance. They can:

    - Be primarily proactive: the MSA initiates inspections and checks whether products are compliant according to the relevant Directives, requiring the CE marking. Certain MSAs perform random checks (i.e. Belgium), while others select specific product/ companies/ sectors based on a risk a based approach (i.e. Netherlands);

    - Be primarily reactive: the MSA reacts to complaints from consumers, associations, competitors or following an accident (i.e. Germany); or

    - Feature a mix of both of these approaches. For instance, the Slovenian MSA states that they perform 80% proactive and 20% reactive activities.

Under both the reactive and proactive approaches, if preliminary assessment leads to *initial suspicion*, the MSA approaches manufacturers, importers and resellers for additional information. The request is usually rather specific (not limited to making documentation available but explaining parts within it) and MSAs get directly in touch with

the investigated economic operator, either via a telephone call or via a visit. During this phase, most of the exchanges of documents happen digitally via e-mail.

According to the interviews, most MSAs stated that they are equipped to **send and receive official documentation in digital form** (such as with electronically signed PDF), even if in certain countries paper documentation is still required. Most MSAs report that paper-based exchanges are rare compared to digital communication and most documentation is produced and stored electronically and printed only if needed. For instance, in Austria, demonstrating compliance is done digitally, except for the Declaration of Conformity which remains paper based because it needs to be signed. In Sweden exchanges of paper documentation have been abolished.

Further, in the construction industry, the Construction Products Regulation (CPR) incentivises a digital Declaration. The Regulation changes the way in which a manufacturer declares compliance. The manufacturer's 'declaration of conformity', now becomes a 'declaration of performance'. The document must contain actual performance data in relation to the essential characteristics. This must be 'made available' to the end user and the Regulation allows for this to be by electronic means, for example by posting on a website. Additionally, some information must be marked on the product and/or its packaging. According to industry representatives, this digital approach has been adopted by most manufacturers in Europe, except for specific SMEs for whom the change away from paper-based demonstration of compliance is not as easy to make.

Finally, even outside construction, representatives noted that the big international manufacturers, frequently already operate voluntary decentralised databases for internal use, to quickly provide compliance documentation worldwide. The key drivers behind this phenomenon include:

- cost minimisation,
- flexibility,
- workflow tools,
- support for multiple compliance requirements worldwide, and
- geographic dispersion of the relevant services.

At the same time, for smaller manufacturers, the economies of scale for setting up a digital compliance system may not exist.

Overall levels of compliance are difficult to estimate given the different approaches to market surveillance across the EU. In addition, such an estimate is outside the scope of this particular study which focuses on the cost and benefits of *demonstrating* compliance only – not on the compliance requirements themselves. However, German authorities for instance estimate an average 30% level of non-compliance across all sectors following the initial request by the MSA.

The majority of concerns arise with respect to imported goods (mainly from Asia/China) rather than manufacturers within the EU. At the same time, market surveillance

authorities pointed out that sometimes it can be difficult to receive technical files from importers because they are not able to obtain the file from the manufacturer abroad. While digital identification of each product (identity of the manufacturer, involved Notified Body, Declaration of Conformity, and a unique identification number of the product which links it to a specific batch) could help EU market surveillance authorities with their requests for further information from third country (e.g. Chinese) authorities, such a system would still require that the underlying information that is fed into it by the third country manufacturer is actually correct.

5.3.3. Share of companies in relevant sectors that fall under the current paper based compliance regime

The remainder of this section provides first results of the CATI survey regarding the current paper based system of demonstrating compliance. Results have been weighted by sector where appropriate.

5.3.3.1. Incidence rate in the sectors covered by the study

The first questions in the CATI survey related to whether the company produces at least one of the documents required to demonstrate compliance (section 5.3.1). Companies that do not produce these documents do not incur the associated costs. There could be different reasons why companies – though classified as operating in one of the sectors covered by this study – do not produce such documentation, including the activity of the company which may not require them to produce any of the relevant documents, lack of awareness of the need to demonstrate compliance or simply a lack of compliance with existing rules.

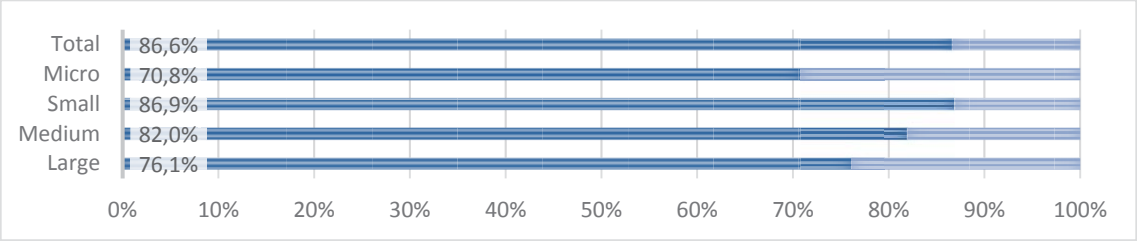
Annex 7.7 provides the incidence rates[76] for all NACE sectors included in the study. The CATI survey results show that there is a significant variation in the incidence rate across sectors. Given these differences, as well as differences in the size (number of companies and turnover) and the structure of these sectors, it is important that CATI findings in the final analysis are weighted by sector.

The figure below presents the overall incidence rate weighted by sector for companies of different size. **The overall incidence rate across the population of enterprises in the sectors covered by this study is 86.6%.**[77] Incidence levels are lower for micro companies (70.85) and higher for small companies (86.9%).

76 The incidence rate reflects the percentage of companies, classified to operate in one of the sectors in the scope of the study, that after accepting to participate in the interview stated that they produce at least one the requested documents: technical documentation and/or declaration of conformity

77 67.4% of companies contacted in the fieldwork said that they produce at least one of the documents within the scope of the research. The overall incidence rate of 86.6% is based on this figure, weighted by sector. Interviews were only taken forward with companies that do produce at least one such document. Other than in this sub-section, all further results presented in this report only cover the companies that produce at least one document (i.e. the companies that do demonstrate compliance), unless otherwise indicated.

Figure 14-14: Incidence rate, by company size

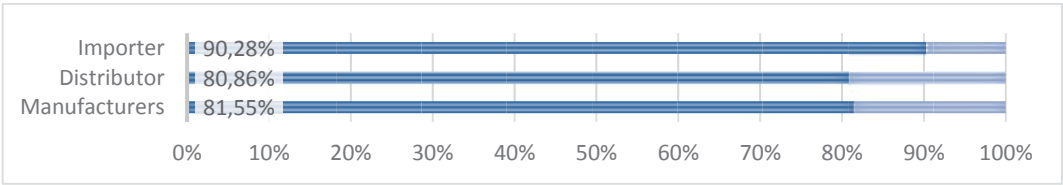


Source: CATI survey, data weighted by NACE code

Among the documents covered, the technical file is the costliest to produce and also the most commercially sensitive. Based on the CATI results and sector weighting, **it is estimated that 81% of all companies in the sectors covered by this study produce a technical file**.

The figure below shows the share of companies by type, size and sector which produce such a technical file. These figures are particularly important in the context of this study because they relate directly to one of the sub-options to be considered (inclusion of the technical file in the digital compliance demonstration system).

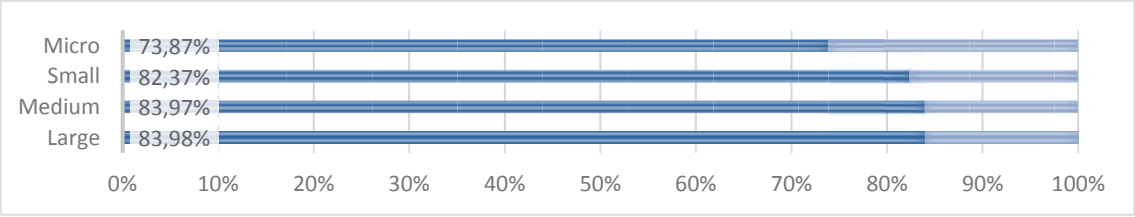
Figure 14-15: Share of companies which demonstrate compliance with the technical file, by company type



Source: CATI survey, data weighted by NACE code

Although 90.28% of importers stated that they produce a technical file compared with only 80.86% of distributors and 81.55% of manufacturers, the vast majority of companies in the sample were in the latter two groups and the results for these two groups are very close to the overall sample mean of 81%. The focus of this report is therefore on sector and company size differences.

Figure 14-16: Share of companies which demonstrate compliance with the technical file, by company size



Source: CATI survey, data weighted by NACE code

In contrast, there is a significant difference in the use of technical files between micro companies and larger companies. Micro companies (the largest group of in the population of companies) are less likely to use the technical file to demonstrate compliance than companies

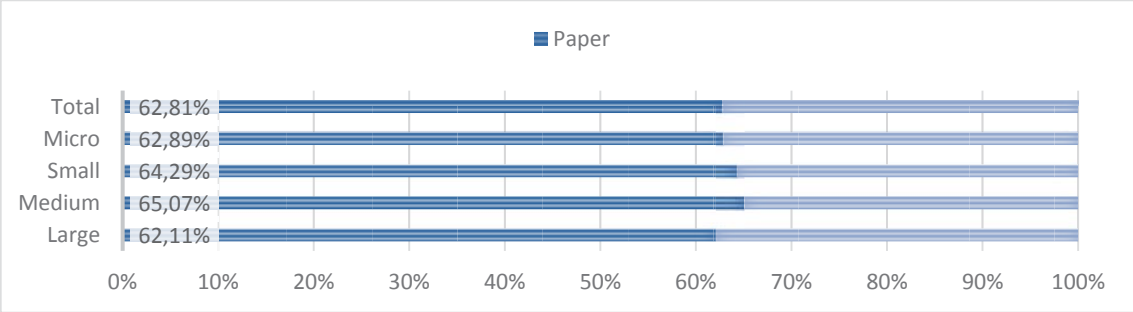
in any of the larger size categories. Differences between small, medium and large companies in the use of the technical file are not significant.

5.3.3.2. Prevalence of paper based compliance demonstration

Among those companies that produced compliance documentation, **62.8% said that they still produce and exchange paper documents with authorities, compared with 38.2% who indicated that they use only digital means to produce and demonstrate compliance to authorities, such as electronically signed PDFs**.

After weighting the data by NACE code, **there is little difference in terms of company size**: Medium companies are most likely to rely on paper (65%) compared with large companies which are more likely to use a digital means for demonstrating compliance (62% paper based).

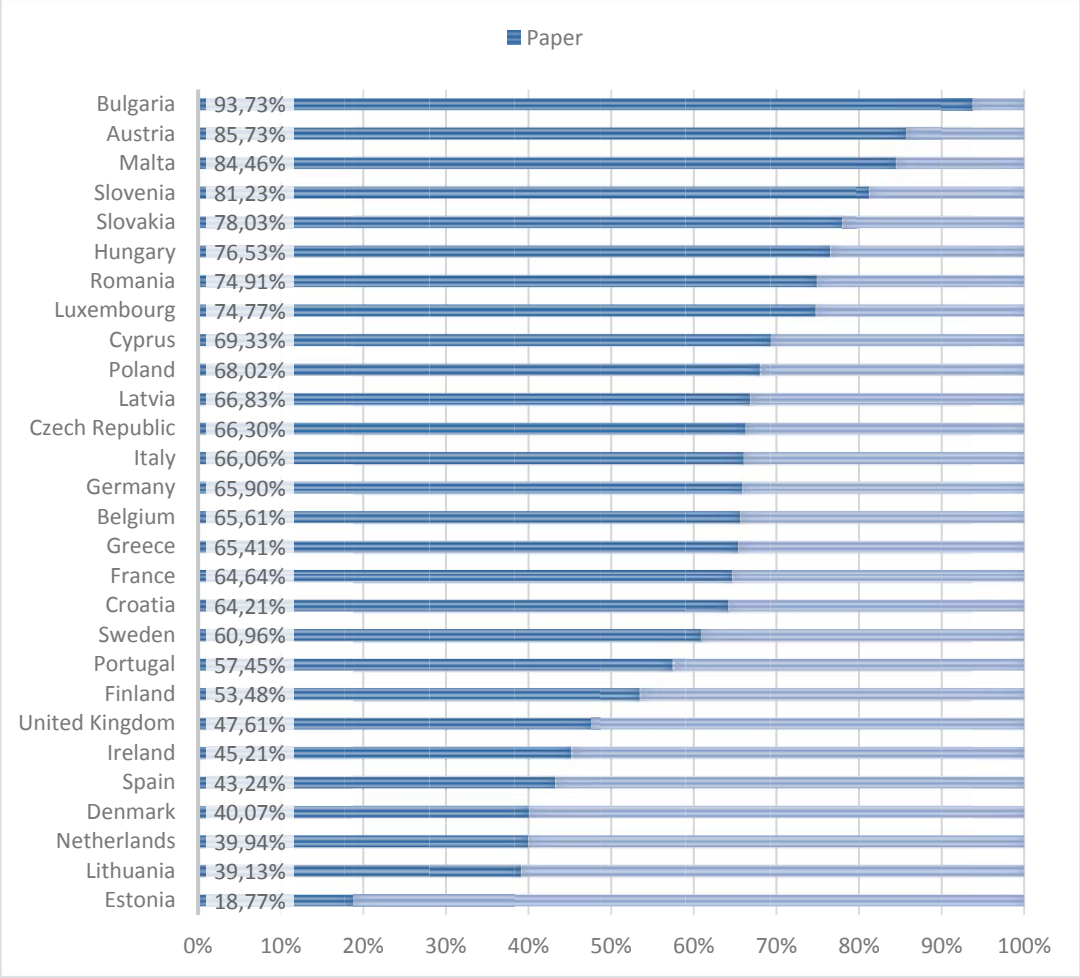
Figure 14-17: Share of companies that use a paper v digital means for demonstrating compliance, by company size



Source: CATI survey, data weighted by NACE code

Across countries, paper based compliance demonstration is the main channel in Bulgaria, Austria, Malta, Slovenia, Slovakia, Hungary, Romania, Luxembourg (more than 70% paper based). In comparison, Denmark, Estonia, Ireland, Lithuania, Netherlands, Spain and the United Kingdom have the greatest prevalence of digital systems to date (more than 50% digital). Estonia specifically is by far the most digital country when it comes to compliance demonstration: according to our survey only 18.8% of companies in Estonia use a paper-based procedure to demonstrate compliance.

Figure 14-18: Share of companies that use a paper v digital procedure for demonstrating compliance, by country



Source: CATI survey, weighted by NACE code.

5.3.3.3. Prevalence of MSA inspections

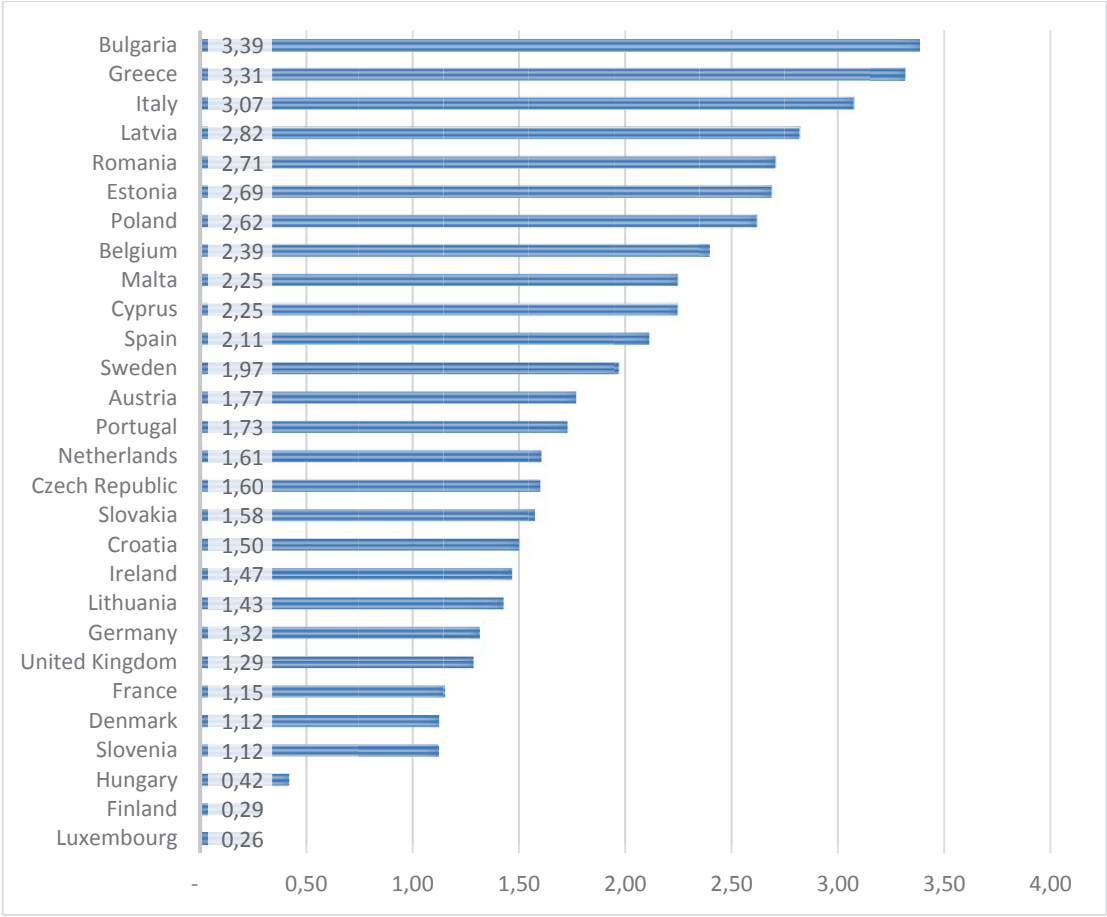
Finally, among those companies that produce compliance documents, **41% indicated that they had been subject to an inspection by a market surveillance authority in the last 5 years**. Responses ranged from a low of 15% in Hungary to a high of 76% in Cyprus.

On average, on the basis of the responses to the CATI, across all relevant sectors we estimate that **there are 1.41 inspections per company every 5 years**. However, this is a global average and differences between countries are significant.

- In Bulgaria, Greece and Italy, frequent inspections are reported – i.e. 3 every 5 years
- In Hungary, Finland and Luxembourg, inspections are reported much less frequently (less than one every 5 years).

It should be noted that the average of 1.41 every 5 years considers all companies, including those that have not been subject to any inspection over the past 5 years.

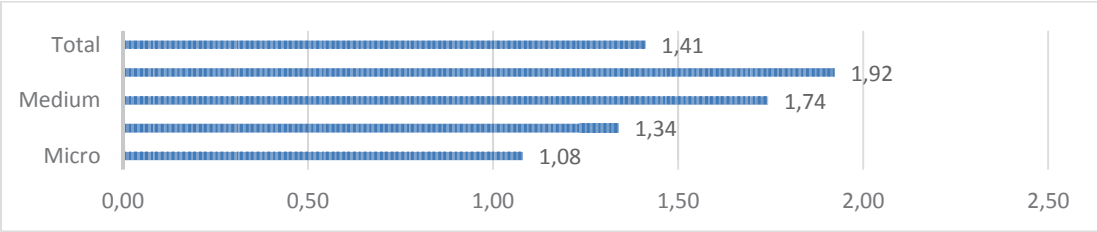
Figure 14-19: Estimated average number of MSA inspections per company every 5 years, by country



Source: CATI survey, weighted by NACE code.

In terms of company size, **inspections are more frequent in bigger companies**. Large companies receive on average 1.92 inspections every 5 years. This number goes down to 1.74 for medium companies, 1.34 for small companies and 1.08 for micro companies. In other words, large companies receive on average almost twice as many MSA inspections compared with micro companies. Finally, 52% Of large companies are likely to receive at least one inspection every 5 years. This number goes down to 47% for medium companies, 40% for small companies and 34% for micro companies.

Figure 14-20: Estimated average number of MSA inspections per company every 5 years, by company size



Source: CATI survey, weighted by NACE code.

5.3.4. Costs of demonstrating compliance under the current regime for demonstrating compliance

5.3.4.1. Cost estimate for companies

According to the result of the CATI interviews, the median respondent reported that the cost of demonstrating compliance (i.e. administrative burden for answering requests from market surveillance authorities regarding documents needed to demonstrate compliance; Displaying (or publishing; updating compliance information for existing products; Complying with different compliance procedures across Member States; IT costs; General labour cost) amounts to 10% of their overall cost of compliance with Union harmonisation legislation. Furthermore, based on the Evaluation of the Internal Market Legislation for Industrial Products[78], the total cost of compliance with such legislation for a firm is approximately 0.48% of its turnover. **We can therefore estimate the cost of demonstrating compliance to be approximately 0.048% of turnover**.

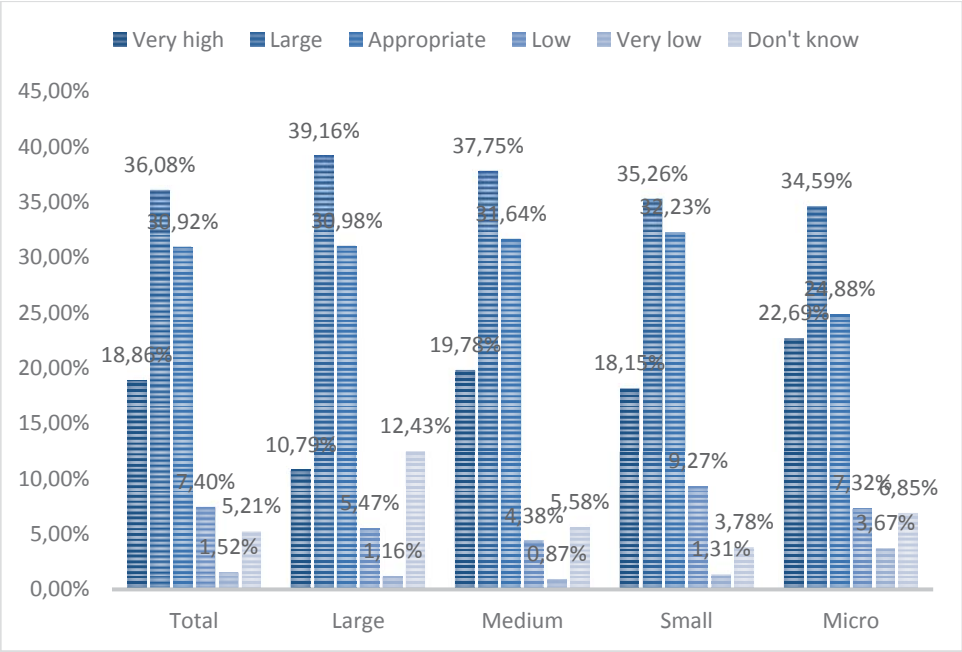
Considering Eurostat data from 2013[79], the turnover of the almost 350,677 companies within the scope of the study (see Annex 7.6) is € 2.03 trillion (€2,026,565.10 million). Given this, a preliminary estimation shows that the total cost of demonstrating compliance is approximately **€ 842.374 m** per year (€ 2.03 trillion * 0.48%*10%*86.6%incidence rate) or **€1,807.41 per company** per year on average.

5.3.4.2. Company perceptions of the level of costs

To put the above cost estimates into context, the CATI survey also asked companies about their perceptions regarding the appropriateness of the current costs of demonstrating compliance. About **55% of respondents believe that today's cost of demonstrating compliance are either high or very high** (Figure 14-21) compared with about one third who considered the costs appropriate and about 9% who thought the costs were low. **Only 11% of large company believes today's cost of demonstrating compliance are very high, compared to twice as many micro enterprises.**

78 http://ec.europa.eu/smart-regulation/evaluation/search/download.do?documentId=9966151
79 Eurostat: http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=sbs_na_sca_r2&lang=en

Figure 14-21: Perceived level of cost under the current regulations and business practices, total and company size

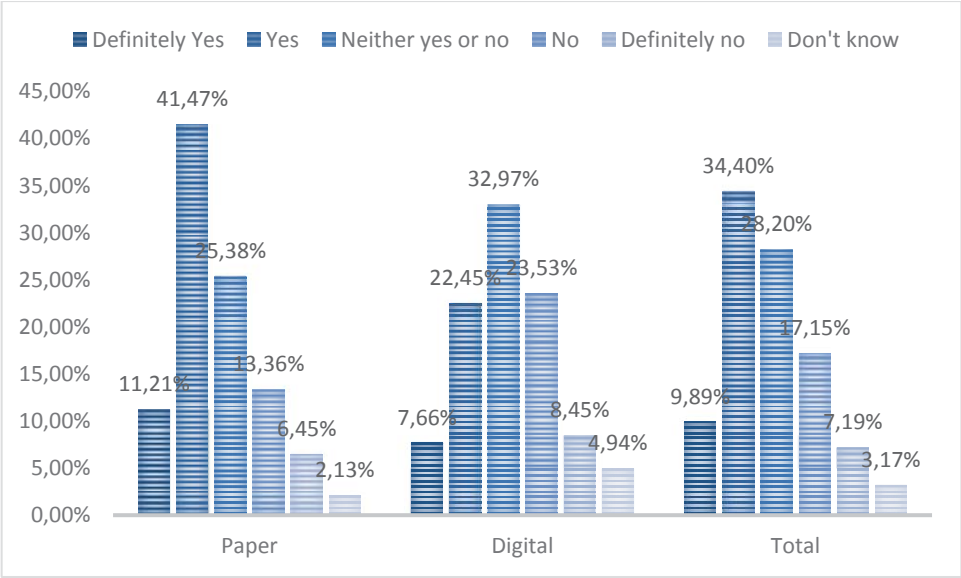


Source: CATI survey, weighted by NACE code

5.3.4.3. Overall company assessment of the current procedures

Finally, regarding the need for change, two fifths of companies considered the paper based procedures to be efficient or very efficient (44.3%) with 31.4% not having a strong opinion either way and **24.3% of respondents considering the current paper based system as inefficient**. There are no significant differences in perceptions of overall efficiency by company size. However, companies that are fully paper based in their demonstration of compliance were overall more satisfied with the status quo than companies which indicated that they demonstrate compliance digitally. This result suggests that companies that have the resources to demonstrate compliance digitally (or that have already invested in digital systems) would like the regulatory environment to "catch up", whereas companies that do not currently have these means are more likely to want to preserve the paper based system.

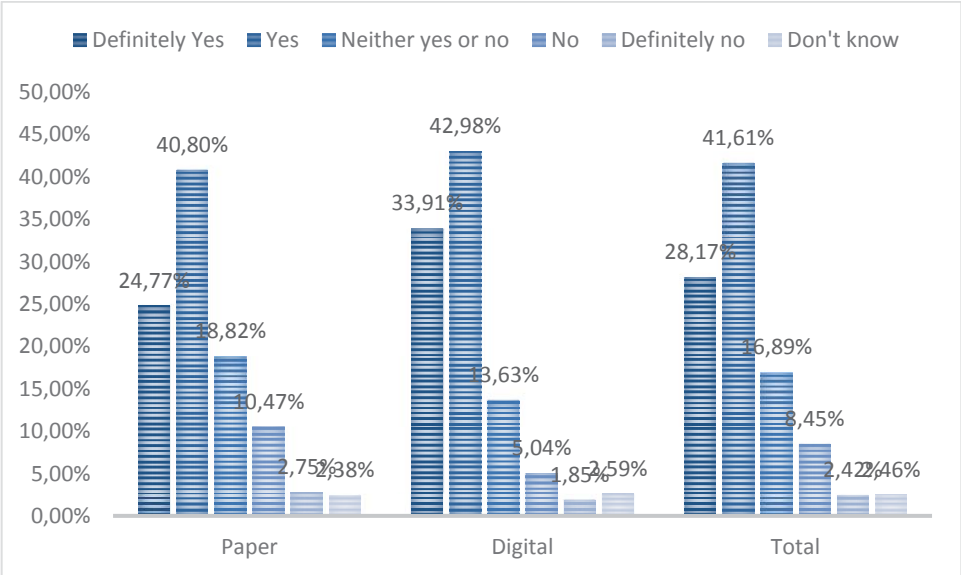
Figure 14-22: Overall, do you find today's paper based procedure of demonstrating compliance efficient?



Source: CATI survey, weighted by NACE

Finally, despite overall rather favourable perceptions of the current paper based system, there is a strong preference among companies for digitalisation. Overall, **more than 69% of respondents think a digital system would be an improvement**, compared with slightly more than 10% who think such a system would be worse than the current one. Like for the previous diagram, preferences for a digital procedure are particularly strong among companies that already do part of their compliance activities digitally.

Figure 14-23: Do you think a digital compliance system would be an improvement compared to todays' procedure of demonstrating compliance?



Source: CATI survey, weighted by NACE

5.3.4.4. Market surveillance authorities and Notified Bodies' costs

Beyond the company's costs, market surveillance authorities also provided (mostly qualitative) information regarding their costs.

Overall, costs of individual activities are very difficult for MSAs to estimate because they work with a fixed budget that cuts across all their activities and it cannot easily be broken down. For this reason, most MSA did not provide data on costs but they specified that this is usually limited to personnel costs and a budget for tests and for acquiring products at point of sale.

In certain countries, the law allows the MSA to ask for products from manufacturers for free (e.g. Germany). However, anecdotal evidence shows that outlays vary widely between countries and sectors:

- The Dutch centralised MSA has a yearly budget of € 12 million, which is being used both for current expenses and for the testing of 6000 products a year on average. The authority has a yearly capacity of 100 FTE divided in:
    - 40 FTE in inspection activities;
    - 30 FTE in testing activities;
    - 30 FTE in strategy and facilitating the infrastructure.
- The Danish Safety Technology Authority estimated an average cost of 2 hours (FTE) for each inspection related to one product and one company.
- The Slovenian MSA for toys, cosmetics, hygiene, and personal care products has a yearly budget of € 4.4 million. With a staff of 88 inspectors, the authority carries out 30,000 products checks a year.
- The Romanian MSA estimated a cost of €14,000 a year for market surveillance of construction products in the category of fixed fire-fighting equipment
- The Estonian MSA estimated a cost of €4000 just for radio equipment

To overcome lack of quantitative data, the research team tried to collect information on how much time is spent on the different activities carried out by MSA and Notified bodies, and to understand which activities require most of the authority's resources.

The table below shows typical responses from MSAs in relation to the costs associated with different market surveillance activities related to demonstrating compliance as well as the results for the 10 Notified bodies who participated in the online survey. As the table shows, MSAs spend most of their resources on carrying out core activities such as inspections and testing. It is important to note that most MSAs highlighted difficulties in interacting with third parties and MSAs in other countries. Even if these activities do not take most of the time, the answers collected suggest possible margins for improvements in those areas.

Table 14-13: Perceptions of costs among MSAs and Notified Bodies for activities related to demonstrating compliance

Type of activity	Cost for MSA	Cost for Notified Bodies (as a percentage of the time spent by the institution on the different activities)
Assessing/collecting the information showing compliance from companies	This is a core activity for MSAs and therefore it takes most of the time and budget	19%
Interacting with market surveillance authorities in other Member States to assess information showing compliance	Very burdensome activity that often leads to no answers.	6%
Interacting with third parties (e.g. consumers, other public bodies, courts, etc) regarding the search for information showing compliance[80]	Very burdensome and time consuming	12%
Costs for archiving/handling of documents showing compliance[81]	Often impossible; EU importers cannot get the required information from manufacturers (intellectual property).	Not significant.
Training of new/existing employees on the process of verifying compliance[82]	No specific training costs were provided	Training is usually provided and it is between 4 and 15 days a year.
Other activities related to searching for information showing compliance	Finding and identifying the batch to which non-compliant product belongs	NA

Finally, MSA costs depend also on the authority's strategy. For example, MSAs that use a reactive approach may have a higher incidence of non-compliance as a percentage of the inspections carried out. For example, the Ministry of Rural Affairs and Consumer Protection of Baden-Württemberg estimated that 30% of all the inspections carried out by the local MSA result in non-compliance. The reason for such a high percentage is that the initiating of checks is triggered by *initial suspicion*.

80 This refers to the costs of producing and distributing copies of compliance documents to other parties when they request them. In the Digital Compliance scenarios (OPTION 1 and OPTION 2), such interaction would most often mean referring third parties to the location of the documents.

81 This includes post stamps, costs for paper and printer ink supplies, costs for handling storage and archiving, as well as costs of discarding documents.

82 This includes trainings, external advice and assistance to staff from other public agencies.

5.3.5. Benefits of demonstrating compliance under the current paper based regime

As expected, in terms of benefits, information provided by both companies and MSAs was mostly qualitative in nature. Most benefits that both companies and market surveillance authorities could name were related not to *demonstrating* compliance but to the system of Union harmonisation legislation in general, which is out of scope of the current study. The benefits of the process to demonstrate compliance are more difficult to isolate but key elements cited included:

Cited by companies

- End-user trust;
- Familiarity with the current system (i.e. the system's benefit is that it has been around for a long time and everyone knows how to deal with it);
- Creation of a level playing field for companies across the EU;

Cited by market surveillance authorities:

- The fact that there is extensive technical documentation but this does not have to be made public and control of technical knowledge, confidentiality and business know-how are maintained within the firm.
- The fact that manufacturers using Harmonised Standards listed under respective EU legislation in the OJEU, benefit from the so-called 'presumption of conformity' until the moment that non-compliance is proven by the Market Surveillance Authorities.
- Ex-post checks by market surveillance authorities are quite specific and usually MSA requests are quickly solved in bilateral communication and exchange of emails or electronic documents with the company, even in the absence of a systematic digital procedure.

5.4. Overview of the policy options

Following the assessment of the baseline in the previous section, this section presents the proposed policy options to address the problems identified with the current paper based approach.

5.4.1. Aim of the potential policy intervention

The immediate objective of a possible Digital Compliance system should be to facilitate the demonstration of product compliance through the digital transmission of compliance information to market surveillance authorities and to reduce the costs of providing/accessing compliance information for manufacturers (especially SMEs), Notified Bodies and authorities, while maintaining the necessary high level of protection of public interests.

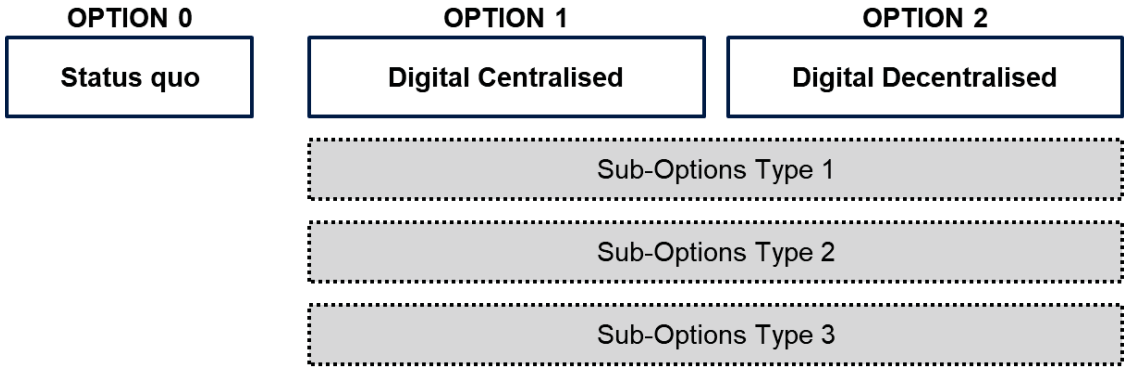
In a Digital Compliance system, manufacturers and Notified Bodies would share information digitally regarding the compliance of a product with the applicable legislation enabling the drafting of the necessary documentation. Market Surveillance authorities would be able to access the required information. Confidentiality issues would need to be taken into account.

It needs to be reiterated that this study deals only with demonstration of compliance. The conformity assessment procedures themselves, covering e.g. testing and affixing of the CE marking, are outside the scope of the study.

5.4.2. Description of each policy option

This section briefly presents the key elements of the policy options, in the form of a "decision tree". The "decision tree" is a decision support tool that uses a tree-like graph that serves as a guide through a sequence of scenarios.

Figure 14-24: Overview of the policy options



Three main policy options will be considered in the cost benefit analysis (see Figure 14-24).

1. **The "status quo" option (Option 0)**: manufacturers are solely responsible for the compliance of their products with the applicable legislation. The demonstration of compliance with Union legislation is done through two main sets of paper based documents:

    a. the technical product documentation; and

    b. the EU Declaration of Conformity.

    Upon a reasoned request, the manufacturer has to provide the competent national authority with all the information and documentation necessary to demonstrate the conformity of a product.

2. A **centralised digital compliance procedure** (Option 1): a central database will be developed, owned and maintained by the European Commission and have the form of an electronic repository of information. Manufacturers can upload information regarding the conformity of a product with the applicable legislation. Notified Bodies can upload information regarding the certificates of conformity. Market surveillance authorities will be able to access this information; and

3. A **decentralised digital compliance procedure** (Option 2): all relevant data will be collected in decentralized databases operated by the individual companies (or on the products themselves). The database can consist of dedicated sections located on the websites of the economic operators, responsible for developing and maintaining their own dedicated websites. Manufacturers will upload and maintain up-to-date information regarding the conformity of a product with the applicable legislation to a dedicated section of their websites. Notified Bodies will upload to a dedicated section of their websites information regarding the certificates they issued, suspended or recalled, and the certificates they refused to issue. Market surveillance authorities will be able to access this information.

For both options (1 and 2), three specific sub-options will be considered.

- The **first sub-option** considers only the introduction of the **digital compliance procedure**, centralised in the case of Option 1 and decentralised in the case of Option 2.

- The **second sub-option** considers the introduction of the digital compliance procedure together with an automatic identification process (**AutoID**) such as barcodes, Radio Frequency Identification devices, smart cards and magnetic stripes, etc.

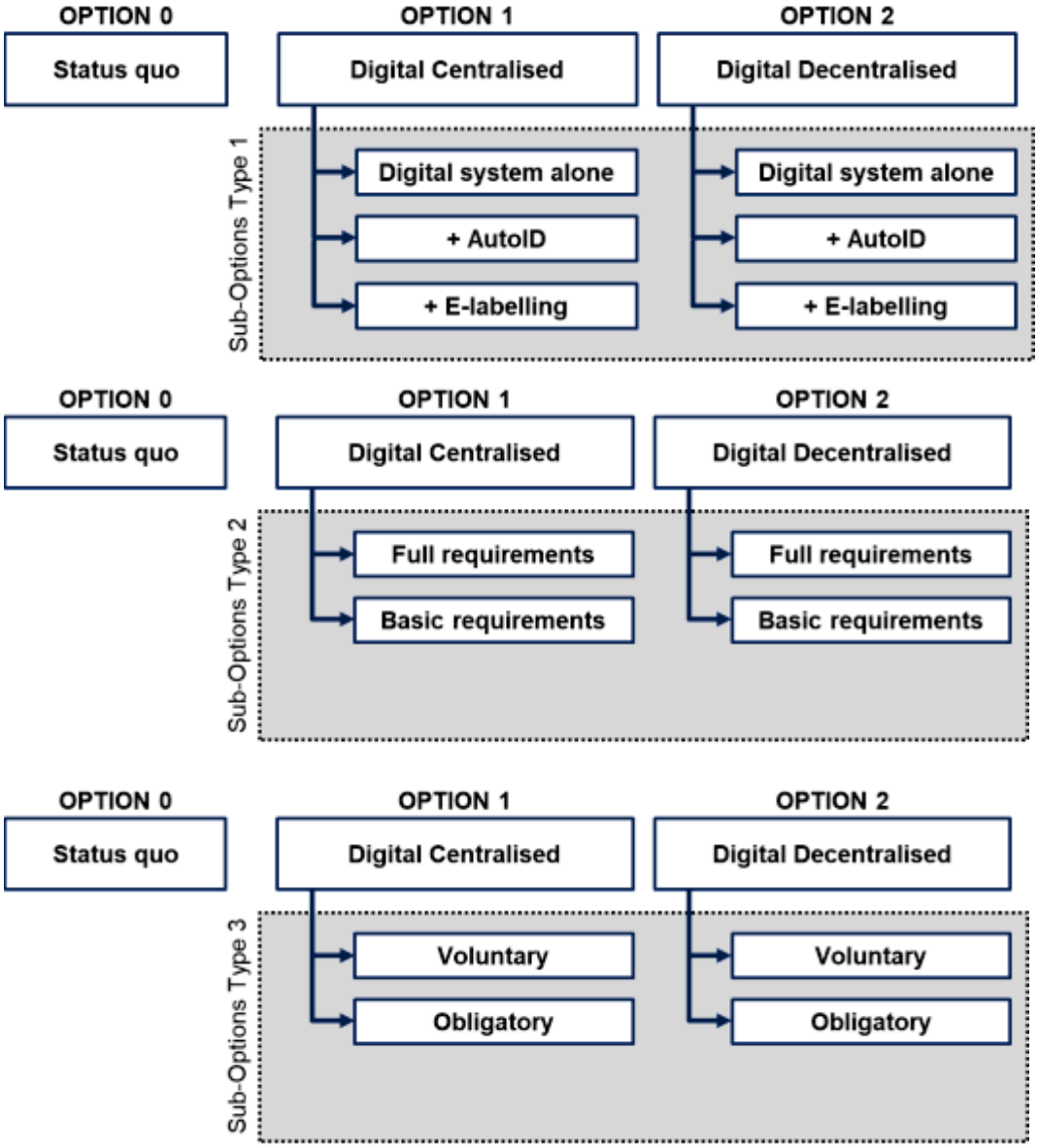
- The **third sub-option** considers the introduction of the digital compliance procedure as well as **e-labelling** to allow manufacturers of electronic devices with a screen to show compliance information electronically through a display rather than on a label affixed to the device (similarly to what has been introduced in the USA with E-LABEL Act in 2014).

For both Options 1 and 2 we will also take into consideration two additional possibilities:

- Digital compliance covers either only the EU declaration of conformity (DOC), contact data of the manufacturer and the certificate of the Notified Body, if such a body has been involved (**Basic**), or also includes the technical file (**Full**) (sub-options Type 2 – see figure below).

- Implementation of the new digital procedure is either **voluntary** or **obligatory** (sub-options Type 3 – see figure below).

Figure 14-25: Sub-options overview



5.5. Assessment of the policy options

This section presents the assessment of the different policy options and sub-options under consideration, including a sensitivity and a brief competitiveness analysis.

5.5.1. Option 1: centralised digital compliance procedure

Under option 1, a database of compliance related documents would be developed, owned and maintained by the European Commission. Manufacturers would be responsible for uploading information regarding the conformity of a product with the applicable legislation. Notified Bodies can upload information regarding the certificates of conformity. Market surveillance authorities would be able to access this information

The simulation first assumes that the centralised digital compliance procedure becomes the mandatory and only way to demonstrate compliance, thus eliminating the current paper based approach and any national databases or repositories of information regarding certificates of conformity. A second estimation considers the possibility that the centralised digital compliance procedure remains voluntary and co-exists alongside the current procedure.

5.5.1.1. Costs to companies

As shown in Figure 14-26, **most economic operators do not think that there will be considerable additional costs in case of basic compliance under Option 1**. As explained above, basic compliance refers to the option where the technical file would not be included in the centralised database and current paper-based procedures would continue to operate for the technical file.

In interviews, only few manufacturing associations were able to estimate their costs but there were a number of indications that should be taken into account in the further design of the option if this is carried forward.

1. There would be a **one-off setup cost** to create an in-house database with electronic versions of the documents to be uploaded into the centralised database as well as a new process for demonstrating compliance. In particular, this database would impose potentially significant costs related to security.

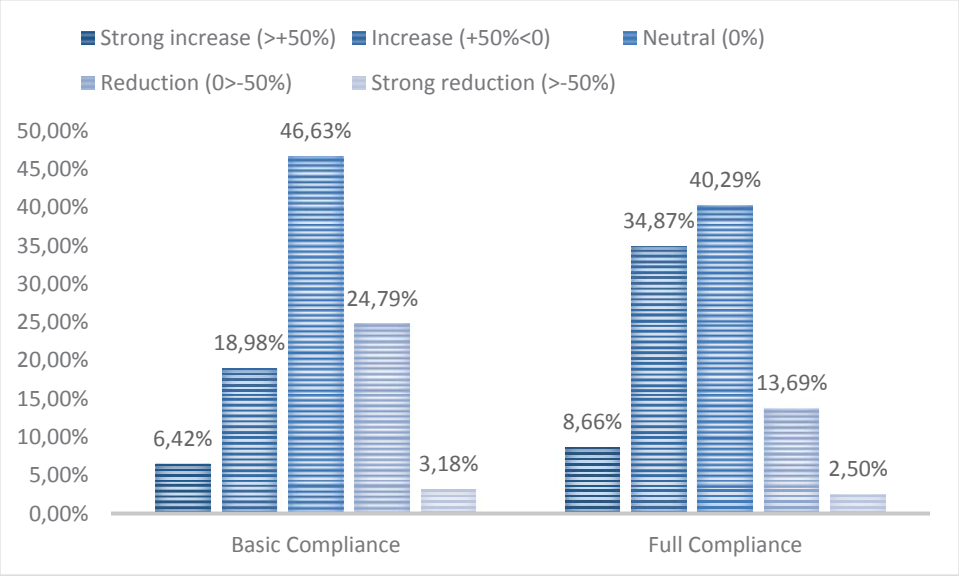
2. The significance of these costs would depend to a large extent on the system that would be implemented under option 1 and how **compatible** it is with each company's current procedures. For instance, the centralised database would require companies to provide information according to a pre-defined format which may not be compatible with the software used in-house at the moment to produce compliance documentation.

3. **Recurring costs** would differ depending on the number of products in each company's portfolio, the user friendliness of the database, and the product life cycle. By way of illustration, in the electric appliances sector there is a turnover of approximately 30% new/ changed models a year which would thus generate significant recurring costs. Regarding user-friendliness, experience with other European portals (ex. ECAS) were not positive due to technical problems and the lack of a functioning helpdesk.

4. If the centralised database requires uploading the technical file, **security costs** would be significantly higher as sensitive information is shared with a third party (the MSA). Interviews showed that under full compliance, this option would be difficult for economic operators to accept.

Overall, business perceptions are that costs would be significantly higher if the digital centralised database were to include the technical file due to the need for higher security and confidentiality standards. Under basic compliance about 25.4% of respondents expected a cost increase, versus 43.5% if the technical file were included in the option. The vast majority of respondents do not expect option 1 to lead to a reduction in costs under either the full or basic scenarios. However, during the interviews, both manufacturers and their associations were unanimous in opposing full compliance due to data sensitivity and the risk of industrial espionage.

Figure 14-26: Option 1 – change in cost of demonstrating compliance, under a "full" or "basic" digital compliance system



Source: CATI survey, weighted by NACE

To turn the above results into quantitative point-estimates, the thresholds specified in the answer options were used. Thus, where a respondent indicated for instance a "strong increase > +50%" this lower bound was used to develop the cost estimate (+25% for respondents who replied "increase", 0% for respondents who replied "neutral", -25% for all respondents who replied "reduction", -50% for respondents who replied "strong reduction").

The Table below breaks down these results to estimate the change in the cost of demonstrating compliance by company size. These results illustrate the importance of distinguishing between company size. Indeed, **small and medium companies, on average expect a small decrease in the costs of demonstrating compliance under the basic scenario (without the technical file), while micro-companies expect an increase in costs of 6.15%**. There is unanimity among companies of all sizes that including the technical file would lead to a significant increase in the costs of demonstrating compliance of between 6.95% (large companies) and 9.52% (medium sized companies).

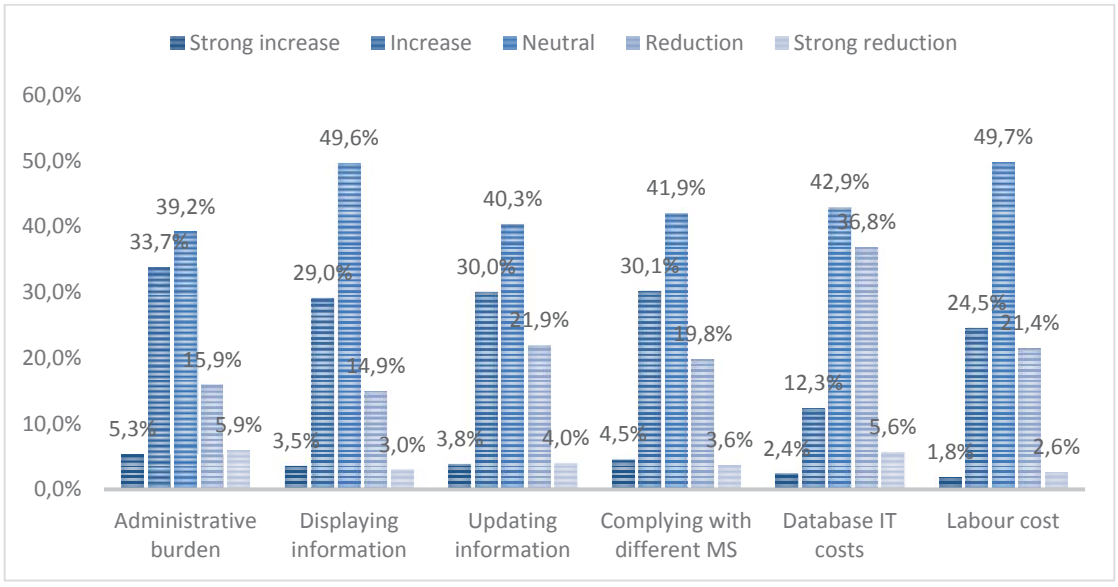
Table 14-14: Estimated percentage change in cost of demonstrating compliance per company size

	Basic	Full
Size	**%**	**%**
Large	1.93%	6.95%
Medium	-2.02%	9.52%
Small	-0.51%	7.98%
Micro	6.15%	7.99%
TOTAL	0.17%	8.37%

Source: CATI survey, weighted by NACE

The figure below provides a further breakdown of the kinds of cost changes companies expect under option 1 (basic compliance). The key cost categories where increases are expected are administrative burden, complying with different Member States, displaying and updating information. In contrast, reductions in costs are expected primarily in database / IT costs.

Figure 14-27: Key cost impacts as a result of Option 1 (basic compliance)



Source: CATI survey, weighted by NACE

Finally, in order to arrive at a monetary cost estimate, we assume that all companies which comply with Union harmonisation legislation under the paper based approach would continue to do so under a centralised digital compliance procedure. Taking the average cost increase under each of the options, it can be estimate that the total additional cost of Option 1 would be as shown in Table 14-15 below. Starting from the baseline calculated in section 5.3.4.1 to estimate the costs of Option 1 we consider:

- Estimated percentage change in cost of demonstrating compliance
    - Basic compliance: 0.17%
    - Full compliance: 8.37%
- Voluntary uptake: 81.87% (as per CATI survey results)
- Incidence rate of technical file: 80.89%

Annex 7.9 summarises the calculation used to estimate the overall costs of demonstrating compliance as well as its NPVs.

Adopting Option 1 would lead to an average increase in recurring costs between € 2.52 and € 122.37 per year.

Under a basic compliance system, the average yearly increase would be between €2.52 (with voluntary uptake) and €3.07 (with mandatory uptake). Under a full compliance system (including the technical file), the average yearly increase would be between €100.18 (with voluntary uptake) and €122.37 (with mandatory uptake). Thus, the increase in recurring costs is significantly lower in case of adoption of a centralised database with basic compliance.

Table 14-15: Company costs under Option 1

Cost of demonstrating compliance			Total	Company Level
Baseline			€ 842,374,938.53	€ 1,807.41
Option 1: Centralised database	Basic Compliance	Voluntary	€ 843,547,347.54	€ 1,809.93
		Mandatory	€ 843,806,975.92	€ 1,810.48
	Full Compliance	Voluntary	€ 889,067,568.70	€ 1,907.60
		Mandatory	€ 899,407,588.05	€ 1,929.78
Change in cost of demonstrating compliance			**Total**	**Company Level**
Option 1: Centralised database	Basic Compliance	Voluntary	€ 1,172,409.02	€ 2.52
		Mandatory	€ 1,432,037.40	€ 3.07
	Full Compliance	Voluntary	€ 46,692,630.17	€ 100.18
		Mandatory	€ 57,032,649.53	€ 122.37
NPV over 10 years			**Total**	**Company Level**
Option 1: Centralised database	Basic Compliance	Voluntary	€ 10,681,696.35	€ 22.92
		Mandatory	€ 13,047,143.46	€ 27.99

	Full Compliance	Voluntary	€ 525,916,461.60	€ 1,128.41
		Mandatory	€ 642,379,945.77	€ 1,378.30

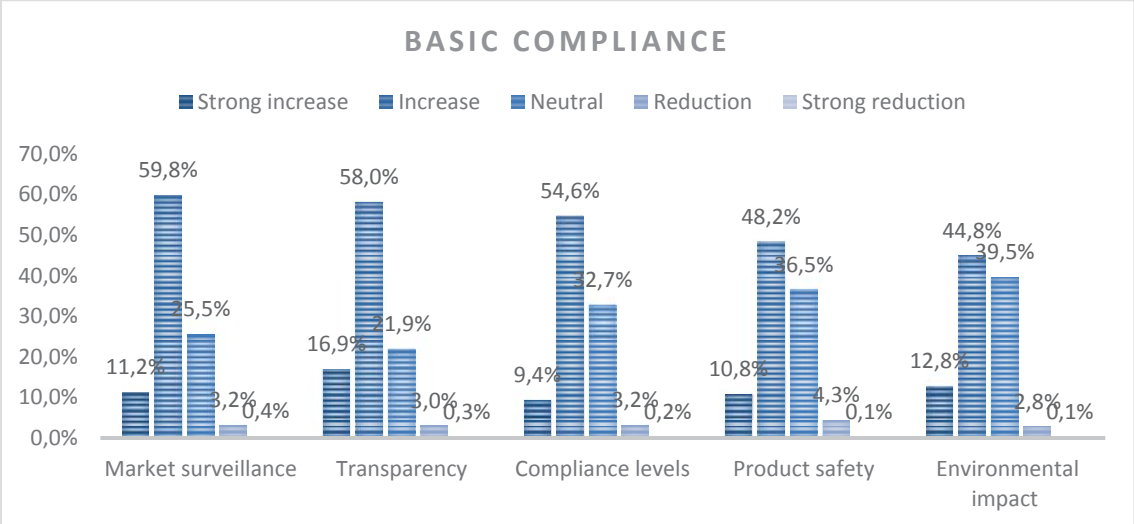
According to stakeholders, given the relatively low number of updates to compliance documentation, micro companies would be unlikely to set up a system to automatically feeddata into a centralised database. As a result, feeding and updating a centralised database would be a more labour-intensive activity for such companies, as compared to Option 2.

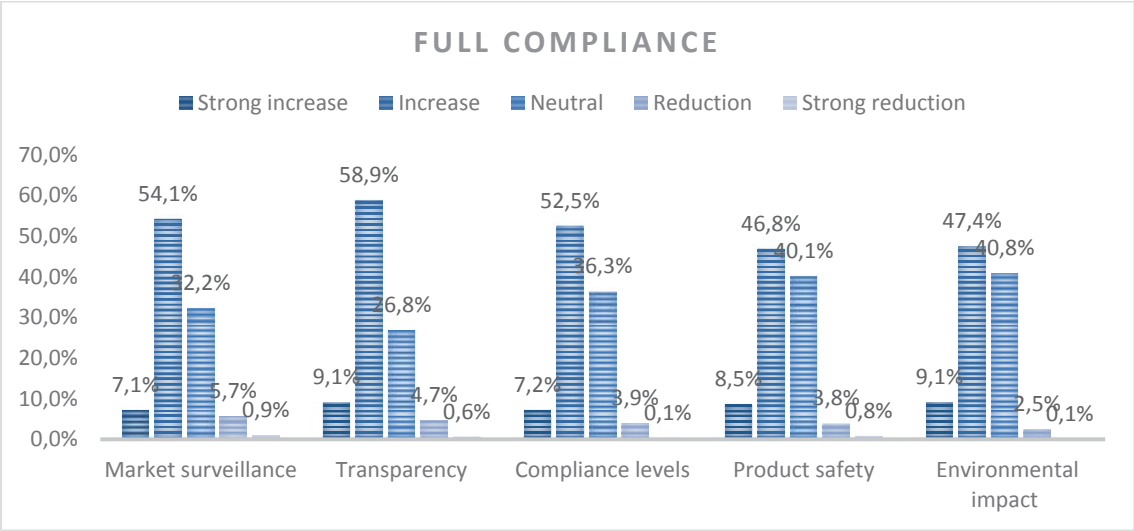
In terms of one-off costs, interviewees where reluctant to provide estimations. Business associations are concerned that big companies would face high one-off cost to adapt their existing compliance software to feed a centralised database. According to business associations big multinational companies invest considerably in setting up compliance software to manage specific and geographically dispersed supply chains that stretch across the European Union and beyond. Feeding a centralised database may require changes in terms of IT structure, IT security and information format. No major one-off costs were highlighted for smaller companies, apart from training costs. Due to security concerns, business associations highlighted that one-off costs would be significantly higher in case of full compliance.

5.5.1.2. Benefits to companies

The figure below shows the key benefits identified by companies as a result of option 1, for both the sub-options with basic and full (i.e. including technical file) compliance. Under basic compliance, improvements are expected by a majority of respondents in terms of market surveillance, transparency, compliance levels, product safety and environmental impacts. Very few respondents (<5% in all cases) expect a negative impact of the option on any of these aspects. The results are very similar for the full compliance scenario (including the technical file) which suggests that companies do not expect much added value from the inclusion of the technical file.

Figure 14-28: Impact of option 1 (basic and full compliance) on benefits of demonstrating compliance





Source: CATI survey, weighted by NACE

5.5.1.3. Costs and benefits to MSAs

For MSAs, the information provided in interviews on costs and benefits was mostly qualitative. The following key conclusions can be drawn:

Overall, MSAs expect that option 1 will increase their costs, including recurring and one-off costs:

1. To introduce a new database will require an increase in the operational budget of the MSA and newly trained personnel to deal with the database and share relevant information with inspectors.

2. In terms of recurring costs, under today's system, the economic operator must provide all the required information in case of an investigation. If they don't do this, the product is judged non-compliant. As mentioned above, requests for information from MSAs are usually quite specific and there is no need to require the full documentation. Under the proposed centralised database, MSAs believe that this would make them responsible for identifying the relevant information in the database themselves. For complex products, this would be very time-consuming and lead to an increase in operating costs.

On the benefits side, the picture for MSAs is rather unclear. The main advantage for MSAs under a compulsory, centralised database including all compliance documents (i.e. with the technical file), is that it **facilitates access to information**[83].

1. While 40% of the MSA interviewed do not believe that a digital system would improve market surveillance from an operational point of view, there may be benefits for the planning of MSA activity (i.e. knowledge of the market, new products, selection of products for investigation, etc.). One MSA noted that there may be lower

83 A similar result could perhaps be reached if a decentralised database is introduced together with an Auto-ID system. See also Section 5.3

risk of non-compliance if the technical file is included in the digital database. Another noted that a digital compliance system could ease access to information.

2. One advantage of the centralised database compared to all other options is the availability of information even if a company does not exist anymore and, compared to paper-based systems, a centralised digital system also has better traceability.

3. If use of the database is compulsory for companies, this would make access to information faster. Indeed, according to one manufacturing association, it currently takes MSAs approximately 6 weeks today to access documentation from economic operators. On the other hand, if the database is not mandatory and if it does not include the technical file then it would be of little use as MSAs would still need to go the manufacturers to access the complete documentation.

4. Finally, MSAs suggested that, while the centralised database should include the technical file, this should only be accessible to the MSA. However, all other documents for demonstrating compliance should be accessible to other companies as well since they do not contain any confidential information and access by competitors may lead to a level of "self-policing" and therefore greater compliance.

5.5.2. Option 2: decentralised database

Under option 2, each manufacturer, importer or distributor would be responsible for uploading information regarding the conformity of a product with the applicable legislation to a website developed and maintained by the company. Notified Bodies and market surveillance authorities would be able to access this information.

As for Option 1, the simulation in Section 5.5.2.1 assumes, first, that the decentralised digital compliance procedure becomes the mandatory and only way to demonstrate compliance, thus eliminating the current paper based approach and any national databases or repositories of information regarding certificates of conformity. A separate simulation assuming a voluntary decentralised database is provided alongside the mandatory option.

5.5.2.1. Costs to companies

As shown in the figure below, **most economic operators do not think that there will be considerable additional costs for basic compliance under Option 2**. Under basic compliance about 30% of respondents expected a cost increase (compared with only 25.4% in option 1), versus 43.6% if the technical file were included in the option (similar to the result under option 1). The vast majority of respondents do not expect option 2 to lead to a reduction in costs under either the full or basic scenarios. However, a significant share of respondents perceives greater additional costs under the full compliance option.

As for Option 1, a number of elements should be taken into account in the design of the option:

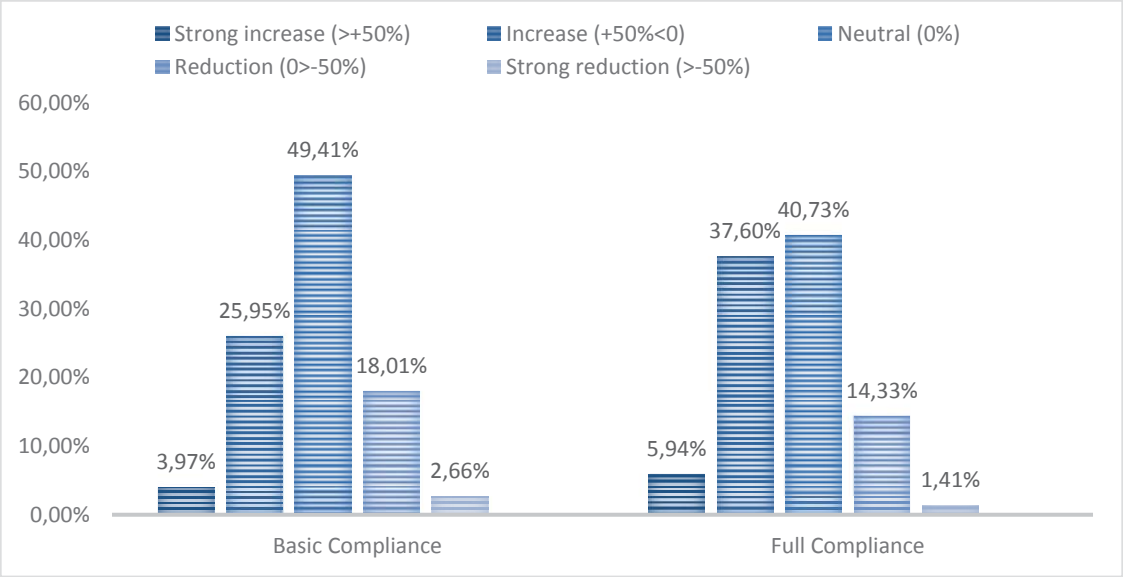
1. There would be a one-off setup cost to create an in-house database with electronic versions of the documents to be uploaded.

2. However, this one-off cost would be lower as compared to Option 1 (according to interviews) since each company would have greater control and knowledge over their own IT system and there would be no compatibility issues.

3. Overall, costs would be higher if the digital decentralised database were to include the technical file. Indeed, as for option 1, manufacturers and manufacturers association were unanimous in opposing full compliance including the technical file due to the confidential nature of the data included in that file.

4. Indeed, interviews suggested that such security risks would be even higher under Option 2 than under Option 1, since access would have to be granted to the MSAs and the full compliance version of option 2 seems to assume that either the technical file would be publicly available or that it would be made available via a restricted account to the MSA which would carry further costs for both companies and the MSA.

Figure 14-29: Option 2 – change in cost of demonstrating compliance



Source: CATI survey, weighted by NACE code

The table below breaks down the above results to estimate the change in the cost of demonstrating compliance by company size.

Unlike under option 1, companies of all sizes expect, on average, a cost increase under option 2 with the largest increases expected by micro-companies (5.64%) and the lowest increases among larger companies (0.79%-1.90% for medium and large companies respectively). It should be noted that the **estimated costs for micro -companies (the largest enterprise population) are lower under this option than under Option 1 and there is almost no difference between the options for large companies.** However, there is unanimity among companies of all sizes that including the technical file would lead to a significant increase in the costs of demonstrating compliance of between 6% (large and medium size companies) and 12% (micro companies).

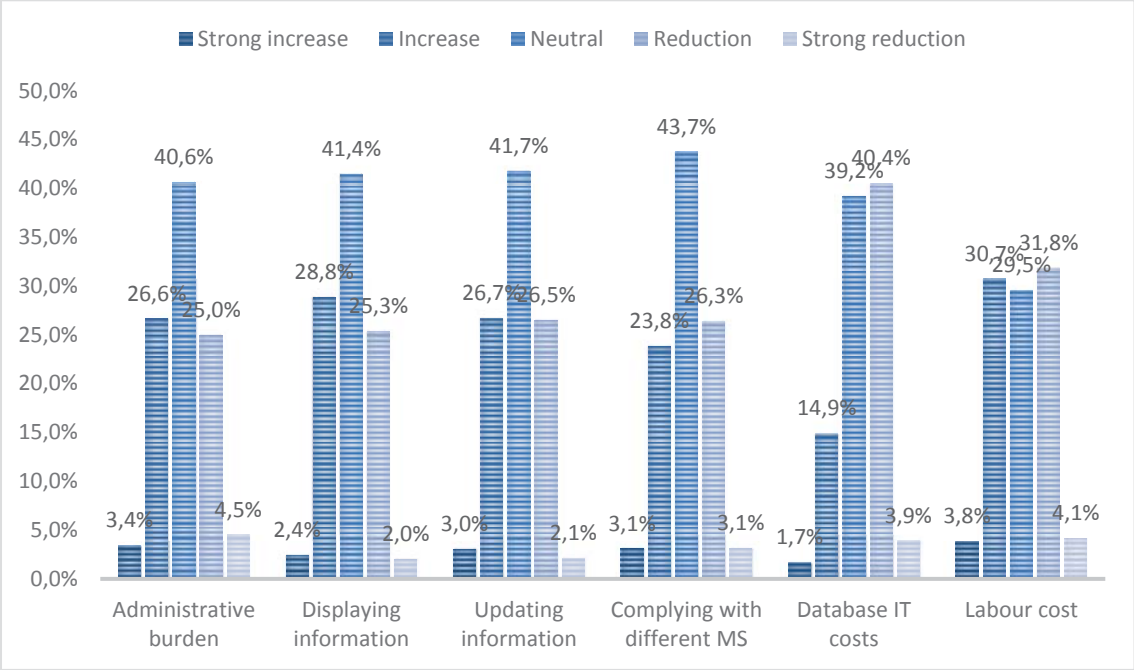
Table 14-16: Estimated change in cost of demonstrating compliance per sector, per company size

	Basic	Full
Size	**%**	**%**
Large	1.90%	6.53%
Medium	0.79%	6.28%
Small	2.89%	8.43%
Micro	5.64%	12.27%
TOTAL	**2.64%**	**8.08%**

Source: CATI survey, weighted by NACE code

The figure below provides a further breakdown of the kinds of costs that are likely to change under option 2. The results here are very similar to option 1 in that the key cost categories where increases are expected are administrative burden, displaying and updating information. In contrast, reductions in costs are expected primarily in database / IT costs. The impact of this option on labour costs is balanced between those who expect a reduction in costs, those who expect an increase and those who expect the option not to lead to any change in this type of costs.

Figure 14-30: Key cost impacts as a result of Option 2 (basic compliance)



Source: CATI survey, weighted by NACE code

Like for option 1, in order to arrive at a monetary cost estimate, we assume that all companies which comply with Union harmonisation legislation under the paper based approach would continue to do so under a decentralised digital compliance procedure. Taking the median cost increase under each of the options, it can be estimate that the total additional cost of Option 2 would be as shown in the table below. Starting from the baseline calculated in section 5.3.4.1 to estimate the costs of Option 2 we consider:

- Estimated percentage change in cost of demonstrating compliance
    - Basic compliance: 2.64%
    - Full compliance: 8.08%
- Voluntary uptake: 74.65%
- Incidence technical file: 80.89%

Annex 7.9 summarises the calculation used to estimate the overall costs of demonstrating compliance as well as its NPVs.

Adopting Option 2 would lead to an average increase in recurring costs of demonstrating compliance between € 39.06 and € 118.13 per year.

Under a basic compliance system, the average yearly increase would be between € 39.06 (with voluntary uptake) and € 47.72 (with mandatory uptake). Under a full compliance system, the average yearly increase would be between € 96.71 (with voluntary uptake) and € 118.13 (with mandatory uptake). The increase in recurring costs is lower in case of adoption of a decentralised database with basic compliance.

Table 14-17: Company costs under Option 2

Cost of demonstrating compliance			Total	Company Level
Baseline			€ 842,374,938.53	€ 1,807.41
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 858,976,126.87	€ 1,846.48
		Mandatory	€ 864,613,636.91	€ 1,855.13
	Full Compliance	Voluntary	€ 883,474,696.33	€ 1,904.13
		Mandatory	€ 897,431,546.43	€ 1,925.54
Change in cost of demonstrating compliance			**Total**	**Company Level**
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 16,601,188.34	€ 39.06
		Mandatory	€ 22,238,698.38	€ 47.72
	Full Compliance	Voluntary	€ 41,099,757.80	€ 96.71
		Mandatory	€ 55,056,607.91	€ 118.13
NPV			**Total**	**Company Level**
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 151,251,696.77	€ 355.92
		Mandatory	€ 202,614,463.18	€ 434.73
	Full Compliance	Voluntary	€ 374,455,609.88	€ 881.14
		Mandatory	€ 501,615,016.59	€ 1,076.27

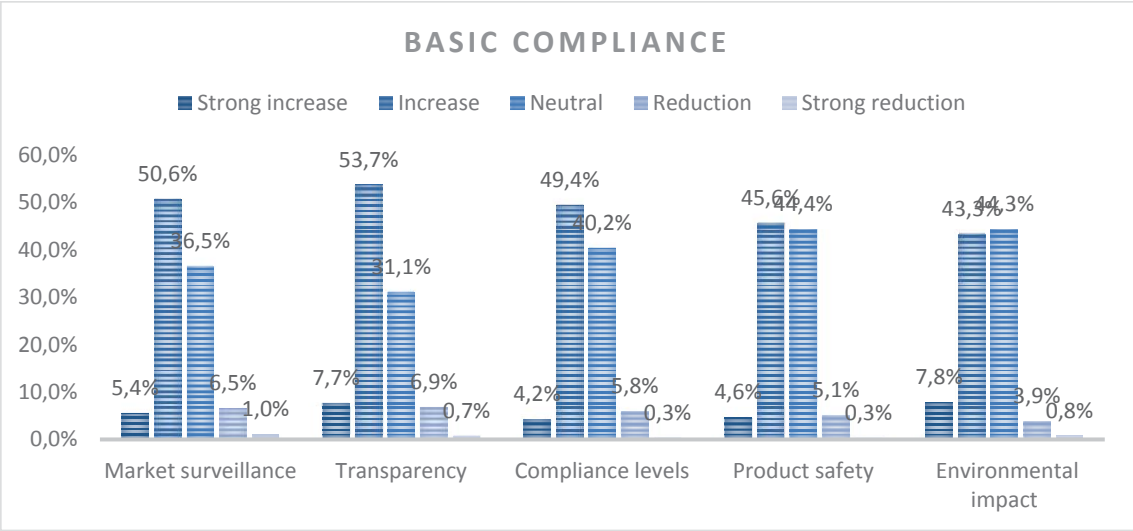
In terms of one-off costs, interviewees were reluctant to provide estimations. Business associations are concerned that small companies would face higher one-off cost when no pre-existing IT structure was set up – even though micro companies estimated the cost of this option to be lower than that of Option 1. Large companies instead, could create profiles for the authorities to allow them limited access to pre-existing databases which are already in use internally. As for Option 1, due to security concerns, business associations highlighted that one-off costs would be higher in case of full compliance.

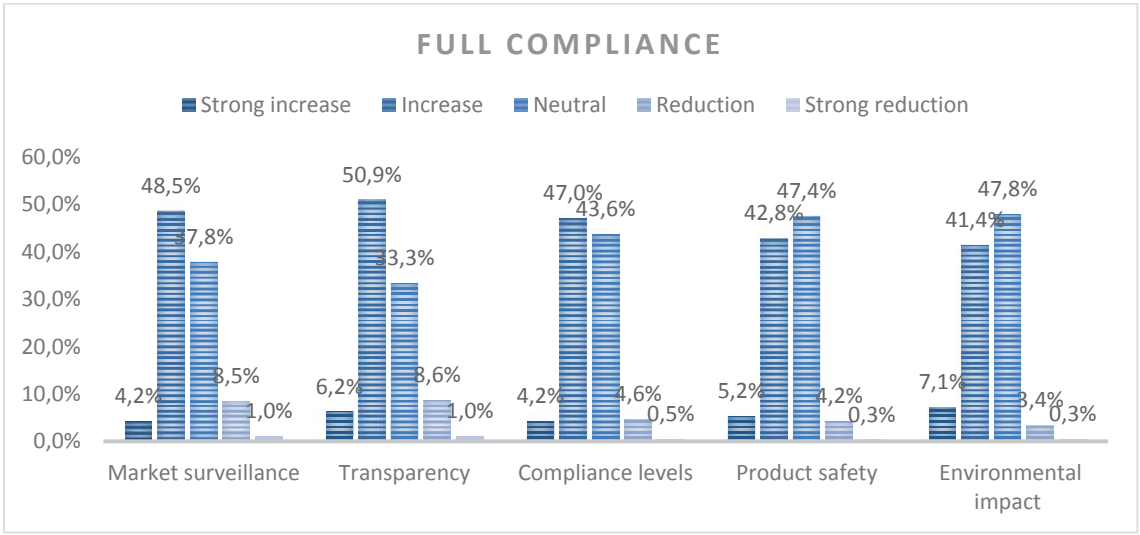
5.5.2.2. Benefits to companies

The figure below shows the key benefits identified by companies as a result of option 2, for both the sub-options with basic and full (i.e. including technical file) compliance. Like for option 1, under basic and full compliance, improvements are expected by a majority of respondents in terms of market surveillance, transparency, compliance levels, product safety and environmental impacts. While very few respondents expect a negative impact of the option on any of these aspects, the results are – on the whole – slightly less positive than they were for option 1. Like for option 1, the results are relatively similar for the full compliance

scenario (including the technical file) which suggests that companies do not expect much added value from the inclusion of the technical file.

Figure 14-31: Impact of option 2 (basic and full compliance) on benefits of demonstrating compliance





Source: CATI survey, weighted by NACE code

5.5.2.3. Costs and benefits to MSAs

With regard to this option there are likely to be very few costs or benefits for MSAs.

This is because a decentralised database would effectively still require MSAs to contact the company to retrieve the relevant documents and to point to the answer to the MSA's specific request within the documents on the manufacturer's website.

This would be even more the case if option 2 was voluntary, since the lack of completeness and the uncertainty regarding whether the documents on the manufacturer's website are fully

updated would further reduce the incentive for MSAs to try and find the desired compliance information on the company website before contacting the manufacturer directly.

As a result, from the MSA's perspective this option would impose potential additional burdens on companies (i.e. creation of a website and uploading of documents in electronic form) without any benefits in terms of time saved during investigations by the MSA.

However, one MSA pointed out that the use of an Auto-ID or e-labelling system could have a significant impact on the costs and benefits of this option from an MSA's perspective since it would greatly facilitate access to relevant and updated information. Introduction of Auto-ID and the potential use of e-labelling for devices with a screen is examined further in the next section.

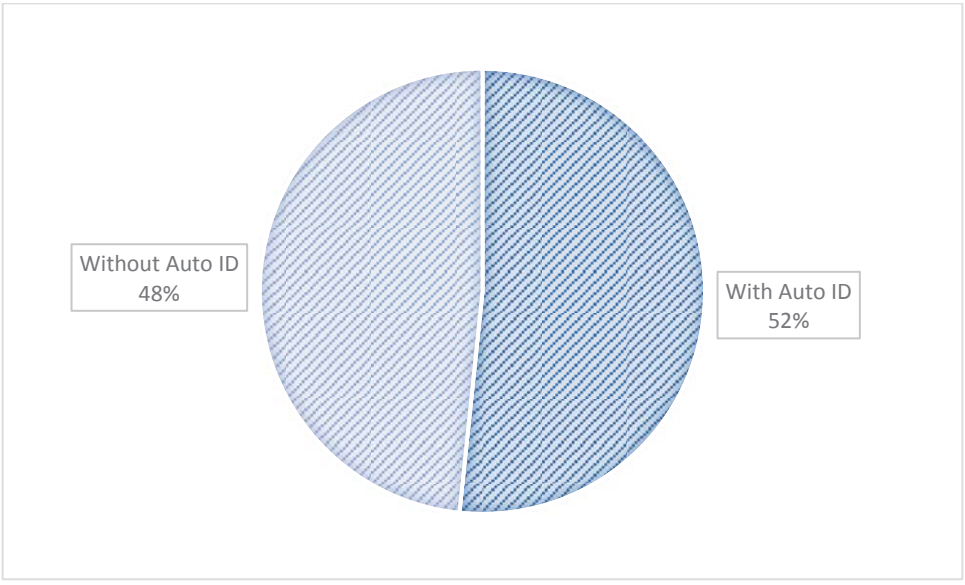
5.5.3. Auto ID and E-labelling

5.5.3.1. Auto ID

Auto ID refers to the method of automatically identifying objects, collecting data about them, and entering them directly into computer systems, without human involvement. Because the process is automated, information is gathered quickly and accurately. The most common technologies used to identify and capture data are barcodes, QR codes, Radio Frequency Identification, smart cards and magnetic stripes.

The technology finds a multitude of applications and it is often used to optimise logistics and supply chain. As a result, according to the CATI survey respondents, **about half of the firms interviewed, stated to currently produce, distribute and import at least one item in their product portfolio already equipped with an automatic identification tag** as shown in the figure below.

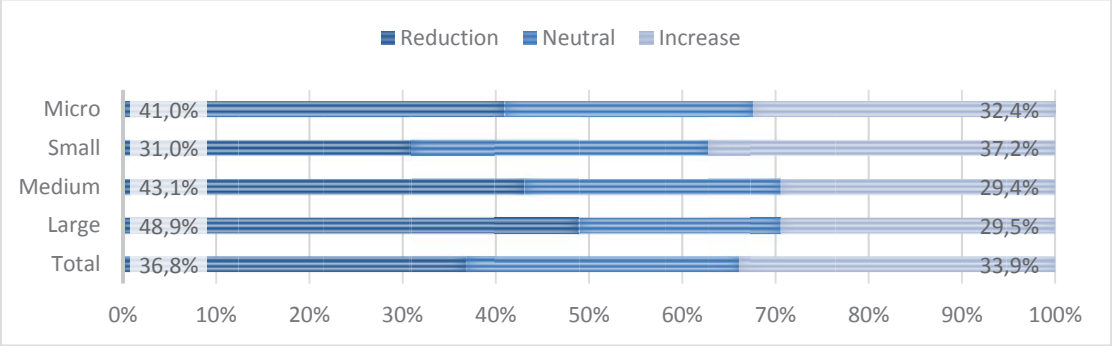
Figure 14-32: Firms currently producing/importing/distributing at least one item equipped with an automatic identification tag



Source: CATI survey, weighted by NACE code

Figure 14-33 summarizes the change in the cost of demonstrating compliance expected by companies if Auto ID technologies were included in the procedure for demonstrating compliance digitally. The overall opinion is fragmented with slightly more than one third of respondents expecting a reduction in cost, about one third expecting an increase and about one third not expecting much change at all. The reason behind this fragmentation may be due to the different impact that the sub-option would have on the different options.

Figure 14-33: Auto ID - change in cost of demonstrating compliance, by size



Source: CATI survey, weighted by NACE code

According to the interviews, stakeholders expect **Auto ID to be particularly useful in case of a decentralised digital compliance system**, since it could contain information on the exact URL where stakeholders can find compliance documentation on the manufacturer's website. For example, producers could add a QR code on the product that stakeholders could use to directly access the appropriate URL on the producer website. In case of Option 1 where information would be stored centrally, there would be little additional benefit from Auto-ID. There were no differences in the impact of Auto ID technologies under full/basic compliance or in terms of the mandatory/voluntary uptake of the different options.

The main benefits identified in the use of Auto-ID technologies are:

- Rapid and accurate identification of items by custom duty, notified bodies, market surveillance authority and consumers
- Potential support in addressing counterfeiting more efficiently
- Effective management of product recalls for manufacturers, distributors and resellers (outside the scope of this study).

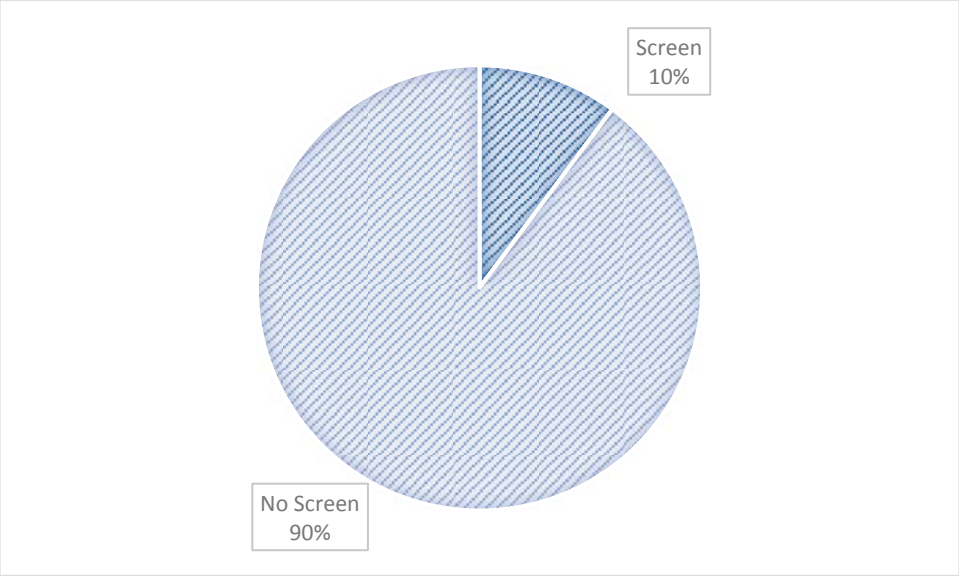
5.5.3.2. E-labelling

E-labelling refers to displaying compliance information in the integral screen of the product (if the product has a screen), whereby no access code or permissions should be required for accessing all the information needed to demonstrate compliance. The information would have to be accessible in no more than three steps in a device's menu.

At the moment, the only legislative EU instrument that provides for e-labelling is Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28). It establishes the conditions under which the instructions for use of medical devices may be provided in electronic form instead of in paper form. It also establishes certain requirements concerning instructions for use in electronic form which are provided in addition to complete instructions for use in paper form relating to their contents and websites. For specific medical devices, the provision of instructions for use in electronic form instead of in paper form can be beneficial for professional users. It can reduce the environmental burden and improve the competitiveness of the medical devices industry by reducing costs, while maintaining or improving the level of safety.

By definition, the use of an e-labelling system would only impact products that contain a screen (computer, smartphone, tablet, etc.). According to the CATI survey, 10%[84] of respondents across all sectors, stated that within their product portfolio they produce, distribute or import electronic devices with a screen that could display information digitally on the screen rather than on a label affixed to the device.

Figure 14-34: Firms currently producing/importing/distributing at least one item currently equipped with a screen

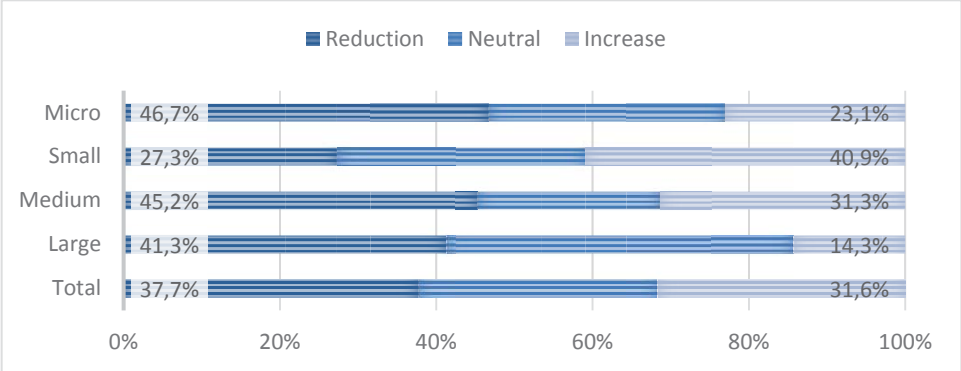


Source: CATI survey, weighted by NACE code

Figure 14-35 summarizes the change in the cost of demonstrating compliance expected by companies in case e-labelling technologies were introduced alongside the main options under consideration. Regardless of company size, the majority of companies believe e-labelling to reduce or have a neutral effect in terms of costs. The benefit seems to be higher for large, medium and micro companies and somewhat smaller for small companies (though this may simply be due to the sector/size make-up of the CATI sample). According to the interviews, stakeholders believe that the impact of e-labelling would be the similar across all options and sub-options.

84 Data weighted by NACE code

Figure 14-35: E-labelling - change in cost of demonstrating compliance, by size



Source: CATI survey, weighted by NACE code

The advantage of E-labelling in terms of costs is not clear, nevertheless during the interviews potential advantages were highlighted:

- E-labelling can include a greater amount of information than regular labels. This would give the possibility to certain companies to display a greater amount of information than today, such as the contacts of the different national offices.
- Reduction in paper used for labelling and manuals.
- Information could be provided in all the official languages avoiding logistical barriers that arise today.
- Possibility (for products that can be updated remotely) to avoid recalls associated with incorrect label information

5.5.4. Options comparison

5.5.4.1. Cost comparison

Following the methodology highlighted in section 5.5.1.1 and 5.5.2.1, Table 14-18 summarises the costs of demonstrating compliance for companies under Option 1 and 2. For all options we observe an increase in costs compared to the baseline. Cost increases are sensibly higher in case of full compliance both for Option 1 and 2 (more than € 100 a year at company level), with Option 1 being slightly higher than Option 2.

With basic compliance, the estimated cost of a centralised database (Option 1) is lower than for a decentralised one (Option 2). At company level, the yearly cost of Option 1 with basic compliance is € 3 or less, while with Option 2 with basic compliance the price goes up to € 39 – 47. Between voluntary and mandatory uptake there is no significant difference on a per company basis though the total cost of the option would be lower since a smaller percentage of the population would incur the cost of switching to the digital compliance demonstration procedure.

Nevertheless, it is important to consider, as mentioned before, that micro companies would be unlikely to set up an automatic feeding of data into a centralised database, given the relatively low number of updates to compliance documentation required from them. As a result, as

described in section 5.5.1.1, feeding and updating a centralised database would be a more labour-intensive and costly activity for micro companies compared with Option 2.

Table 14-18: Cost of demonstrating compliance to companies (Cost comparison)

Cost of demonstrating compliance			Total	Company Level
Baseline			€ 842,374,938.53	€ 1,807.41
Option 1: Centralised database	Basic Compliance	Voluntary	€ 843,547,347.54	€ 1,809.93
		Mandatory	€ 843,806,975.92	€ 1,810.48
	Full Compliance	Voluntary	€ 889,067,568.70	€ 1,907.60
		Mandatory	€ 899,407,588.05	€ 1,929.78
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 858,976,126.87	€ 1,846.48
		Mandatory	€ 864,613,636.91	€ 1,855.13
	Full Compliance	Voluntary	€ 883,474,696.33	€ 1,904.13
		Mandatory	€ 897,431,546.43	€ 1,925.54
Change in cost of demonstrating compliance			**Total**	**Company Level**
Option 1: Centralised database	Basic Compliance	Voluntary	€ 1,172,409.02	€ 2.52
		Mandatory	€ 1,432,037.40	€ 3.07
	Full Compliance	Voluntary	€ 46,692,630.17	€ 100.18
		Mandatory	€ 57,032,649.53	€ 122.37
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 16,601,188.34	€ 39.06
		Mandatory	€ 22,238,698.38	€ 47.72
	Full Compliance	Voluntary	€ 41,099,757.80	€ 96.71
		Mandatory	€ 55,056,607.91	€ 118.13

Table 14-19 summarizes the NPV of the costs of demonstrating compliance to companies under Option 1 and 2. The NPV is calculated based on a 10-year period and a social discount rate of 4%, as suggested by the European Commission Better Regulation "Toolbox"[85].

$$NPV = \sum_{t=0}^{T} \frac{(B_t - C_t)}{(1+r)^t}$$

Where:

85 http://ec.europa.eu/smart-regulation/guidelines/toc_tool_en.htm

B_t = benefits in Euros received in year *t*

C_t = costs in Euros received in year *t*

r = discount rate

Table 14-19: Net Present Value of the different options (cost to companies)

NPV			Total	Company Level
Option 1: Centralised database	Basic Compliance	Voluntary	€ 10,681,696.35	€ 22.92
		Mandatory	€ 13,047,143.46	€ 27.99
	Full Compliance	Voluntary	€ 425,411,687.11	€ 912.77
		Mandatory	€ 519,618,525.85	€ 1,114.90
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 151,251,696.77	€ 355.92
		Mandatory	€ 202,614,463.18	€ 434.73
	Full Compliance	Voluntary	€ 374,455,609.88	€ 881.14
		Mandatory	€ 501,615,016.59	€ 1,076.27

According to business associations, one off costs are always higher in case of full compliance due to security concerns, while there is no apparent difference in one off costs between the voluntary/mandatory sub-options (except that these costs would only be incurred by those companies that take up the option in the voluntary scenario).

As described in section 5.5.1.1 and 5.5.2.1, one off costs are higher for larger companies in the case of Option 1 due to need to adapt company IT systems to be compatible with the centralised database, while they can potentially affect more smaller businesses in the case of Option 2 due to the need for each business to set up its own IT system.

From the European Commission perspective, the introduction of a centralised database would be costlier, both in terms of recurring and one-off costs since the Commission would need to set up the database, maintain it, ensure security as well as provide assurance that documents available on the database are fully up to date. Under full compliance (i.e. with the technical file), the centralised database option would be even costlier due to security concerns.

Furthermore, both the centralised and decentralised database options would effectively still require MSAs to contact the company to retrieve the relevant documents and to assist the MSA in identifying the answer to the its specific query within the compliance documents.

This would be even more the case if the option was voluntary, since lack of completeness and uncertainty regarding whether the documents on the manufacturer's website are fully updated would further reduce the incentive for MSAs to try and find the desired compliance information on the company website (or in a centralised database) before contacting the manufacturer directly.

Furthermore, for MSAs the introduction of a new centralised database would require an increase in the operational budget and newly trained personnel to deal with the database and share relevant information with inspectors. However, one MSA pointed out that the use of an Auto-ID or e-labelling system could potentially have a significant impact on the costs and benefits of option 2 from the authority's perspective since it would greatly facilitate access to relevant and updated information.

5.5.4.2. Benefits comparison

Table 14-20 visually compares the benefits highlighted in section 5.5.1.2 and 5.5.2.2, as well as the inputs received from the interviews conducted with MSAs and industry representatives. While it was not possible to quantify the magnitude of the benefits generated by the proposed options (because those benefits are – for the most part – not quantifiable), the table compares the different options with one another to identify which option would lead to the greatest benefits. For companies, due to the use of a structured survey questionnaire in the CATI with 1700 companies across the sectors within scope, it was possible to quantify the benefits (though not to monetise them). For each option, the estimate is the sum of the average benefits estimated for each category of potential benefits included in the survey questionnaire (i.e. access to information; transparency; compliance levels, etc.). Each response was code using a Likert scale from -2 (strongly negative) to +2 (strongly positive). The first result is that, even for companies, all proposed options have a overall positive impact on the types of potential benefits that were investigated. Furthermore, Option 1 scores higher than Option 2 and in both cases companies declared that introducing a basic compliance system would have greater benefits for them than a system that also includes the technical file.

Option 1 (centralised database) improves access to information as well as transparency of that information under both the basic and full compliance scenarios. Option 2 also improves access to information as well as transparency, but to a smaller extent. The difference between the two options is highlighted both by the CATI survey, as well as by the interviews. According to MSAs, if compliance information is not centralised it might be harder to access and monitor it, even though the use of Auto ID technology could fill this gap. Decentralised data are also harder to compare and analyse since they might be stored using different data formats. Furthermore, in the case of a decentralised database with full compliance, the commercial sensitivity of the technical file would require strict access limitations which would lower the benefit in terms of ease of access to information and transparency.

Finally, according to companies and MSAs both Option 1 and 2 could have a small benefit in terms of compliance levels, product safety and environmental impact.

For all categories of benefits, the voluntary sub-option would reduce the overall impact of the proposed option.

- For access to information and transparency, the reduction is due to lack of comprehensive and reliable information that is fully updated.

- For compliance levels and product safety, the reduction is due to the fact that companies that fail to comply or do not respect product safety regulation would be less likely to switch to a digital compliance procedure.

- The lower environmental impact is explained by the lower share of companies adopting a digital procedure for demonstrating compliance.

Table 14-20: Benefits comparison, assuming adoption of Auto ID

Benefits comparison			Access to information	Transparency	Compliance levels	Product safety	Environmental impact	Overall estimate of benefits according to companies
			Interviews with MSA, Notified bodies and industry representatives					*CATI company survey**
Option 1: Centralised database	Basic Compliance	Voluntary	**	**	**0**	**0**	*	2.47
		Mandatory	***	***	*	*	**	
	Full Compliance	Voluntary	**	**	**0**	**0**	*	2.06
		Mandatory	***	***	*	*	**	
Option 2: Decentralised database	Basic Compliance	Voluntary	**	**	**0**	**0**	*	1.48
		Mandatory	***	***	*	*	**	
	Full Compliance	Voluntary	**	**	**0**	**0**	*	1.18
		Mandatory	*	*	*	*	**	

Note: * the quantitative estimate is based on the average across all categories of benefits and for all companies. It ranges from -2 (strongly negative impact) to +2 (strongly positive impact)

5.5.4.3. Conclusions of options comparison

The table below shows the comparison between cost and benefits according to companies. It is important to highlight that the cost structure does not include one off costs, which could potentially alter the outcome.

The results show that based purely on the responses of companies consulted in the CATI survey, the centralised database with basic a compliance solution (i.e. without the technical file) would bring the highest benefit per euro cost. Including the technical file in the option would, in turn lead to a much worse return in the perception of businesses.

Overall, Option 1 and Option 2 under basic compliance present the best cost/benefit ratio, with Option 1 Basic being overall the cheapest. Consistent with the quantitative results below, the "basic compliance" option is far less costly than "full compliance" including the technical file.

It is important to highlight that the results below are driven by the recurring cost differential between the options for companies. The comparison does not take into account one -off costs or the costs and benefits for other stakeholders (Commission, MSAs, notified bodies, and customs bodies).

Table 14-21: Cost-benefit comparison (company perspective)

NPV		NPV Company Level (based on the mandatory option)	Overall estimated benefits of the option for companies	Overall assessment (i.e. Benefit/cost)
Option 1: Centralised database	**Basic Compliance**	**€ 27.99**	**2.47**	**0.08825**
	Full Compliance	€ 1,114.90	2.06	0.00185
Option 2: Decentralised database	Basic Compliance	€ 434.73	1.48	0.00340
	Full Compliance	€ 1,076.27	1.18	0.00110

The above quantitative conclusions only cover the perceptions of companies. For the full options appraisal, one-off costs and the input of other stakeholders, which was mostly qualitative, need to be considered alongside that of companies.

According to the qualitative data collected, **one off costs are potentially higher for large companies under Option 1 and potentially higher for micro companies under Option 2**. Large companies tend to have more complex and globalised supply chains for their production process. Technological products can sometimes be made-up of more than a thousand different components produced worldwide. This results in large enterprises developing different tools, software, and procedures to manage complexity and ensure compliance. In order to automatically feed a centralised database, large companies would have to sustain a significant one-off adaptation costs to ensure safe data transmission in the correct format. Large companies would also have to initially invest to mitigate any security risk as a result of feeding an external database. Companies and sector representatives agreed that to set up and to manage a decentralised database would be cheaper for large companies as it would be easier to adapt it to today's procedures. On the contrary, micro companies do not usually have complex procedures to demonstrate compliance and they lack complex pre-existing structures (IT, management of global supply chains and internal procedures). In this case a decentralised database system could imply higher one off-costs due to the need to set up an internal database which did not exist before.

According to the qualitative data collected, **ongoing costs are expected to be lower for micro companies under Option 2 than under Option 1**. Given the lower number of updates to compliance documentation, micro companies would be unlikely to set up a system to automatically feed data into a centralised database. As a result, feeding and updating a centralised database would be a more labour-intensive activity for micro companies compared to updating the decentralised database under Option 2. As a result, ongoing costs for micro companies are expected to be lower under Option 2.

One off and recurring costs would be higher for the European Commission under Option 1 (a centralised database managed by the Commission). From the perspective of the European Commission, the introduction of a centralised database would be costlier, both in terms of recurring and one-off costs, since the Commission would need to set up the database, maintain it, ensure its security, as well as to provide assurance that documents available on the database are fully up to date. Under full compliance (i.e. with the technical

file), the centralised database option would be even costlier due to security concerns. The Commission's involvement in database management is not foreseen under Option 2.

According to MSAs, both a centralised and a decentralised database would effectively still require them to contact the company to retrieve the relevant documents and to point to the answer to the MSA's specific request, regardless of the level of compliance (full/basic). As of today, companies have to reply to specific MSA' requests. Even if provided with the technical documentation, it would be very expensive for MSAs to retrieve specific information without the involvement of the manufacturing companies.

Both MSAs and manufacturers agreed that the MSA's cost of accessing data under a decentralised system would be lower if Auto ID technology was combined with the digitisation of the process for demonstrating compliance.

As a result of the above considerations, option 2 (decentralised database) with basic compliance supported by Auto-ID technology emerges as the most desirable option.

5.5.5. Competitiveness analysis

According to the Better Regulation toolbox (Tool #17)[86], EU initiatives are likely to impact competitiveness when they affect at least one of the following:

- A sector's capacity to produce products at a lower cost and/or offer them at a more competitive price (cost/price competitiveness). The cost of an enterprise's operations includes the cost of inputs (including resources and energy) and production factors which may be directly or indirectly affected by the policy proposal;

- The quality or the originality of a sector's supply of goods or services (innovative competitiveness) - technological development and innovation (of products and/or processes) are of primary importance for both the cost of inputs and the value of outputs;

- Effective market competition and undistorted access to markets including inputs and materials, public procurement, etc.;

- The sector's market shares on international markets.

In order to measure the extent to which an initiative affects competitiveness three aspects therefore need to be considered:

- **Cost competitiveness** (i.e. the extent to which a proposal affects competitiveness by raising costs for some companies but not for others)

- **Innovation competitiveness** (i.e. the extent to which a proposal affects the propensity of / the likelihood of success of innovation among some companies but not others)

- **International competitiveness** (i.e. the extent to which a proposal affects the ability of European companies to compete with non-European companies)

86 http://ec.europa.eu/smart-regulation/guidelines/tool_17_en.htm

What is important to keep in mind when assessing competitiveness (and what makes it different from the cost benefit analysis above) is its focus on systematic *differences* in costs and benefits across different groups of companies rather than the focus on the *level* of costs and benefits that forms the core of the cost-benefit assessment.

Cost competitiveness

As reported in section 5.5.1.1, 5.5.2.1 and summarised in the table below, the options could affect cost competitiveness because they impact companies differently depending on their size. Overall, micro companies tend to be the most affected by changes in compliance demonstration procedures If the proposed options do raise costs for the smallest companies more than they do for larger firms (as shown in Section 5.5.1.1 and 5.5.2.1) then this will result in a deterioration of cost competitiveness for the smallest companies.

At the same time, the cost impacts identified in this report are not likely to be significant enough to substantially alter the market position of companies depending on their size. Furthermore, in the longer term, the benefits of digitisation would accrue faster to smaller firms if they adopt these tools now rather than only in the future. Finally, it has also been argued that one off costs for large companies could be very high (e.g. for option 1, the centralised database) due to the need for such a database to be interrogable with the compliance management software that larger companies have already invested in.

On the whole, therefore, this report concludes that cost competitiveness implications of the proposed initiatives would **not be significant.**

International competitiveness

In terms of international competitiveness, since the new procedures on demonstrating compliance would apply to European manufacturers, distributors and importers of products from outside the EU, there would not be an international impact. It would be expected that any costs in terms of demonstrating compliance (minimal though they might be) would be passed on by importers to foreign manufacturers. However, for European companies that sell their products both in the EU and in third countries, recurrent and one-off costs to switch to a digital procedure for demonstrating compliance would put them at a disadvantage compared to local manufacturers in third countries which do not sell into the EU. However, given the limited magnitude of costs estimated under all of the options in this report, any such disadvantage would **not be significant.**

Innovation competitiveness

No innovation competitiveness impacts are expected under any of the options since these are unlikely to lead to fundamental changes to products that are currently on the market.

5.6. Conclusions and recommendations

5.6.1. Conclusions

The analysis presented in this report has led to the following conclusions:

- Most companies (86.6%) in the sectors concerned by Union harmonisation legislation do demonstrate compliance via technical product documentation, the declaration of conformity or product traceability.

- About half of companies (41%) in the relevant sectors in Europe are subject to a market surveillance inspection every 5 years and about 38.2% indicated that they already use digital means for demonstrating compliance (e.g. exchanging documents with MSAs electronically) – though there are large differences across countries.

- The overall costs of demonstrating compliance are significant at €1,807.41 per company or over €800 million per year on average across the EU economy.

- More than half of companies believe these costs to be "high" or "very high" and more than 69% think a digital system for demonstrating compliance would be an improvement, compared with only about 10% who think such a system would be worse than the current one.

- Both the proposed options are unlikely to lead to very significant changes in the cost of demonstrating compliance for companies, especially if the basic sub-option (without the technical file) is chosen.

    - In terms of recurring costs:

        - Option 2 is the least costly for micro-companies, the largest share of the enterprise population under study

        - Option 1 is the least costly for large companies – though the difference between the options is not very significant for these larger companies

    - In terms of one-off costs:

        - Smaller companies may incur initial set-up costs to develop an in-house compliance demonstration database under option 2.

        - Larger companies would incur initial costs to ensure interoperability between their existing in-house regulatory compliance systems and that of the centralised database under option 1.

- From the Commission's perspective, there would be additional costs under option 1 (centralised database) assuming this database would be managed by the Commission. There would be no additional costs under option 2 (decentralised database).

- There is strong opposition from companies to including the technical file in any digital system due to confidentiality and security concerns.

- If the technical file were included in the proposed options, these cost increases would be significantly higher due to the complexity of the document and its sensitive nature.

- If the options were made **voluntary**, a large share of respondents indicate that they would take up the digital procedure for demonstrating compliance (excluding the technical file) (82% for option 1 and 75% for option 2).

- On the **benefits** side, for MSAs a mandatory centralised database could facilitate and speed up access to information, especially regarding traceability (e.g. for companies that do not exist anymore). Such a centralised databased would also support the exchange of information with MSAs in other countries, which is currently a source of frustration and delay.

- However, benefits would be limited by the fact that MSAs usually need to contact the manufacturer directly with very specific requests and questions and this would still be required under a digital system which only makes full documents available.

- In addition, the digital system would only be useful to MSAs if it was complete and always up to date which would not be the case under the voluntary sub-option.

- **Auto-ID** technology would help improve a decentralised database system, since allows to rapidly and accurately identify data stored in a decentralised structure. 52% of companies in the sectors covered by Union harmonisation legislation already include an automatic identification tag.

- In combination with Auto-ID technology the decentralised database option (option 2) would offer similar access to information for MSAs as the centralised database.

- Finally, **e-labelling** can help increase the amount of information compared to regular labels and can help improve logistics (since it can store more languages than regular labels). However, it would only apply to about 10% of companies in the sectors covered by Union harmonization legislation.

5.6.2. Recommendations

Considering the high cost of full compliance (i.e. including the technical file) under both options, significant initial set-up costs especially for the smallest companies under the centralised database (option 1), and possible compatibility difficulties in feeding such a centralised database (option 1), the results of the study suggest that the **decentralised database for basic compliance** would be the best option among those considered in this assessment.

The fact that this option exhibits somewhat higher recurring costs for larger companies is counterbalanced by the fact that it is less costly for the largest group of companies (micro-businesses) and the lower costs for the Commission which does not need to be involved in database management under this option. From the perspective of MSAs there is little difference in the costs of option 1 and 2 (or the benefits assuming the option is supplemented by the adoption of Auto-ID technology).

Furthermore, introduction of **Auto ID technology** could greatly help the adoption of such a decentralised database for basic compliance, since it would improve speed and ease of access to information for authorities.

While the full benefits of this option would only materialise under the mandatory scenario (i.e. if all companies used the digital procedure for demonstrating compliance) the transition to a digital procedure would be facilitated if the option were initially made voluntary for companies. This would allow all stakeholders (MSAs, companies, notified bodies, and other authorities) to familiarise themselves with the system, develop the required in-house skills and put in place a digital compliance demonstration system in their own time.

Indeed, three quarters of companies have indicated that they would be likely to take up a voluntary decentralised database option. However, voluntary take-up by businesses should be monitored to assess whether a move to a mandatory scenario might be required in the future.

5.7. Annexes

5.7.1. List of references from the literature review

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5.7.2. Stakeholder list

SH mapping.xlsx

5.7.3. Interview guides

Interview guide - manufacturers repre

Interview guide - market surveillance

5.7.4. Online survey

Online survey - market surveillance

5.7.5. CATI survey questionnaire

CATI questionnaire.docx

5.7.6. List of sectors covered, number of enterprises, employment and turnover

NACE CODE	Number of enterprises (Eurostat SBS - data as of 2013)	Number of persons employed (Eurostat SBS - data as of 2013)	Turnover or gross premiums written (Eurostat SBS - data as of 2013) - million Euro
NACE 13.92 Manufacture of made-up textile articles, except apparel	24,334.00	175,000.00	14,865.10
NACE 15.20 Manufacture of footwear	20,337.00	288,100.00	26,110.40
NACE 20.51 Manufacture of explosives	549.00	17,300.00	

NACE CODE	Number of enterprises (Eurostat SBS - data as of 2013)	Number of persons employed (Eurostat SBS - data as of 2013)	Turnover or gross premiums written (Eurostat SBS - data as of 2013) - million Euro
NACE 22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	1733 (2011)	125,600.00	43,418.80
NACE 22.19 Manufacture of other rubber products	5,983.00	208,000.00	
NACE 22.21 Manufacture of plastic plates, sheets, tubes and profiles	7,000.00	257,600.00	58,976.50
NACE 22.23 Manufacture of builders' ware of plastic	12,628.00	243,300.00	32,000.70
NACE 24.20 Manufacture of tubes, pipes, hollow profiles and related fittings, of steel	2,000.00	117,800.00	31,510.00
NACE 24.51 Casting of iron	1,870.00	96,400.00	14,814.00
NACE 24.52 Casting of steel	500.00	32,900.00	4,276.50
NACE 25.11 Manufacture of metal structures and parts of structures	n/a	691,400.00	86,406.40
NACE 25.21 Manufacture of central heating radiators and boilers	2,124.00	57,000.00	10,991.00
NACE 25.29 Manufacture of other tanks, reservoirs and containers of metal	3,096.00	73,500.00	9,611.00
NACE 25.30 Manufacture of steam generators, except central heating hot water boilers	n/a	42,000.00	8,308.20
NACE 25.99 Manufacture of other fabricated metal products n.e.c.	38,878.00	356,900.00	44,258.70
NACE 26.11 Manufacture of electronic components	7,259.00	201,000.00	44,040.70

NACE CODE	Number of enterprises (Eurostat SBS - data as of 2013)	Number of persons employed (Eurostat SBS - data as of 2013)	Turnover or gross premiums written (Eurostat SBS - data as of 2013) - million Euro
NACE 26.12 Manufacture of loaded electronic boards	3,137.00	87,500.00	14,484.50
NACE 26.20 Manufacture of computers and peripheral equipment	5,932.00	81,700.00	
NACE 26.30 Manufacture of communication equipment	n/a	180,200.00	
NACE 26.40 Manufacture of consumer electronics	2,690.00	62,100.00	21,144.50
NACE 26.51 Manufacture of instruments and appliances for measuring, testing and navigation	11,112.00	386,800.00	70,507.10
NACE 26.60 Manufacture of irradiation, electromedical and electrotherapeutic equipment	1,934.00	54,100.00	
NACE 27.12 Manufacture of electricity distribution and control apparatus	n/a	402,400.00	81,408.70
NACE 27.40 Manufacture of electric lighting equipment	7,265.00	154,800.00	28,162.60
NACE 27.51 Manufacture of electric domestic appliances	2,094.00	177,200.00	38,424.90
NACE 27.52 Manufacture of non-electric domestic appliances	2,109.00	47,400.00	5,182.50
NACE 27.90 Manufacture of other electrical equipment	n/a	187,900.00	28,956.20
NACE 28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	1,735.00	242,500.00	85915.3 (2011)

NACE CODE	Number of enterprises (Eurostat SBS - data as of 2013)	Number of persons employed (Eurostat SBS - data as of 2013)	Turnover or gross premiums written (Eurostat SBS - data as of 2013) - million Euro
NACE 28.12 Manufacture of fluid power equipment	1,909.00	114,200.00	20,615.10
NACE 28.13 Manufacture of other pumps and compressors	2,326.00	146,700.00	32,529.30
NACE 28.14 Manufacture of other taps and valves	2,326.00	138,900.00	29,728.20
NACE 28.15 Manufacture of bearings, gears, gearing and driving elements	2,825.00	199,300.00	36,191.50
NACE 28.21 Manufacture of ovens, furnaces and furnace burners	2,109.00	47,400.00	8,990.00
NACE 28.22 Manufacture of lifting and handling equipment	8,991.00	263,300.00	54,271.50
NACE 28.23 Manufacture of office machinery and equipment (except computers and peripheral equipment)	1,135.00	20,000.00	4,017.80
NACE 28.25 Manufacture of non-domestic cooling and ventilation equipment	8,581.00	230,100.00	43,325.00
NACE 28.29 Manufacture of other general-purpose machinery n.e.c.	14,902.00	335,700.00	68,023.50
NACE 28.41 Manufacture of metal forming machinery	4,325.00	145,900.00	45,096.80
NACE 28.49 Manufacture of other machine tools	4,085.00	81,700.00	12,000.00
NACE 28.91 Manufacture of machinery for metallurgy	2,706.00	49,700.00	10,217.80
NACE 28.92 Manufacture of machinery for mining, quarrying and construction	3,514.00	161,300.00	40,064.20

NACE CODE	Number of enterprises (Eurostat SBS - data as of 2013)	Number of persons employed (Eurostat SBS - data as of 2013)	Turnover or gross premiums written (Eurostat SBS - data as of 2013) - million Euro
NACE 28.93 Manufacture of machinery for food, beverage and tobacco processing	6,017.00	123,300.00	22,384.80
NACE 28.94 Manufacture of machinery for textile, apparel and leather production	2,121.00	55,300.00	11,072.80
NACE 28.95 Manufacture of machinery for paper and paperboard production	900.00	n/a	
NACE 28.96 Manufacture of plastics and rubber machinery	2,545.00	63,700.00	13,693.40
NACE 28.99 Manufacture of other special-purpose machinery n.e.c.	10,735.00	261,200.00	50,655.30
NACE 29.10 Manufacture of motor vehicles	n/a	1,041,600.00	600,000.00
NACE 29.31 Manufacture of electrical and electronic equipment for motor vehicles	n/a	207,000.00	28,092.10
NACE 30.12 Building of pleasure and sporting boats	4,307.00	45,900.00	8,061.50
NACE 32.30 Manufacture of sports goods	4,476.00	40,100.00	5,928.20
NACE 32.40 Manufacture of games and toys	5,043.00	53,000.00	
NACE 32.50 Manufacture of medical and dental instruments and supplies	60,000.00	487,100.00	63,145.70
NACE 32.99 Other manufacturing n.e.c.	28,500.00	140,500.00	14,686.30
TOTAL	**350,677**	**9,501,300**	**2,026,565.10**

5.7.7. List of NACE sectors and description

NACE 2	Description	Incidence rate[87]
13.92	Manufacture of made-up textile articles, except apparel	59.85%
15.2	Manufacture of footwear	100.00%
20.51	Manufacture of explosives	48.28%
22.11	Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	51.11%
22.19	Manufacture of other rubber products	48.77%
22.21	Manufacture of plastic plates, sheets, tubes and profiles	69.93%
22.23	Manufacture of builders' ware of plastic	100.00%
24.2	Manufacture of tubes, pipes, hollow profiles and related fittings, of steel	100.00%
24.51	Casting of iron	83.33%
24.52	Casting of steel	100.00%
25.11	Manufacture of metal structures and parts of structures	54.20%
25.21	Manufacture of central heating radiators and boilers	93.43%
25.29	Manufacture of other tanks, reservoirs and containers of metal	55.87%
25.3	Manufacture of steam generators, except central heating hot water boilers	55.87%
25.99	Manufacture of other fabricated metal products n.e.c.	69.52%
26.11	Manufacture of electronic components	67.33%
26.12	Manufacture of loaded electronic boards	64.60%
26.2	Manufacture of computers and peripheral equipment	69.91%
26.3	Manufacture of communication equipment	69.55%
26.4	Manufacture of consumer electronics	93.15%
26.51	Manufacture of instruments and appliances for measuring, testing and navigation	75.28%
26.6	Manufacture of irradiation, electromedical and electrotherapeutic equipment	65.51%
27.12	Manufacture of electricity distribution and control apparatus	77.92%
27.4	Manufacture of electric lighting equipment	69.52%

87 The incidence rate reflects the percentage of companies that after accepting to participate to the interview stated that they do not produce technical documentation and/or declaration of conformity

NACE 2	Description	Incidence rate[87]
27.51	Manufacture of electric domestic appliances	80.46%
27.52	Manufacture of non-electric domestic appliances	93.43%
27.9	Manufacture of other electrical equipment	67.16%
28.11	Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	68.98%
28.12	Manufacture of fluid power equipment	100.00%
28.13	Manufacture of other pumps and compressors	88.07%
28.14	Manufacture of other taps and valves	100.00%
28.15	Manufacture of bearings, gears, gearing and driving elements	48.43%
28.21	Manufacture of ovens, furnaces and furnace burners	87.37%
28.22	Manufacture of lifting and handling equipment	100.00%
28.23	Manufacture of office machinery and equipment (except computers and peripheral equipment)	69.91%
28.25	Manufacture of non-domestic cooling and ventilation equipment	80.46%
28.29	Manufacture of other general-purpose machinery n.e.c.	75.28%
28.41	Manufacture of metal forming machinery	56.78%
28.49	Manufacture of other machine tools	69.52%
28.91	Manufacture of machinery for metallurgy	69.05%
28.92	Manufacture of machinery for mining, quarrying and construction	61.72%
28.93	Manufacture of machinery for food, beverages and tobacco processing	91.67%
28.94	Manufacture of machinery for textile, apparel and leather production	69.40%
28.95	Manufacture of machinery for paper and paperboard production	100.00%
28.96	Manufacture of plastics and rubber machinery	68.65%
28.99	Manufacture of other special-purpose machinery n.e.c.	65.85%
29.1	Manufacture of motor vehicles	70.11%
29.31	Manufacture of electrical and electronic equipment for motor vehicles	69.52%
30.12	Building of pleasure and sporting boats	52.08%
32.3	Manufacture of sports goods	77.78%

NACE 2	Description	Incidence rate[87]
32.4	Manufacture of games and toys	93.15%
32.5	Manufacture of medical and dental instruments and supplies	75.41%
32.99	Other manufacturing n.e.c.	55.13%

5.7.8. SIC to NACE conversion table

NACE mapping.xlsx

5.7.9. CBA methodology and sensitivity analysis.

5.7.9.1. CBA methodology

This annex summarises the calculation used to estimate the overall costs of demonstrating compliance as well as its NPVs.

Option 1/Basic compliance/Voluntary

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + (option 1 basic change as % of baseline * voluntary uptake option 1)*

Option 1/Basic compliance/Mandatory

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + option 1 basic change as % of baseline)*

Option 1/Full compliance/Voluntary

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + (option 1 full change as % of baseline * voluntary uptake option 1)*

Option 1/Full compliance/Mandatory

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + option 1 full change as % of baseline)*

Option 2/Basic compliance/Voluntary

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + (option 2 basic change as % of baseline * voluntary uptake option 2)*

Option 2/Basic compliance/Mandatory

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + option 2 basic change as % of baseline)*

Option 2/Full compliance/Voluntary

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + (option 2 full change as % of baseline * voluntary uptake option 2)*

Option 2/Full compliance/Mandatory

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + option 2 full change as % of baseline)*

The NPV values are calculated based on a 10-year period and a social discount rate of 4%, as suggested by the European Commission Better Regulation "Toolbox"[88].

$$NPV = \sum_{t=0}^{T} \frac{(B_t - C_t)}{(1+r)^t}$$

5.7.9.2. Sensitivity analysis

The estimation of the baseline cost of demonstrating compliance is based on several assumptions. While most of the estimation is based on an extensive CATI survey, weighted by NACE sector to reflect the structure of the European enterprise population in the sectors covered by the study, the assumption (H_0) that the total cost of compliance is 0.48% as a

88 http://ec.europa.eu/smart-regulation/guidelines/toc_tool_en.htm

percentage of turnover is based on the Evaluation of the Internal Market Legislation for Industrial Products.[89]

By relaxing the assumption H_0, different scenarios are created:

- Best case scenario: H_0 = 0.24% (-50%)
- Worst case scenario: H_0 = 0.72% (+50%)

Table 14-22 summarises the NPV of Option 1 and 2 for both scenarios. Given the linearity of the model, the impact of the change in assumption affects all options equally. Thus, whether compliance costs are reduced or increased by 50% affects the overall costs of each of the two options but it does not affect the choice of the most appropriate option. Furthermore, even such a significant difference in the cost of compliance would at best lead to a 10-year total saving of €557.45 per company and at worst to an additional cost over 10 years of €557.45

Table 14-22: Sensitivity analysis, impact of best- and worst-case scenarios for the cost of demonstrating compliance under each option

Best Case scenario (H_0 = 0.24%)			NPV, total	NPV, company
Option 1: Centralised database	Basic Compliance	Voluntary	-€ 5,340,848.17	-€ 11.46
		Mandatory	-€ 6,523,571.73	-€ 13.99
	Full Compliance	Voluntary	-€ 212,705,843.55	-€ 456.39
		Mandatory	-€ 259,809,262.93	-€ 557.45
Option 2: Decentralised database	Basic Compliance	Voluntary	-€ 75,625,848.39	-€ 177.96
		Mandatory	-€ 101,307,231.59	-€ 217.36
	Full Compliance	Voluntary	-€ 187,227,804.94	-€ 440.57
		Mandatory	-€ 250,807,508.29	-€ 538.13
Worst case scenario (H_0 = 0.72%)			NPV, total	NPV, company
Option 1: Centralised database	Basic Compliance	Voluntary	€ 5,340,848.18	€ 11.46
		Mandatory	€ 6,523,571.73	€ 14.00
	Full Compliance	Voluntary	€ 212,705,843.56	€ 456.38
		Mandatory	€ 259,809,262.92	€ 557.45
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 75,625,848.38	€ 177.95
		Mandatory	€ 101,307,231.59	€ 217.37

89 http://ec.europa.eu/smart-regulation/evaluation/search/download.do?documentId=9966151

	Full Compliance	Voluntary	€ 187,227,804.95	€ 440.58
		Mandatory	€ 250,807,508.30	€ 538.14

Another sensitivity test consists of varying assumptions regarding the take-up time of the sub-options under both the voluntary and mandatory scenarios. Indeed, even under a mandatory scenario, not all companies will comply instantly with requirements. Under a voluntary scenario, take-up will be slower and it will take longer to achieve the estimated take-up as reported in the CATI survey.

Table 14-23 summarises the NPV of Option 1 and 2 for different take-up rates. In this scenario, take-up rate assumptions are:

- Under mandatory compliance it takes 4 years for all companies to comply with the new requirements (t_1 = 40%; t_2 = 60%; t_3 = 90%; t_4 = 100%)

- Under voluntary compliance the full voluntary up take rates (x = 81.87%; 74.65%) are reached after 9 years (t_1 = x*40%; t_2 = x*60%; t_3 = x*70%; t_4 = x*75% t_5 = x*80%; t_6 = x*85%; t_7 = 90%; t_8 = x*95%; t_9 = x*100%;)

Table 14-23: Sensitivity analysis, impact of gradual take-up rate of each option on cost estimates

Up-take			NPV, total	NPV, company
Option 1: Centralised database	Basic Compliance	Voluntary	€ 7,841,413.10	€ 16.82
		Mandatory	€ 10,837,238.28	€ 23.25
	Full Compliance	Voluntary	€ 312,293,915.39	€ 670.06
		Mandatory	€ 431,606,335.57	€ 926.06
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 111,033,584.70	€ 238.24
		Mandatory	€ 168,295,935.65	€ 361.10
	Full Compliance	Voluntary	€ 274,887,155.42	€ 589.80
		Mandatory	€ 416,652,233.14	€ 893.98

As this table shows, reducing the speed of take-up significantly reduces overall costs under all the options but it does not affect the relative position of the options and therefore does not affect the overall decision on which option would be least costly.

The estimation of the baseline costs of demonstrating compliance is based on several assumptions and variables that do not consider the differences in company size. However, as seen throughout the report, company size does matter. The table below shows the main variables used to estimate the cost of demonstrating compliance broken down by company

size. The cast estimates in the baseline and for each option seen previously in this report use only the average across companies of all sizes (the last row in the table below).

Table 14-24: Change in variables by company size

Size	Incidence rate	Technical file	% change in cost Option 1		% change in cost Option 2	
			Basic	Full	Basic	Full
Large	76.1%	84.0%	1.93%	6.95%	1.90%	6.53%
Medium	82.0%	84.0%	-2.02%	9.52%	0.79%	6.28%
Small	86.9%	82.4%	-0.51%	7.98%	2.89%	8.43%
Micro	70.8%	73.9%	6.15%	7.99%	5.64%	12.27%
Total	**86.6%**	**80.9%**	**0.17%**	**8.37%**	**2.64%**	**8.08%**

Source: CATI survey, weighted by NACE code

Disaggregating cost estimates by company size leads to the estimates in the table below. It is important to highlight that figures for turnover and number of companies by size and sector are not available on Eurostat. Therefore, the specific cost estimates in the table below should only be considered as an approximation of the annual cost for companies of different sizes.

But the table does show accurately which option is least/most costly in each company size category. For example, while in the total sample – not considering company size – option 1 appears least costly, this is not the case for micro-companies for whom option 2 is less costly. This result for micro-companies is very important considering that according to Eurostat, 82.94% of manufacturing companies fall within this category.[90]

Table 14-25: Analysis by company size (yearly change in cost of demonstrating compliance compared to baseline)

Analysis by Size (yearly change in cost)	Total	Large	Medium	Small	Micro

90 Eurostat: http://ec.europa.eu/eurostat

Option 1: Centralised database	Basic Compliance	Voluntary	**€ 2.52**	**€ 28.56**	-€ 29.89	-€ 7.55	€ 91.00
		Mandatory	€ 3.07	€ 34.88	**-€ 36.51**	**-€ 9.22**	€ 111.16
	Full Compliance	Voluntary	€ 100.18	€ 86.39	€ 118.33	€ 97.30	€ 87.37
		Mandatory	€ 122.37	€ 105.52	€ 144.54	€ 118.85	€ 106.72
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 39.06	€ 28.11	€ 11.69	€ 42.76	**€ 83.46**
		Mandatory	€ 47.72	€ 34.34	€ 14.28	-€ 52.23	€ 101.94
	Full Compliance	Voluntary	€ 96.71	€ 81.17	€ 78.06	€ 102.79	€ 134.17
		Mandatory	€ 118.13	€ 99.14	€ 95.34	€ 125.55	€ 163.89

Source: CATI survey, weighted by NACE code

5.7.10. Mapping of Union harmonisation legislation by sector

Overview Table - New Version - Proco

5.8. Evaluation

The assessment of the different ways to promote digital compliance show that schemes based on *voluntary* provision of compliance information would perform less in effectiveness than compulsory variants, and would only have very limited to negligible less costs implications on businesses. While voluntary systems have the benefit of flexibility, they would be quite unreliable for interested persons who would consult the database/web-sites, since the absence of a declaration of conformity would not automatically mean that there is no declaration of conformity. The voluntary variants were therefore not further considered in the impact assessment.

The encouragement or prescription *of particular labelling requirements or specific technologies* (e.g. e-labelling, quick-scan / bar-codes) could be problematic due to the variety of the technical solutions present in the market. An important standardization effort would be needed to avoid complex validation procedures by the various categories of user, which may limit the validity of the multiple techniques that are currently available. For example, a law enforcer may be obliged to use many different smartphone applications for each technique or brand. The most significant issue, however, is the variety of techniques in the different domains and sectors, which can become a hurdle for the users, which belong to the professional categories of law enforcers and retailer/distributors.

The option of *e-labelling* furthermore could only apply to products with a display or screen, i.e. essentially appliances, machinery and radio equipment. e-labelling requires that the user be provided with prominent instructions on how to access the required labelling and regulatory information, in either the packaging material or another easily accessible format, at the time of purchase, and that these instructions be available on the product-related website, if one exists. However, when a consumer is considering purchasing a product, he/she cannot usually turn on the product and use the electronic display to access the labelling and regulatory information. Likewise, when distributors and other intermediaries and market surveillance authorities would examine the compliance of the products, they most likely cannot access the electronic display. E-labelling would not address the main problem driver that it should address, i.e. the transparency of compliance information to consumer and traders in the supply chain, nor facilitation of exchange of compliance information with market surveillance authorities. E-labelling is therefore not further considered in this impact assessment.

6. FEEDBACK FROM MEMBER STATES ON "FAST-TRACK" INFORMATION RECEIVED FROM COMPANIES PERFORMING RECALLS

Member States were asked to provide their views on proposals for 5 changes to the publication of RAPEX notifications on the public website[91] as well as on the publication of

91 RAPEX Contact Points meeting of 14 October 2016

information received from companies performing voluntary recalls. The feedback received from Member States is summarised as follows:

A majority of Member States fully supported a "fast-track" publication on a central EU website of information received from companies regarding recalls they performed voluntarily with a view to ensuring that the general public is swiftly informed as soon as possible after the measure is taken. They overall agreed that such a system would enable the consumers who have acquired a dangerous product to receive information about the risks that the product poses and to discontinue using it, which will ensure better consumer protection.

At the same time, Member States pointed out that it must be made clear that such voluntary reporting by the companies is different from RAPEX notifications as it does not involve any investigation or approval by the competent authority. Similarly, this voluntary reporting does not exempt economic operators from their obligations under the relevant EU legislation. In addition, a formal validation by the Commission of such voluntary publication of information on recalls should take place. Member States further pointed out that the information published should not include an assessment by the economic operator of the level of the risk posed by the product, as this could lead to confusion for the consumers when there is a disagreement with the assessment carried out by the competent authorities. On the other hand, such voluntary reporting could include factual information useful for consumers, such as clear description of the product, including picture of the product and of the packaging; indication of bar or batch codes; a clear, factual and concise description of the risk to the consumer; clear description of what the consumer needs to do with the contact details of the manufacturer etc.