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REFIT EVALUATION

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) 466 final} - {SWD(2017) 467 final} -
{SWD(2017) 468 final} - {SWD(2017) 470 final}

Contents

Glossary

Product	A substance, product or good produced through a manufacturing process other than food, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction (Article 15(4) of Regulation (EC) No 765/2008 or 'the Regulation').
Market surveillance provisions	Articles 15 to 29, Article 38 and Article 41 of Regulation (EC) No 765/2008 and the corresponding definitions and financing provisions,
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 (Article 2(17) of the Regulation).
Market surveillance authority or MSA	An authority of a Member State responsible for carrying out market surveillance on its territory.
Union harmonisation legislation	Any Union legislation harmonising the conditions for the marketing of products (Article 2(21) of the Regulation).
Sector legislation	Legislation that is part of the Union harmonisation legislation.
GPSD	General Product Safety Directive - Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety
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 (Article 2(3) of the Regulation).
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 (Article 2(4) of the Regulation).
Importer	Any natural or legal person established within the Union who places a product from a third country on the Union market (Article 2(5) of the Regulation).
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 (Article 2(6) of the Regulation)
Economic operators	The manufacturer, the authorised representative, the importer and the distributor (Article 2(7) of the Regulation).
AdCo	The Administrative Coordination group of the authorities responsible for market surveillance with respect to one or more instruments of Union harmonisation legislation.
Recall	Any measure aimed at achieving the return of a product that has already been made available to the end user (Article 2(14) of the Regulation).
Withdrawal	Any measure aimed at preventing a product in the supply chain from being made available on the market (Article 2(15 of the Regulation)).
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 (Article 2(1) of the Regulation)
Placing on the market	The initial making available of a product on the Union market (Article 2(2) of the Regulation).
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* (system referred to in Article 22 of the Regulation).
ICSMS	Internet-supported information and communication system for market surveillance authorities in the EU - *https://webgate.ec.europa.eu/icsms/ (*system referred to in Article 23 of the Regulation).

1. INTRODUCTION

A large range of non-food consumer products (like toys, mobile phones, electrical appliances, laptops etc.) and more sophisticated products (e.g. machines, pressure equipment, measuring instruments, equipment to be used in explosive atmospheres etc.) sold on the Single Market are subject to common EU rules concerning public safety, security, environmental protection, etc. This set of rules is referred to as Union technical legislation.

Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (hereinafter also referred to as "the Regulation") was adopted to address the lack of coherence in the implementation and enforcement of Union technical legislation ensuring the free movement of non-food products[1] (hereinafter also referred to as "products") within the EU. The purpose of the Regulation is therefore to ensure that these products are subject to adequate controls by public authorities so that if found to be, for instance, dangerous for consumers, workers or the environment, they could be taken off the EU market promptly.

The Regulation has four main elements:

(1) It lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing conformity assessment activities;

(2) It lays down the general principles of the CE marking;

(3) It provides a framework for the market surveillance of products to ensure that those products fulfil the requirements providing a high level of protection for public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers and the protection of the environment and security.

(4) It provides a framework for controls on products from third countries.

This evaluation only relates to the third and fourth element above, i.e. **the framework for the market surveillance of products and for controls on products from third countries**[2]. Therefore, it focuses on Articles 15 to 29, Article 38 and Article 41 of the Regulation and the corresponding definitions and financial provisions of the Regulation (hereinafter 'market surveillance provisions').

The **purpose of this evaluation** is to assess the effectiveness, efficiency, coherence, relevance and EU added value of the market surveillance provisions on the basis of the evaluation questions set out in section 3. Its results feed into the impact assessment that will accompany the legislative proposal strengthening the enforcement of Union harmonisation legislation on products. This proposal is one of the deliverables of the Single Market Strategy[3], according to which the Commission will *'launch a comprehensive set of actions to*

1 According to Article 15(4), the market surveillance provisions apply to substances, preparations or goods 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.
2 The other elements will be subject to another evaluation at a later stage.
3 Commission Communication COM(2015)550 'Upgrading the Single Market: more opportunities for people and business'.

further enhance efforts to keep non-compliant products from the EU market by strengthening market surveillance and providing the right incentives to economic operators'.

This evaluation covers the period from 2010 (date of application of the Regulation) until 2015, compared to the situation before 2010. It is part of the Commission's work programme, according to which *'the Commission will act to strengthen the single market in goods, notably by facilitating the mutual recognition and addressing the increasing amount of non-compliant products on the EU market through REFIT revisions of the relevant legislation. This will allow entrepreneurs to offer their products more easily across borders while offering incentives to boost regulatory compliance and restoring a level playing field to the benefit of businesses and citizens*[4].'

The **findings of the evaluation** suggest that while its main goal to ensure that products sold on EU market are safe and compliant with applicable rules remains extremely relevant, the Regulation has been only partly effective in achieving its objectives. As a consequence the legal framework for product controls and its implementation should be further improved.

2. BACKGROUND TO THE INITIATIVE

2.1. Description of the initiative and its objectives

2.1.1. Objectives and roles of the market surveillance provisions

The intervention logic of Regulation (EC) No 765/2008 could be summarised as follows[5]. Three main **needs** or drivers led to the definition of the Regulation's strategic objectives: (1) to address the lack of market surveillance enforcement within the EU; (2) to increase credibility of CE marking in the internal market; and (3) to ensure the free movement of goods within the EU, together with product safety and the protection of public interests. The two **strategic objectives** of the Regulation – aiming to respond to the abovementioned needs - are to (1) ensure a level playing field among economic operators through the elimination of unfair competition of non-compliant products and to (2) strengthen the protection of public interests through the reduction of the number of non-compliant products[6]. The strategic objectives are then disaggregated into three **specific objectives** representing the operational orientations of the EU action. In order to achieve the strategic and specific objectives, the EC has defined **a set of activities** to be implemented, including those in the Regulation in the form of **provisions**. For instance, in order to achieve a reduction in the number of non-compliant products, the Regulation sets the framework for controls of products on the internal market (Ch. III, section 2) and of those imported from third countries (Ch. III, section 3). These provisions are expected to produce a number of key **results** and to eventually trigger the Regulation's **impacts**. For instance, the resulting lower number of non-compliant products will generate a higher and more uniform protection of consumers across the EU.

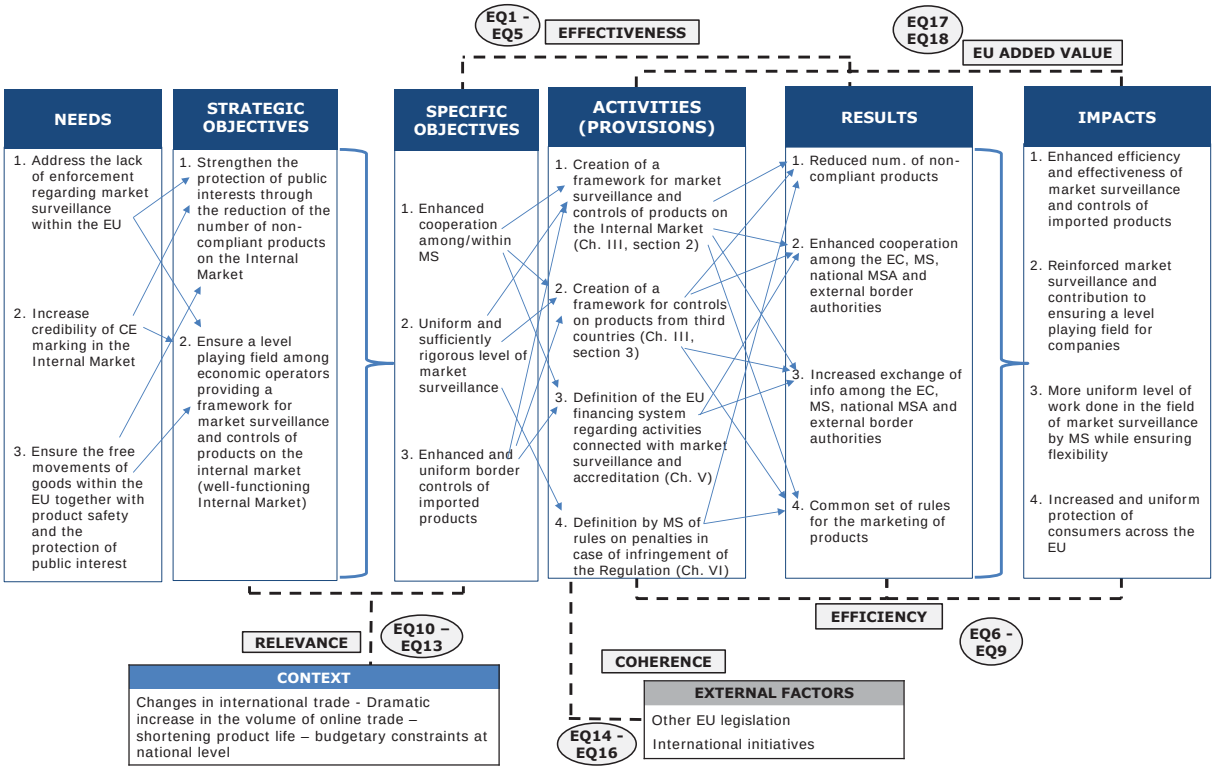
The figure below outlines the Regulation's intervention logic in relation to the evaluation criteria and questions that guided the study and that will be further described in the following

4 COM(2016)710.
5 SEC(2007)173.
6 Recital 1 of the Regulation.

chapter. The arrows represent the links/trigger mechanisms between needs and objectives, and objectives, provisions and results.

The intervention logic below also presents the **evaluation questions** (and related criteria) helping in the assessment of the overall performance of the market surveillance provisions, having identified its working mechanisms. As shown in the figure below, the evaluation questions relating to **relevance** assess whether the objectives of the market surveillance provisions are still adequate in the current **context**. The **effectiveness** questions are based on measurements of the market surveillance provisions' results to determine whether it has achieved its objectives. The **efficiency** questions assess whether the market surveillance provisions have proportionally delivered their results, given the established provisions. In order to better understand how the interaction among the above elements works and delivers the expected changes over time, the intervention logic needs to consider **external factors** (including other EU legislation) that may influence the performance of the market surveillance provisions: the **coherence** questions evaluate whether these provisions are consistent with those factors. The **EU added value** questions aim at understanding if the provisions set out have served to obtain the expected impacts.

Figure 1: Intervention logic



2.1.2. Scope of the evaluation

This evaluation only relates to the market surveillance provisions, i.e. the following parts of the Regulation:

- Chapter I – General provisions: This Chapter specifies the **scope** of the Regulation and the main **definitions** relevant for market surveillance.

- Chapter III – EU market surveillance framework and controls of products entering the EU market. Chapter III covers the **functioning of market surveillance of products subject to the EU harmonisation legislation.** It defines the products covered by the market surveillance infrastructures and programmes, as well as the roles and responsibilities of the European Commission, Member States, national Market surveillance authorities and other relevant actors.

  – In particular, *Section 1* defines the **scope of application** of the provisions on market surveillance and control of imported products. It also sets out the **general obligation to carry out market surveillance and take restrictive measures** for products 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.

  – *Section 2 "EU market surveillance framework"* sets out the obligations of the EU MS regarding the **organisation** of national authorities and **measures** to be adopted in the case of products presenting a serious risk. The Section provides an overview of the duties of national Market surveillance authorities and their **cooperation with competent authorities** in other EU MS or in third countries. The Regulation also states the **principles of cooperation and exchange of information** between all relevant actors in the field of market surveillance.

  – *Section 3 "Controls of products entering the EU market"* entrusts **powers and resources to authorities in charge of external border control** of products entering the EU market and defines in which situations such authorities shall not release a product for free circulation or, in case of suspension, shall release the product. Moreover, Section 3 defines the measures to be taken by Market surveillance authorities if a **product presents a serious risk or does not comply with the EU harmonisation legislation.**

- Chapter V – EU Financing. Includes provisions on the **financing system** for obtaining the results expected by the Regulation. More specifically, it lists the activities eligible for financing and the arrangements on financial procedures. The Regulation also foresees the possibility of covering administrative expenses for all management and monitoring activities necessary for the achievement of its objectives.

- Chapter VI – Final provisions. The last two provisions subject to the evaluation are **Article 38**, which refers to the possibility of the adoption by the EC of **non-binding guidelines on the Regulation implementation**, and **Article 41,** which obliges the EU MS to lay down **rules on penalties for economic operators** applicable to infringements of the provisions of this Regulation.

2.1.3. Complementary nature of the market surveillance provisions

Some **market surveillance rules** are laid down **in sector specific Union legislation.** They set out in detail how and when a market surveillance authority should intervene when a non-compliant product is found. Market surveillance authorities should 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. The first level of control are usually 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 compliance with the applicable essential requirements, and the contents of the EU declaration of conformity.

The **market surveillance provisions in the Regulation complement and strengthen existing provisions in Union harmonisation legislation** providing more general principles for the organisation and tools for the implementation of control activities.[7] The Regulation indicates that, in accordance with the principle of lex specialis, it should apply only in so far as there are no specific provisions with the same objective, nature or effect in other existing or future rules of Union harmonisation legislation. The corresponding provisions of the Regulation therefore do not apply in the areas covered by such specific provisions[8].

The Regulation does not affect the substantive rules of existing Union legislation setting out the rules and procedures to be observed by authorities and businesses when market surveillance is performed, but it should nonetheless enhance their operation.

The complementarity between the market surveillance provisions in the Regulation and those in Union harmonisation legislation has been remarkably improving over the last years through the alignment of sector-specific rules to those of Decision No 768/2008/EC[9], which was adopted together with the Regulation. The Decision includes reference provisions to be incorporated whenever product legislation is revised, working as a "template" for future product harmonisation legislation. The relation between the two sets of markets surveillance rules is illustrated in the following table. At the time of writing, several sector-specific directives and regulations were aligned with these reference provisions and further aligning proposals are pending[10].

Table 1: Market surveillance provisions in Regulation (EC) No 765/2008 and new sector legislation

MARKET SURVEILLANCE MEASURES AND STRUCTURES	REGULATION (EC) No 765/2008	*NEW SECTOR LEGISLATION*[11]
MARKET SURVEILLANCE PROCEDURES		
Obligations of economic operators vis-à-vis market surveillance authorities *(information and cooperation)*	**No**	**Yes**
Identification of economic operators *(obligation for economic operators to identify the economic operators who supplied the product and the economic operator to whom the product was supplied)*	**No**	**Yes**
Definition of formal non-compliance *(e.g. markings wrongly or not affixed, declaration of conformity missing, technical documentation not available or incomplete etc.)*	**No**	**Yes**
Procedures for dealing with non-compliant products *(i.e. corrective actions, information obligations, restrictive measures, recalls etc.)*	**No**	**Yes**
Market surveillance measures (i.e. role of market surveillance authorities)	**Yes**	**No but legislation refers to Regulation (EC)**
Products presenting a serious risk (i.e. Member States must ensure		

7 Recitals 2 and 3 of the Regulation.
8 Recital 5 of the Regulation.
9 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008D0768&locale=en
10 See footnote 21 and section 2 in Annex 4.
11 See section 2.1 of Annex 4.

that products which present a serious risk requiring rapid intervention, are recalled, withdrawn or that their being made available on their market is prohibited)		**No 765/2008**
Restrictive measures (i.e. procedural safeguards, statement of reasons, right to be heard, remedies etc.)		
Exchange of information — Rapid Information System for products presenting a serious risk		
General information support system (ICSMS) on issues relating to market surveillance activities, programmes and related information on non-compliance with Union harmonisation legislation, including identification of risks, results of testing carried out, provisional restrictive measures taken, contacts with the economic operators concerned and justification for action or inaction		
Union safeguard procedure	**No**	**Yes**
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 infringe-ments of the provisions of the Regulation**	**Penalties for economic operators applicable to infringements of the provisions of sector legislation**

2.2. Consumer Safety and Market Surveillance Package (2013)

The Commission proposed in 2013 a major overhaul of the market surveillance framework for non-food products through a new single regulation on market surveillance[12]. Its aim was to combine the market surveillance rules currently spread across the Union harmonisation legislation. All products would be subject to the same rules except where the specific characteristics of a category of products would state otherwise. Furthermore, procedures for the notification by Member States of information about products presenting a risk and corrective measures taken would be streamlined.

12 Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council, COM(2013)75 - 2013/0048 (COD). This proposal was accompanied by a Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC, COM(2013)78 - 2013/0049 (COD)

However, the negotiations between the European Parliament, the Council and the Commission have stalled for a long time. 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 because of a proposed provision on the introduction of a mandatory marking of origin on industrial products, known as the "Made in" provision (article 7 of the Consumer Safety draft regulation*[13]*). In March, eleven member states in favour of maintaining the "Made in" provision, presented a compromise proposal based on the deletion of article 7 and the introduction of mandatory marking of origin in a limited amount of sectorial legislation, combined with a revision clause. The presidency verified that positions within the Council remain unchanged*[14].' The discussions on this proposal were not resumed and it is reasonable to assume that any progress on this proposal in view of its adoption by the co-legislator is highly unlikely.

2.3. Baseline

2.3.1. Regulatory aspects

Before the Regulation, the framework for product controls to assure their conformity with EU rules was incomplete and inhomogeneous[15]. This was based on:

- Regulation (EEC) No 339/93 that set up common procedures for controlling the products coming from non-EU countries but it did not contain an explicit obligation to carry out those controls;

- the General Product Safety Directive 2001/95/EC[16] (hereinafter 'GPSD') that exclusively concerns controls of conformity of consumer products with safety requirements, i.e. only part of EU acquis and

- few scattered provisions embedded in sector-specific EU harmonisation legislation.

Being the responsibility (and a prerogative) of Member States, enforcement only had an ancillary role in EU harmonisation legislation until the adoption of the Regulation. The harmonisation legislation that existed in 2007 did not in general address market surveillance. Most instruments contain a very general clause obliging Member States to ensure that only products in compliance with the requirements of the directive are placed on the market. In the New Approach directives the safeguard clause procedure obliged national authorities to notify the Commission whenever they take a measure restricting the free circulation of a potentially dangerous product. The Commission had to issue an opinion on whether the measure is justified or not.

In respect of consumer goods, these general provisions in the sector directives were completed by the provisions of the General Product Safety Directive 2001/95/EC ('GPSD').

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13 i.e. Proposal for a Regulation of the European Parliament and of the Council on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC, COM(2013)78 - 2013/0049 (COD)

14 http://www.consilium.europa.eu/en/meetings/compet/2016/05/26-27/

15 Section 2.2.6 of the impact assessment SEC(2007)173 accompanying the legislative proposal for the Regulation; see also point 2.1 of Annex 4.

16 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 11, 15.1.2002, p. 4–17.

The GPSD has created a horizontal framework ensuring the safety of consumer products. To this end it sets out a number of obligations for manufacturers, importers and distributors as well as certain obligations for Member States as regards the organisation of market surveillance. The GPSD also established a network of authorities of the Member States competent for product safety aimed at facilitating operational collaboration on market surveillance and other enforcement activities. Moreover, the GPSD set up a European rapid alert system for dangerous non-food products for the rapid exchange of information requiring rapid intervention (RAPEX). It ensures information about dangerous products identified in the Member States is quickly circulated between the Member States and the Commission. The GPSD applies to the harmonised sectors like toys, cosmetics, etc., in so far as the relevant harmonisation directives have themselves not provided for specific rules.

However, the mechanisms established by the GPSD were not sufficient to ensure a coherent level of enforcement of Union harmonisation legislation throughout the EU. While harmonisation legislation covers both consumer and non-consumer products, the GPSD focuses on consumer protection. Therefore, its mechanisms are not applicable to whole range of products covered by Union harmonisation legislation. Hence RAPEX did not allow for exchange of information on dangerous industrial products like machinery or lifts, which present a risk for workers or users. Furthermore only health and safety aspects were covered by this system, and environmental risks were not taken into consideration.

While the GPSD contains an obligation for Member States to take part in the cooperation mechanism, the obligations it imposes on Member States to organise and perform market surveillance are rather general. For this reason differences in the various Member States still continued to persist, leading to a different level of protection and enforcement within the EU[17].

2.3.2. Level of non-compliance in 2008

According to the impact assessment of 2008, the share of non-compliant products could only be crudely estimated and the situation differed very much from sector to sector and from Member State to Member State. Nevertheless, the available information indicated that a significant proportion of the products on the market do not comply with the legal requirements. In 2004, for example, 33% of industrial products were found not to be in conformity with the legislation in Germany. The following table summarises the findings.

Table 2: Indications from stakeholders on the share of non-compliant products on the market in 2008.

Source	**Share of non-compliant products on the market**
SME Test panel	The majority of SMEs could not provide figures. Where figures were given, they differed considerably from sector to sector as well as between Member States. The figures ranged from 4%-51%, the average being 24%.
Enterprise questionnaire	Most respondents could not provide figures but indicated that the problem was important. However, below is an overview of the estimates provided: Electro-technical sector: 10-30% (up to 50 % in the luminaires sector) Mechanical sector: 5-7 % Medical devices: 10-30% Construction products: 10-30%

17 Section 2.2.6 of the impact assessment SEC(2007)173 accompanying the legislative proposal

Market surveillance authorities	Electro-technical 10-70 % Medical Devices 2-20 %, Construction products 2-30 % Recreational Craft 1 %

There are some indications in ICSMS, although the system was only used by a smaller group of Member States:

Table 3: Indications from stakeholders on the share of non-compliant products on the market.

Year	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

3. EVALUATION QUESTIONS

The following box presents eighteen evaluation questions, framed within the five evaluation criteria that have been answered to assess the market surveillance provisions of the Regulation.

Effectiveness

EQ1. *Are the results in line with what is foreseen in the impact assessment for the Regulation, notably as to the specific objectives of (i) enhanced cooperation among Member States/within Member States, (ii) uniform and sufficiently rigorous level of market surveillance, (iii) border controls of imported products?*

EQ2. *Are there specific forms of the implementation of the Regulation at Member State level that render certain aspects of the Regulation more or less effective than others, and – if there are – what lessons can be drawn from this?*

EQ3. *To what extent has the different implementation (i.e. discrepancies in the implementation) of the initiative in Member States impacted on the effectiveness of the measures on the objective?*

EQ4. *How effective was the measure as a mechanism and means to achieve a high level of protection of public interests, such as health and safety in general, health and safety at workplace, the protection of consumers, protection of the environment and security? What have been the quantitative and qualitative effects of the measure on its objectives?*

EQ5. *How effective was the measure as a mechanism and means to achieve a level playing field among businesses trading in goods subject to EU harmonisation legislation? What have been the quantitative and qualitative effects of the measure on its objectives?*

Efficiency

EQ6. What are the regulatory (including administrative) costs for the different stakeholders (businesses, consumers/users, national authorities, Commission)?

EQ7. What are the main benefits for stakeholders and civil society that derive from the Regulation?

EQ8. To what extent have the market surveillance provisions been cost effective?

EQ9. Are there any significant differences in costs (or benefits) between Member States? If so, what is causing them?

Relevance

EQ10. To what extent are market surveillance provisions of the Regulation still relevant in light of for instance of increasing online trade, the increase in imports from third countries, shortening product life, increasing budgetary constraints at national level, etc.?

EQ11. To what extent do the effects of the market surveillance provisions satisfy (or not) stakeholders' needs? How much does the degree of satisfaction differ according to the different stakeholder groups?

EQ12. Is there an issue on the scope (i.e. all EU product harmonisation legislation) of the measure or some of its provisions?

EQ13. Is the concept of lex specialis still a suitable interface between the market surveillance provisions in the Regulation and those in other (notably sector) legislation?

Coherence

EQ14. To what extent are the market surveillance provisions coherent internally?

EQ15. To what extent are the market surveillance provisions above still coherent with other Union legislation on market surveillance on non-food products?

EQ16. To what extent are these provisions coherent with wider EU policy?

EU added value

EQ17. What is the additional value resulting from the market surveillance provisions at EU level, compared to what could be achieved by Member States at national and/or regional levels?

EQ18. To what extent do these provisions support and usefully supplement market surveillance policies pursued by the Member States? Do the provisions allow some sort of 'control' by the EU on the way national authorities carry out market surveillance?

4. METHOD

4.1. Sources

This evaluation builds partly on an external study carried out by a consultant. The methodology of the study consisted of desk research, field research and case studies. The results of the study and its methodology are set out in Annex 4 which builds on, and analysed Annexes 1 to 3 and 5 to 9[18].

In addition, this evaluation uses the market surveillance programmes of Member States, the results of the review and the assessment set out in Annex 7, the first report on the implementation of the Regulation[19], and other documents set out in the Annex of this evaluation, including the evaluation of Union harmonisation legislation[20].

Yet, it is important to keep in mind the complementary nature of the market surveillance provisions and the fact that Union harmonisation legislation has evolved fundamentally, especially with regard to market surveillance. As mentioned in section 2.1.3 Regulation (EC) No 765/2008 and Decision 768/2008/EC were the starting point for the introduction of specific market surveillance procedures in Union harmonisation legislation. Since their adoption, almost twenty directives and regulations[21] with market surveillance procedures were adopted by the European Parliament and the Council and referring directly to the market surveillance provisions.

Therefore, it is quite difficult to separate the effectiveness, the efficiency, the relevance and the EU added value of, on the one hand, the market surveillance provisions in the Regulation and, on the other, the market surveillance procedures in these directives and regulations. Nonetheless, this evaluation focuses specifically on the market surveillance provisions in the Regulation and will separate them from any other elements set out in other legal instruments. Their coherence will be examined in the section on coherence.

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18 See section 4 of Annex 4.

19 Commission report COM(2013)77 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 339/93

20 COM(2014)25 and SWD(2014)23.

21 Directive 2009/48/EC on the safety of toys; Directive 2010/35/EU on transportable pressure equipment; Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products; 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; Directive 2013/53/EU on recreational craft and personal watercraft and repealing Directive 94/25/EC; 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; 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; Directive 2014/30/EU on the harmonisation of the laws of the Member States relating to electromagnetic compatibility; 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; 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; Directive 2014/33/EU on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts; 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; 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; 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; 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; Directive 2014/90/EU on marine equipment and repealing Council Directive 96/98/EC; Regulation (EU) 2016/424 on cableway installations and repealing Directive 2000/9/EC; Regulation (EU) 2016/425 on personal protective equipment and repealing Council Directive 89/686/EEC; Regulation (EU) 2016/426 on appliances burning gaseous fuels and repealing Directive 2009/142/EC.

4.2. Limitations – robustness of findings

The baseline data are quite limited and are hardly comparable with the current data[22]. In addition, Union harmonisation legislation was amended for several products since 2008, which may have an impact on the findings on formal non-compliance since this type of non-compliance was less prominent in the previous legislation. Formal non-compliance also includes, for example, missing warnings and information for consumers on the packaging. Therefore, it could also lead to safety problems.

There were some significant data gaps, especially as regards availability, reliability and structure[23]. Triangulation was used wherever possible[24]. In particular:

(1) Significant gaps in data availability make it difficult to provide a complete picture of the *dimension of product non-compliance across the EU*. In light of this constraint, it is difficult to draw robust conclusions on the effectiveness of the Regulation in reducing product non-compliance with respect to the years prior to its entry into force. In order to have at least a partial overview of the issue, two solutions have been implemented:

- RAPEX notifications were used as a proxy for measuring product non-compliance, although they only relate to products that pose (serious or "other") risks to the health of consumers/users and thus represent an underestimation of the real dimension of non-compliance,

- some indicators provided in national reports (number of product-related accidents/user complaints, corrective actions taken by economic operators, inspections resulting in findings of non-compliance, inspections resulting in restrictive measures taken by MSAs) were also be used as proxies for product non-compliance, where information was available[25].

(2) The analysis of the *implementation* and the *cost-benefits analysis* encountered main difficulties due to the differing levels of detail in the information provided by Member States' authorities, as to market surveillance activities carried out and available resources. Information was only partially or not available at all for a large number of countries.

Finally all the steps presented for the *market analysis* were subject to the following issues: (i) Definitions of sectors/products in the regulation are usually different from nomenclatures used within statistics; (iii) Statistics at the sectorial/product level use different nomenclatures (e.g. intra EU trade uses the Standard International Trade Classification [SITC], production values use the PRODuction COMmunautaire [PRODCOM] nomenclature, business demographics uses the Statistical Classification of Economic Activities in the European Community [NACE]); (iii) Difficulties in identifying harmonised sectors in case EU

22 See section 4.3.1 of Annex 4.
23 See section 4.3 of Annex 4. The mitigation measures are set out in section 4.3.3.
24 See throughout Annex 4.
25 The evaluation only considered sectors where information on the abovementioned indicators was reported by at least 15 Member States, in **nine out of 30 sectors**. Sectors excluded for which **less than 15 Member States** report information on the relevant indicators: cosmetics, construction, aerosol, simple pressure vessels, transportable pressure equipment, lifts, cableways, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, explosives, appliances burning gaseous fuels, electrical equipment under EMC, electrical and electronic equipment under RoHS and WEEE and batteries, chemical, motor vehicles and tyres, recreational craft, marine equipment, non-road mobile machinery, fertilizers, other consumer products under GPSD. Moreover, the group of Member States may vary, depending on the indicator and sector considered.

legislation introduced harmonised rules that apply only to some products within sectors. As a result, the outcomes of this analysis are to be regarded as indicative estimates.

5. IMPLEMENTATION STATE OF PLAY (RESULTS)

5.1. Market surveillance structures and measures

According to Article 16(1) of the Regulation, "*Member States shall organise and carry out market surveillance as provided for in this Chapter [i.e. on General requirements]*". The Regulation does not set out explicit obligations as to how market surveillance shall be organised at the national level, this being left to Member States' prerogative. Therefore, market surveillance is organised differently at the national level in terms of the sharing of competences and powers between Market surveillance authorities[26]. In this regard, three types of overall organisation models have been implemented by Member States, although with a number of additional country-specific nuances:[27]

– **Centralised,** where activities are carried out by one or few Market surveillance authorities. This model is applied in Bulgaria, the Czech Republic, Luxembourg, Malta, Portugal, and Slovakia.

– **Decentralised at the sectoral level**, where several Market surveillance authorities operate and have different competences, depending on the sector where they perform market surveillance activities. This model is adopted in Belgium, Cyprus, Croatia, Denmark, Estonia, France, Greece, Ireland, Italy, Latvia, Lithuania, Poland, the Netherlands, Romania, Slovenia and Sweden.

– **Decentralised at the regional/local level**, where numerous Market surveillance authorities have enforcement responsibilities on specific geographical areas of competence. Austria, Finland, Germany, Hungary, Spain and the United Kingdom follow this organisational structure.

The following boxes provide an overview of the organisation models implemented respectively by Italy and Germany.

Box 1: The Italian organisational model of market surveillance

The Italian model of market surveillance is **decentralised at the sectoral level**. The **Ministry of Economic Development (MISE)** is the main national MSA and acts as a coordination body for the different enforcement authorities conducting market surveillance in the field, for relations and negotiations at the EU level, for the use of Rapid Exchange of Information System (RAPEX) and Information and Communication System for Market Surveillance (ICSMS), and for the establishment of *ad hoc* budgets and objectives. The MISE has general responsibilities over all sectors covered by Regulation 765/2008. Different ministries are in charge of market surveillance in various sectors within the scope of the Regulation. For instance, the **Ministry of the Interior** is responsible for market surveillance of explosives, while chemicals fall under the responsibility of the **Ministry**

26 For further details, see section 5.2.1 of Annex 4
27 See section 6.1.3 of Annex 4.

of Health. The **Ministry of Infrastructure and Transportation** controls the largest number of product categories. Each ministry organises its own market surveillance enforcement system.

Other relevant enforcement bodies are:

- **The Institute for Environmental Protection and Research – ISPRA**, under the Ministry of the Environment, which is in charge of enforcing Regulation 765/2008 regarding noise emissions for outdoor equipment.[28]
- **The Italian Economic and Financial Police – Guardia di Finanza (GdF)**, under the Ministry of Economy and Finance. Market surveillance activities are undertaken by the Special Unit for the Protection of Markets which exercises its powers on toys, personal protective equipment, low-voltage electronics and electromagnetic compatibility. The Guardia di Finanza operates autonomously within the territory or in collaboration with the Customs Authority. It can also file RAPEX notifications.
- **The Chamber of Commerce, coordinated by Unioncamere** that report to the Ministry of Economic Development. Their activities are based on annual bilateral agreements, establishing the number and the sectors of the planned inspections. Inspected sectors vary from year to year and can include toys, textile and footwear labelling, as well as electrical equipment.
- **The Local Health Units (Azienda Sanitaria Locale, ASL)**, under the Ministry of Health. They carry out health and safety inspections in the workplace. Although their core mission is not primarily related to market surveillance, they can sometimes find evidence of non-compliance in plants, machinery, medical devices or personal protective equipment during their inspections.
- **The special unit of the Italian Police Carabinieri, NAS**. It is a law enforcement body under the Ministry of Health, focused on health and safety controls covering several product categories. In particular, this unit of the Carabinieri monitors activities under the General Product Safety Directives (GPSD), toys, medical devices, plant protection products, as well as health products – all within the scope of the Regulation 765/2008.

The **National Customs Authority** is responsible for product checks at the border and it is mainly active near airports and harbours through its local offices.

The analysis of the Italian system has identified certain strengths and weaknesses of this model of organisation. First of all, while it is organised in a pyramidal way, with the MISE as the main body responsible for national market surveillance and in charge of coordination. Overall, however, it seems that there are **no formal channels or established standard procedures through which the different ministries can coordinate** their activities. As a consequence, although the MISE may have the formal powers over MSAs' activities, in practice it has no power of control over their budgets and therefore on priority setting. Indeed, it seems that market surveillance, in the context of Regulation 765/2008, is just one of the many tasks that each enforcement body has to deal with on a daily basis. Second, sectoral decentralisation has led to different product sectors being under the responsibility of the most appropriate ministry or institution, thus providing a **higher level of specific knowledge**. However, this **adds complexity to the management and uniformity of market surveillance** at the national level. In particular, the fact that every ministry internally organises its own market surveillance structure for each product category leads to variation in the ways the different sectors are controlled and managed. Moreover, fragmentation throughout the territory may hinder authorities' response times. In this context, an overlap of competences may also happen. A critical operational issue is the **integration of Regulation 765/2008 with other sectoral legislation**, given that the primary responsibility for the enforcement of the Regulation is under the MISE, while the enforcement of some sectoral laws is under the responsibility of the relevant ministries. Moreover, some sectors can be controlled by multiple authorities, as in the case of GPSD. Therefore, there may be cases where **products need multiple evaluations and validations** in order to be allowed to enter the market.

Box 2: The German organisational model of market surveillance

28 Directive 2000/14/EC on the approximation of the laws of the Member State relating to noise emissions in the environment by equipment for use outdoors.

Germany is characterised by a structure **decentralised at the regional/local level**, where competences are shared among various Land authorities. Germany is a Federal Republic made up of **16 Länder** whose **ministries** are separate from the Federal Government, both from a policy and financial point of view. The Federal Government and Federal Ministries are responsible for the overall legislation (laws and regulations), while the 16 Länder are in charge of the enforcement of this legislation. Resources for market surveillance are therefore provided by the Länder themselves.

The 16 Länder coordinate their enforcement action through several committees, where representatives from the Land ministries and MSAs regularly meet. Committees are focused on selected sectors. The biggest committee is the **Working Committee on Market Surveillance – AAMÜ**, which covers the largest number of sectors within the scope of Regulation 765/2008.[29] Another coordination body is the **Central Authority of the Länder for Technical Safety (ZLS).** The ZLS was set up to centralise some market surveillance tasks, such as the creation of product risk profiles and the forwarding of RAPEX notifications, instead of having them repeated for all of the 16 Länder. The ZLS has more operational tasks than the other coordination committees and can even enforce the law under special conditions and following the Länder's requests (for instance, when a market surveillance case involves several Länder or has international relevance). Another pillar of the German coordination strategy is represented by the extensive use of **ICSMS**, which national authorities are very familiar with, as it was first developed in Germany. As already mentioned, ICSMS is crucial to avoiding duplication of work, a possible deficiency of decentralised structures.

At the central level, three Federal MSAs enforce market surveillance in specific product sectors:

- **The Federal Network Agency – BNetzA**, under the Federal Ministry of Economy and Energy, is responsible for market surveillance in two sectors: electrical equipment under the Electro-Magnetic Compatibility Directive[30] and radio and telecommunications equipment under the Radio and Telecommunication Terminal Equipment Directive;[31]
- **The Federal Authority for Maritime Equipment and Hydrography – BSH**, under the Federal Ministry of Transport and Digital Infrastructure, is responsible for the marine equipment sector;
- **The Federal Motor Transport Authority – KBA**, under the Federal Ministry of Transport and Digital Infrastructure, is responsible for motor vehicles.

Three additional Federal agencies are also involved in the context of market surveillance, though they are not responsible for enforcement in individual product sectors, the **Federal Institute for Occupational Safety and Health – BAuA**,[32] the **Federal Institute for Materials Research and Testing – BAM**,[33] and **the Federal Agency for Environment – UBA**.[34]

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29 AAMÜ covers the following sectors: equipment and protective systems intended for use in potentially explosive atmospheres, simple pressure vessels, aerosol dispensers, transportable pressure equipment, machinery, lifts, noise emissions for outdoor equipment, electrical appliances and equipment under the Low Voltage Directive (LVD), appliances burning gaseous fuels, personal protective equipment (PPE), toys, recreational craft, other products under GPSD. Source: German Product Safety Act.

30 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).

31 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.

32 BAuA is a governmental institution with R&D functions that advises the Federal Ministry of Labour and Social Affairs in all matters of safety and health, especially in work-related fields. In consultation with the Federal Ministry of Labour and Social Affairs, the BAuA participates in national, European and international committees for the formulation of regulations and standards. The Federal Institute collaborates with the institutes which operate within its field of work.

33 BAM is a scientific and technical Federal institute under the Federal Ministry for Economic Affairs and Energy. It tests, researches and advises to protect people, the environment and material goods. According to its founding decree, BAM is responsible for the development of safety in technology and chemistry; for the implementation and evaluation of physical and chemical tests of materials and facilities, including the preparation of reference processes and reference materials; for the promotion of knowledge and technology transfer within its areas of work; for advising the Federal Government, industry, and national and international organisations in the fields of material technology and chemistry.

34 UBA is the central environmental authority. It plays an important role in the enforcement of national and European environmental law, for example in the field of industrial chemicals, plant protection products, medicinal products, and washing and cleansing agents. If a risk to human health or the environment exists, it recommends conditions of use, use restrictions or bans. UBA's specialists also work to improve scientific knowledge about chemicals and their risks, and formulates science-based

The **Central Customs Authority** (Generalzolldirektion) is responsible for many fields other than those related to the Regulation (e.g. drugs, weapons, human health, and environment). It also coordinates, manages and supervises the 270 local Customs offices, which are in charge of border controls.

The analysis of the German system has identified certain strengths and weaknesses of this model of organisation. A clear strength of the system is that the German organisational structure establishes a responsible authority for each product sector where tasks are well defined and **competences clearly split**. Therefore no overlapping occurs between the Federal and the Land level in terms of market surveillance responsibilities in all sectors covered by the Regulation. Nonetheless, s**ubstantial resources are required** to replicate a market surveillance system in 16 Länder. Furthermore, particularly in the case of Customs, the high number of organisational entities involved in the organisation of market surveillance makes **difficult to identify the 'right partner'** to deal with market surveillance issues. Even more importantly this organisational model has required **many efforts to ensure the necessary level of coordination** (e.g. the establishment of permanent, *ad hoc* coordination bodies such as the ZLS, the organisation of workshops, meetings and events to create an 'informal' network of market surveillance actors). The **efficiency of the several coordination tools** seems also to be an issue. Germany is indeed planning to create a single, general coordination board covering all product categories and ensuring further alignment between the Federal, the Land and the European level that would rationalise the existing coordination mechanisms.

Section 5.2 of Annex 4 and section 2 of Annex 7 provide a detailed country-by-country overview of the current situation in terms of structures relevant to the implementation of the market surveillance provisions with regards to the organisation of market surveillance at the national level, the market surveillance activities to detect non-compliant products, the existing coordination and cooperation mechanisms within/among Member States, and the measures taken against non-compliant products.

recommendations for the improvement of environmental and climate protection instruments. It does not only assess environmental health risks to adults and children, but also develops action programmes designed to reconcile environmental and health protection requirements. Its experts also provide advice to municipalities and the Federal States on environmental health issues.

Figure 2: The Italian organisational model of market surveillance

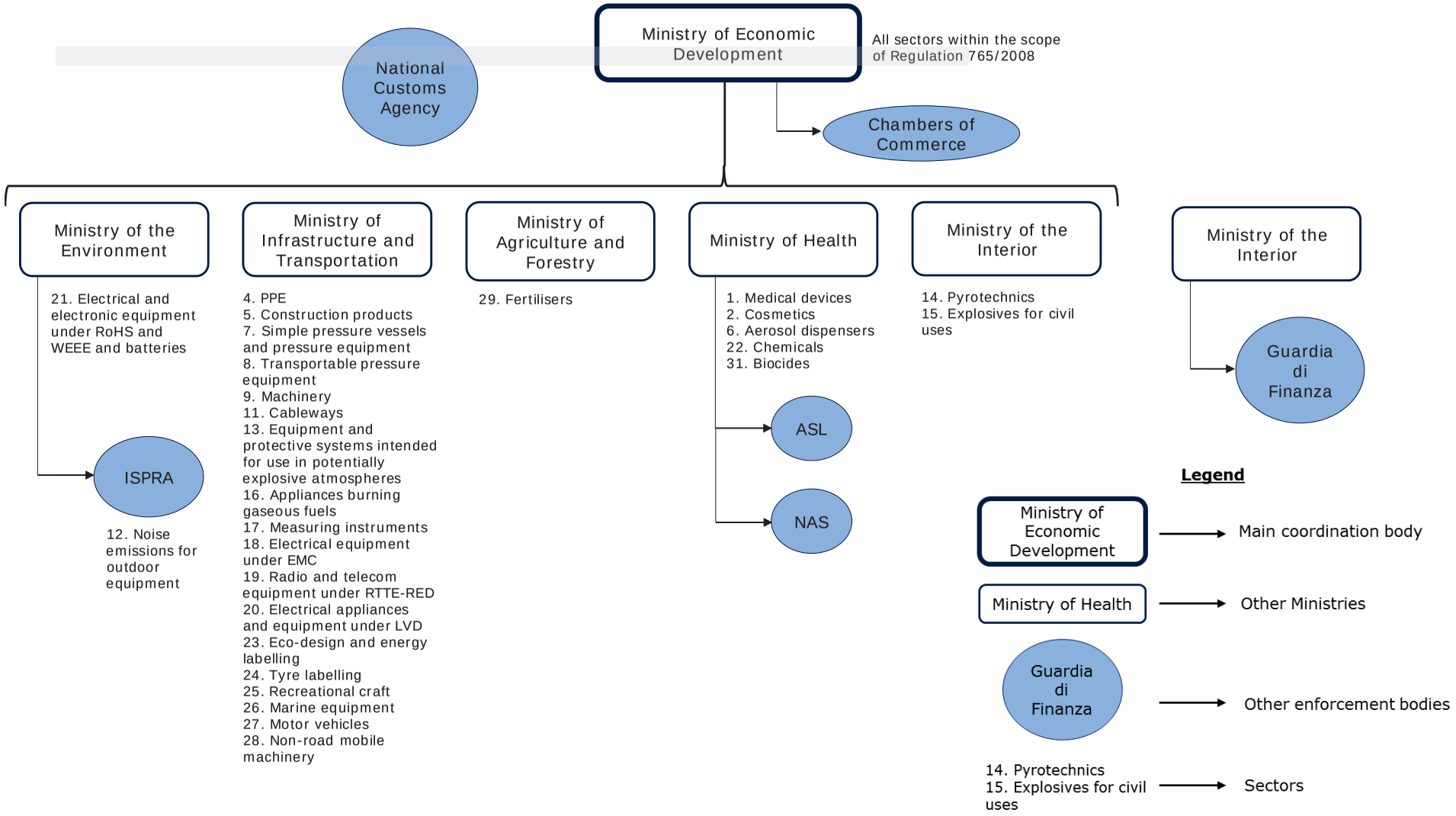
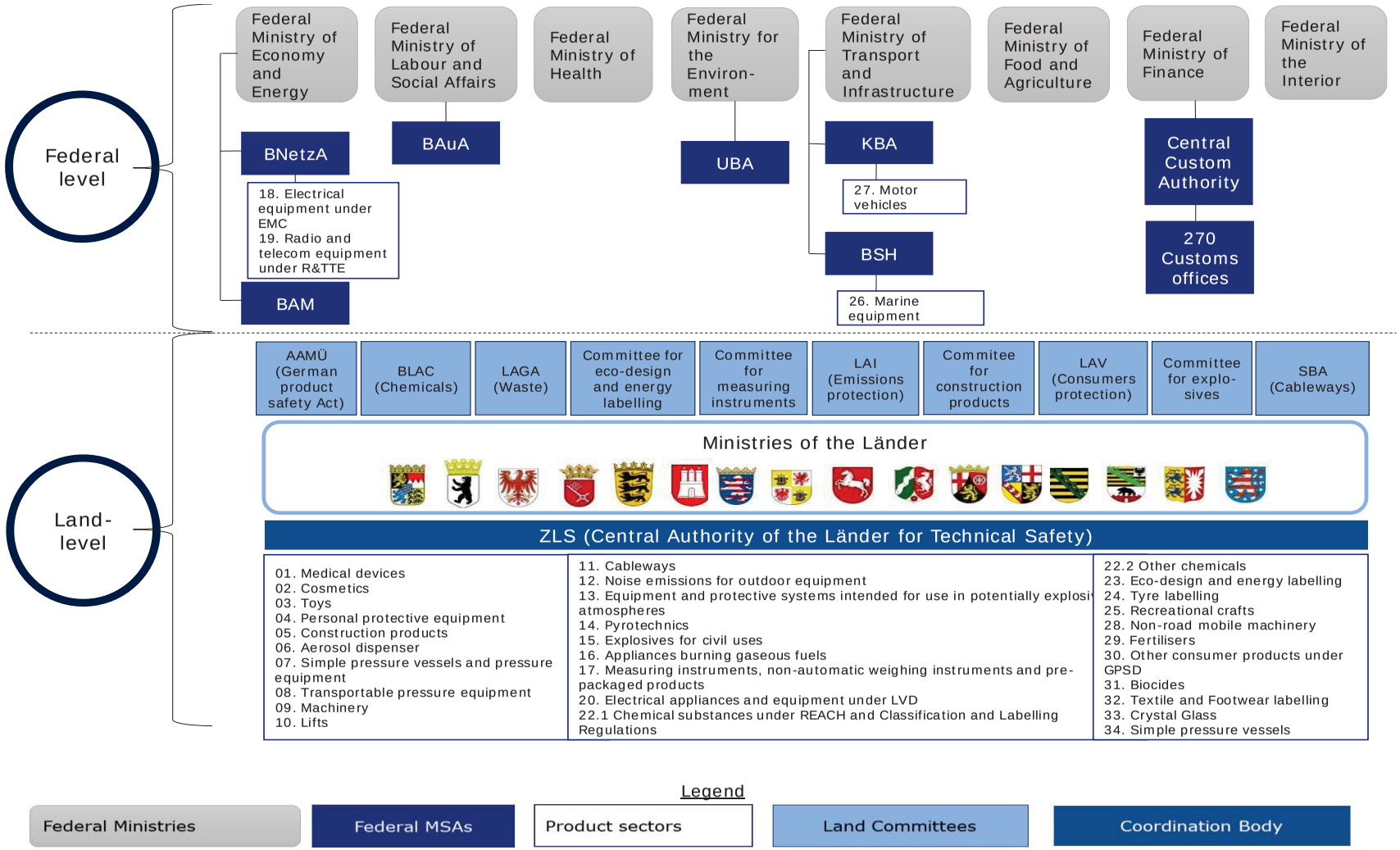


Figure 3: The German organisational model of market surveillance



5.2. Additional information

5.2.1. Exchange of information (ICSMS, notifications of restrictive measures, national market surveillance programmes and reports on activities)

The market surveillance provisions in the Regulation foresee instruments for the exchange of information between Member States[35]. They include RAPEX[36] and ICSMS[37] as key tools for the cross-border exchange of information and work sharing between market surveillance authorities.

While RAPEX is successfully used for dangerous consumer products posing a risk to the health and safety in the context of the GPSD[38], it is much less used for the other serious risks covered by Article 20 of Regulation (EC) No 765/2008:

Table 4: RAPEX notifications under Regulation (EC) No 765/2008

Year	Professional Products	Electromagnetic disturbance	Incorrect measurement	Environmental risk
2012	31	0	0	4
2013	53	8	1	63
2014	32	1	0	32
2015	24	1	0	35
2016	47	0	0	41
Total	**187**	**10**	**1**	**175**

Almost all Member States now use ICSMS, after a slow take-up[39]. 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, declarations of conformity, pictures, etc.). However, Member States use the system to different degrees, as illustrated in the diagram below which shows the numbers of product information put into 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 variation between different market surveillance authorities on their use of the system.

35 See section 1 of Annex 8.

36 RAPEX (Rapid Exchange of Information System) is an information system between Member States and the EC on measures and actions taken in relation to products posing serious risk to the health and safety of consumers. http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm . RAPEX was established by the GSPD and subsequently extended by Articles 20 and 22 of the Regulation to all harmonised products.

37 ICSMS (Information and Communication System for Market Surveillance) is the information and communication system for the pan-European Market Surveillance, referred to in Article 23 of Regulation (EC) No 765/2008.

38 http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/reports/index_en.htm

39 Section 3.5 of COM(2013)77 provides for an overview of the implementation of ICSMS between 2010-2013.

Figure 4: Use of ICSMS by all EU/EEA Member States in 2016[40] :

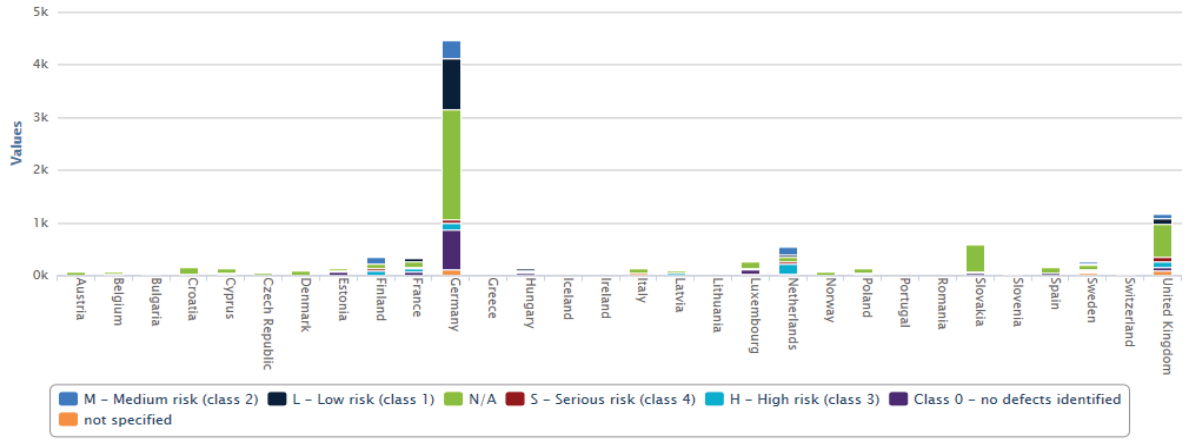
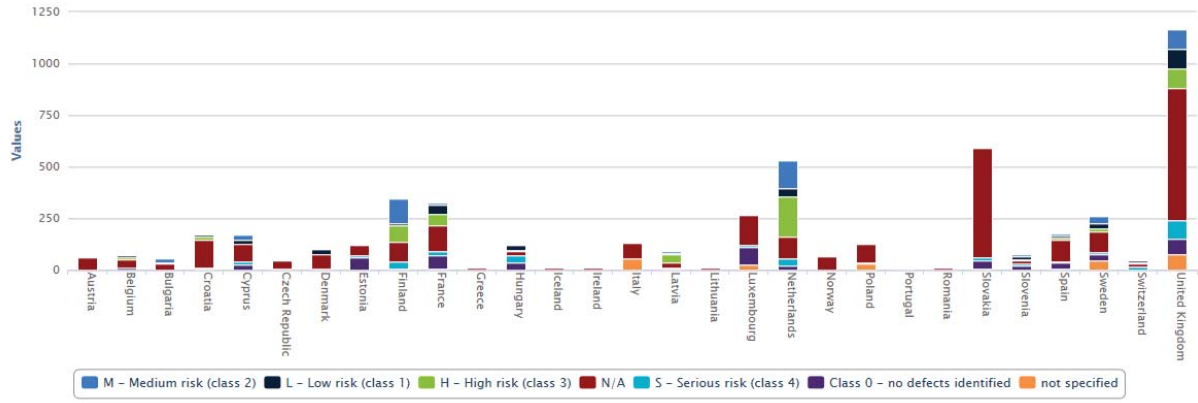


Figure 5: Use of ICSMS by EU/EEA Member States excluding Germany in 2016:



In addition to this, it is worth mentioning that sector specific Union legislation also sets out an obligation for Member States' competent authorities to communicate to the other Member States restrictive measures taken against non-compliant products. This procedure is often referred to as the 'safeguard clause procedure'. 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[41]. Recent guidance discussed at expert's working group level clarifies principles for cooperation based on the existing legal framework and the link between these obligations and the use of the RAPEX and ICSMS tools[42]. 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'

40 No entries are recorded for Malta and Liechtenstein.

41 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.

42 Guidance on cross-border cooperation among EU market surveillance authorities (http://ec.europa.eu/DocsRoom/documents/17108/attachments/1/translations).

sectors many Member States do not actually notify any measures and the number of notifications is decreasing overtime[43].

The market surveillance provisions in the Regulation require Member States to draw market surveillance programmes and to periodically review and assess the functioning of their activities at least every four years (Articles 18(5) and 18(6)). All Member States communicated market surveillance national programmes and reports to review and assessed the functioning of market surveillance activities during the first four years of application of the Regulation[44]. However, since the Regulation does not provide any details on the content of the programmes and reports, the sectorial coverage and the quality of information contained in this documentation varies remarkably from Member States to Member State[45]. Comparability of information is also an issue.

5.2.2. Cooperation

Since 2013, on the basis of the Regulation financing provisions, the European Commission provides logistical and financial support for informal cooperation between national authorities that takes place by means of the so-called Administrative Cooperation groups (hereinafter 'AdCos')[46] in a number of sectors. AdCos participants discuss several issues related to the market surveillance, elaborate common guidance documents and sometimes carry out joint enforcement actions. According to the feedback received from AdCos this support has proven beneficial in increasing and stabilising the rate of participation of national authorities in the meetings.

Table 5: Participation in AdCo meetings

AdCo[47]	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								

43 See section 1.2 in Annex 8.

44 Programmes and reports are available at: http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation_en

45 http://ec.europa.eu/DocsRoom/documents/15241/attachments/1/translations

46 https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups_en

47 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.

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/SVPD	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 6: Joint actions organised within AdCos and number of Member States (MS) participating[48]

AdCo	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)	
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[49]	2012-2013: Log Splitters (about 8 MS) 2012-2015:	Boom saws (3 MS)		Portable chain-saws and vehicle servicing lifts* (9-10 MS)

48 Most joint actions are indicated under the year during which they were launched, although projects lasted two or more years.

49 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.

	Firewood Processors (about 7-8 MS) (1) 2011-2015: Impact Post Drivers (3-4 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.

Some joint market surveillance campaigns were financed by the European Commission on the basis of financing provisions included in the market surveillance provisions. In particular, the following calls for proposals were issued since 2013:

- 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 a 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 in the field of machinery safety and LED floodlights. The grants that have been awarded are in the form of 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 Finnish authority, while the other was coordinated by the "Prosafe" foundation[50].

- 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 two calls for proposals were launched with a higher maximum budget foreseen for EU financing of 750 000 EUR and 540 000 EUR respectively, but no proposals were received.

50 http://www.prosafe.org/about-us/contentall-comcontent-views/what-is-prosafe

5.2.3. Infringement proceedings

The Commission did not launch any infringement proceedings related to the market surveillance provisions. There have been two complaints from economic operators but both cases were closed in the absence of a clear breach of the Regulation.

It is unclear whether the limited number of complaints is due, either to the clarity of the provisions, or to the fact that the market surveillance provisions are not very known with businesses. The fact that these provisions only set minimum requirements for market surveillance leaving Member States with high discretion in their implementation, and the relative uncertainty on the precise scope of the Regulation may also have had an impact.

Furthermore, there were no judgements from the Court of Justice about the provisions.

6. ANSWERS TO THE EVALUATION QUESTIONS

6.1. Effectiveness

EQ1 - Are the results in line with what is foreseen in the impact assessment for the Regulation, notably with regards to the specific objectives of (i) enhanced cooperation among Member States, (ii) uniform and sufficiently rigorous level of market surveillance, (iii) border controls of imported products?

6.1.1. Enhanced cooperation among Member States

The impact assessment for the Regulation foresaw that cooperation and information exchanged would be considerably improved under the preferred option. The market surveillance provisions have indeed improved substantially the cooperation between Member States which nevertheless often remains difficult due to the high degree of fragmentation in market surveillance competences and the slow take up of the different tools to share information and coordinate enforcement work[51].

6.1.1.1. Exchange of information (ICSMS, notifications of restrictive measures, national market surveillance programmes and reports on activities)

Statistics presented in section 5 and information gathered from stakeholders show that the use of ICSMS by Market surveillance authorities is still limited, or that some Member States do not even use ICSMS at all. Even within Member States there is a great variation between Market surveillance authorities in their use of the system. This hampers the possibility of capitalising the work carried out by other authorities and creates a duplication of effort, which is the case when the system is properly used, as shown by the German practice analysed in case study 2. Also, the possibility for Market surveillance authorities and Customs to make use of test reports drafted by Market surveillance authorities in other EU countries seems to be limited[52]. On the other hand a number of Market surveillance authorities pointed out the burden due to the filling-in of both ICSMS and internal/national databases because of

51 See section 5.1.1.1 of Annex 4 and Annex 8.
52 See section 6.1.1 of Annex 4.

compatibility issues.. Further frequent issues concern the lack of adaptations to insert sector-specific information into ICSMS and there being no opportunity to update information along the progress of the case. The low user-friendliness to ease data entry, difficulties in finding instructions on how to use ICSMS and linguistic barriers are also reported as minor issues that could be improved[53].

As for RAPEX, its use has significantly increased over the years, both in terms of the number of notifications and follow-up actions. Moreover, the number of follow-ups outweighed the number of total notifications from 2014, this possibly indicating that RAPEX is more and more recognised and used as an information tool for enforcing market surveillance. However, the use of RAPEX across Member States differs, indicating that some Member States are more proactive while others are more reactive in dealing with notifications. Yet, there are doubts on the full use of RAPEX considering that the number of notifications made in the system is not proportionate to the size of the national markets. [54] For instance, Cyprus notifies on average more than Poland, Sweden and Romania. An obstacle to the use of RAPEX is the perceived redundancy of having different notification procedures and communication tools: some market surveillance authorities think that ICSMS, RAPEX and the safeguard clause should be integrated within a single information system to avoid double encoding of information and inconsistencies[55]. On the other hand, as mentioned in section 5 the safeguard clause procedure set out in sector specific Union legislation appears largely underexploited by Member States[56].

The market surveillance programmes are considered potentially very useful by stakeholders because they are an opportunity to define market surveillance strategies and to inform consumers. The programmes are also useful to avoid overlapping of market surveillance actions, working as a tool for cooperation between market surveillance authorities. They can even contribute to ensuring a level playing field in Europe, since they allow Member States to acknowledge the differences in the enforcement actions and possibly to eliminate them[57]. The national 'review and assessment' reports can importantly contribute to improving the effectiveness and efficiency of market surveillance activities since they help in verifying and monitoring implemented activities.

However, the requirements of the provision on these programmes and reports are rather general, and this has led to the development of different practices in the preparation of these documents and hindered the provision of relevant information. Several efforts were made at experts' level to build common templates and procedures to capitalise the tools, which led to increasing uniformity in the content of the programmes[58]. Nevertheless, information contained therein is often too generic to serve as a planning tool. Furthermore, many programmes are shared by Member States too late (i.e. months after the start of the period they refer to) to be able to learn from each other's experience and enhancing collaboration[59]. As regards national reports, important information gaps and issues of comparability of data

53 See section 6.1.1 of Annex 4
54 See section 8.5.2 of Annex 4
55 See section 6.1.1 of Annex 4.
56 See section 1.2 in Annex 8.
57 See section 5.3 of Annex 4.
58 See for instance point 3 and point 5 in: http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=23085&no=1
59 See section 5.3 of Annex 4.

limit the possibility to have a complete overview of market surveillance activities in the internal market.

6.1.1.2. Cooperation

The sub-optimal use of information systems to exchange information hampers also cooperation between Member States - that is mainly based on the use of those systems and on European-level initiatives (namely ability to respond and/or complement each other enforcement action, cooperation through AdCos, and joint actions)[60].

Besides the sub-optimal use of information systems, cooperation between Member States faces additional challenges. Even if the majority (77%) of Market surveillance authorities and Customs consulted state that they cooperate with authorities based in other Member States and the large majority of Market surveillance authorities declare that they notify other Member States (75%), most of the Market surveillance authorities (78%) rarely restrict the marketing of a product following the exchange of information on measures adopted by another EU MSA against the same product.

The respondents to the Public Consultation[61] indicate that market surveillance authorities rarely restrict the marketing of a product following the exchange of information about measures adopted by another market surveillance authority in the EU against the same product. This occurs "*sometimes*" according to 34% of stakeholders and "*never* " according to 8% of respondents, while a minority declare that it occurs "*very often*" (12%) or "*always*" (6%). Cross-border cooperation remains problematic, according to the respondents[62].

According to informal feedback from national experts, requests for mutual assistance among authorities in different Member States to supply each other with information or documentation and to carry out appropriate investigations are made and followed up only occasionally.

Furthermore, a closer look at ICSMS shows that, more than 80% of the cases transferred from one market surveillance authority to another ('baton passing') through the system are done within the same country. In addition, many of the cases that one market surveillance authority wishes to transfer to its colleagues in another Member State are rejected. The main reason for many rejections is that the 'target authority' considers itself as geographically or materially not competent to handle the case; a lack of resources was also frequently argued.

60 See section 6.1.1 of Annex 4.
61 See section 8.5.2 of Annex 4.
62 Point 2.3.4 of Annex 2.

Figure 6: Baton passing in ICSMS among Member States (status December 2016)**:**

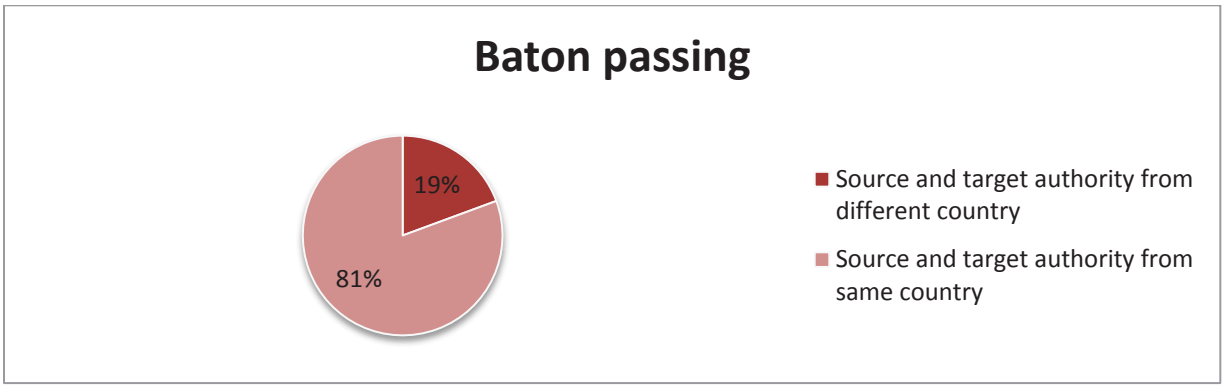
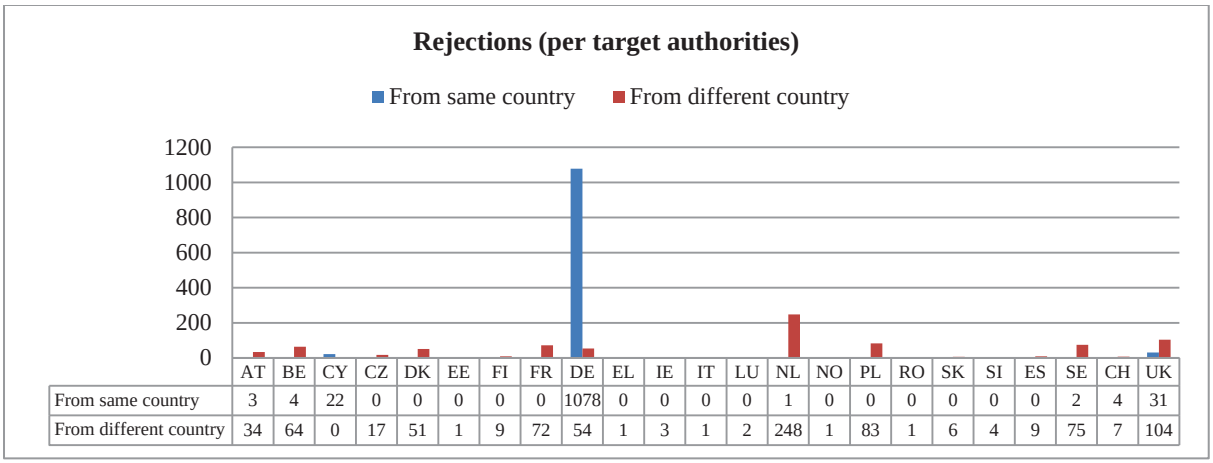
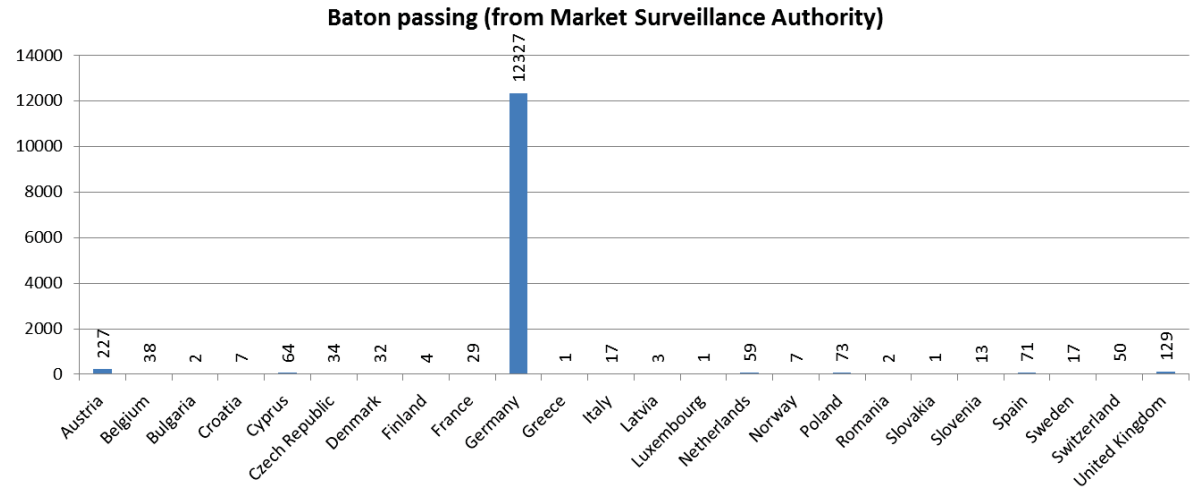


Figure 7: Rejections of baton passing in ICSMS (December 2016):



	AT	BE	CY	CZ	DK	EE	FI	FR	DE	EL	IE	IT	LU	NL	NO	PL	RO	SK	SI	ES	SE	CH	UK
From same country	3	4	22	0	0	0	0	0	1078	0	0	0	0	1	0	0	0	0	0	0	2	4	31
From different country	34	64	0	17	51	1	9	72	54	1	3	1	2	248	1	83	1	6	4	9	75	7	104

Figure 8: Baton passing initiated in ICSMS (December 2016):



6.1.1.3. AdCos

Authorities contacted through targeted interviews confirmed that participating in AdCos work proves to be essential for coordinating actions and keeping an eye on what Market

surveillance authorities in other Member States do, as well as learning from each other. Furthermore, the number of AdCo groups has increased with respect to the period previous to the implementation of the Regulation, rising from "more than ten" to the current twenty-five This could possibly indicate an incentive to cooperate on sectoral market surveillance issues due to the introduction of the Regulation.

However, not all Market surveillance authorities participate in this form of administrative cooperation. Figures presented in section 5 show that 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 the case of CABLE, NOISE and TPED only about 30-40% of Member States were involved. Furthermore, according to the feedback received from AdCo Chairs, many Member States representatives participating in the meetings do not get actively involved in common discussions and activities. In light of this, the Commission has increased its support for these groups, underlining that the chairpersons bear a remarkable burden when organising meetings and that many Market surveillance authorities cannot attend due to budgetary constraints.

6.1.1.4. EU financing

The overview provided in section 5 on EU financing made available on the basis of Regulation (EC) No 765/2008 shows that the initial calls for proposals launched by the Commission were very successful but the following calls were not. The reason for the limited use of EU financing of cooperation activities seems to be related to the complexity of administrative processes, both at the EU level as within the authorities who are also subject to national administrative rules. Notwithstanding simplifications in the grant management rules for EU co-funded projects and increased co-funding rates, market surveillance authorities have difficulties to take-up funding made available at EU level in the form of project grants[63]. For each project a new partnership between different Member State authorities has to be constituted. The management of a project places a considerable burden on the lead authority expected to coordinate work with partners in other Member State authorities and to make financial commitments on their behalf. Member States complain about the lack of an administrative framework for the management of these actions and of the available money[64].

6.1.1.5. Provisional conclusion

Coordination and cooperation mechanisms are significantly developed, consisting of an impressive number of initiatives, and all stakeholders recognise them as useful. However, they have not reached a level that can be considered satisfactory, especially considering those existing among Member States. In particular, despite the fact that necessary tools are in place to ensure cross-border market surveillance cooperation, they are not used to an extent sufficient to trigger effective coordination and efficient work sharing among surveillance authorities in the Single Market. There is still a need for higher level exchange of information, follow-up to enforcement carried out by other authorities and joint surveillance actions[65].

63 See Annex 8.1.5.
64 http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=28611&no=1
65 See section 6.1.1 of Annex 4.

6.1.2. Uniform and sufficiently rigorous level of market surveillance

The 2007 impact assessment of the Regulation was not very explicit on this point but foresaw that the preferred option would allow a more effective and efficient market surveillance. Furthermore, the relevant provisions in the Regulation are drafted in such general terms that it is impossible to measure precisely the progress that was made since 2010. 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*'.

Nonetheless, a satisfactory level of uniformity and rigorousness of market surveillance has not been achieved yet. As regards the organisation of market surveillance at national level, Member States have implemented the Regulation in many different, specific forms, in terms of distribution of competences[66] and internal coordination mechanisms, level of deployed resources (financial, human and technical), market surveillance strategies and approaches, powers of inspection and sanctions and penalties for product non-compliance. Apparently, there is no provision of the Regulation that has been implemented identically in at least two Member States.

6.1.2.1. Organisational model, resources, strategic approach to market surveillance, monitoring systems

Firstly, the organisation of market surveillance is different across Member States, not only in terms of the level of centralisation of the organisational model (see section 5), but also in terms of available resources (financial, human, and technical). The amount of resources made available cast some doubts on the ability of market surveillance authorities to *'perform appropriate checks on the characteristics of products on an adequate scale*'.

Significant differences exist across countries regarding the availability of resources and numbers of inspections performed by the EU Member States in order to accomplish the tasks set out in the Regulation.

- Available figures show that 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[67].

- The total budget available to all Member States' authorities having reported the information, in nominal terms[68] 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[69].

66 See previous section 5, section 5.2 of Annex 4 and section 2 of Annex 7.
67 The analysis in Annex 8 section 3 shows the number of Member States having indicated at least some information on resources available for market surveillance for selected sectors and the simple average of resources reported.
68 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.
69 See section 5.2.1 of Annex 4.

- 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[70]. Furthermore, at least 12 Member States complain about the resources being limited[71].

Figure 9: Contribution of each MS to the total budget available in nominal terms to MSA at EU level over 2010-2013[72]

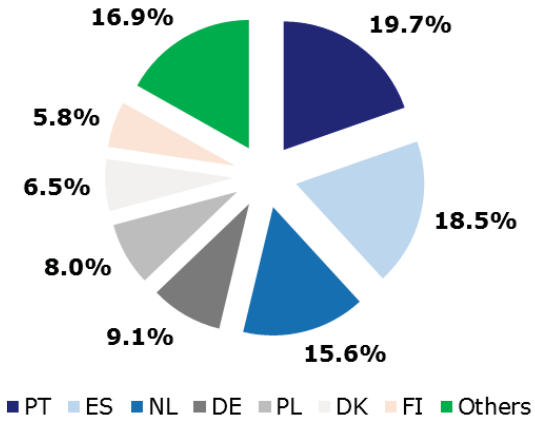
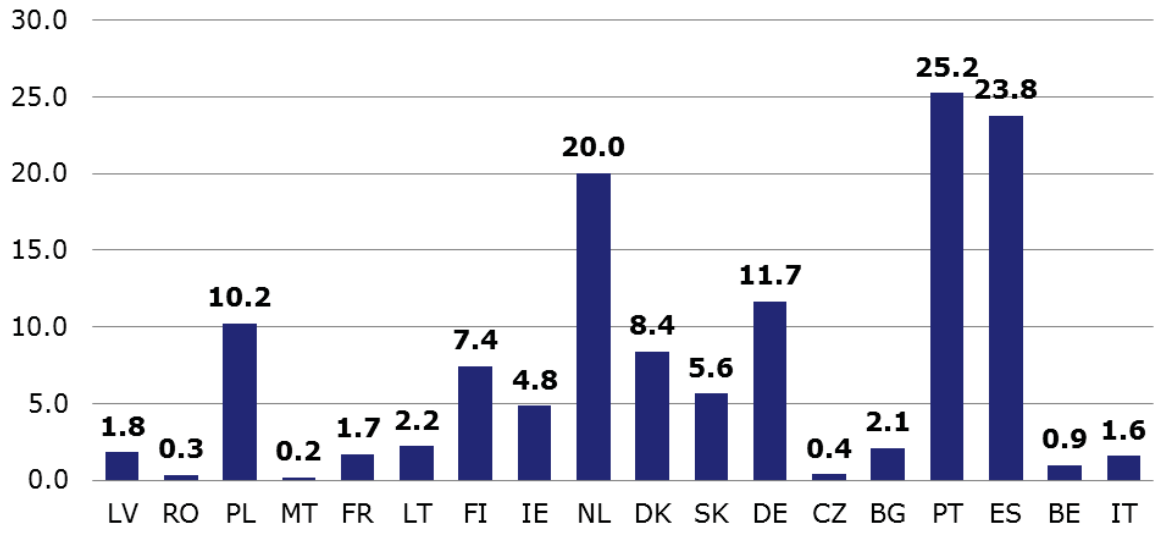


Figure 10: Annual budget available to MSAs in nominal terms, average 2010-2013, € M[73]



70 See section 5.2.1 of Annex 4.

71 See section 3 of Annex 7. Regarding the resources dedicated to the enforcement of chemicals which were not included in the previous analysis, market surveillance authorities are generally satisfied with their level of technical resources, while they consider their financial and human resources insufficient or limited, which impedes the achievement of all activities required under REACH (See Annex 8 section 3.2 and http://ec.europa.eu/environment/chemicals/reach/reports_en.htm.)

72 Please consider that data for the UK are not available. "Others" includes France.

73 The figure about France only captures budget for product testing in state-owned laboratories and therefore underestimates the actual level of resources.

Figure 11: Total budget available to 19 MSAs in nominal terms during 2010-2013, € M

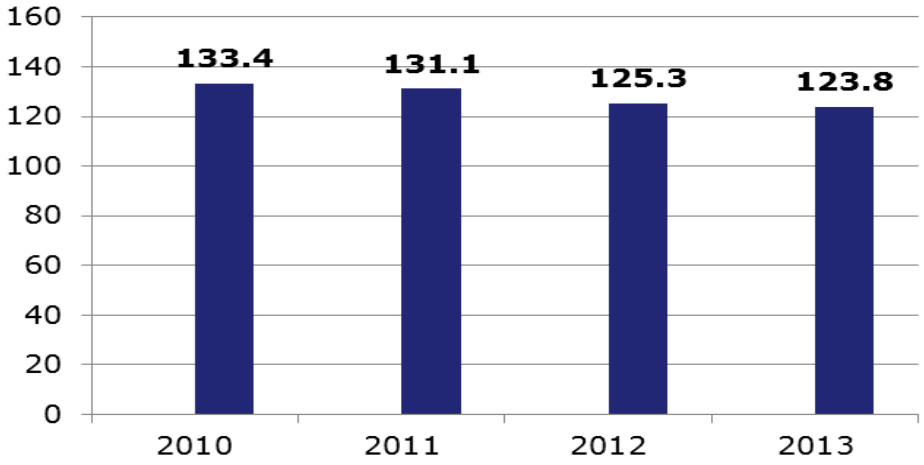
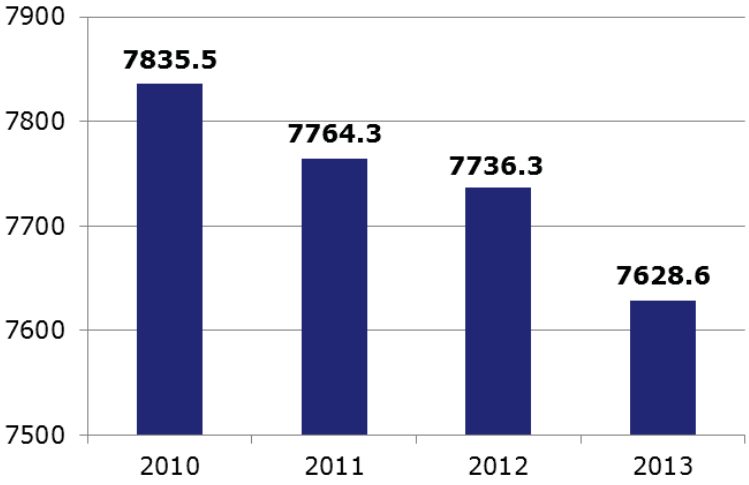


Figure 12: Total staff resources available to MSAs (FTE units) during 2010-2013[74]

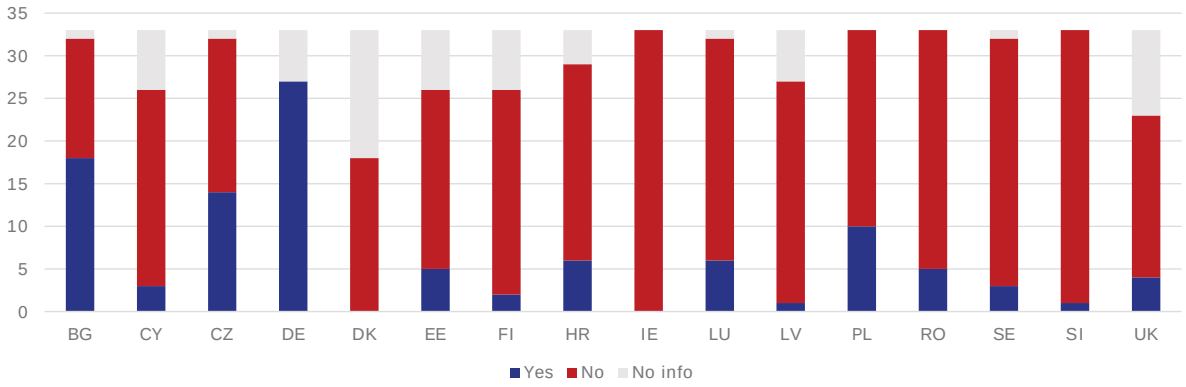


Furthermore, the availabilities of laboratories for product testing widely very across Member States, though a widespread lack of testing capacity can be identified[75].

74 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.

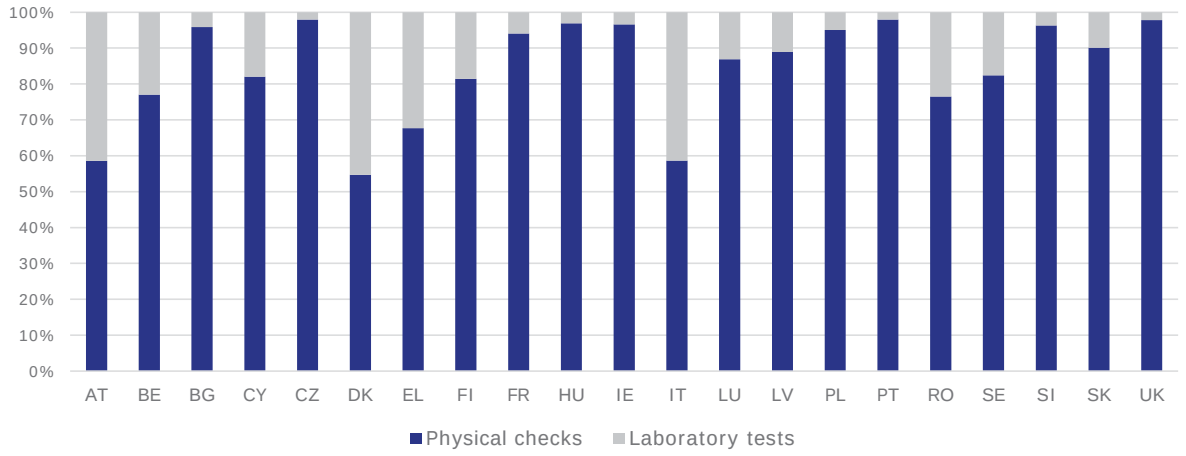
75 For further details, see section 6.1.1 of Annex 4.

Figure 13: Market surveillance authorities' availability of in-house laboratories for product testing in 33 sectors covered by the Regulation[76]



The availability of resources seems to influence the depth of market surveillance controls. Some Member States perform a lot more physical checks of product than testing, and also have few in-house laboratories. Other Member States give higher importance to administrative aspects than to technical aspects, when checking compliance. Therefore, the intensity of enforcement activities varies across countries.

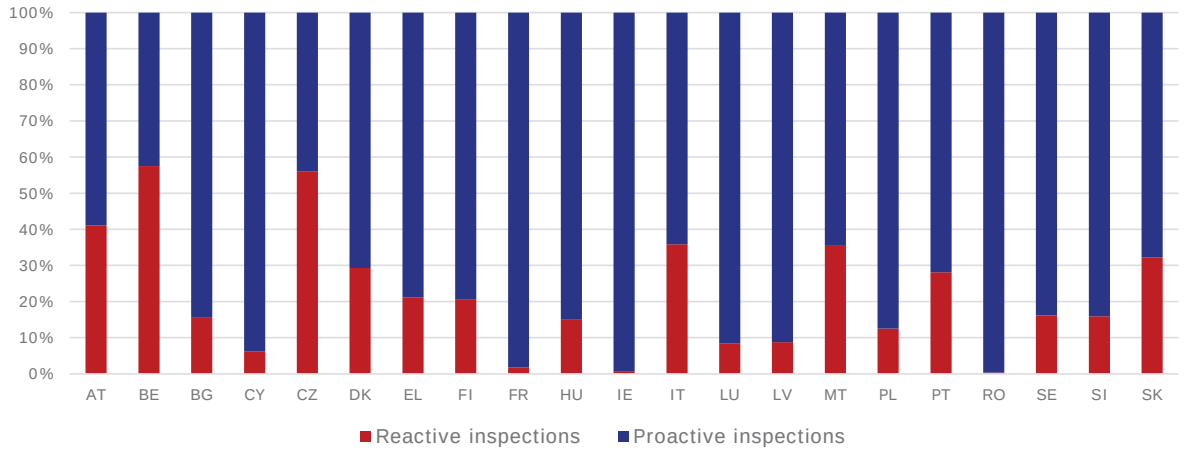
Figure 14: Share of physical checks and of laboratory tests performed on total inspections, average 2010-2013[77]



A further element of differentiation is represented by Market surveillance authorities' strategies of market surveillance.

76 See section 6.1.1 of Annex 4.
77 See section 6.1.1 of Annex 4.

Figure 15: Average of reactive vs proactive Market surveillance authorities' inspections between 2010 and 2013[78]



In order to assess to what extent market surveillance activities are proportionate to the dimension of the national market, the total number of inspections carried out by Market surveillance authorities has been compared respectively to the number of inhabitants and to the number of enterprises active in the harmonised sectors per Member State. It is stressed that both indicators represent imperfect proxies for the size of national markets and the results of the comparisons should be interpreted carefully:

- The first analysis suggests that in many sectors and many Member States the number of inspections is rather low in comparison with total population[79]. Figures for the number of laboratory tests are much smaller, confirming that the large majority of inspections focused mainly on documentary and possibly visual checks of conformity. It is also noted that information provided by Member States on inspections carried out often only covers a subset of sectors where market surveillance should take place.[80] In some cases these information gaps may be interpreted as an indication of the lack of market surveillance activities.

- The second analysis shows that the average correlation between the number of inspections and the number of enterprises per Member State– though positive - is very low (i.e. 0.15), therefore suggesting that Market surveillance authorities' activities and efforts are not related to market dimensions[81]. However the interpretation of the actual values per Member State cannot be pushed further due to several shortcomings of this proxy[82].

78 See section 6.1.1 of Annex 4.

79 For instance yearly inspections per 10 000 inhabitants in most Member States having reported information range from 0.5 to 17 for medical devices, from 0.4 to 11 for pressure equipment and simple pressure vessels, from 0.3 to 13 for transportable pressure equipment, from 0.1 to 10 for lifts, etc. – The findings for all sectors and for all member states having providing information can be seen in Section 5 of Annex 7.

80 See sections 3.1 and 5 of Annex 7.

81 See section 6.1.1 of Annex 4.

82 It is considered that the number of enterprises used for the index does not reflect the actual market dimension in the relevant Member State: market surveillance is performed on products, but the relevant manufacturing enterprises do not necessarily have to be based in the same Member State; furthermore, manufacturers may market different types and quantities of products; wholesalers and retailers are also duty holders that can be inspected by authorities but they are not included in the indicator.

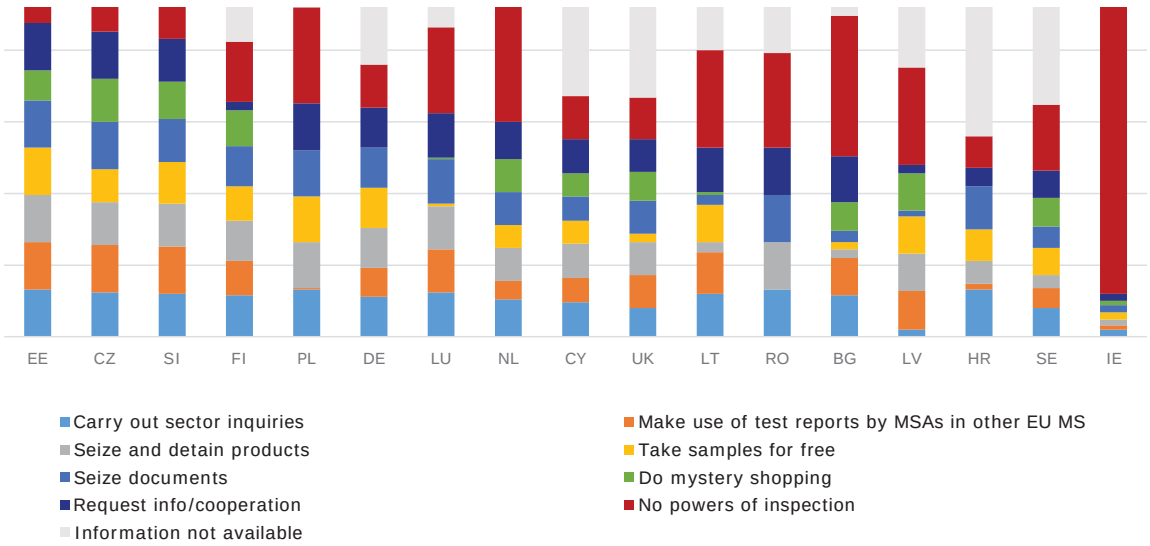
Finally, heterogeneity exists in the system of monitoring and reporting set up by the Regulation, i.e. the national reports. As discussed, the Regulation aims to create a framework for market surveillance controls and sets up a monitoring system (through Article 18(6)) to supervise how and to what extent these controls are performed. However, national reports are not uniform or comparable across Member States, and present a significant number of gaps and inconsistencies. These issues reflect the existing differences in the organisation models – which make it for instance difficult to collect and/or aggregate data on market surveillance activities – but also differences in market surveillance approaches – e.g. the different interpretations of what an inspection is.

6.1.2.2. Powers of national authorities

Differentiation has been assessed also in terms of powers of inspection, which are differently attributed to national Market surveillance authorities (and across Market surveillance authorities within the same Member State) as they are established by different national legislative frameworks. Whereas core powers such as performing documentary and visual checks, physical checks on products, inspection of business's premises, and product testing, are common to most Member States, additional powers can be granted to Market surveillance authorities depending on the Member State and the sector considered, which makes the approach to inspections heterogeneous across Member States and sectors. The same picture applies to Customs that can have different powers depending on the Member State considered. For instance, the power to destroy products and to recover from economic operators the related costs is granted to Customs in some countries, but not all[83].

The following figure displays the extent of the inspection powers in a sample of Member States for which relevant information was available.

Figure 16: Extent of inspection powers in 17 EU Member States, considering 33 sectors covered by the Regulation[84]



83 See section 6.1.1 of Annex 4.

84 AT, BE, DK, EL, ES, FR, HU, IT, MT, PT, SK are not reported due to lack of data. The height of the bars equals the sum of each of the 33 sectors covered by the Regulation where a given power is granted.

Differences in the allocation of powers are evident also when looking at powers related to online trade, which as the following box shows, represent a specific issue where a more uniform market surveillance approach would be required across Member States.

Box 3 – Market surveillance of online sales[85]

Online sales have become an important issue for market surveillance. The analysis undertaken highlights the following specificities as relevant to understand the challenges market surveillance faces in the case of online sales:

- Online sales are characterised by a high number of small consignments, with goods most of the time directly delivered to consumers;
- The number of existing web shops is huge;
- Even though a web shop is shut down, it is very easy to create a new web shop changing the name and the domain in a short time; as a result, unsafe products withdrawn/banned from the EU market can return on the market through a different website or under a different legal name;
- In many cases, the number of parties and intermediaries determine a complex distribution chain, where especially the role of fulfilment houses[86] and commercial platforms is not clear;
- Economic operators are often located in third countries and Authorities are not informed in advance that products are being imported;
- Online channels can be used to make unsafe, withdrawn products return on the market;
- Consumers are not fully aware of the risks associated with buying products online.

Vis-à-vis these specificities, the majority of stakeholders face specific issues related to online sales and current market surveillance does not seem to be fully effective to online sales for various reasons.

First, specific **powers** of inspections and sanctioning related to online sales are present only in few Member States: most Market surveillance authorities do not have enough power to deal with products sold online and powers of sanction are generally not extended to those kinds of product.

Second, irrespective of the existence of explicit powers, bodies, or procedures for online sales, **enforcement activities** are not straightforward: market surveillance on products sold online is particularly challenging for most Member States, due to both the high volumes of products and websites involved (that would require resources that are not available), and the difficulties in inspecting and sanctioning the responsible economic operator given the complex (and sometimes invisible) distribution chain, with products most of time directly delivered to consumers.

Third, in some cases, in light of the already mentioned complex distribution chain, the same **identification of the responsible economic operator** is challenging, and even when authorities have the power to shut down websites, this might take several months and the action is ineffective since, as described above, sellers can change name and domain in a short time.

Difficulties are exacerbated in **the case of cross-border online sales**, where action –that should be particularly fast- is lengthy and costly due to jurisdictional constraints and becomes basically irrelevant when third countries are involved. Indeed, tackling websites outside of the EU is very difficult: communication and response by economic operators even when clearly identified are very limited, and cooperation with Authorities from different countries is not always fast and effective. Moreover, border controls of goods sold online are particularly difficult since there is no previous information about shipments, Authorities are not informed in

85 See section 6.1.1 of Annex 4.

86 According to the Blue Guide: "*Fulfilment houses represent a new business model generated by e-commerce. Products offered by online operators are generally stored in fulfilment houses located in the EU to guarantee their swift delivery to EU consumers. These entities provide services to other economic operators. They store products and, further to the receipt of orders, they package the products and ship them to customers. Sometimes, they also deal with returns. There is a wide range of operating scenarios for delivering fulfilment services. Some fulfilment houses offer all of the services listed above, while others only cover them partially. Their size and scale also differ, from global operators to micro businesses*". Further and more specific guidance is available in the Online Guidance Notice.

advance that products are being imported, and often there are no electronic declarations.

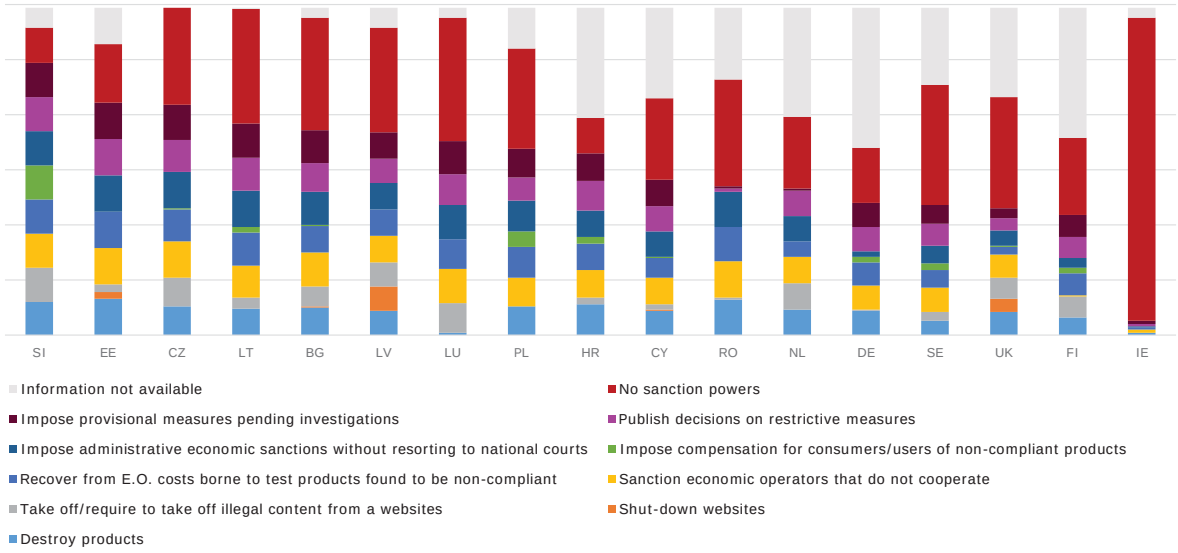
Despite some Member States having tailored strategies to tackle online sold products, **the current market surveillance approach to online sales is still conducted in a fragmented and uncoordinated way.**

As a result, non-compliance of products sold online is a real issue, especially when e-commerce popularity has increased amongst consumers and when 78% of participants to the targeted survey reported that there are non-compliance issues related to online trade. Controls effectively performed are considerably less than those that are necessary. As a consequence, also the incentive for economic operators to be compliant is low, considering the low risk of being caught and effectively punished.

In light of this, the current level of protection and legal support to consumers is lower if compared to that for products marketed through other distribution channels.

Similarly, the sanctioning powers in 17 EU Member States, considering the 33 sectors covered by the Regulation examined in national reports are widely distributed across sectors and Member States.

Figure 17: Extent of sanctioning powers in 17 EU Member States, considering 33 sectors covered by the Regulation[87]



These differences highlight that while some powers of inspection and powers of sanctions are uniformly attributed across Member States, others are not, with considerable differences that lead to different models of enforcement power across the EU.

Finally, a high level of heterogeneity can also be traced in the level of sanctions and related procedures. The mapping performed shows that the level of penalties differs both among Member States and across sectors. Similarly, procedures for imposing sanctions differ. In some Member States, Market surveillance authorities can directly impose administrative monetary sanctions together with restrictive measures. In other Member States instead, Market surveillance authorities are obliged to recur to Courts even to impose administrative

87 AT, BE, DK, EL, ES, FR, HU, IT, MT, PT and SK are not reported due to lack of data. The height of the bars equals the sum of each of the 33 sectors covered by the Regulation where a given power is granted.

monetary sanctions. As result of these differences, the current system of penalties and sanctioning powers does not provide sufficient deterrence.

The lack of uniformity in authorities' powers and national procedures can also explain the difficulty of market surveillance experts to endorse the common lines discussed in the context of administrative cooperation because ultimately those are not binding within their national administrations and vis-à-vis national courts. This contributes to explaining the lack of European perspective in the organization of national surveillance.[88]

6.1.2.3. Provisional conclusion

The heterogeneity existing across Member States in the implementation of the Regulation allows the conclusion to be drawn 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 proper enforcement.

This lack of uniformity allows market surveillance to be more rigorous in some Member States than in others. Potential effects are a less effective deterrence power and an unequal level playing field among businesses in some Member States, this also potentially generating an unbalance in the level of product safety across Europe.

As for the general rigorousness of market surveillance in the Single market, the serious lack of data and inhomogeneity of national reports do not allow for a thorough assessment. However, the analysis of information available on the amount of resources attributed to market surveillance and activities reported cast some doubts on the ability of market surveillance authorities to perform checks at an adequate scale. Lack of relevant information may in some cases be an indication of actual enforcement gaps. Furthermore the low usability of data available in national reports is already a finding itself of a drawback of the Regulation in the achievement of its objectives, inasmuch as the major evidence on its functioning (i.e. the effectiveness of market surveillance controls) is so fragmented to render difficult its analysis. The insufficient rigorousness of market surveillance is also supported by the stakeholders' perception about the incapacity of the Regulation to deter rogue traders,[89] and the discrepancies in the penalty framework.

6.1.3. Border controls of imported products

Although stakeholders indicate that powers attributed by the Regulation to Customs are adequate and the procedures for the control of products entering the EU market foreseen by Articles 27 to 29 of the Regulation are clear, easy to apply, and still relevant, checks of imported products seem to be insufficient. Border control is indeed one of the most challenging tasks for market surveillance nowadays, in light of the increasing importance of EU trade with third countries.

Imports of harmonised goods from third countries represent a large 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 € billion. Many respondents to the public

88 See section 4 of Annex 9.

89 As confirmed by 83% and 89% of economic operator/civil society representatives (n=15, n=16) - for checks of Market surveillance authorities and checks of Customs respectively – and by 75% of Market surveillance authorities and Customs (n=64). See section 6.1.1 of Annex 4.

consultation found it difficult to indicate the proportion of products imported from third countries in their sector[90]; however the general perception among stakeholders is that imports are affected by non-compliance[91]. 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, it is often difficult to trace and intercept non-compliant products imported from outside the EU and entering through numerous entry points[92]. The main difficulties relating to controls of imported products are due to a lack of jurisdiction of Market surveillance authorities outside of their Member State, and to a lack of direct communication between Market surveillance authorities and businesses, particularly – again - in the context of online sales. As a consequence, businesses are not willing to collaborate with Market surveillance authorities' requests for corrective actions, for information/documentation or for paying penalties for non-compliance. 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. Despite some existing informal international cooperation arrangements the number of non-compliant products that can effectively be traced backed to the economic operator and sanctioned at the source in 3rd countries remains limited[93].

Other issues specifically inherent to online sales relate to products directly mailed to consumers, to the high number of intermediaries and to the low level of consumers' awareness concerning the risks of buying products online.

Table 8: RAPEX notifications by country of origin

	2006-2009			2010-2015		
Country of origin	**Notifications**	**Annual average**	**% of total**	**Notifications**	**Annual average**	**% of total**
China	2,952	738	54%	6,862	1,143.7	**59%**
Turkey	108	27	2%	402	67	**3%**
Germany	271	67.75	5%	380	63.3	**3%**
United States	121	30.25	2%	298	49.7	**3%**
Italy	212	53	4%	243	40.5	**2%**
France	107	26.75	2%	196	32.7	**2%**
United Kingdom	88	22	2%	174	29	**2%**
India	44	11	1%	170	28.3	**1%**

90 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%.

91 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.

92 See chapters 6.1 and 6.2 of the evaluation and sections 6.1 and 6.2 of Annex 4 of the evaluation.

93 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.

Table 8: RAPEX notifications by country of origin						
	2006-2009			2010-2015		
Japan	98	24.5	2%	167	27.8	**1%**
Poland	87	21.75	2%	155	25.8	**1%**
Taiwan	79	19.75	1%	119	19.8	**1%**
Spain	58	14.5	1%	111	18.5	**1%**
Other	1,232	308	23%	2,288	381	**20%**
Total	**5,457**	**1,364.25**	**100%**	**11,565**	1,927.5	**100%**

Source: RAPEX database

Because of resource constraints the number of product compliance checks by customs remains fairly limited in relation to the number of imports[94]. Stakeholders often report that the order of magnitude of controls in one of the biggest harbours is only 0.1%.

6.1.4. Conclusion as regards EQ1

The above sections show the specific objectives identified in the impact assessment for the Regulation ((i) enhanced cooperation among Member States, (ii) uniform and sufficiently rigorous level of market surveillance, (iii) border controls of imported products) were only partly fulfilled.

EQ2 - Are there specific forms of the implementation of the Regulation at Member State level that render certain aspects of the Regulation more or less effective than others, and – if there are – what lessons can be drawn from this?[95]

EQ3 - To what extent has the different implementation (i.e. discrepancies in the implementation) of the initiative in Member States impacted on the effectiveness of the measures on the objective?[96]

The Regulation has been differently implemented across the EU. The first element of differentiation between Member States is their national organisation of market surveillance structures[97].

Each Member State organises market surveillance in a way that best suits its particular cultural and legal framework or legal system, so that there is no "*one size fits all*". The lack of structured data on product non-compliance and on market surveillance activities makes the establishment of a causal link between the national organisation and the effectiveness of enforcement action not straightforward. Organisational models influence how market surveillance is performed, resulting in differences across the EU. For instance, as shown in the figure below, Member States with a centralised structure need to rely on fewer and

94 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. See also Annex 7: 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)).

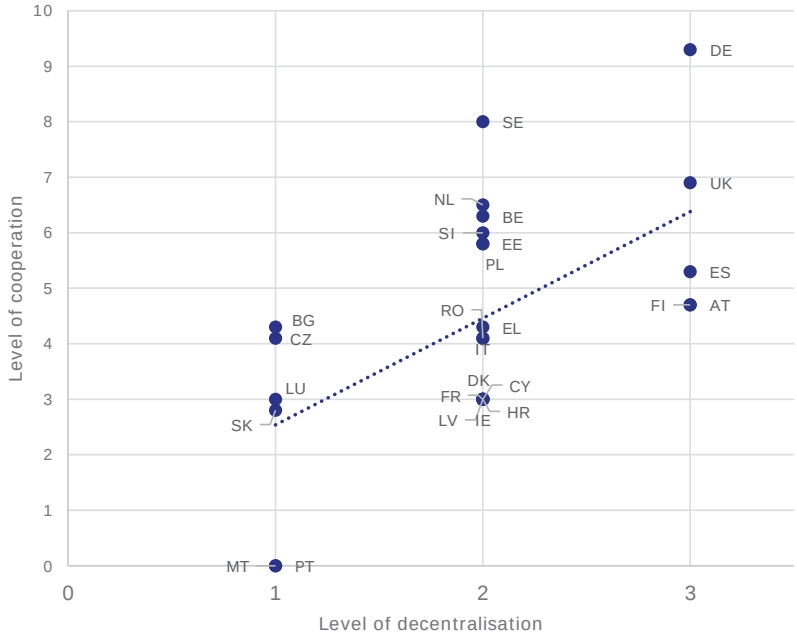
95 For further details, see section 6.1 of Annex 4.

96 For further details, see section 6.1 of Annex 4.

97 See section 5.1 of this report

simpler cooperation tools. In contrast, the more a Member State is decentralised, the more it needs to set up numerous and complex cooperation mechanisms.[98]

Figure 18: Existing correlation between the level of decentralisation of market surveillance and the complexity of cooperation tools within a Member State[99]



Crucial elements for the effectiveness of decentralised models are a clear attribution of tasks among authorities and to each MSA (i.e. that market surveillance is not just one "*among other tasks*" that a MSA has to perform in its daily activities – this also impacting on cost-effectiveness), the existence of a coordination board, the possibility for each MSA to have direct contacts with Customs, the visibility (to the public) of identity and contacts of relevant competent authorities. As far as the sector-decentralised model is concerned, formal channels and procedures for coordination are essential to have coherent policy approaches in different sectors. The crucial aspect for the local-decentralised model is to have a strong coordination body granting not only coherent policy approaches in different regions, but also coordination of investigations via a common database and a tool for common decision making.

A second element of differentiation is represented by available resources. As discussed, financial, human and technical resources vary greatly across Member States. There are

98 The figure compares two qualitative indexes. The "x" axis measures the degree of decentralisation of a national market surveillance structure based on the three models identified: 1=centralised; 2=decentralised at sectoral level; 3=decentralised at local/regional level. The "y" axis measures the degree of cooperation within the single Member State, taking into consideration the cooperation mechanisms/tools described in section 5.2.1. Each cooperation mechanism/tool has been assessed on the basis of three dimensions: the *scope* of its activities related to market surveillance, its *duration over time* and its *coverage* (i.e. in terms of stakeholders' representativeness). Each of these dimensions has been given a rating from 0 to 1, and the overall value of each mechanism results from the sum of the values of its dimensions. Therefore, a permanent ad hoc body for coordinating market surveillance activities rates 3, since it is permanent (duration=1), it involves all relevant stakeholders (coverage=1) and its scope of activities is the widest (scope=1). A bilateral agreement instead rates 1.1 (coverage=0.1; scope=0.1; duration=0.9). The level of cooperation within a Member State results from the sum of the values of each cooperation mechanism in use therein.

99 HU and LT have been not taken into consideration due to lack of data on existing cooperation mechanisms. The correlation between the two variables is quite significant, equal to 0.6760. It is to be noted that the coordination mechanisms used for this graph are those cited in Member States' national programmes, therefore not all coordination tools actually existing at the national level might have been taken into account. See section 6.1.3 of Annex 4.

significant differences in terms of budget availabilities to implement the Regulation's provisions across Member States. Overall, the budget available for market surveillance decreased between 2010 and 2013 though variations at the national level did not follow a common trend. The budget indeed increased in nine Member States, decreased in seven and remained stable only in two. Possibly as a consequence of budget reduction, the number of inspectors also decreased. This picture suggests a diffused lack of resources for Market surveillance authorities, as also widely confirmed by stakeholders. In general, this is indicated as one of the main bottlenecks to market surveillance implementation and effective deterrence.

The different levels of resources however have implications on the way Market surveillance authorities perform their tasks and therefore deserve consideration. For instance, Market surveillance authorities' market knowledge in order to target checks is not sufficient in sectors that require specific skills. Moreover, few market surveillance authorities have their own in-house laboratories for product testing in the construction and in the chemical sector. Testing products is more costly and time consuming than simple documentary checks, since it often involves test laboratories and an officer is usually able to check only a few products per week (excluding the follow-up activities). The excessive costs of testing have been reported as the most likely explanation for the low level of surveillance in some sectors and they are, therefore, another possible explanation for the data gaps in the national reports. Inspections and testing in some areas are so costly that Market surveillance authorities usually perform or consider performing only documentary checks, this further confirming an unequal enforcement of market surveillance across sectors and across Member States. The higher or lower availabilities of laboratories for product testing seems to confirm a tendency to perform more or less laboratory tests at the national level.
The availability of resources also influences Market surveillance authorities' criteria for prioritisation of monitoring and enforcement activities. For instance, Market surveillance authorities and Customs determine the "adequate scale" of controls first on the basis of financial and human resources rationalisation, and then of product risk level. However, the Regulation requires Member States to give Market surveillance authorities all the resources they need "*for the proper performance of their tasks*". This would imply that first Market surveillance authorities determine their targets in terms of controls, and sufficient resources would be given as a consequence. This may actually explain the low number of controls. Interestingly, the German Product Safety Act defines the adequate number of products to be tested by means of a "sample rate" (i.e. 0.5 products per thousand inhabitants per year, as an indicative target for each Federal State). The establishment of a clear benchmark makes it easier to calculate the number of MSA working hours and staff needed to perform such tests. However, the measure of adequate scale also depends on product features (i.e. whether it is a serial or single product).

Differences are also traced in Market surveillance authorities' strategies for market surveillance. In general, proactive market surveillance is more cost-efficient than reactive market surveillance, because required resources can be defined in advance. However, not all market surveillance activities can be planned ahead. In order to avoid duplication, a market surveillance authority should check ICSMS and any other appropriate platforms (e.g. national database) to see if the same product has already been assessed. Once again it can be concluded that market surveillance is not uniform across the EU, being also strategically influenced by the level of resources, which is different from one Member State to another.

Powers attributed at the national level and the role of Customs in enforcing the Regulation influence the effectiveness of border control. For instance, based on the available data, 16 Member States do not have in-house testing laboratories for any (or almost any) sectors. The lack of laboratories, resulting in the impossibility for Customs to perform more in-depth and time-efficient controls, hinders potential improvement in border controls. However, in some Member States where Customs do not have laboratories, this shortcoming is compensated by Market surveillance authorities having their own laboratories in some sectors. On the one hand, this confirms that the testing is performed. On the other hand, the intervention of two different authorities (i.e. Market surveillance authorities and Customs) could make procedures slower.

Furthermore, controls are expected to be tougher in Member States where Customs act as Market surveillance authorities. If Customs have market surveillance powers, there is a substantial extension of their area of competence and a significant need for in depth expertise. While Customs powers are essential for the control of traded products, the introduction of Regulation (EC) No 765/2008 highlights the need for cooperation between Customs and Market surveillance authorities and with other EU Customs as a crucial element for enhancing market surveillance on imported products. In this respect, there are notable differences across Member States.

Overall, it seems these discrepancies are made possible by the general requirements set in the Regulation. This lack of specificity concerns the obligations of Member States as regards organisation (Article 18(3)). The Regulation foresees that Member States shall entrust Market surveillance authorities with the powers, resources and knowledge necessary for the proper performance of their tasks. However, without setting any minimum criteria or thresholds, this results in a wide variety of implementation forms, especially in terms of endowments of powers and resources. These are not always sufficient to grant an effective enforcement. The same considerations can be drawn of Article 19, stating that Market surveillance authorities shall perform "*appropriate checks of products on an adequate scale*". As discussed, the "intensity" of market surveillance and the types of checks performed vary across Member States, this further deepening the differences in the enforcement levels.

Article 18(5)-(6) requires a periodical update of national programmes and a review of the functionality of market surveillance activities every four years, but it does not mention any timing for update, neither does it provide any specific methodologies for the review. The provision therefore does not foresee the provision of structured information from Member States to the European Commission relating to market surveillance activities, which is particularly evident in light of all the data limitations of national programmes and reports described in previous sections. This lack of harmonisation makes the national programmes and reports not immediately comparable across countries, which is a missed opportunity for Member States to benchmark and learn from each other's experiences.

The Regulation does not include specific provisions related to certain forms of cooperation between Member States, notably mutual assistance. This clearly impacts on the existing cooperation mechanisms and tools, as described in the previous sections. Finally, the Regulation is not specific enough to set a minimum and/or a maximum level of penalties, or any principles to define them. As discussed, this results in wide differences in the minimum/ maximum amounts within and across Member States, which lower the enforcement deterrence power.

An additional enabling factor has been identified in the (lack of) cooperation between enforcement authorities and businesses. Among the main reasons for product non-compliance in the internal market there seems to be a lack of economic operators' knowledge on the relevant legislative requirements to be complied with, as well as a deliberate choice to exploit market opportunities at the lowest cost, possibly due to low incentives to comply with the existing rules. Several stakeholders expressed a need for a higher level of information flow from Market surveillance authorities to businesses and more practical guidance for economic operators. In the context of the interviews, an EU industry association suggested giving economic operators that are willing to comply the opportunity to do so before imposing sanctions, while another EU industry association suggested organising educational campaigns targeting economic operators.

EQ4 - How effective was the measure as a mechanism and means to achieve a high level of protection of public interests, such as health and safety in general, health and safety at workplace, the protection of consumers, protection of the environment and security? What have been the quantitative and qualitative effects of the measure on its objectives?

The table below presents the average annual number of RAPEX notifications per category of products divided into two periods, i.e. 2006-2009 and 2010-2015, where 2010 is the year of the Regulation's entry into force.

Table 9: 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%
Childcare articles and children's equipment	72	62.17	-14%
Clothing, textiles and fashion items	1,54.5	512.67	232%
Communication and media equipment	7.25	13.50	86%
Construction products	0.75	9.33	1,144%
Cosmetics	66.75	75.83	14%
Decorative articles	18.5	15.17	-18%
Electrical appliances and equipment	158.5	181.33	14%
Food-imitating products	30.25	22.33	-26%
Furniture	12.5	13.00	4%
Gadgets	4.25	2.00	-53%
Gas appliances and components	9.5	8.33	-12%
Hand tools	3.5	0.83	-76%
Hobby/sports equipment	29.75	32.67	10%
Jewellery	6.5	32.67	403%
Kitchen/cooking accessories	10.25	10.17	-1%
Laser pointers	9.25	16.67	80%
Lighters	27	23.17	-14%
Lighting chains	31.75	31.83	0%
Lighting equipment	77	56.50	-27%
Machinery	22.5	20.17	-10%
Motor vehicles	154.75	183.17	18%
Other	10.75	41.83	289%
PPEPPE	13.25	32.17	143%
Pyrotechnic articles	0.5	14.83	2,866%
Recreational crafts	6.5	4.33	-33%
Stationery	7.5	2.17	-71%
Toys	393.75	458	16%
Total	**1209.25**	**1927.5**	**59%**

Overall, these increasing trends are consistent with those reflected in the national reports. As reported therein, Market surveillance authorities' inspection activities resulting in a finding of non-compliance registered a positive average annual growth over the period 2010-2013 (13%), rising from 11,945 in 2010 to 18,316 in 2013[100].

In order to better understand these increasing trends, it was useful to verify whether the average number of notifications is correlated wto the value of harmonised products traded in the internal market over the two periods considered (i.e. 2006-2009 and 2010-2015). However, since the product categories included in RAPEX slightly differ from the classifications available for the market analysis, only the following product categories were examined; a positive growth in the number of notifications is registered in five categories:

Table 10: Annual average value of harmonised traded products and average number of RAPEX notifications by product category over the periods 2006-2009 and 2010-2015[101]

Product category	***Value of Harmonised traded products (Average '06-'09 €)***	***Value of Harmonised traded products (Average '10-'15 €)***	*Δ% Traded products*	*Δ% RAPEX Notifications*
Chemicals	1,067,897,632,898	1,106,833,111,374	3.6%	103%
Construction	156,586,485,690	128,882,492,028	**-17.7%**	**1,144%**
Textiles	104,626,637,224	104,598,300,839	**-0.03%**	**232%**
Cosmetics	17,870,226,314	15,421,496,892	**-13.7%**	**14%**
Appliances burning gaseous fuels	2,236,818,858	2,062,761,701	-7.8%	-12%
Machinery	278,111,694,212	271,828,263,683	-2.3%	-10%
Motor vehicles and tractors	338,802,673,379	329,544,444,282	**-2.7%**	**18%**
Simple pressure vessels and pressure equipment	243,498,460,356	248,009,349,724	1.9%	-
Personal protective equipment	33,664,105,623	35,624,391,429	5.8%	143%
Pyrotechnics	2,314,375,580	2,302,762,034	**-0.5%**	**2,866%**
Recreational craft	6,185,094,424	5,755,650,303	-6.9%	-33%
Toys	9,359,483,585	12,004,549,187	28.3%	16%
Total	**2,261,153,688,142**	**2,262,867,573,475**	**0.1%**	**59%**

Overall, there are still many products in the EU market that do not comply with legislative requirements. Similarly, the number of restrictive measures imposed by market surveillance authorities in reaction to non-compliant products has increased. Interestingly, the most significant increases have been registered in the most "coercive" measures (i.e. seizure,

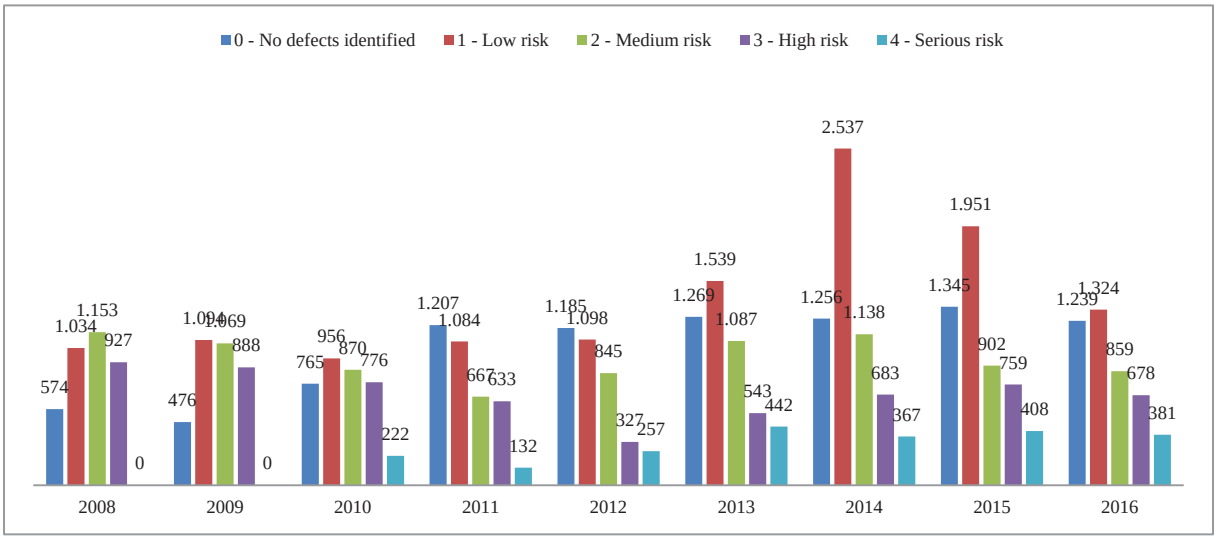
100 See section 5.3 of Annex 4.
101 See section 6.1.2 of Annex 4.

withdrawal, destruction). Other measures such as requests for information or corrective actions have even decreased. This could indicate that not only has non-compliance increased, but that its seriousness has worsened. Similar conclusions can be drawn on the measures undertaken by economic operators to correct non-compliance.

These findings are confirmed by data from ICSMS:

Table 11: Data from 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**



The evidence of an increasing number of non-compliant products covered by harmonisation legislation (as demonstrated by the rising number of RAPEX notifications and of restrictive measures taken by Market surveillance authorities) allows a conclusion to be drawn that the Regulation is not fully effective in relation to its strategic objectives of strengthening the protection of public interests through the reduction of the number of non-compliant products on the Internal Market and of ensuring a level playing field among economic operators providing a framework for market surveillance and controls of products. On the one hand, the increasing product non-compliance threatens the achievement of a high level of protection of public interests as long as these products present risks to consumers and end-users. On the other hand, a level-playing field among businesses trading goods subject to EU harmonisation legislation risks not being achieved as long as there is still the possibility for rogue traders to disregard legal requirements and sell non-compliant products.

EQ5. How effective was the measure as a mechanism and means to achieve a level playing field among businesses trading in goods subject to EU harmonisation legislation? What have been the quantitative and qualitative effects of the measure on its objectives?[102]

As already discussed, the Regulation has been implemented in different ways across Member States, resulting in an unequal level playing field among businesses in some Member States. Moreover, these discrepancies diminish the Regulation's effectiveness in achieving a level playing field, inasmuch as they influence regulatory/ administrative costs to businesses across Member States (e.g. preparing documents and information requested by Market surveillance authorities/Authorities in charge of EU external border controls in implementing surveillance measures). Similarly, these discrepancies influence market behaviour (e.g. decision of companies to enter the EU market via certain Member States)

On the other hand, however, the average number of RAPEX notifications has increased from one period to another in most Member States, with very few exceptions, which suggests that the Regulation has apparently triggered an increase in enforcement. Similarly, the number of restrictive measures imposed by Market surveillance authorities in reaction to non-compliant products has increased.

Table 12: Average annual number of RAPEX notifications on measures undertaken by market surveillance authorities over 2005-2009 and over 2010-2015

	2005-2009	2010-2015	Δ%	Total
Recall	184.4	288	56%	2,648
Withdrawal	428.2	803	88%	6,959
Destruction	11.8	18	55%	169
Ban	242	236	-2%	2,627
Seizure	10	27	167%	210
Corrective Actions	21.2	16	-27%	199
Information	16	2	-91%	89
Total	**913.6**	**1,389**	**52%**	**12,901**

Source: RAPEX database

Similar conclusions can be drawn on the measures undertaken by economic operators to correct non-compliance. Since the entry into force of the Regulation, the most significant increase has been registered in the average number of notifications relating to product destructions.

Table 13: Average annual number of RAPEX notifications on measures undertaken by economic operators over 2005-2009 and over 2010-2015

Measure	2005-2009	2010-2015	Δ%	Total
Recall	225.8	334.7	48.2%	**3,137**
Withdrawal	334	332.7	-0.4%	**3,666**
Destruction	15.8	35.3	123.6%	**291**

102 See section 6.1.2 of Annex 4.

Table 13: Average annual number of RAPEX notifications on measures undertaken by economic operators over 2005-2009 and over 2010-2015				
Measure	**2005-2009**	**2010-2015**	**Δ%**	**Total**
Ban	10.8	15.8	46.6%	**149**
Information	28.8	3.3	-88.4%	**164**
Total	**615.2**	**721.8**	**17.3%**	**7,407**

Source: RAPEX database

In conclusion, it is fair to say that the Regulation has not yet created a level playing field for businesses across the EU in light of the significant discrepancies in its implementation and of the dimension of product non-compliance. An unequal implementation also creates disparities in the level of enforcement and thus differences in the burden of controls borne by economic operators, which in some Member States and in some sectors is higher than in others. In addition, the increase in the number of non-compliant products signals that there are rogue traders that can still benefit from lower compliance costs, thus further hindering the achievement of a level-playing field within the internal market.

6.2. Efficiency

EQ6. What are the regulatory (including administrative) costs for the different stakeholders (businesses, consumers/users, national authorities, Commission)?[103]

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.

As regards economic operators the evaluation has looked at possible costs related to information obligations as defined in Article 19 of the Regulation which are perceived as insignificant. On the other hand there is no evidence of any regulatory costs from the implementation of the market surveillance provisions. Compliance costs for businesses stem from the requirements in the harmonisation legislation, not from market surveillance provisions. Conversely, stakeholders argue that weak implementation would lead to supplementary costs. They indicate that ineffective controls at the EU's external borders might create discrimination against European manufacturers as compared to their non-European competitors in the European internal market as well as the associated distortions of competition. They also suggested that the identification of non-compliant products might be reinforced by more effective cooperation between industry and authorities. In this way, market surveillance authorities could take advantage of manufacturers' technical knowledge and might be in a better position to identify non-compliant products on the market and more efficiently set appropriate priorities for market surveillance activities.

No regulatory costs have been identified for consumers/users.

Most of the costs of the market surveillance provisions are borne by Member States and their market surveillance authorities[104]. Enforcement costs for authorities are estimated on the basis

103 See section 6.2 of Annex 4.
104 For further details, see section 5.2.1 of Annex 4

of all financial resources assigned to market surveillance activities including communication and enforcement, related infrastructures as well as projects and measures aimed at ensuring compliance of economic operators with product legislation. Considering the limitations of the available data in terms of completeness and comparability, an estimation of the costs related to surveillance obligations is only possible for a limited number of countries that provided complete and reliable data in the reports. Even if the nominal budget for the countries considered remained virtually constant, the yearly number of inspections increased by 21%, while the yearly average number of tests in laboratories decreased by 7%.

Table 14: Market surveillance authorities' average number of inspections, costs of inspections and cost of tests

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)/(c)	(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
Av.	5,264,722	0.92%	7,493	21%	703	770	-7%	6,837

The fact that every Member State defines its own market surveillance approach (e.g. distribution of competence, interpretation of the concept of appropriate scale of controls, penalties) creates a high variation in the ways the different sectors are controlled and managed. Moreover, fragmentation throughout the Internal Market may interfere with Authorities' early action and generate additional costs for businesses. Favouring a more consistent approach to market surveillance would there help reducing regulatory burden on economic operators. Different approaches may also reduce the efficiency of the market surveillance when responsibilities of national authorities are not primarily related to market surveillance of non-food products within the meaning of the Regulation and this creates overlapping and duplication of activities.

The analysis of the efficiency of the Regulation has been limited by the evident poor quality of data included in the national reports both in terms of completeness and comparability. This definitely shows the need for an in-depth reflection of the monitoring mechanisms in place that should allow the European Commission to get an updated and realistic picture on the implementation of the Regulation within the scope of this evaluation.

In addition there seems to be room for improvement in the drafting of national programmes. The administrative burden relating to this provision indeed seems sometimes higher than the benefits, especially because certain aspects of market surveillance activities do not change every year[105].

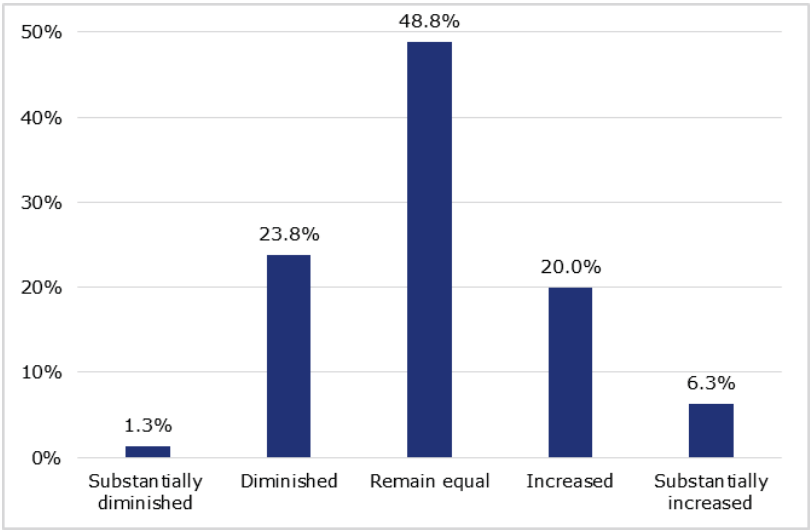
Streamlining the procedures for the notification of non-compliant products, which is currently carried out thorough two separate systems (Rapex and ICSMS), could further reduce administrative burden for authorities[106].

Unavailability of data about costs incurred by Member States Authorities in charge of market surveillance before 2008 did not allow for the calculation of additional costs deriving from new obligations introduced by the Regulation.

EQ7. What are the main benefits for stakeholders and civil society that derive from the Regulation?[107]

During interviews, business' associations were asked whether their industry had benefited from cost savings since the entry into force of the Regulation. The majority of the associations did not report cost savings as a result of the implementation of the Regulation in terms of administrative and operational tasks if compared to the situation prior to 2008. Furthermore, most stakeholders involved did not perceive a substantial variation in product non-compliance considering the period from 2010 to 2015; however the number of stakeholders that perceived an increase in product non-compliance is higher than the numbers of the stakeholders that perceived that product non-compliance diminished. This seems to be also confirmed by the increased number of RAPEX notifications and corrective measures taken by the Market surveillance authorities in the last few years.

Figure 19: Perceived level of product non-compliance in the last 5 years (80 responses)

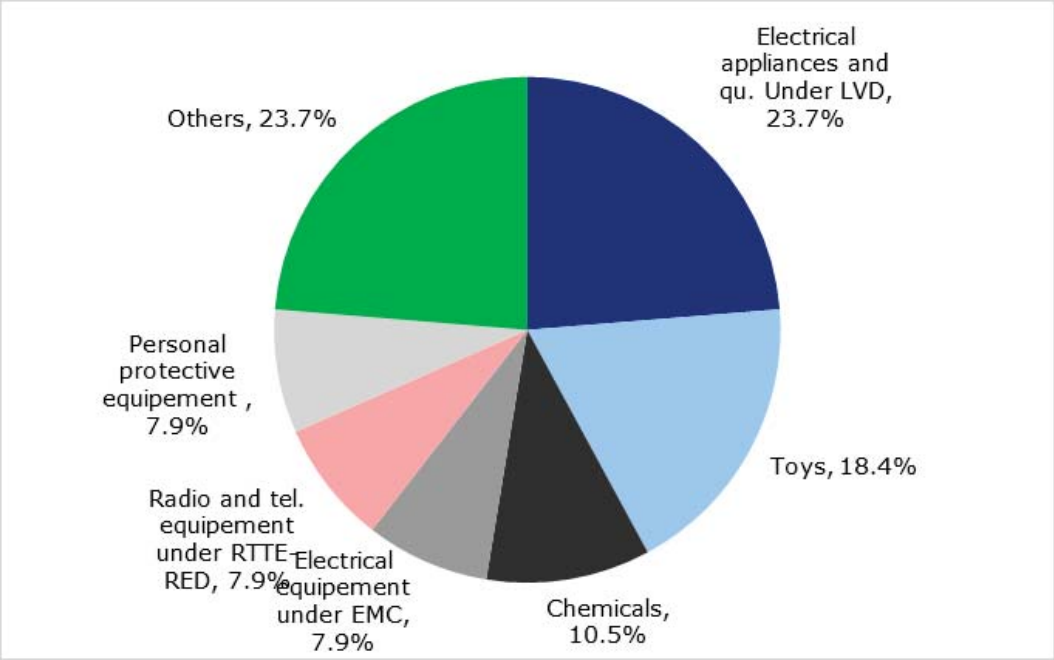


The analysis of responses to the survey highlights also that 'Toys', 'Chemicals' and 'Electrical appliances under the Low Voltage Directive' seem to be the sectors were the

105 See section 6.1.4.
106 See section 6.1.1.1.
107 For further details, see section 6.2.2 of Annex 4.

product non-compliance is more problematic. However, only for toys and chemicals is this perception confirmed by the indicators used to measure product non-compliance in the internal market.

Figure 20: Sectors heavily affected by product non-compliance (34 responses)



Therefore, the Regulation does not seem to be producing the envisaged benefits and the problem relatng to product non-compliance still remains. However, it is not possible to measure how this has impacted safety and uniform protection of consumers across the EU.

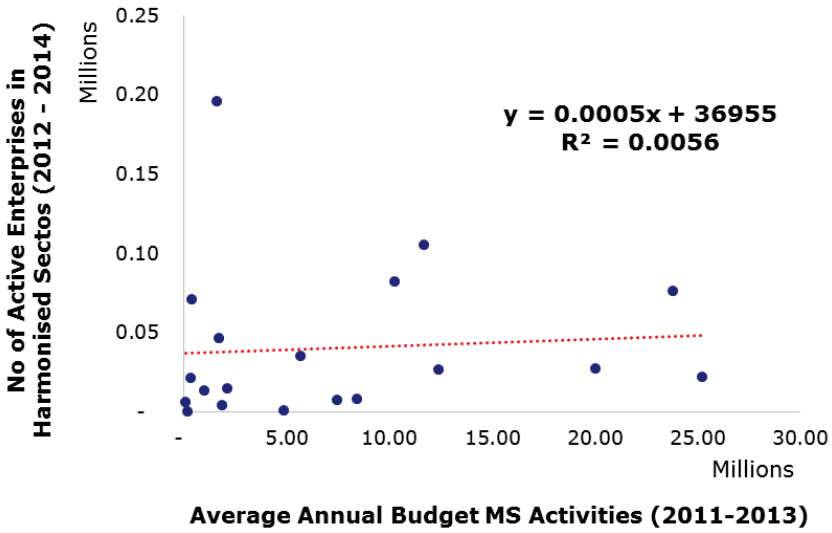
EQ8. To what extent have the market surveillance provisions been cost effective?[108]

EQ9. Are there any significant differences in costs (or benefits) between Member States? If so, what is causing them?

Table 14 on Market surveillance authorities' average number of inspections, costs of inspections and cost of tests show significant differences in the costs between Member States. The low correlation between the number of inspections and the size of national markets was explained in section 6.1.2.1. This is further proved by the comparison of the financial resources allocated to surveillance activities at Member State level with the size of local market of harmonised products when (imperfectly[109]) measured by the average number of enterprises active in the national market as the average annual budgets allocated to MSA activities are not correlated with the number of enterprises active in the harmonised sectors.

108 See section 6.2.3 of Annex 4.
109 See footnote 82 in section 6.1.2.1.

Figure 21: Average annual budget available to Market surveillance authorities in nominal terms vs average no. of enterprises active in Harmonised sectors



Source: Authors' elaboration on data from national reports and SBS (2016)

The differences in the budgets allocated to MSA activities and average costs might be related to the fact that Member States have different organisational models requiring different levels of financial resources. However, another possible explanation might be sought in the different approaches followed by Market surveillance authorities in reporting data concerning the used financial resources as well as the performed activities (e.g. definition of 'inspection').

With regards to benefits, evidence already shown on the increase in the adoption of restrictive measures and corrective actions undertaken by economic operators shows that product non-compliance increased consistently from 2006-2009 to 2010-2015. As already mentioned, this data could be interpreted in two opposite ways, inasmuch as an increase in RAPEX notifications may also imply that Market surveillance authorities have become more effective in finding – and thus correcting – non-compliance. In any case, they indicate that a number of non-compliant products are still made available in the Single Market and that therefore the goals of the Regulation have not been fully achieved. No differences have been identified in country-specific patterns.

6.3. Relevance

EQ10. To what extent are market surveillance provisions of the Regulation still relevant in light of for instance increasing online trade, the increase in imports from third countries, shortening product life, increasing budgetary constraints at national level, etc.?[110]

The relevance of the market surveillance provisions in view of new developments is becoming increasingly problematic:

The overall limited relevance of the Regulation to online sales, including from third countries, is underlined by stakeholders. The concepts of 'online trade' and 'e-commerce' do not appear

110 See section 6.3 of Annex 4.

in the provisions, and the definitions do not refer to online traders[111]. One could argue that the provisions are sufficiently neutral to cover which ever form of trade, but the input from interested parties clearly shows that the market surveillance provisions fail to provide clear solutions for market surveillance on online trade, notwithstanding the existing guidance[112]. Market surveillance on products sold online is particularly challenging, and the Regulation does not seem to be able to properly address related specificities. Specifically, the Regulation does not include specific provisions covering online sales, nor does it provide for definitions that account for its specificities. As mentioned above, the same definitions of "*making available on the market*" and "*placing on the market*" do not consider the complex distribution chains of online sales, as also highlighted by some stakeholders when discussing both import from third countries and online sales. Also, when considering the economic operators involved in the online sales supply chain, the Regulation does not reflect the latter complexity, for example leaving a grey area on whether fulfilment houses, which according to various stakeholders represent an increasing concern, should be subject to market surveillance. In general the Regulation does not specify if and how surveillance authorities can request information and cooperation from new types of economic actors playing a role in the supply of online sales but who may not fall within the traditional definitions of economic operators.

Box 4 – Fulfilment service providers[113]

During the last years, there was a lively debate among market surveillance authorities and businesses whether the market surveillance provisions also apply to new types of businesses in e-commerce, such as 'fulfilment service providers'.

Fulfilment services can be described as services provided by a company that will store products, receive orders, package products and ship them to customers. There is a wide range of operating scenarios for delivering fulfilment services. Some fulfilment service providers offer all of the services listed above, while others only cover them partially. Their size and scale also differ, from global operators to micro businesses operating from small premises. Their willingness to collaborate with authorities also varies; some fully cooperate with authorities, while others do not, mostly because they are not aware of the safety and compliance obligations applicable to the products they store/deliver.

This new business model of use of fulfilment service providers raises challenges for authorities, especially when the economic operator selling the goods (manufacturer, online platform) is located outside the EU and the transfer occurs directly between that economic operator and the consumer located in the EU, without any identifiable responsible economic operator within the EU to be held accountable. The only identifiable EU economic operator in the supply chain is the fulfilment service provider that stores the goods.

When only the fulfilment service provider is located in the EU, the only way for authorities to verify that products comply with EU applicable legislation is to contact the fulfilment service provider, which may not cooperate on a voluntary basis. In order to take investigatory or enforcement actions, authorities would need a strong legal basis which prevents any risks to successful prosecution.

Products stored in such fulfilment houses are considered to have been supplied for distribution, consumption or use in the EU market and thus placed on the EU market. When an online operator uses a fulfilment house, by shipping the products to the fulfilment house in the EU the products are in the distribution phase of the supply chain. The Commission indicated that the activities of fulfilment service providers go beyond those of parcel service providers that provide clearance services, sorting, transport and delivery of parcels. The complexity of the business model they offer makes fulfilment service providers a necessary element of the supply chain and

111 For further details, see the section on coherence.

112 See points 3.4 and 3.5 of 'Commission Notice — The 'Blue Guide' on the implementation of EU products rules 2016', OJ C 272, 26.7.2016, p. 1.

113 See also section 4.2.6, 6.3.1 and 6.3.2 of Annex 4, and box 1 above.

therefore they can be considered as taking part in the supply of a product and subsequently in placing it on the market. Thus, where fulfilment service providers provide services as described above which go beyond those of parcel service providers, they should be considered as distributors and should fulfil the corresponding legal responsibilities. Taking into account the variety of fulfilment houses and the services they provide, the Commission concluded that the analysis of the economic model of some operators may conclude that they are importers or authorised representatives[114]. However, several member States indicated that this guidance is unsatisfactory.

The market surveillance provisions in the Regulation provide national authorities with basic powers (request information, take product samples, enter business premises) however they do not specifically take into account the shortening life of a number of mass products, which require for instance increased cooperation with the relevant economic operator, ability to act quickly to restrict the marketing of non-compliant goods (also taking necessary interim measures) and informing consumers.

Similarly, the market surveillance provisions only address in very general terms that Member States have to entrust their market surveillance authorities 'with the powers, resources and knowledge necessary for the proper performance of their tasks.' Yet, it is undisputable that the resources for market surveillance authorities were reduced in many Member States[115] as a direct consequence of budgetary constraints, and that the market surveillance provisions were not relevant in addressing this problem.

EQ11. To what extent do the effects of the market surveillance provisions satisfy (or not) stakeholders' needs? How much does the degree of satisfaction differ according to the different stakeholder groups?[116]

Overall, the Regulation meets stakeholders' needs in the sense that it is relevant in relation to their needs. Stakeholders consider the existence of market surveillance provisions as a major step forward, compared to the situation before 2010, while pointing to cross-border cooperation and controls at the external borders as areas where progress can be made[117].

Market surveillance authorities identified different topics to which the Regulation does not provide satisfactory answers and where progress could be made ('common challenges')[118]:

(1) 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.

(2) 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

114 Commission Notice - The 'Blue Guide' on the implementation of EU products rules 2016, OJ C272 of 26 July 2016, p. 1. Further and more specific guidance is available in the Online Guidance Notice.
115 See section 5.2.1 of Annex 4.
116 See section 6.3 of Annex 4.
117 See sections 2.3.4, 2.3.5 and 2.4 of Annex 2.
118 Section 4.1.1 of Annex 2.

and the nomenclature used by market surveillance authorities, which hamper cooperation in some areas.

(3) 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.

(4) 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;

(5) 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.

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

Consumer and business organisations views point in the same direction. They indicate that Regulation (EC) No 765/2008 goes in the right direction to achieve effective or efficient enforcement of EU product rules but that market surveillance should be further strengthened[119].

EQ12. Is there an issue on the scope (i.e. all EU product harmonisation legislation) of the measure or some of its provisions?[120]

Article 15 of Regulation (EC) No 765/2008 defines '[Union] *harmonisation legislation*' as '[Union] *legislation harmonising the conditions for the marketing of products*'. Union harmonisation legislation includes the legislation that expressly confirms that the market surveillance provisions apply[121]. Other Union harmonisation legislation also refers to these

119 For example, http://www.beuc.eu/publications/unsafe-consumer-goods-eu-market-call-stricter-controls/html, https://www.businesseurope.eu/sites/buseur/files/media/position_papers/internal_market/2016-10-31_final_be_sp_enforcement_compliance_in_goods.pdf and http://www.orgalime.org/page/market-surveillance-and-customs-controls. See also the overview of position papers on http://ec.europa.eu/DocsRoom/documents/21663.

120 See section 6.3.1 of Annex 4.

121 Directive 2009/48/EC on the safety of toys; Directive 2010/35/EU on transportable pressure equipment; Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products; 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; Directive 2013/53/EU on recreational craft and personal watercraft and repealing Directive 94/25/EC; 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; 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; Directive 2014/30/EU on the harmonisation of the laws of the Member States relating to electromagnetic compatibility; 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; 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; Directive 2014/33/EU on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts; 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; 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; 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; 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; Directive 2014/90/EU on marine equipment and repealing Council Directive 96/98/EC; Regulation (EU) 2016/424 on cableway installations and repealing Directive 2000/9/EC; Regulation (EU) 2016/425 on personal protective equipment and repealing Council Directive 89/686/EEC; Regulation (EU) 2016/426 on appliances burning gaseous fuels and repealing Directive 2009/142/EC.

provisions[122]. Although there is no cross-reference between the market surveillance provisions and the legislation listed below, there seems to be no doubt among stakeholders that the definition of Article 15 includes the so-called 'New Approach' legislation as well as other legislation on non-food products[123].

Yet, it is unclear whether Articles 15 to 26 of the market surveillance provisions[124] apply to other directives and regulations. For example, the question arises if other Union legislation falls within the scope of Regulation (EC) No 765/2008, and especially Union legislation that either regulates certain aspects of the marketing of products, or merely restricts or prohibits the marketing of products[125]. Some confusion on the scope of the Regulation has emerged also from the analysis of national reports (some of which added sectors not in the scope of the Regulation), and considering input from economic operators.

Notwithstanding the lack of clarity of the scope, there seems to be a common understanding that Union legislation that regulates commercial practices[126] is excluded from the scope of the market surveillance provisions. Its enforcement is subject to Regulation (EC) No 2006/2004 of the European Parliament and of the Council of 27 October 2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws (the Regulation on consumer protection cooperation).

122 Article 12 of Regulation (EC) No 1222/2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters obliges Member State to ensure, in accordance with Regulation (EC) No 765/2008, that the authorities responsible for market surveillance verify compliance with Articles 4, 5 and 6 of the Regulation, relating to the responsibilities of tyre suppliers, tyre distributors, vehicle suppliers and vehicle distributors ; Article 18 of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment obliges Member States to carry out market surveillance in accordance with Articles 15 to 29 of Regulation (EC) No 765/2008; Recital (14) of 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 indicates that the market surveillance in Member States of products covered by this Regulation is subject to Regulation (EC) No 765/2008 and Directive 2001/95/EC ; Article 65 of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products lays down that Member States have to make the necessary arrangements for the monitoring of biocidal products and treated articles which have been placed on the market to establish whether they comply with the requirements of the Regulation, and that Regulation (EC) No 765/2008 applies accordingly ; Article 5(4) of Regulation (EU) No 167/2013 on the approval and market surveillance of agricultural and forestry vehicles and Article 6(4) of Regulation (EU) No 168/2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles specify that Member States should organise and carry out market surveillance and controls of vehicles, systems, components or separate technical units entering the market in accordance with Chapter III of Regulation (EC) No 765/2008. Other provisions of the Regulation oblige economic operators to cooperate with national authorities in accordance with Article 20 of Regulation (EC) No 765/2008; According to recital (12) of 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, Chapter III of Regulation (EC) No 765/2008, in accordance with which Member States are required to carry out market surveillance and control products entering the Union market, applies to the products covered by this Regulation.

123 See point 5.1 in Annex 5 for a detailed list.

124 Articles 27 to 29 refer to Union legislation

125 Directive 85/374/EEC concerning liability for defective products; Directive 89/459/EEC on the approximation of the laws of the Member States relating to the tread depth of tyres of certain categories of motor vehicles and their trailers; Directive 91/477/EEC on control of the acquisition and possession of weapons; Directive 2000/53/EC on end-of life vehicles; Regulation (EC) No 273/2004 on drug precursors; Regulation (EC) No 689/2008 concerning the export and import of dangerous chemicals; Regulation (EC) No 1102/2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury; Directive 2009/43/EC simplifying terms and conditions of transfers of defence-related products within the Community; Regulation (EU) No 995/2010 laying down the obligations of operators who place timber and timber products on the market; Regulation (EU) No 258/2012 implementing Article 10 of the United Nations' Protocol against the illicit manufacturing of and trafficking in firearms, their parts and components and ammunition, supplementing the United Nations Convention against Transnational Organised Crime (UN Firearms Protocol), and establishing export authorisation, and import and transit measures for firearms, their parts and components and ammunition; Directive 2014/60/EU on the return of cultural objects unlawfully removed from the territory of a Member State.

126 Directive 93/13/EEC on unfair terms in consumer contracts, Directive 98/6/EC on consumer protection in the indication of the prices of products offered to consumers, Directive 1999/44/on certain aspects of the sale of consumer goods and associated guarantees, Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market, Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2011/83/EU on consumer rights.

The issue of the scope was also raised in a UK public consultation[127] about the pending 'Market Surveillance proposal'[128], 13 respondents (7 trade associations, 2 government agencies, 1 local authority, 1 individual, 1 micro business and 1 'other') did not think the scope gave enough clarity on the coverage provided by market surveillance activity on certain products, whilst 19 respondents (9 trade associations, 2 government bodies, 2 local authorities, 5 large businesses and 1 'other') thought that it did. Of those that considered that the proposal's scope did give enough clarity, 4 respondents (3 trade associations, 1 government body) thought that, although the scope was generally sufficiently clear, clarification was needed for specific provisions pertinent to their own interests. Similar remarks were made by European business associations and during the Council Working Party meetings about the proposal.

EQ13. Is the concept of lex specialis still a suitable interface between the market surveillance provisions in the Regulation and those in other (notably sector) legislation?[129]

The market surveillance provisions constitute 'lex generalis' in two ways:

- Firstly, Article 15(2) specifies that each of the provisions of Articles 16 to 26 (i.e. the Union market surveillance framework) apply in so far as there are no specific provisions with the same objective in Union harmonisation legislation.

- Secondly, Articles 27, 28 and 29 (i.e. controls of products entering the Union market) apply to all products covered by Union legislation in so far as other Union legislation does not contain specific provisions relating to the organisation of border controls.

The purpose of this 'lex generalis'-principle is to solve any conflict between legal rules. One way to organise relationships between different legal rules is to conceive them in terms of relations between what is "general" to what appears "particular". The question of how to deal with specialised sets of rules in their relationship to general law and to each other is usually dealt with by two sets of doctrines: the interpretative maxim *lex specialis derogat lex generali* and the doctrine of self-contained regimes. Legal literature generally accepts the lex specialis as a valid general principle of law[130]. In accordance with the principle *lex specialis derogat legi generali*, special provisions prevail over general rules in situations which they specifically seek to regulate[131]. Many stakeholders consider that the concept of lex specialis is a suitable interface to address market surveillance in specific sectors, as it is relevant and causes no difficulties in implementation[132].

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127 https://whitehall-admin.production.alphagov.co.uk/government/uploads/system/uploads/attachment_data/file/261938/bis-13-1295-product-safety-and-market-surveillance-package-summary-of-responses-2.pdf

128 COM(2013)75 – Proposal for a Regulation of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council.

129 See section 6.3.1 of Annex 4.

130 International Law Commission, Study Group on Fragmentation, Koskenniemi, 'Fragmentation of International Law: Topic (a): The function and scope of the lex specialis rule and the question of 'self-contained regimes':An outline', http://legal.un.org/ilc/sessions/55/pdfs/fragmentation_outline.pdf, pp. 3-4.

131 Judgment of the Court of Justice of 30 April 2014 in Barclays Bank, C‑280/13, ECR, EU:C:2014:279, paragraph 44; Judgment of the General Court of 22 April 2016, Italian Republic v European Commission, Case T-60/06 RENV II, ECLI:EU:T:2016:233, paragraph 81.

132 Section 5.3 of Annex 4.

One of the difficulties in the lex specialis rule follows from the relative unclarity of the distinction between "general" and "special". It follows that no rule can be determined as general or special in the abstract, without regard to the situation in which its application is sought. Thus, a rule may be applicable as general law in some respect while it may appear as a particular rule in other respects[133]. This principle is often difficult to apply in practice and requires a careful comparison between two sets of rules. As a result, it is not straightforward to assess which provisions of the Regulation apply and which articles of the sector-specific legislation are covered by the lex specialis principle. These interpretation problems often result in an excessive administrative burden and in legal uncertainty[134].

6.4. Coherence

EQ14 -To what extent are the market surveillance provisions coherent internally?[135]

As for internal coherence, overall, the market surveillance provisions of the Regulation are consistent within themselves and in the scope of the legislation. Furthermore roles and tasks of all different stakeholders concerned by the Regulation are well-defined and no duplication of activities has been traced. The analysis – supported by stakeholders' opinions - has not identified any overlaps or contradictions between the Regulation's provisions in scope of this study. However, some areas for improvements have been identified. In this respect, there are areas where further guidance and clarity would be beneficial For instance, the Regulation does not provide any specific methodology to be followed by the Member States to review and assess the functionality of the surveillance activities. Similarly, the Regulation does not include provisions related to the principles of cooperation between the Member States (i.e. spontaneous and/by request provision of information, fullest availability for cooperation, reciprocity basis, including in case of negative response/no information). At present, provisions about the implementation of market surveillance are too general, thus allowing for significant differences in the implementation of the Regulation in terms – for instance – of communication and collaboration tools existing within/among Member States, endowments of powers and resources, "adequacy" of checks.

EQ15 - To what extent are the market surveillance provisions above still coherent with other Union legislation on market surveillance on non-food products?[136]

Most of the market surveillance provisions are coherent with other Union legislation setting out market surveillance procedures, especially the legislation that expressly refers to the market surveillance provisions.

They are also coherent with the Union rules on the enforcement of intellectual property rights. An efficient and effectively enforced intellectual property infrastructure is necessary to avoid commercial-scale intellectual property rights (IPR) infringements that result in economic harm. Directive 2004/48/EC on the enforcement of intellectual property rights lays down the measures, procedures and remedies necessary to ensure the enforcement of intellectual property rights within the single market. In addition, Regulation (EU) No 608/2013

133 International Law Commission, Study Group on Fragmentation, Koskenniemi, 'Fragmentation of International Law: Topic (a): The function and scope of the lex specialis rule and the question of 'self-contained regimes':An outline', http://legal.un.org/ilc/sessions/55/pdfs/fragmentation_outline.pdf, p.5.

134 Section See section 6.3 of Annex 4.

135 See section 6.4.1 of Annex 4.

136 See section 6.4.2 of Annex 4.

concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003 sets out the conditions and procedures for action by the customs authorities where goods suspected of infringing an intellectual property right are, or should have been, subject to customs supervision or customs control within the customs territory of the Union, particularly goods declared for release for free circulation, export or re-export, goods entering or leaving the customs territory of the Union and goods placed under a suspensive procedure or in a free zone or free warehouse.

Yet, there is a substantial difference between the enforcement of, on the one hand, 'private' intellectual property rights and, on the other, public safety and consumer protection rules that all products should comply with. The fact that a product is infringing an intellectual property right is already a strong signal that the product is not likely to comply with Union harmonisation legislation. However, the measures taken pursuant to Directive 2004/48/EC and Regulation (EU) No 608/2013 allow these products to be removed from the market and prevent them from entering the market so that enforcement of Union harmonisation legislation is no longer necessary under these circumstances. Therefore, the market surveillance provisions seem to be coherent with the Union rules on the enforcement of intellectual property rights.

Nonetheless, the market surveillance provisions show some incoherencies with other instruments of EU law that can give rise to interpretation difficulties and so raise regulatory costs for businesses and authorities. The following incoherencies were identified:

a) Economic operator[137]

The definition of 'economic operators' in Regulation (EC) No 765/2008 and the definition of economic operators in other Union harmonisation legislation are sometimes incoherent. Article 2 of Regulation (EC) No 765/2008 defines economic operators as '*the manufacturer, the authorised representative, the importer and the distributor.*' However, several pieces of Union harmonisation legislation create obligations for businesses which are not considered 'economic operators' for the purpose of Regulation (EC) No 765/2008[138]. The consequence is

137 See also section 6.3.1 of Annex 4.

138 Regulation (EC) No 273/2004 on drug precursors applies to two categories of businesses, namely *'operators'* (i.e. any natural or legal person engaged in the placing on the market of scheduled substances) and *'users'* (i.e. any natural or legal person other than an operator who possesses a scheduled substance and is engaged in the processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, transformation or any other utilisation of scheduled substances); Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) distinguishes the manufacturer, the importer, the distributor, the producer of an article (i.e. any natural or legal person who makes or assembles within the EU an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition) and the downstream user (i.e. any natural or legal person established within the Union, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities); Similarly, Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures provides also contains obligations for the producers of an article and downstream users; Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators defines economic operators as '*any producer, distributor, collector, recycler or other treatment operator'*; Directive 2013/53/EU on recreational craft and personal watercraft introduced specific obligations for the '*personal importer*' vis-à-vis the market surveillance authorities; Directive 2014/33/EU on lifts extended the market surveillance obligations to the 'installers' of lifts; 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 applies to two categories of traders, namely the *'dealer'* (i.e. a retailer or other person who sells, hires, offers for hire-purchase or displays products to end-users) and the *'supplier'* (i.e. the manufacturer or its authorised representative in the Union or the importer who places or puts into service the product on the Union market. In their absence, any natural or legal person who places on the market or puts into service products covered by this Directive is considered a supplier); Directive 2010/35/EU on transportable pressure equipment defines the '*economic operator'* not only as the manufacturer, the authorised representative, the importer and the distributor but also includes *'the owner or the operator acting in the course of a commercial or public service activity, whether in return for payment or free of charge'*. The latter are also subject to the market surveillance obligations laid down in the Directive.

that some important provisions of Regulation (EC) No 765/2008 cannot be applied. For example, it allows market surveillance authorities to '*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, and, where it is necessary and justified, enter the premises of economic operators and take the necessary samples of products. They may destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary*.' This will not be possible for economic operators that are not included in the definition of Regulation (EC) No 765/2008.

Conversely, the obligation for market surveillance authorities to cooperate with economic operators regarding actions which could prevent or reduce risks caused by products made available by those operators, will not apply to other businesses than manufacturers, authorised representatives, importers and distributors. The same thing goes for the obligation of market surveillance authorities of one Member State which decide to withdraw a product manufactured in another Member State, to inform the economic operator concerned at the address indicated on the product in question or in the documentation accompanying that product.

b) Intermediary services providers under the E-commerce Directive 2000/31/EC

Furthermore, the coherence between the market surveillance provisions and the liability regime of intermediary service providers whose liability is regulated by the Electronic Commerce Directive 2000/31/EC is not entirely clear in many cases. Intermediary service providers carrying out hosting activities benefit from an exemption of liability for damages or criminal sanctions related to the content provided by third parties using their networks. However, the liability exemption is not absolute. In the case of hosting activities, which are the most relevant for the product safety and compliance area, the exemption only applies if the intermediary service provider has no actual knowledge or awareness about the illegal nature of the information hosted and upon obtaining such knowledge or awareness of the illegal content (for instance by a 'sufficiently precise and adequately substantiated' notice, it acts expeditiously to remove it or disable access. If they do not fulfil these conditions, they cannot be covered by the exemption and thus they can be held liable for the content they host.

Following Article 15 of the E-commerce Directive, Member States cannot impose either a general obligation on these providers to monitor the content or a general obligation to actively seek facts or circumstances indicating illegal activity. This means that national authorities cannot establish a general obligation for intermediaries to actively monitor their entire internet traffic and seek elements indicating illegal activities such as unsafe products. The ban on requesting general monitoring, however, does not limit public authorities in establishing specific monitoring requirements, although the scope of such arrangements have to be targeted.

In practice, this means that national authorities can contact the hosting providers who, when notified of unlawful activity, if they want to benefit from the exemption of liability, have to remove or disable the content, meaning that the unsafe/non-compliant products would no longer be accessible to EU customers through their services. Yet, in many cases, these national authorities are not necessarily the market surveillance authorities who usually can only act with respect to 'economic operators'.

c) The GPSD

A specific interpretation problem could arise when the 'lex specialis'-principle is combined with Article 15(3) which specifies that the application of the market surveillance provisions do not *'prevent market surveillance authorities from taking more specific measures as provided for in Directive 2001/95/EC*.' The coherence problems relate to the definitions of the GPSD which differ from those of the Regulation. For instance, the definitions of "distributor", "withdrawal", "recall" are different from one piece of legislation to the other, while the definitions of "serious risk" and "dangerous products" are set in the GPSD and not in Regulation 765/2008, though the latter widely refers to these concepts. Moreover, the boundary between the GPSD and the Regulation is not always clear as the two pieces of legislation sometimes seem to overlap[139]. These issues were specifically addressed by the Commission in the legislative proposal put forward in 2013, which is still pending.

EQ16. To what extent are these provisions coherent with wider EU policy?

Wider EU policy on the enforcement of Union legislation, by national authorities, evolved quite profoundly since the market surveillance provisions started applying. The European Commission that came into office in November 2014 has created increasing jobs, growth and investment its top priority and is pursuing it by deepening the Single Market across sectors and policy areas. Better enforcement of Union legislation is one of the key tools to achieve a fairer internal market which is one of the ten policy areas to be tackled under President Juncker's Agenda for Jobs, Growth, Fairness and Democratic Change[140]. Consequently, many new initiatives were tabled by this Commission in order to improve the enforcement of Union legislation by national authorities.

- In the area of food and feed, 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[141] will increase Member States' ability to prevent, eliminate or reduce health risks to humans, animals and plants. The new Regulation provides a package of measures that will strengthen the enforcement of health and safety standards for the whole agri-food chain. The new rules will gradually become applicable with the main application date being 14 December 2019.

- Furthermore, the Commission put forward a proposal for the reform of the Consumer Protection Cooperation (CPC) Regulation[142], which governs the powers of enforcement authorities and the manner in which they can cooperate. The reform addresses the need to better enforce EU consumer law, especially in the fast evolving digital sphere. The

139 See section 6.4.2 of Annex 4.

140 https://ec.europa.eu/commission/sites/beta-political/files/juncker-political-guidelines-speech_en_0.pdf.

141 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.

142 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.

proposal for an improved Regulation will equip enforcement authorities with the powers they need to work together faster and more efficiently.

- In addition, the Commission proposed new rules to enable Member States' competition authorities to be more effective enforcers of EU antitrust rules[143]. 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. It aims to ensure that when applying the same legal basis national competition authorities have the appropriate enforcement tools, in order to bring about a genuine common competition enforcement area. The proposed rules, once adopted, will provide the national competition authorities with a minimum common toolkit and effective enforcement powers.

- Stronger enforcement powers are also key issues in other recent legislative initiatives[144].

Therefore, it is obvious that, in the light of wider EU policy as outlined before, strengthening market surveillance provisions would be coherent with wider EU policy.

The coherence of market surveillance provisions with the EU's policy of helping SMEs and start-ups to grow could be enhanced. Far too many obstacles remain for SMEs, start-ups and young entrepreneurs looking to grow in the Single Market. In particular, SMEs complain about understanding and complying with regulatory requirements. This means that non-compliance should be prevented by helping SMEs to understand and comply with these requirements. However, the provision of information about regulatory requirements is a missing element in the market surveillance provisions and in Union harmonisation legislation in general.

6.5. EU added value

EQ17. What is the additional value resulting from the market surveillance provisions at EU level, compared to what could be achieved by Member States at national and/or regional levels?[145]

The benefits of having a single piece of European legislation harmonising market surveillance instead of several different pieces of national legislation are widely recognised by stakeholders. By setting common requirements relating to the marketing of products, the Regulation per se already achieves a result which cannot be attained by a single Member State's action. This is particularly relevant if we consider that the shortcomings in one Member State's market surveillance system are likely to affect a considerable number of other Member States, in light of the absence of national borders within the internal market.

143 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.

144 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; the incoming new Regulation on energy efficiency labelling and 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.

145 See section 6.5 of Annex 4.

The analysis of the EU added value as per the specific provisions of the Regulation shows that some of them achieve a higher EU added value when compared to others.

The EU added value of the Regulation mainly stems from provisions envisaging common information systems favouring administrative cooperation and enhancing collaboration between customs and Market surveillance authorities. The Regulation has improved cooperation among actors involved in market surveillance activities. In this regard, the management of the RAPEX and ICSMS system at the EU level should not be disregarded, as they are two valuable tools that increase and enhance the exchange of information and open possibilities of collaboration between Member States. Moreover, the framework provided by the Regulation is useful in defining national market surveillance and the control of imported products policies. By clarifying the role of Customs, for instance, the Regulation has also enhanced their channels and opportunities of collaboration with other EU authorities. This benefit appears particularly important for "small countries".

The EU added value linked to provisions dealing with market surveillance organisations at the national level is limited, mainly because the Regulation does not provide clear guidance on how to have a more homogenous market surveillance system. Finally, it is worth recalling provisions on national programmes and reports. Although they could provide significant EU added value in terms of monitoring of the enforcement of market surveillance, the lack of binding criteria on how they should be drafted and interpreted makes these documents far less relevant than initially expected.

Overall the Regulation therefore has the potential to contribute to the protection of safety and other public interests underpinning Union product harmonisation legislation, to the establishment of a level playing field and to the improvement of the free movement of goods. The harmonisation of rules is reported as a benefit. The Regulation facilitates transparency and unambiguous interpretation of rules, together with cooperation between countries and relevant authorities.

However, the potential for the Regulation to achieve a full EU added value is still hindered by the sub-optimal level of cross-border exchange of information and cooperation, persisting difficulties in dealing with cross-border non-compliance the lack of a uniform implementation of the market surveillance framework at the national level and the insufficient rigour of controls, including on imported products.

EQ18. To what extent do these provisions support and usefully supplement market surveillance policies pursued by the Member States? Do the provisions allow some sort of 'control' by the EU on the way national authorities carry out market surveillance?

The general view is that the market surveillance provisions support and usefully supplement market surveillance policies pursued by the Member States, especially in cross-border situations[146]. Yet, there seems to be convergence of views that they do not do so sufficiently. The relevant provisions and their implementation should then be profoundly improved.

The current market surveillance provisions do not attribute to the EU institutions any powers to 'control' the way national authorities carry out market surveillance. As mentioned the

146 See annexes 2, 6 and 7.

generality of the provisions setting out minimum requirements for the organisation and the performance of market surveillance does not allow setting benchmarks against which to assess national activities at EU level. On the other hand the market surveillance provisions seem to attribute to the Commission the role of facilitator in relation to the exchange of information among Member States.

7. CONCLUSIONS

7.1. Effectiveness

The Regulation has been **only partly effective** in achieving its specific and strategic objectives**.**

Although **coordination and cooperation** has developed significantly, and is recognised as useful, they have not reached a level that can be considered satisfactory. In particular, despite the tools (i.e. RAPEX, ICSMS) that are in place to ensure cross-border market surveillance cooperation, they are not sufficiently used by Member States. As a result, Market surveillance authorities do not fully benefit from the advantages of these systems as they rarely restrict the marketing of a product following the exchange of information on measures adopted by another EU MSA against the same product. Also, the possibility for Market surveillance authorities and Customs to make use of finding (including test reports) by Market surveillance authorities in other EU countries and avoid duplication of work seems to be limited. The value of administrative cooperation which is essential for coordinating actions and learning from best practice is diminished by a lack of active participation in AdCos. The issue of limited resources is often invoked by Market Surveillance authorities to explain sub-optimal use of available coordination tools. In addition because the bulk of the market surveillance framework (powers, procedures) is set nationally authorities perceive market surveillance as a national matter and fail catch the spill over effects of their activities on the functioning of the Single Market. Moreover the lack of an administrative framework for the management of cross-border projects represents an important obstacle to their involvement in actions coordinated with other Member States.

Uniformity and rigorousness of market surveillance has not been achieved yet, due to the significant differences across Member States in the implementation of the Regulation as to the organisation of market surveillance at the national level, the availability of resources (financial, human and technical), the strategies of market surveillance, the powers of inspection and of sanctions and the systems of monitoring and reporting. The general character of the Regulation's requirements is likely to have allowed these different implementations.

The heterogeneity existing across Member States in the implementation of the Regulation allows an inference to be drawn 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 proper enforcement. As for its rigorousness, the serious lack of data and inhomogeneity of national reports do not allow for a thorough assessment. However, on the basis of the information available, the amount of resources attributed to market surveillance and activities reported cast some doubts on the ability of market surveillance authorities to perform checks at an adequate scale. Lack of relevant information may in some cases be an indication of

actual enforcement gaps. The insufficient rigorousness of market surveillance is further supported by the stakeholders' perception about the incapacity of the Regulation to deter rogue traders and the discrepancies in the penalty framework.

The **border controls on imported products** seem insufficient. The main difficulties are due to a lack of jurisdiction of the Market surveillance authorities outside of their Member State, particularly in the context of online sales.

The Regulation is not fully effective in relation to its strategic objectives of strengthening the protection of public interests and of ensuring a level playing field among economic operators through the reduction of the number of non-compliant products on the Internal Market. Data available actually point to the persistence and possibly to the increase of non-compliant products.

Moreover, national discrepancies in the implementation of the Regulation diminish its effectiveness in achieving a level playing field, inasmuch as they create disparities in the level of enforcement which influence regulatory/administrative costs to businesses across Member States and market behaviour.

The evaluation identified a number of **enabling factors**, relating to the different national implementations, which made the implementation of the Regulation more or less effective, eventually impacting the achievement of its objectives.

The level of decentralisation of market surveillance structures for instance, impacts the level of existing cooperation and collaboration between national Market surveillance authorities. The more a Member State is decentralised, the more it will need numerous and complex coordination mechanisms.

Resources are certainly a second enabling factor. The lack of resources is considered one of the main bottlenecks to market surveillance implementation and effective deterrence. The different levels of resources have implications on the way Market surveillance authorities perform their tasks. For instance, Market surveillance authorities' market knowledge in order to target checks is not sufficient in sectors that require specific skills. Moreover, the excessive cost of testing is the most likely explanation for the low level of surveillance, which in some sectors is limited to mere documentary checks. Similarly, resources also influence Market surveillance authorities' criteria for prioritisation of monitoring and enforcement activities, impacting on the "adequate scale" of controls (foreseen by Article 19 and 24). At the same time, resources influence strategies for market surveillance, which could be proactive rather than reactive.

Powers attributed at the national level and the role of Customs in enforcing the Regulation influence the effectiveness of border control. Controls are indeed expected to be tougher in Member States where Customs act as Market surveillance authorities. Cooperation between Customs and Market surveillance authorities and with other EU Customs are a crucial element for enhancing market surveillance on imported products. In this respect, there are notable differences across Member States.

Overall, it seems that these discrepancies are due to the general nature of the requirements set out in the Regulation. This lack of specificity relates to Member States' obligations as regards organisation, powers, resources and knowledge necessary to Market surveillance authorities

for the proper performance of their tasks. The provision on national reports and programmes is also general, as it does not foresee the transmission of structured information from Member States to the European Commission relating to market surveillance activities, which is particularly evident in light of all the data limitations highlighted in the study. Moreover, the Regulation does not include specific provisions relating to the principles of cooperation between Member States. Finally, the Regulation is not specific enough to set a minimum and/or a maximum level of penalties, or any principles to define them. As discussed, this results in wide differences in the minimum/ maximum amounts within and across Member States, which lowers its power as an enforcement deterrent.

An additional enabling factor identified is the (lack of) cooperation between enforcement authorities and businesses. Among the main reasons for product non-compliance in the internal market is a lack of economic operators' knowledge on the relevant legislative requirements to be complied with, as well as a deliberate choice to exploit market opportunities at the lowest cost, possibly due to low incentives to comply with the existing rules.

7.2. Efficiency

Most of the **costs** of the market surveillance provisions are **borne by Member States** and their market surveillance authorities. Costs incurred by Market surveillance authorities vary considerably from one Member State to another. These differences might be related to different national organisational models requiring different levels of both human and financial resources. However, another possible explanation is the different approach followed by Market surveillance authorities in reporting data concerning the used financial resources as well as the performed activities. Data available suggests that the average annual budgets allocated to MSA activities over the 2010-2013 period do not correlate to the size of the market. The analysis of the efficiency of the Regulation has however been limited by the evident poor quality of data included in the national reports both in terms of completeness and comparability.

The fact that Member States define their own market surveillance approach creates a big variation in the ways the different sectors are controlled and managed. This may also reduce the efficiency of the market surveillance when responsibilities of national authorities are not primarily related to market surveillance of non-food products within the meaning of the Regulation and this creates an overlap and duplication of activities.

With respect to **costs for economic operators**, information costs caused by the Regulation are perceived as insignificant. On the other hand business stakeholders point to the negative impact that some of the across-the-board inconsistencies in the approach to market surveillance followed by different Member States have on them. They also stress that the current enforcement mechanism is not able to create a level playing field for businesses that are selling products in the Internal Market. This might reduce businesses' willingness to comply with the rules and discriminate businesses that abide by the rules against those who do not.

In terms of **benefits** there is no evidence of cost savings for businesses as a result of the implementation of the Regulation in terms of administrative tasks or operational tasks if compared to the situation prior to 2008. Furthermore**, the expected improved safety for**

consumers and other product users and level playing field for businesses are not confirmed by RAPEX notifications and by the statistics on the implemented restrictive measures at national level. An increase in RAPEX notifications and surveillance measures may also imply that Market surveillance authorities have become more effective in finding – and thus correcting - non-compliance making products dangerous. However this underlines that the Regulation is still not able to increase businesses' willingness to comply with the rules, thereby discriminating businesses that abide by the rules against those who do not.

Efficiency gains might be achieved by more effective cooperation between industry and authorities. In this way, market surveillance authorities can take advantage of manufacturers' technical knowledge and may be in a better position to identify non-compliant products on the market and set appropriate priorities for market surveillance activities.

7.3. Relevance

The relevance of the Regulation has been assessed in terms of its scope (including its definitions and concept of *lex specialis*) and in view of stakeholders' needs, including those related to new/emerging issues.

The analyses highlighted that a number of stakeholders find the **scope** of the Regulation not fully clear. Difficulties in understanding the Regulation's scope might be exacerbated by technological developments introducing new forms of products.

The Regulation's **definitions** are generally clear and appropriate, however they are not fully complete and up-to-date, especially when considering the need to cover also online sales.

The Regulation is overall relevant when considering current **stakeholders' needs** associated to its general and specific objectives (cooperation and exchange of information, border controls) but it becomes less relevant with looking at needs related to new/emerging dynamics (increasing online trade, budgetary constraints at national level, market dynamics that require a fast reaction)**.** As for online trade, for instance, the Regulation neither includes specific provisions covering online sales, nor does it provide for definitions that account for its specificities.

7.4. Coherence

Coherence of the Regulation has been evaluated at two levels: internal coherence of the provisions of the Regulation within themselves, and external coherence of the Regulation with the GPSD and sectoral legislations in its scope.

None of the stakeholders reported problems about **internal coherence**. The Commission could not identify any major internal incoherencies. However, the specification of some provisions currently very general would support more coherence in the implementation of market surveillance.

As for **the external coherence** some issues have been identified in relation to **the GPSD**, whose definitions are not always aligned with those of the Regulation. Moreover, the boundary between the GPSD and the Regulation is not always clear. These issues were tackled by the Commission in the legislative proposal put forward in 2013.

Finally, the coherence of the Regulation **with sectoral directives** is safeguarded to a sufficient extent by the existence of the *lex specialis* provision. Nonetheless, in certain cases, discrepancies and gaps in the definitions and terminology provided in the different pieces of legislation diminish the overall clarity of the framework for market surveillance, although they do not hinder the implementation of the Regulation. The discrepancies and gaps different sector specific legislations could be addressed when the sector legislation in question is reviewed to align them with the horizontal definitions of Regulation (EC) N° 765/2008.

7.5. EU added value

Overall the benefits of having a single piece of European legislation on **harmonising market surveillance** instead of several different pieces of national legislation are widely recognised by stakeholders. The harmonisation of rules is seen as contributing to the protection of safety and other public interests underpinning Union product harmonisation legislation, to the establishment of a level playing field and to the improvement in the free movement of goods. The Regulation facilitates transparency and unambiguous interpretation of rules.

The EU added value of the Regulation mainly stems from provisions envisaging **common information systems** favouring administrative cooperation and enhancing **collaboration between customs and Market surveillance authorities**.

However, the potential for the Regulation to achieve **full EU added value is still hindered** by the sub-optimal level of cross-border exchange of information and cooperation, persisting difficulties in dealing with cross-border non-compliance, the lack of uniform implementation of the market surveillance framework at the national level and the insufficient rigour of controls, including imported products.

7.6. REFIT potential

The evaluation identified the following main areas where regulatory burdens could be minimised and rules could be simplified:

- 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 could be addressed when the sector legislation in question is reviewed;[147]

- 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[148]. 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

147 See chapter 6.4
148 See chapters 5.1, 6.1.1 and 6.2.

controls, penalties, degree of cross-border cooperation) could be reduced. Coordination mechanisms within Member States should be improved and simplified[149];

- The 'market surveillance programmes' and reports on activities carried out could also benefit from simplification and more strategic use[150];

- 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[151].

149 See chapters 5.1, 6.1.2 and 6.2. See also reply to EQ3.
150 See chapter 6.1.
151 See chapters 6.1.3 and 6.3.

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PART 2/3

COMMISSION STAFF WORKING DOCUMENT

REFIT EVALUATION

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 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) 466 final} - {SWD(2017) 467 final} -
{SWD(2017) 468 final} - {SWD(2017) 470 final}

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 evaluation and issued its opinion on 07/04/2017. The Board made several recommendations. Those were addressed in the revised report as follows:

RSB recommendations	Modification of the report
(B) Main considerations	
The Board acknowledges a significant effort to collect evidence on non-compliant	

products as part of the evaluation work.	
However, the Board considers that the report contains important shortcomings that need to be addressed, particularly with respect to the following issues:	See below
(1) The evaluation report is not a self-standing document.	
(2) The evaluation fails to deliver evidence-based findings and conclusions.	
Against this background, the Board gives a negative opinion and considers that in its present form this report does not provide sufficient input for the associated Impact Assessment.	
(C) Further considerations and adjustment requirements	
(1) Self-standing evaluation report	
The evaluation report should be a self-standing document.	The SWD and the annexes were fundamentally redrafted so that the evaluation became a self-standing document.
It should include the main findings of the underlying external evaluation study and other available evidence, which are now in the annexes.	Done in section 4, 5.1, 6 and 7 of the SWD.
The report should present evidence in a structured way, following a clear intervention logic and addressing all the evaluation criteria.	New intervention logic in section 2.1.1. All evaluation criteria are examined separately in section 6 of the SWD (except EQ2/EQ3 and EQ8/EQ9 which are examined jointly for the sake of clarity)
The report should be clear about limitations of what the available evidence can reasonably demonstrate.	Done in section 4 of the SWD as a summary of the limitations set out in Annex 4.
As a REFIT exercise, the evaluation should also assess the scope for simplification and reduction of regulatory burden.	Done in section 7.6 of the SWD.
(2) Scope	
The report should more clearly present the scope and limitations of the evaluation.	Scope and limitations explained in section 2.1.2 of the SWD

It should provide an explanation of the existing legislative framework and how the provisions are implemented in Member States.	Explained in 2.1.2, 2.1.3 and 2.3.1, and in detail in Annex 5.
The report should draw conclusions from the diversity of national practices.	Done mainly in section 6.1 but it is a recurrent feature throughout the text.
It should substantiate the fact that penalties are not high enough. It should explain the links with sectoral legislation and how mutual recognition and customs policy work together.	The penalties are examined in sections 6.1.2.2, 6.1.2.1, 6.1.3 and under EQ3, and in several other places of the text, and in greater detail on pp. 105-108 of Annex 4. Links with sector legislation explained in section 2.1.3 and table 1 of the SWD, and in Annex 5. Border controls explained in more detail essentially in section 6.1.3 of the SWD, under EQ3, and section 2 of Annex 8.
Against this background, it should clarify the scope and benchmarks used for the evaluation.	Done in section 2.1 of the SWD
It should add relevant information from previous impact assessments and evaluations	Full list in section 8.14 of Annex 4.
(3) Conclusion	
The report should align its conclusions with the revisions required for the other sections. They should clearly set out main lessons learned and how far evidence supports them. As such, the conclusions should provide a solid basis for the scope and problem definition of the parallel impact assessment for future policy developments in the area.	Done in section 7 of the SWD.

The Regulatory Scrutiny Board (RSB) of the European Commission assessed the revised version of the present evaluation and issued a positive opinion on 31/05/2017. The Board made few final recommendations that were addressed in the revised evaluation as follows:

RSB recommendations	Modification of the report
(B) Main considerations / (C) Further considerations	
(1) Further elaboration if the REFIT dimension throughout the evaluation.	The relevant aspects were consistently referred to in the sections on effectiveness and efficiency. The reasons why regulatory burden reduction concerns mainly authorities are explained.

(2) Additional explanations on how market surveillance works in practice in a Member States.	A detailed overview on the organisation of market surveillance in two Member States was added.
(3) Reader friendliness.	The introduction in particular is now a bit less technical and includes a summary of main findings.

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)

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 latest 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 last 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 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 have a stronger convergence between the the ICSMS and RAPEX platforms.

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 section 4.1 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.

ANNEX 3: METHODS AND ANALYTICAL MODELS USED IN PREPARING THE EVALUATION

The methodology used in preparing the valuation consists of the desk research, the field research and the case studies.

The desk research focused on an in-depth review of the national market surveillance programmes and reports drafted by Member States pursuant to Article 18(6) of Regulation (EC) 765/2008[2] covering also the sectoral impact assessments drafted by the European Commission[3] for the relevant product categories covered by the Regulation, together with other policy documents relevant for market surveillance such as the Impact Assessment (IA) for the Regulation or the IA for the Product Safety and Market surveillance Package.

The market analysis is aimed at providing an understanding of the market for which EU harmonised product rules exist and at assessing the main trends in the intra EU trade of harmonised products. In order to identify the variables to be included in the analysis, we started from the reference list of sectors included in the EC template in its version published on 26 October 2015 and we tried to identify the available statistics that are useful for the scope of the study. A two-stage approach was implemented: an analysis at the sectoral level oriented towards the macro dimension and an analysis at the product level focused on the value of products that are traded within the EU internal market and for which EU harmonised rule exist (hereafter *harmonised products*).

Results from these analyses have been combined to identify the sectors whose trade value in harmonised products is more relevant.

The field research made use of a combination of field research tools, namely five targeted surveys and 23 interviews, plus the results of a Public Consultation launched by the Commission.[4]

As for the **geographical coverage** of the stakeholder consultation, all EU Member States, together with Iceland, Norway, Switzerland and Turkey, were involved in the consultation.

Five thematic case studies aimed at gathering a deeper understanding of all the issues covered by the evaluation questions. Each case study required four interviews for in-depth investigation.

Detailed analysis of each method is provided in Annex 4.

2 Article 18(6) states that "*Member States shall periodically review and assess the functioning of their surveillance activities. Such reviews and assessments shall be carried out at least every fourth year and the results thereof shall be communicated to the other Member States and the Commission and be made available to the public, by way of electronic communication and, where appropriate, by other means."*

3 Decision 768/2008/EC sets out the common principles and procedures that the EU legislation must follow when harmonising conditions for marketing products in the European Economic Area. At the time of writing, 20 directives and regulations have been aligned with these reference provisions. The Impact Assessments drafted for the respective legislative proposals have been considered in light of the data they report on the state of the art of or possible issues with the implementation of market surveillance in the relevant sectors.

4 The European Commission launched a public consultation on the evaluation of the market surveillance provisions of Regulation (EC) No 765/2008 and on actions to enhance enforcement and compliance in the Single Market for goods. The Consultation ran from 28 June to 31 October 2016.

ANNEX 4: EX-POST EVALUATION OF REGULATION (EC) NO 765/2008

ABSTRACT (EN)

Regulation (EC) No 765/2008 aims at strengthening the protection of public interests, through reducing the number of non-compliant products on the EU Internal Market, and at ensuring a level playing field among economic operators, providing a framework for market surveillance and controls of products.

The evaluation aimed at understanding to what extent the Regulation has achieved these objectives. Moreover, it analysed the Regulation's practical implementation in the EU Member States and assessed the market for products in its scope.

The evaluation concluded that the Regulation is not fully effective in achieving its objectives. Moreover, it has a limited cost effectiveness due to its partial achievement of both expected results and impacts, and to both resources allocated to enforcement and related activities not being correlated to the size of surveyed markets. The needs addressed by the Regulation are still relevant, although there exist a number of issues that could call this into question, particularly with respect to increasing online trade and budgetary constraints at national level. Moreover, the scope of the Regulation is not fully clear and its market surveillance provisions suffer from a lack of specificity. This allowed for different implementations at the national level, which impact on the level of uniformity and rigorousness of market surveillance controls across the EU. Finally, the coherence of the Regulation with respect to the GPSD and sectoral directives is not straightforward and this reduces the clarity of the overall framework for market surveillance.

ABSTRACT (FR)

Le règlement (CE) N° 765/2008 vise à renforcer la protection des intérêts publics en réduisant le nombre de produits non conformes sur le marché intérieur de l'Union Européenne (EU). Il vise également à assurer des conditions équitables entre les opérateurs économiques en fournissant un cadre pour la surveillance du marché et le contrôle des produits.

L'objectif de l'évaluation était de comprendre dans quelle mesure le règlement a atteint ces objectifs. En outre, les analyses de la mise en œuvre du règlement dans les États membres et du marché inclut dans son champ d'application ont été conduites.

En conclusion, il apparait que le règlement n'est pas pleinement efficace dans l'accomplissement de ses objectifs. De plus, il a un rapport coûts-efficacité limité en raison de l'accomplissement partiel soit des résultats soit des impacts attendus, ainsi que des ressources deployées et des activités connexes à l'exécution qui ne sont pas corrélées à la taille des marchés contrôlés. Les besoins abordés par le règlement sont toujours pertinents, bien qu'il existe des problèmes susceptibles de les remettre en question, en particulier en ce qui concerne l'augmentation des pratiques de commerce en ligne et des contraintes budgétaires au niveau national. En outre, le champ d'application du règlement n'est pas entièrement clair et ses dispositions manquent de spécificité. Ceci a conduit à des implémentations différentes au niveau national, qui ont eu un impact sur le niveau d'uniformité et de rigueur des contrôles du marché dans l'UE. Enfin, la cohérence du règlement par rapport à la DSGP et aux directives sectorielles n'est pas toujours évidente, ce qui réduit la clarté du cadre général de la surveillance du marché.

ABSTRACT (DE)

Die Verordnung (EG) Nr. 765/2008 hat das Ziel, die öffentlichen Interessen zu schützen, indem sie die Anzahl der nichtkonformen Produkte im europäischen Binnenmarkt reduziert und durch die Vorgabe eines Rahmens für die Marktüberwachung und die Produktkontrolle allen Wirtschaftsakteuren die selben Wettbewerbsbedingungen garantiert.

Die Evaluation hatte zum Ziel, zu verstehen, in welchem Ausmass die Marktüberwachungsbestimmungen der Verordnung ihre Zielsetzung erreicht haben. Zudem wurde die konkrete Umsetzung dieser Bestimmungen in den EU Mitgliedstaaten analysiert und der Markt für Waren im Geltungsbereich der Verordnung festgestellt.

Die Evaluation kam zu dem Schluss, dass die Verordnung ihr Ziel nicht vollständig erreicht hat. Ausserdem weist diese eine eingeschränkte Kostenwirksamkeit auf, was einerseits darauf zurückzuführen ist, dass die erwarteten Ergebnisse und Auswirkungen nur teilweise realisiert wurden, und andererseits auf eine fehlende Korrelation der Durchsetzungsressourcen und –tätigkeiten mit der Größe der befragten Märkte. Die in der Verordung angegangenen Bedürfnisse sind immer noch relevant, obwohl eine gewisse Anzahl an mit der Marktüberwachung der Online-Verkäufe und den steigenden nationalen Haushaltszwängen verbundenen Angelegenheiten besteht, die dies in Frage stellen könnten. Zudem ist der Rahmen der Verordung nicht eindeutig definiert und die darin enthaltenen Marktüberwachungsbestimmungen leiden unter einem Mangel an Spezifität. Dies hat auf nationaler Ebene zu verschiedenen Implementationen geführt, welche die Einheitlichkeit und Rigorosität der europaweiten Marktüberwachungskontrollen beeinträchtigen. Die Schlüssigkeit der Verordnung, was die Richtlinie über die allgemeine Produktsicherheit und die sektorspezifischen Richtlinien betrifft, ist nicht eindeutig und dadurch reduziert sich die Klarheit der gesamten Rahmenbedingunen der Marktüberwachung.

EXECUTIVE SUMMARY (EN)

Regulation (EC) No 765/2008 (hereinafter also referred to as 'the Regulation') setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93[5] has been applicable since 1 January 2010. The Regulation has the strategic objectives of '*strengthening the protection of public interests through the reduction of the number of non-compliant products on the EU Internal Market* and *ensuring a level playing field among economic operators',* providing a framework for market surveillance and product control.

The evaluation

The evaluation performed aimed at understanding to what extent the Regulation has achieved its original objectives in terms of **effectiveness, efficiency, relevance, coherence, and EU added value**. Moreover, it analysed the **practical implementation of the Regulation** in EU Member States and assessed the **product market within the scope of the Regulation.**

This evaluation also aimed to contribute to the **identification of the relevant set of actions** supporting this Regulation within the framework of the Single Market Strategy.

5 Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries.

Effectiveness

The evaluation concluded that **the Regulation is not fully effective.**

In particular, although **a plethora of coordination and communication mechanisms and tools for information exchange** exist within and between the individual Member States and with third countries, **these do not work efficiently or effectively enough** (e.g. Market surveillance authorities (MSAs) rarely restrict the marketing of a product following the exchange of information on measures taken by other MSAs; and in the context of products manufactured outside the national territory, MSAs find it difficult to contact the economic operator even if it is based in another EU Member State). Moreover, Member States have implemented the Regulation in **many different iterations,** with substantial variations in terms of organisational structures, level of resources deployed (financial, human and technical), market surveillance strategies and approaches, powers of inspection, and sanctions and penalties for product non-compliance. Finally, although Customs' powers are perceived as adequate and procedures for border controls are clear and appropriate, **checks on imported products are still considered inadequate** in light of **increasing import from third countries** – particularly China – and **online sales**.

All these elements have had an impact on achieving **uniform and sufficiently rigorous controls**. Thus, they have also had an impact on the effectiveness of the measure in achieving its objectives in terms of protecting public interests and the level playing field for EU businesses.

The Regulation's effectiveness towards achieving its objectives is also thrown into question by **the increasing number of non-compliant products** included in its scope, as demonstrated by the rising number of RAPEX notifications and restrictive measures taken by MSAs. An important reason for product non-compliance in the internal market seems to relate in particular to a **lack of knowledge among economic operators** about the applicable legislative requirements.

Efficiency

The Regulation introduces costs for Member States and, to a more limited extent, for economic operators. The former are related to organisational, information, surveillance, and cooperation obligations; costs for economic operators relate to information obligations, as defined in Article 19 of the Regulation.

The budget allocated to MSAs **in nominal terms varies considerably from one Member State to another**. These differences might be related to the fact that Member States have different organisational models requiring different levels of financial resources. However, another possible explanation might be sought in the different approaches followed by MSAs in reporting data on the level of financial resources used and on activities performed.

The fact that Member States are free to define their own approaches to market surveillance created a significant variation in the way the different sectors are controlled and managed. Moreover, **fragmentation of control activities throughout the internal market may interfere with timely action by the authorities and cause additional costs for businesses**.

As regards costs for economic operators, **information costs** are not perceived as significant although **some cross-border inconsistencies still remain** and the **current enforcement mechanism is unable to create a level playing field for those businesses** marketing products in the internal market. This **might reduce businesses' willingness to comply with the rules** and discriminate against businesses that abide by the rules and those who do not.

The analysis of RAPEX database and of national reports highlighted that **product non-compliance increased consistently** from 2006-2009 to 2010-2015.

The limited cost effectiveness of the market surveillance provisions is confirmed by the fact that neither the average annual budgets allocated to MSA activities nor their variation during the period 2011-2013 correlate with the size of the market (i.e. number of enterprises active in the harmonised sectors).

Relevance

Overall, the Regulation is relevant, although the study concluded there were issues which could put this into question.

For instance, t**he scope** of the **Regulation** is not fully clear. This drawback could eventually be exacerbated by technological developments which introduce new types of products. As for the Regulation's **definitions**, although they are generally clear and appropriate, they are not **complete and up to date**, especially when considering the need to address online sales. The concept of *lex specialis* represents a suitable interface to address market surveillance in specific sectors. However, some issues have emerged regarding a lack of clarity in the scope of market surveillance rules in sector-specific legislation.

Considering the relevance of the Regulation to **stakeholders' needs,** the analysis concluded that it is relevant to some extent. Overall, it is relevant when considering current needs associated to its general and specific objectives, but it becomes less relevant when referring to the needs related to new/emerging dynamics, especially with reference to **increasing online trade and budgetary constraints at the national level**.

Coherence

The evaluation concluded that **the Regulation's market surveillance provisions are coherent within themselves**; **and** the roles and tasks of all the different stakeholders are well defined and there are no traces of duplication of activities. However, they suffer from a lack of specificity, which has allowed for discrepancies in implementation of the Regulation at the national level. As for **external coherence**, some issues have been identified **between the GPSD and the Regulation** mainly in terms of definitions provided, which are not always aligned. Moreover, the boundary between the two legislations is not always clear. Similarly, the **Regulation's coherence with sectoral directives** is questioned, as there are discrepancies and gaps in the definitions and terminology provided in the different legislative pieces. Although not hindering the implementation of the Regulation, these inconsistencies diminish the overall clarity of the framework for market surveillance, causing some uncertainties in its application.

EU added value

The analysis focused on assessing the EU added value as per the Regulation's **specific provisions**. Its EU added value mainly stems from provisions envisaging common **information systems for cooperation and coordination, favouring administrative cooperation, and enhancing collaboration between Customs and MSAs.** Conversely, the EU added value provided by provisions related to **collaboration between Member States, market surveillance organisation at national level** and **national programmes and reports** has not reached its full potential.

RÉSUMÉ (FR)

Le règlement (CE) N° 765/2008 (ci-après dénommé "le règlement") fixant les prescriptions relatives à l'accréditation et à la surveillance du marché pour la commercialisation des produits est devenu applicable depuis le 1er janvier 2010. Le règlement vise à *renforcer la protection des intérêts publics à travers la réduction du nombre de produits non conformes sur le marché intérieur de l'UE* et *à assurer l'égalité des conditions entre les opérateurs économiques, en fournissant un cadre pour la surveillance du marché et le contrôle des produits*.

L'évaluation

L'évaluation portait sur les dispositions de surveillance du marché du règlement. L'objectif était de comprendre dans quelle mesure le règlement a atteint ses objectifs en termes **d'efficacité, d'efficience, de pertinence, de cohérence et de la valeur ajoutée de l'UE**. En outre, les analyses de la mise en œuvre du règlement dans les États membres et du marché inclut dans son champ d'application ont été conduites.

Cette évaluation visait également à **identifier les actions** qui appuient le présent règlement dans le cadre de la Stratégie du marché unique.

Efficacité

En conclusion, il apparait que **le règlement n'est pas pleinement efficace.**

Bien qu'il **existe une pléthore de mécanismes et d'outils de coordination et de communication pour l'échange d'informations** au sein et entre les différents États membres et avec les pays tiers, **ceux-ci ne fonctionnent pas efficacement ou efficientement** (par exemple, les autorités de surveillance du marché restreignent rarement la commercialisation d'un produit suite à l'échange d'informations sur les mesures prises par d'autres autorités de surveillance et, dans le cadre de produits fabriqués en dehors du territoire national, les autorités de surveillance ont des difficultés à contacter l'opérateur économique même s'il est basé dans un autre État membre de l'UE. En outre, **les États membres ont mis en œuvre le règlement de différentes façons**, avec des variations substantielles en termes de structures organisationnelles, de niveau de ressources déployées (financières, humaines et techniques), de stratégies et d'approches de surveillance du marché, de pouvoirs d'inspection et de sanction, et de pénalités pour les produits non conformes. Enfin, bien que les pouvoirs des douanes soient perçus comme adéquats et que les procédures de contrôle des frontières soient claires et appropriées, **les contrôles des produits importés sont encore considérés comme insuffisants** à la lumière des importations croissantes en provenance de pays tiers - en particulier de la Chine - et des ventes en ligne.

Tous ces éléments ont eu un impact sur **l'uniformité et la rigueur des contrôles**. Par conséquent, ils ont également eu un impact sur l'efficacité de la mesure à atteindre de ses objectifs en termes de protection des intérêts publics et de conditions équitables pour les entreprises de l'UE.

L'efficacité du règlement dans la réalisation de ses objectifs est également mise en question par **l'augmentation du nombre de produits non conformes** inclus dans son champ d'application, comme en témoigne le nombre croissant des notifications sur RAPEX et des mesures restrictives prises par les autorités de surveillance du marché. Une raison importante pour la non-conformité des produits sur le marché intérieur semble concerner en particulier **un manque de connaissance des opérateurs économiques des exigences législatives applicables**.

Efficience

Le règlement introduit de nouveaux coûts pour les États membres et, de manière plus limitée, pour les opérateurs économiques. Les coûts pour les États membres sont liés aux obligations d'organisation, d'information, de surveillance et de coopération. Les coûts pour les opérateurs économiques sont liés aux obligations d'information définies à l'article 19 du règlement.

Le budget alloué aux autorités de surveillance du marché en termes nominaux varie considérablement d'un État membre à l'autre. Ces différences pourraient être liées au fait que les États membres ont des modèles organisationnels différents, qui nécessitent différents niveaux de ressources financières. Cependant, une autre explication pourrait être explorée attrayant aux différentes approches suivies par les autorités de surveillance du marché dans la déclaration des données concernant les ressources financières utilisées ainsi que les activités réalisées.

Le fait que les États membres soient libres de définir leurs propres approches à la surveillance du marché a créé une forte variation dans la manière dont les différents secteurs sont contrôlés et gérés. En outre, **la fragmentation des contrôles dans l'ensemble du marché intérieur peut entraver l'action opportune des autorités et générer des coûts supplémentaires pour les entreprises**.

En ce qui concerne les coûts pour les opérateurs économiques, **les coûts de l'information** sont perçus comme non significatifs, mais **des incohérences transfrontalières subsistent, et le mécanisme d'application actuel n'est pas en mesure de créer des conditions de concurrence équitables pour les entreprises** qui vendent des produits dans le marché intérieur. Ceci **pourrait réduire la volonté des entreprises de se conformer aux règles** et discriminer les entreprises qui respectent les règles contre celles qui ne le font pas.

L'analyse de la base de données RAPEX et des rapports nationaux a mis en évidence que **la non-conformité des produits a augmentée constamment** de 2006-2010 à 2010-2015. Une augmentation des notifications RAPEX et des mesures de surveillance peut également signifier que les autorités de surveillance sont devenues plus efficaces à détecter -et donc à corriger- les produits non conformes. Cependant, cela souligne aussi que le règlement n'est pas toujours capable d'accroître la volonté des entreprises de se conformer aux règles, discriminant ainsi les entreprises qui respectent les règles contre celles qui ne le font pas.

Le faible rapport coût-efficacité des dispositions de surveillance du marché est confirmé par le fait que ni les budgets annuels moyens alloués aux activités des autorités de surveillance du marché ni leurs variations par rapport à la période 2011-2013 ne sont corrélées avec la dimension du marché (c'est-à-dire le nombre d'entreprises actives dans les secteurs harmonisés).

Pertinence

Globalement, **le règlement est pertinent**, même si l'étude a identifié des problèmes susceptibles de remettre cette conclusion en question. Par exemple, **le champ d'application du règlement n'est pas entièrement clair**. Cette limitation pourrait être exacerbée par les développements technologiques qui introduisent de nouvelles typologies de produits. En ce qui concerne **les définitions** du règlement, même si elles sont généralement claires et appropriées, elles ne sont pas entièrement complètes et mises à jour, surtout lorsque l'on envisage de cibler les ventes en ligne. Le concept de *lex specialis* représente une interface adaptée à la surveillance du marché dans des secteurs spécifiques. Certaines questions ont néanmoins émergé en ce qui concerne le manque de clarté dans le champ d'application des dispositions de surveillance du marché dans les législations sectorielles.

En ce qui concerne la pertinence du règlement pour les besoins des parties prenantes, l'analyse a conclu que **le règlement est pertinent dans une certaine mesure**, car il est globalement pertinent lorsque l'on considère les besoins actuels associés à ses objectifs généraux et spécifiques. Toutefois, il devient moins pertinent si on examine les besoins liés aux dynamiques nouvelles/émergentes, en particulier en ce qui concerne l'augmentation du commerce en ligne et des contraintes budgétaires au niveau national.

Cohérence

L'évaluation a conclu que **les dispositions de surveillance du marché du règlement sont cohérentes en elles-mêmes**. Les rôles et les tâches de tous les acteurs concernés sont bien définis et aucune duplication des activités n'a été identifiée. Cependant, ces dispositions souffrent d'un manque de spécificité, qui a permis les divergences citées dans la mise en œuvre du règlement au niveau national.

En ce qui concerne la **cohérence externe**, **certains problèmes ont été identifiés entre la DSGP et la réglementation**, principalement en termes de définitions, qui ne sont pas toujours alignées. En outre, la démarcation entre les deux législations n'est pas toujours claire. **La cohérence du règlement avec les directives sectorielles est mise en question** de manière similaire. En effet, des divergences et des lacunes dans les définitions et la terminologie dans les différents textes législatifs ont été observées. Bien qu'elles n'empêchent pas la mise en œuvre du règlement, ces incohérences diminuent la clarté générale du cadre de la surveillance du marché, ce qui entraîne des incertitudes quant à son application.

Valeur ajoutée de l'UE

L'analyse a porté sur l'évaluation de la valeur ajoutée de l'UE conformément aux dispositions spécifiques du règlement. La valeur ajoutée du règlement résulte principalement des dispositions prévoyant **des systèmes d'information communs pour la coopération et la coordination, favorisant la coopération administrative et renforçant la collaboration entre les autorités douanières et de surveillance du marché**. En revanche, la valeur ajoutée de l'UE apportée par les dispositions relatives à la collaboration entre les États membres, à

l'organisation de la surveillance du marché au niveau national et aux programmes et rapports nationaux n'a pas atteint son plein potentiel.

List of abbreviations

AdCO	Administrative Cooperation Group
CBA	Cost-benefit analysis
CLP	Classification, labelling and packaging
DG	Directorate-General
DG GROW	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DG JUST	Directorate-General for Justice and Consumers
DG TAXUD	Directorate-General for Taxation and Customs Union
EC	European Commission
EEA	European Economic Area
EMC	Electro-magnetic compatibility
EU	European Union
FTE(s)	Full-time equivalent(s)
GPSD	General Product Safety Directive
IA	Impact assessment
ICSMS	Information and Communication System on Market Surveillance
IDB	Injuries database
IMP-MSG	Internal Market for Products – Market Surveillance Group
LVD	Low Voltage Directive
MS	Member State(s)
MSA(s)	Market surveillance authority(ies)
NACE	Nomenclature Générale des Activités Économiques dans les Communautés Européennes
PA	Public authority
PPE	Personal protective equipment
PROSAFE	Product Safety Forum of Europe

RAPEX	EU Rapid Alert System for dangerous non-food products
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RED	Radio Equipment Directive
R&TTE	Radio and telecommunication terminal equipment
RoHS	Restriction of hazardous substances
SBS	Structural business statistics
SME(s)	Small- and Medium-sized Enterprise(s)
ToR	Terms of reference
WEEE	Waste electrical and electronic equipment

List of countries

AT	Austria
BE	Belgium
BG	Bulgaria
CY	Cyprus
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
EL	Greece
ES	Spain
FI	Finland
FR	France
HR	Croatia
HU	Hungary
IE	Ireland
IT	Italy
LT	Lithuania

LU	Luxembourg
LV	Latvia
MT	Malta
NL	Netherlands
PL	Poland
PT	Portugal
RO	Romania
SE	Sweden
SI	Slovenia
SK	Slovakia
UK	United Kingdom

1. INTRODUCTION

This report responds to the request for services concerning an *ex-post* evaluation of the application of the market surveillance provisions of Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93. The request for services was issued by the European Commission (EC), Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) unit B1.

The study was led by EY with the support of Technopolis Group and Nomisma. The evaluation took place from July 2016 until May 2017.

1.1 Scope of the evaluation

The subject of this evaluation is **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.

The scope of the study is defined as follows:

- **Legislation:** Regulation (EC) No 765/2008, with specific reference to some selected articles:
  - Chapter I, Article 2 (1) to (7), (14), (15), (17), (18), (19) and (21), on definitions;
  - Chapter III (i.e. Articles 15 to 29) on the EU market surveillance framework and controls on products entering the EU market;
  - Chapter V (i.e. Articles 31 to 37) as regards the Union's financing of market surveillance activities;
  - Articles 38 and 41 of Chapter VI, respectively, provide for the possible adoption by the Commission of non-binding guidelines in consultation with stakeholders, and obliges Member States to lay down rules on penalties for economic operators applicable to infringements of the provisions of the Regulation and to take all measures necessary to ensure that they are implemented;
- **Time frame:** the period from 2010 (date of application of the Regulation) to 2015, compared to the situation before 2010;
- **Territory:** the 28 EU Member States;
- **Stakeholders:** national authorities responsible for market surveillance of non-food products falling within the scope of Regulation (EC) No 765/2008, external border controls authorities, businesses and selected representatives from organisations of stakeholder categories (e.g. industry and SMEs, consumers and user associations).

1.2 Purpose of the evaluation

The overall objectives of the study are to:

- Evaluate to what extent the Regulation has achieved its original objectives in terms of **effectiveness, efficiency, relevance, coherence and EU added value**;

- Analyse the **legal and practical implementation of the Regulation** in EU Member States in order to identify particular issues and problems;

- Provide a **better understanding of the market of mass consumer products and selected categories of professional goods in the EU**, identifying the main trends in international trade and evaluating the relevant environmental, social and economic impacts deriving from implementation of the Regulation.

Bearing in mind that Regulation (EC) No 765/2008 sets out the legal framework for removing non-compliant products from the market in the area of EU harmonisation legislation, its evaluation will contribute to the **identification of the relevant set of actions supporting this Regulation within the framework of the Single Market Strategy**.

1.3 Structure of this report

This final report provides the full results of the analyses.

In more detail, **Chapter 1** presents a summary of the scope and objectives of the evaluation.

Chapter 2 presents the background of the Regulation, including the legislative framework and the main provisions of the Regulation. It also includes the intervention logic framework used as a basis for the evaluation process.

Chapter 3 presents the evaluation questions, framed within the five evaluation criteria, which were answered to assess the Regulation and how the criteria are to be understood.

Chapter 4 presents the evaluation methodology used in the study, comprising desk research, field research (section 4.2.2) and case studies. Furthermore, it details difficulties encountered during the data-collection phase due to the lack of information and data limitations, together with the mitigation measures adopted.

Chapter 5 is mainly descriptive and presents the implementation state of play, particularly the market analysis, the dimension of product non-compliance and implementation of the Regulation at the national level.

Chapter 6 provides detailed answers to the evaluation questions, according to each evaluation criteria, and on the basis of the evidence gathered.

Chapter 7 includes conclusions on the effectiveness, efficiency, relevance, coherence, and EU added value of the Regulation.

Finally, the **Annexes** include the results of the stakeholder consultation, five case studies, an overview of the penalties imposed by Member States for infringements relating to Regulation (EC) No 765/2008, tables presenting data on laboratories and powers available to national MSAs and Customs across Member States, the mapping of national reports and programmes), evaluation grids, the questionnaires of the targeted surveys and interviews, some specific data on the market, and the list of information sources.

2. BACKGROUND OF THE INITIATIVE

2.1 Legislative background

The mid-1980s marked the beginning of a period of profound legislative revision relating to the marketing of products in the EU, with the adoption of the so-called **'New Approach'**. The aim was to focus EU legislation only on the essential public interests requirements with which products must comply, leaving the definition of detailed technical requirements with standards. The New Approach contributed to the establishment of the European standardisation process[6] and the creation of EU harmonisation legislation.[7]

With **Regulation (EEC) No 339/93**, the EU institutions focused, for the first time, on a **market surveillance framework** and on common procedures for controlling products coming from non-EU countries to assure their conformity with the safety rules applicable in the internal market.

As the next step along the harmonisation path, in 2001, the EU legislator enhanced the level of consumer safety by adopting Directive 2001/95/EC – the so-called **General Product Safety Directive (GPSD)**. Considering the principle of *lex specialis*, the general safety requirement of the GPSD did not apply to medical devices or cosmetics and other product categories which fall under **specific EU harmonisation legislation**. Nevertheless, in most cases, some of its market surveillance provisions applied to consumer products falling under these rules at least until the alignment of those provisions to the reference provisions of Decision 768/2008/EC (see below). However, those market surveillance provisions did not apply to non-consumer products or to consumer products subject to requirements not related to safety.

In 2002, the EC initiated a public consultation to identify the main weaknesses of the 'New Approach Directives'. The results suggested the need for a reform process focusing on the lack of confidence in the notified institutions and throughout the whole notification process, weaknesses in market surveillance and the need for more enforcement measures, inconsistencies between different directives, and a misunderstanding of the value and role of CE marking. During subsequent years, a vibrant dialogue among EU institutions, EU Member State experts and relevant stakeholders has led to the review of the New Approach initiatives[8] and to the adoption of the **New Legislative Framework (NLF)** in 2008. The latter strengthened rules for product marketing, the free movement of goods, the EU market surveillance system and European conformity marking for the free marketability of products in the European Economic Area (EEA) (internal market).

As a result, following an impact assessment, the EU institutions adopted **Regulation (EC) No 765/2008** setting out the requirements for accreditation and market surveillance relating to the

6 The European standardisation system has played an important role for Member States as regards the free movement of goods. In addition, due to the "New Approach", a vast amount of industrial products legislation has been harmonised within the EU by means of only 30 Directives over the period 1987-2000.

7 At the beginning of the 1990s, in conjunction with the adoption of the Treaty of Maastricht on the European Union and the creation of the Economic and Monetary Union, the EU institutions' harmonisation function in the domain of the EU Single Market has been strengthened. On the one hand, the EU developed a policy to reinforce European standardisation, covering any technical requirements for product specification while, at the same time, giving more flexibility to manufacturers to conform to the requirements and to demonstrate product compliance with the relevant legislation. The European standardisation process has been consolidated by a number of legislative documents, including Council Directive 93/68/EEC that amended specific sector-harmonised legislations, introducing the CE marking. On the other hand, with the EU Customs Code, the EU supported Customs Authorities and traders in ensuring the correct application of custom legislation and the right of traders to be treated fairly.

8 SEC(2007) 173/2 Commission Staff Working Document accompanying document to the proposal for a Regulation of the European Parliament and the Council setting out requirements for accreditation and market surveillance relating to the marketing of products and a decision of the European Parliament and the Council on a common framework for the marketing of products. Impact Assessment.

marketing of products and repealing Regulation (EEC) No 339/93. With specific regard to market surveillance, such legislation:

- Sets obligations for EU countries to carry out market surveillance and to prohibit or restrict the marketing of dangerous or non-compliant products, providing a high level of protection of public interests;
- Lays down minimum common requirements for the organisation of market surveillance authorities (MSAs) at the national level;
- Provides MSAs with the powers to obtain all necessary documentation from economic operators in order to evaluate product conformity and act accordingly;
- Includes obligations for EU countries to ensure cooperation at national and cross-border levels and provides for specific tools to coordinate activities carried out by national surveillance bodies across the EU;
- Sets obligations to perform border controls of products entering the EU and lays down a procedure for the cooperation between market surveillance and Customs authorities.

Moreover, it lays down rules on:

- The concepts applicable in the field of product marketing;
- The organisation and operation of accreditation of conformity-assessment bodies;
- The general principles of the CE marking.

The scope of Regulation (EC) No 765/2008 was to establish an overarching framework on market surveillance, putting in place an overall policy and infrastructure across the Union without having to detail legislative provisions sector by sector. Furthermore, it aimed to address a certain lack of coherence in the implementation and enforcement of technical legislation regarding the free circulation of products within the EU.[9]

Together with the Regulation and within the NLF, the EU legislators also adopted **Decision No 768/2008/EC**[10] on a common framework for marketing products in the EU, and **Regulation (EC) No 764/2008** laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another EU country. Decision No 768/2008/EC includes reference provisions to be incorporated whenever product legislation is revised, working as a 'template' for future product harmonisation legislation. The reference provisions also cover relevant market surveillance procedures which are considered as complementary to the provisions of Regulation (EC) No 765/2008. However, they are not directly applicable and thus need to be incorporated into sector-specific harmonisation rules. Therefore, in recent years, a main objective of the Commission has been to bring product harmonisation legislation in line with the reference provisions of Decision No 768/2008/EC. At the time of writing, the following Directives and Regulations had been aligned with these reference provisions:

9 As for the GPSD and according to the principle of *lex specialis*, this Regulation applies only insofar as there are no other specific provisions with the same objective, nature or effect in other existing or future rules of EU harmonisation legislation.

10 Decision No 768/2008 sets out the common principles and procedures that the EU legislation must follow when harmonising conditions for marketing products in the European Economic Area (EEA.) The EC Decision focuses on rules for CE marking and on a common set of different conformity assessment procedures, the so-called 'modules', related to assessing different risks.

- Toy Safety – Directive 2009/48/EU;
- Transportable pressure equipment – Directive 2010/35/EU;
- Restriction of Hazardous Substances in Electrical and Electronic Equipment – Directive 2011/65/EU;
- Construction products – Regulation (EU) No 305/2011;
- Pyrotechnic Articles – Directive 2013/29/EU;
- Recreational craft and personal watercraft – Directive 2013/53/EU;
- Civil Explosives – Directive 2014/28/EU;
- Simple Pressure Vessels – Directive 2014/29/EU;
- Electromagnetic Compatibility – Directive 2014/30/EU;
- Non-automatic Weighing Instruments – Directive 2014/31/EU;
- Measuring Instruments – Directive 2014/32/EU;
- Lifts – Directive 2014/33/EU;
- ATEX – Directive 2014/34/EU;
- Radio equipment – Directive 2014/53/EU;
- Low Voltage – Directive 2014/35/EU;
- Pressure equipment – Directive 2014/68/EU;
- Marine Equipment – Directive 2014/90/EU;
- Cableway installations – Regulation (EU) 2016/424;
- Personal protective equipment – Regulation (EU) 2016/425;
- Gas appliances – Regulation (EU) 2016/426

Further proposals on medical devices and *in vitro* diagnostic (IVD) medical devices were very recently adopted.

In 2013, to further strengthen consumer safety and market surveillance rules, the EC adopted the so-called **Product Safety and Market Surveillance Package**.[11]

Currently, at the EU level, the basic market surveillance infrastructures comprises: (i) the **RAPEX system,**[12] through which Member States notify the Commission and other Member States about

11 The legislative procedure for the adoption of the Regulations proposed in the package is still pending.

measures taken against products posing serious risks (the Commission then disseminates the information to other Member States); (ii) the general information support system intended to collect other information about market surveillance activities performed by Member States, the so-called **ICSMS** (Information and Communication System for Market Surveillance);[13] (iii) the exchange of information on **market surveillance programmes and** (*ex-post*) **on activities carried out**; (iv) policy discussions on the implementation of product legislation through experts groups – e.g. administrative cooperation groups (**AdCOs**),[14] Internal Market for Products – Market Surveillance Group (IMP-MSG); and (iv) **joint enforcement actions** co-financed by the EU budget via grants.

2.2 Main provisions of the Regulation

Given the scope of this study presented in section 1.1, the current evaluation assesses several articles included in Chapter I, Chapter III, Chapter V and Chapter VI, specifically relating to market surveillance and detailed below.

Chapter I – General provisions

This chapter specifies the **scope** of the Regulation and the main **definitions** relevant for market surveillance.

Chapter III – EU market surveillance framework and controls of products entering the EU market

Chapter III covers the **functioning of market surveillance of products subject to EU harmonisation legislation.** It defines the products covered by the market surveillance infrastructures and programmes, as well as the roles and responsibilities of the EC, Member States, national MSAs and other relevant actors.

In particular, *Section 1* defines the **scope of application** of the provisions on market surveillance and control of imported products. It also sets out the **general obligation to carry out market surveillance and take restrictive measures** for products found to be dangerous or non-compliant in relation to any product categories subject to EU harmonisation law, and to inform the EC and other Member States.

Section 2 EU market surveillance framework sets out the obligations of the EU MS regarding the **organisation** of national authorities and **measures** to be adopted in case of products presenting a serious risk. The section provides an overview of the duties of national MSAs and their **cooperation with competent authorities** in other EU MS or in third countries. The Regulation also states the **principles of cooperation and exchange of information** between all relevant actors in the field of market surveillance.

Section 3 Controls of products entering the EU market entrusts **powers and resources to authorities in charge of external border control** of products entering the EU market and defines the situations whereby such authorities shall not release a product for free circulation or, in case of

12 RAPEX (Rapid Exchange of Information System) is an information system between MS and the EC on measures and actions taken in relation to products posing serious risk to the health and safety of consumers: http:/ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm. RAPEX was actually established by the GSPD and subsequently extended to the Regulation onto all harmonised products.

13 ICSMS is an information and communication system for the pan-European market surveillance. A general information support system set up by the European Commission for the exchange of information between MSAs, according to Article 23 of Regulation (EC) No 765/2008. Source: European Commission (2017), *Good Practice for Market Surveillance*.

14 European cooperation on market surveillance takes place through informal groups of MSAs, called Administrative Cooperation Groups (AdCOs). The members of these groups are appointed by MS and represent national authorities competent for market surveillance in a given sector.

suspension, shall release the product. Moreover, this section defines the measures to be taken by MSAs if a **product presents a serious risk or does not comply with EU harmonisation legislation.**

Chapter V – EU financing

This chapter includes provisions on the **financing system** for obtaining the results expected by the Regulation. More specifically, it lists the activities eligible for financing and arrangements on financial procedures. The Regulation also foresees the possibility of covering administrative expenses for all management and monitoring activities necessary to achieve its objectives.

Chapter VI – Final provisions

The last two provisions evaluated are **Article 38**, which refers to the possibility of the EC's adoption of **non-binding guidelines on Regulation implementation**, and **Article 41,** which obliges the EU MS to lay down **rules on penalties for economic operators** for infringing the provisions of this Regulation.

2.3 Intervention logic framework

The intervention logic of the market surveillance provisions of Regulation (EC) No 765/2008 is crucial for clarifying the objectives and enhancing the understanding of the evaluation process. As explained in the Better Regulation Toolbox #41: 'Designing the evaluation', reconstruction of the intervention logic allows the evaluator to understand how the Regulation was expected to work, and identify the causal links among the different dimensions as well as the contextual elements that affect the current framework. The intervention logic framework is thus summarised below on the basis of the market surveillance provisions in the scope of this evaluation.

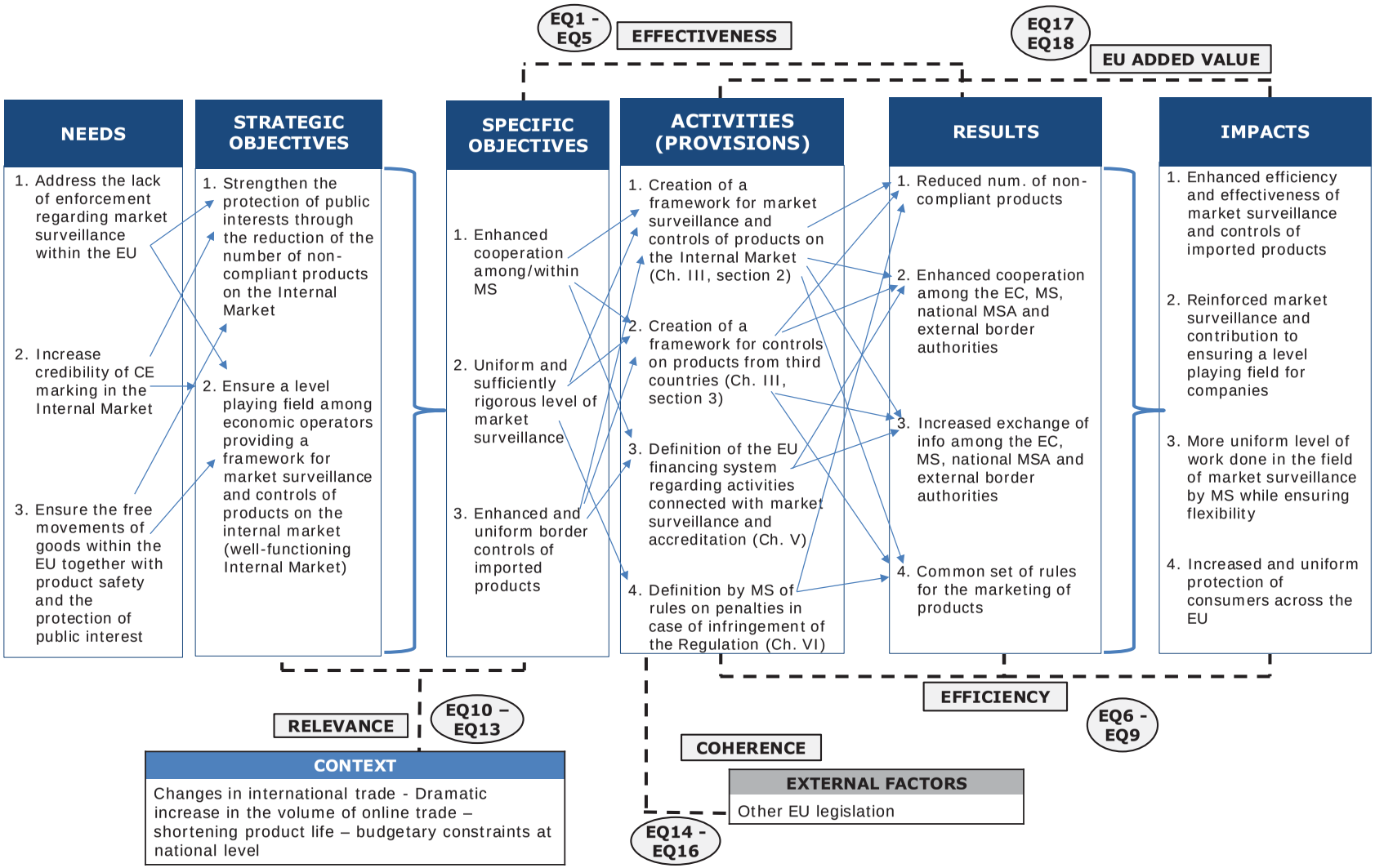
Three main **needs** or drivers led to the definition of the Regulation's strategic objectives: (1) *to address the lack of market surveillance enforcement within the EU*; (2) *to increase the credibility of CE marking in the internal market*; and (3) *to ensure the free movement of goods within the EU together with product safety and the protection of public interest*. The two **strategic objectives** of the Regulation – aiming to respond to the above-mentioned needs - are: (1) *to ensure a level playing field among economic operators through the elimination of unfair competition of non-compliant products;* and (2) *to strengthen the protection of public interests through the reduction of the number of non-compliant products*. The strategic objectives are then disaggregated into three **specific objectives** representing the operational orientations of the EU action. To achieve the strategic and specific objectives, the EC has defined **a set of activities** to be implemented, and included them in the Regulation in the form of **provisions**. For instance, to reduce the number of non-compliant products, the Regulation sets the framework for controls of products on the internal market (Ch. III, section 2) and of those imported from third countries (Ch. III, section 3). These provisions are expected to produce a number of key **results** and to eventually trigger the Regulation's **impacts**. For instance, the resulting lower number of non-compliant products will generate greater and more uniform protection of consumers across the EU.

The intervention logic below also presents the **evaluation questions** (and related criteria) contributing to assessing the overall performance of the Regulation, having identified its working mechanisms. As shown in the figure below, the evaluation questions related to **relevance** assess whether the Regulation's objectives are still adequate in the current **context**. The **effectiveness** questions are based on measurements of the Regulation's results to determine whether it has achieved its objectives. The **efficiency** questions assess whether the Regulation has proportionally

delivered its results, given the established provisions. To better understand how the interaction between the above elements works and delivers the expected changes over time, the intervention logic must consider **external factors** that may influence the Regulation's performance: the **coherence** questions evaluate whether the Regulation is consistent with those factors. The **EU added value** questions aim at understanding if the provisions set out have served to obtain the expected impacts.

The figure below outlines the Regulation's intervention logic in relation to the evaluation criteria and questions that guided the study and that will be further described in the following chapter. The arrows represent the links/trigger mechanisms between needs and objectives, and objectives, provisions and results.

Figure 4-1 - Intervention logic of the Regulation



Source: EY

3. EVALUATION QUESTIONS

The box below presents 18 evaluation questions, framed within the five evaluation criteria that had been answered to assess the Regulation.

The evaluation criteria were understood to mean:

- **Effectiveness**: whether and to what extent the Regulation's objectives in terms of ensuring a level playing field among economic operators by eliminating unfair competition of non-compliant products and strengthening the protection of public interests have been achieved at both national and EU levels (EQs 1-5).

- **Efficiency**: whether the Regulation has proportionally delivered its results in terms of resources used. The analysis included an assessment of the costs and benefits as perceived and reported by stakeholders. (EQs 6-9).

- **Relevance**: whether the Regulation's objectives still correspond to current problems, needs and challenges, arising in particular from online sales, increase in imports from third countries, shortening product life, increasing budgetary constraints at the national level (EQs 10-13).

- **Coherence**: whether the Regulation is consistent within itself, with other market-relevant pieces of EU legislation on non-food products surveillance and within the wider EU policy framework (EQs 14-16).

- **Added value**: to what extent the results of the EU action are additional to the value that would have resulted from action at Member State level (EQs 17 and 18).

Effectiveness

EQ1. Are the results in line with what is foreseen in the impact assessment for the Regulation, notably as to the specific objectives of: (i) enhanced cooperation among Member States/within Member States, (ii) uniform and sufficiently rigorous level of market surveillance; and (iii) border controls of imported products?

EQ2. How effective was the measure as a mechanism and means to achieve a high level of protection of public interests, such as health and safety in general, health and safety at workplace, the protection of consumers, protection of the environment and security? What have been the quantitative and qualitative effects of the measure on its objectives?

EQ3. How effective was the measure as a mechanism and means to achieve a level playing field among businesses trading in goods subject to EU harmonisation legislation? What have been the quantitative and qualitative effects of the measure on its objectives?

EQ4. Are there specific forms of the implementation of the Regulation at Member State level that render certain aspects of the Regulation more or less effective than others , and – if there are – what lessons can be drawn from this?

EQ5. To what extent has the different implementation (i.e. discrepancies in the implementation) of the initiative in Member States impacted on the effectiveness of the measures on the objective?

Efficiency

EQ6. What are the regulatory (including administrative) costs for the different stakeholders (businesses, consumers/users, national authorities, Commission)?

EQ7. What are the main benefits for stakeholders and civil society that derive from the Regulation?

EQ8. To what extent have the market surveillance provisions been cost effective?

EQ9. Are there any significant differences in costs (or benefits) between Member States? If so, what is causing them?

Relevance

EQ10. To what extent are market surveillance provisions of the Regulation still relevant in the light for instance of increasing online trade, the increase in imports from third countries, shortening product life, increasing budgetary constraints at national level, etc.?

EQ11. To what extent do the effects of the market surveillance provisions satisfy (or not) stakeholders' needs? How much does the degree of satisfaction differ according to the different stakeholder groups?

EQ12. Is there an issue on the scope (i.e. all EU product harmonisation legislation) of the measure or some of its provisions?

EQ13. Is the concept of lex specialis *still a suitable interface between the market surveillance provisions in the Regulation and those in other (notably sector) legislation?*

Coherence

EQ14. To what extent are the market surveillance provisions coherent internally?

EQ15. To what extent are the market surveillance provisions above still coherent with other Union legislation on market surveillance of non-food products?

EQ16. To what extent are these provisions coherent with wider EU policy?

EU added value

EQ17. What is the additional value resulting from the market surveillance provisions at EU level, compared to what could be achieved by Member States at national and/or regional levels?

EQ18. To what extent do these provisions support and usefully supplement market surveillance policies pursued by the Member States? Do the provisions allow some sort of 'control' by the EU on the way national authorities carry out market surveillance?

4. METHODOLOGY

This chapter summarises the tools and techniques used in the study to answer the evaluation questions. The final section describes data limitations and the solutions applied to the problems encountered.

4.1 Evaluation grids

The approach to answering the evaluation questions has been defined in specific evaluation grids presenting:

- The **judgment criteria** used to specify the meaning of the evaluation question;
- The **analytical approach** used to answer the evaluation question, given the judgement criteria;
- The **indicators** used to evaluate the achieved results as well as to identify potential shortcomings;
- The **sources of information**, including primary sources (i.e. stakeholders) and secondary sources, i.e. existing documents, publications, reports.

All evaluation grids are presented in Annex.

4.2 Overview on data collection and analysis tools

This section provides a synthesis of the main data collection and analytical tools used in the study: desk research, field research and case studies.

4.2.1 Desk research

4.2.1.1 Implementation

The desk research focused on an in-depth review of the national market surveillance programmes and reports drafted by Member States pursuant to Article 18(6) of Regulation (EC) 765/2008.[15] However, with particular regard to data for assessing the implementation of the Regulation at the national level, the analysis of national reports and programmes presented a number of lacks. In order to fill-in these gaps and following a specific request from the Steering Group, a template for data collection was sent to IMP-MSG representatives and Customs, requiring them to provide information on powers of sanction and control and availability of test laboratories across different sectors. The template was based on the same list of sectors published on the Commission's website on November 2016 for the preparation of national market surveillance programmes,[16] and the list of sectors presented therein has also been used for the market analysis. **The list should be considered as a non-exhaustive reference list of sectors falling within the scope of Regulation (EC) No 765/2008.** The template, presented in the table below, is an updated version of that presented in Annex.

15 Article 18(6) states that "*Member States shall periodically review and assess the functioning of their surveillance activities. Such reviews and assessments shall be carried out at least every fourth year and the results thereof shall be communicated to the other Member States and the Commission and be made available to the public, by way of electronic communication and, where appropriate, by other means*."

16 Available at: http://ec.europa.eu/DocsRoom/documents/20141

Table 4-1 – Non-exhaustive list of sectors in scope of the Regulation used for data collection

N.	*Product sectors*	*Relevant legislation*
1	Medical devices (including in vitro diagnostic 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 emissions 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

N.	*Product sectors*	*Relevant legislation*
22/B	Other chemicals (Detergents, Paints, Persistent Organic Pollutants, Fluorinated greenhouse gases, Ozone Depleting Substances, etc.)	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
23	Eco-design and Energy Labelling; Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	Directives 2009/125/EC and 2010/30/EU; Directive 1992/42/EEC
24	Tyre labelling	Regulation (EC) 1222/2009
25	Recreational craft	Directive 1994/25/EC - Directive 2013/53/EU
26	Marine equipment	Directive 96/98/EC -Directive 2014/90/EU
27	Motor vehicles and Tractors	Directive 2002/24/EC - Regulation (EU) 168/2013; Directive 2007/46/EC; Directive 2003/37/EC - Regulation (EU) 167/2013
28	Non-road mobile machinery	Directive 97/68/EC
29	Fertilisers	Regulation (EC) 2003/2003
30	Other consumer products under GPSD	Directive 2001/95/EC
31	Biocides	Regulation (EU) 528/2012
32	Textile and Footwear labelling	Regulation (EC) 1007/2011 and Directive 94/11/EC
33	Crystal glass	Directive 69/493/EEC

Source: EC (2016)

The desk research also covered the sectoral impact assessments drafted by the European Commission[17] for the relevant product categories covered by the Regulation, together with other policy documents relevant for market surveillance, such as the impact assessment (IA) for the Regulation and the IA for the product safety and market surveillance package. Moreover, a number of reports and studies on market surveillance issues have also been considered, such as EC (2017),[18] EP (2009),[19] Panteia (2014)[20] and PROSAFE (2013).[21] For more details on the information sources see Annex.

17 Decision No 768/2008/EC sets out the common principles and procedures that the EU legislation must follow when harmonising conditions for marketing products in the EEA. At the time of writing, 20 directives and regulations have been aligned with these reference provisions. The IAs drafted for the respective legislative proposals have been considered in light of the data they report on the state of the art of or possible issues with the implementation of market surveillance in the relevant sectors.

18 Task Force of AdCOs' experts (2017), Good Practice for Market Surveillance.

19 European Parliament (2009), Effectiveness of Market Surveillance in the Member States. Directorate A: Economic and Scientific Policies. IPOL/A/IMCO/ST/2009-04.

20 Panteia and Centre for Strategy and Evaluation Services (CESS) (2014), Good Practice in Market Surveillance Activities related to Non-Food Consumer Products sold Online.

21 PROSAFE (2013). Best Practices Techniques in Market Surveillance. http://www.prosafe.org/library/knowledgebase/item/best-practices-techniques-in-market-surveillancehttp://www.prosafe.org/library/knowledgebase/item/best-practices-techniques-in-market-surveillance

4.2.1.2 Market analysis

The market analysis set out to provide an understanding of the market for which EU harmonised product rules exist and to assess the main trends in the intra-EU trade of harmonised products. To identify the variables to be included in the analysis, we considered the sectors listed in the EC template for national programmes in the version published on November 2016, and we tried to identify statistics useful for the scope of the study (see Table 4-1).

We implemented a **two-stage approach**:

- An analysis at the sectoral level oriented towards the macro dimension, looking at:
  - The number of economic operators active within the economic sectors for which EU harmonised product rules exist (hereafter harmonised sectors);
  - The harmonised sector's current contribution to the EU economy;
- An analysis at the product level focused on the value of products traded within the EU internal market and for which EU harmonised rules exist (hereafter harmonised products).

All data were extracted from three databases:

- Structural Business Statistics (SBS)[22] provided by Eurostat to describe the structure of harmonised sectors and measure their economic performance;
- PRODCOM - Statistics by Product[23] provided by Eurostat to estimate the value of harmonised products;
- International trade database, containing data since 1988 by Standard International Trade Classification (SITC),[24] provided by Eurostat to estimate the value of intra-EU trade of harmonised products.[25]

Results from these analyses have been combined to identify those sectors where trade value in harmonised products is more relevant.

In detail, the approach comprised the following steps:

- **Step 1**. Identification of EU legislative acts introducing harmonised product rules (i.e. harmonising legislation);
- **Step 2**. Review of EU legislation introducing harmonised product rules;
- **Step 3**. Identification of the corresponding NACE Divisions (DIGIT 2) and NACE group (DIGIT 3) impacted by the EU Regulation (i.e. harmonised sectors);

22 http://ec.europa.eu/eurostat/web/structural-business-statistics
23 http://ec.europa.eu/eurostat/web/prodcom/overview
24 http://ec.europa.eu/eurostat/web/international-trade-in-goods/data/database
25 Correspondence between SITC and NACE classification has been done in accordance to the Reference and management of Nomenclatures (RAMON).

- **Step 4**. Selection of the most appropriate products (NACE group – DIGIT 4) for which harmonised product rules exist and that should be included in the analysis.

All the above steps were needed to overcome the following issues:

- Definitions of sectors/products in the Regulation are usually different from nomenclatures used within statistics;
- Statistics at the sectoral/product level use different nomenclatures (e.g. intra-EU trade uses the SITC, production values use the PRODuction COMmunautaire (PRODCOM) nomenclature, business demographics uses the Statistical Classification of Economic Activities in the European Community - NACE);
- Difficulties in identifying harmonised sectors in cases where EU legislation introduced harmonised rules that only apply to some products within sectors.

For the **sectoral-level** analysis, data were extracted from the Eurostat structural business statistics (SBS) database[26] based on NACE Rev.2 classifications. In particular, we considered:

- Business demographic variables (i.e. number of enterprises);
- Input-related variables: labour input (e.g. number of people employed);
- Output-related variables (i.e. turnover, value added).

Results of this analysis refer to the **indicators** detailed in the table below.

Table 2 - Indicators for the sector-level analysis

Dimension	*Indicator*	*Definition*
Business demography	Number of enterprises	Number of active enterprises
Input	Number of people employed	Number of people aged 15 and over (or 16 and over in IE) who worked – even if just for one hour per week – for pay, profit or family gain.
Output	Value added at factor cost	The value added at factor cost is the gross income from operating activities after adjusting for operating subsidies and indirect taxes. The value added at factor cost is calculated 'gross' as value adjustments (such as depreciation) are not subtracted.[27]
	Turnover	'Turnover' comprises the totals invoiced and corresponds to market sales of goods supplied to third parties.[28]

26 We used the annual enterprise statistics for special aggregates of activities (NACE Rev. 2) (sbs_na_sca_r2) and the annual enterprise statistics by size class for special aggregates of activities (NACE Rev. 2) (sbs_sc_sca_r2), available at: http://ec.europa.eu/eurostat/web/structural-business-statistics/data/database

27 http://ec.europa.eu/eurostat/ramon/nomenclatures/index.cfm?TargetUrl=DSP_GLOSSARY_NOM_DTL_VIEW&StrNom=CODED2StrNom=CODED2&StrLanguageCode=EN&IntKey=16619885&RdoSearch=BEGIN&TxtSearch=value%20added%20at%20factor20factor%20cost&CboTheme=&IsTer=&IntCurrentPage=1&ter_valid=0

28 It includes all duties and taxes on the goods or services invoiced by the unit except the VAT invoiced by the unit vis-à-vis its customer and other similar deductible taxes directly linked to turnover. It also includes all other charges (transport, packaging, etc.)

The analysis at the **product level** aimed at understanding the market value of all traded products for which EU harmonised product rules exist.[29] The **indicators** considered in the analysis have also been extracted from Eurostat statistics currently available and are presented in the following table.

Table 3 - Indicators for the product-level analysis[30]

Indicator	*Definition*	*Coverage*	*Time frame*	*Source*
Value of sold production	This indicator provides the monetary value of sold products.	EU-28	2008-2015	PRODCOM – Statistics by product[31]
Value of extra EU imports	This indicator provides the monetary value of imported products from non-EU countries.	EU-28	2008-2015	
Value of extra EU exports	This indicator provides the monetary value of exported products to non-EU countries.	EU-28	2008-2015	
Value of intra-EU imports	This indicator provides the monetary value of imported products by all EU countries from other EU countries.	EU-28	2008-2015	EU trade since 1998 by SITC[32]

All EU-28 Member States have been considered and the period covered by data is 2008-2015.

While the sectoral-level analysis provided an estimate of the **number of economic operators potentially impacted by the Regulation's market surveillance provisions** and of how they are contributing the EU economy, the analysis at the product level gave **an assessment of the value of traded goods that should comply with the existing harmonised product rules**.

4.2.1.3 Cost-benefit analysis

To measure costs and benefits of the Regulation, the following elements have been analysed:

- Regulatory costs for the different stakeholders (MSAs and businesses);
- Main benefits for stakeholders and civil society deriving from the Regulation;
- Cost effectiveness of market surveillance provisions;
- Proportionality of the Regulation and differences between Member States.

The existing data were used for:

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passed on to the customer, even if these charges are listed separately in the invoice. Reduction in prices, rebates and discounts as well as the value of returned packing must be deducted. Income classified as other operating income, financial income and extra-ordinary income in company accounts is excluded from turnover. Operating subsidies received from public authorities or the institutions of the European Union are also excluded.

29 Only intra- EU trade is considered for the analysis.

30 Source: http://appsso.eurostat.ec.europa.eu/nui/setupMetadata.do (document named Help for Indicators).

31 http://ec.europa.eu/eurostat/web/prodcom/data/excel-files-nace-rev.2

32 http://ec.europa.eu/eurostat/web/international-trade-in-goods/data/database

- Measuring the **inputs** (i.e. financial and human resources) used by MSAs in order to meet surveillance obligations deriving from the Regulation. MS should declare budget allocated to market surveillance and enforcement activities, including related infrastructures and projects and measures aimed at ensuring economic operators' compliance with product legislation. These measures should also include communication activities (consumer/business information and education), enforcement, staff remuneration, direct costs of inspections, laboratory tests, training, and office equipment costs. This means that data included in the national reports might be considered as the best source of information in order to estimate the regulatory costs for national authorities. In particular, the following dimensions have been identified as relevant for this purpose:

  - **Financial resources** available for market surveillance activities;

  - **Human resources available** for market surveillance activities.

- Assessing how authorities' market surveillance is meeting surveillance obligations (**results**). National reports were used to verify:

  - Number of inspections performed by year and by sector

  - Number of tests performed by year and by sector

- Evaluating the levels of compliance for harmonised products and the perceived effectiveness of the Regulation in ensuring a level playing field for businesses (**impacts**). Businesses and business associations took part in the targeted survey. In addition, 10 targeted interviews were conducted with these stakeholders to investigate:

  - Whether the Regulation introduced any type of cost on consumers/end-users (e.g. derived from Article 19 stating that the MSAs may require economic operators to make available documentation and information regarding the products, to present test reports, or certificates attesting conformity);

  - Whether introduced costs affect disproportionately a particular category of stakeholders;

  - Whether the measures taken by MSAs are proportionate to their objectives and effective in ensuring product compliance and a level playing field for businesses;

  - Whether any differences emerged across Member States in implementing the Regulation.

To measure the cost effectiveness of the Regulation, the analysis looked at the extent to which the desired effects (results and impacts) had been achieved at a reasonable cost.

Furthermore, proportionality of the Regulation and significant differences between Member States were also considered. In particular, the analysis assessed whether Member States incur costs to meet their surveillance obligations that are proportionate to the national markets of harmonised products (i.e. number of active enterprises active in the national markets).

4.2.2 Field research

The overall stakeholder consultation process for the evaluation of Regulation (EC) No 765/2008 began in June 2016 and continued until February 2017. It collected inputs from a wide range of stakeholders through different tools, namely:

- A public consultation[33] – involving 239 stakeholders;
- Five targeted consultations based on online surveys, involving 119 stakeholders and addressing:
  - Member State coordinating authorities in charge of implementing the Regulation;
  - MSAs in charge of enforcing the Regulation, including AdCO representatives;
  - Customs authorities;
  - Economic operators and industry associations;
  - Consumer and user associations.
- 39 interviews:[34]
  - 9 of general character to further investigate the most relevant issues emerging from the desk and field research;
  - 20 targeted interviews aimed at building the five case studies;
  - 10 for collecting additional data for the cost-benefit analysis (CBA).

The public consultation and the five targeted consultations were conducted prior to the interviews, as the latter were aimed at complementing and triangulating the information collected and clarifying any emerging issues.

As for the **geographical coverage** of the stakeholder consultation, all EU Member States, together with Iceland, Norway, Switzerland and Turkey, were involved.

In chapter 6, when analysing data retrieved from the field research, percentages are calculated based on the actual number of answers received for each question in the targeted surveys or public consultation, thereby excluding:

- Answers that did not provide any information, i.e. 'I do not know';
- The 'not applicable' answers, i.e. when the specific question was not asked to some respondents as it was outside of their area of competence (in the targeted surveys);
- The 'no answer received', i.e. when the respondent decided to skip the question (in the targeted surveys).

33 The EC launched a public consultation on the evaluation of the market surveillance provisions of Regulation (EC) No 765/2008 and on actions to enhance enforcement and compliance in the Single Market for goods. It ran from 28 June to 31 October 2016.

34 The initial number of interviews foreseen was 40, but one relevant interviewee declined to participate.

In practice, percentages often have different calculation bases, and the base is usually below 239 for the public consultation and less than 119 for the targeted surveys.

A detailed overview of the stakeholder consultation is presented in Annex.

4.2.3 Case studies

Five thematic case studies aimed to develop a deeper understanding of all the issues covered by the evaluation questions. Each case study required four interviews for in-depth investigation.

Notably, the case studies allowed for:

- Ensuring a higher level of detail which would not have been feasible with reference to all the EU Member States and all the non-food products. Case studies have been used to produce useful insights on specific topics that emerged during the evaluation, and have helped in gaining a better understanding of the overall situation in the EU and the results achieved by the Regulation in different areas and activities;

- Illustrating in practical terms the implications and impacts of specific issues and understanding the causal links between the intervention and the achievements/results/ impacts;

- Providing more detailed and better evidence for answers to the evaluation questions;

- Identifying best practices and approaches.

The five case studies are reported in Annexes 0 to 0.

4.3 Data limitations

This section discusses the problems encountered, particularly the issues concerning data limitations related to the desk and field research.

4.3.1 Data gaps in the desk research

4.3.1.1Data gaps in estimates of product non-compliance

To assess the Regulation's effectiveness in achieving its strategic objectives (i.e. protection of public interest and creation of a level playing field), an **estimation of the dimension of product non-compliance across the EU and at the national level** was necessary. However, significant data gaps and limitations made it difficult to provide a complete and reliable picture of the phenomenon. In order to attain at least a partial estimate of the issue, two solutions were implemented which **had to rely on a number of assumptions**.

First, although **RAPEX notifications** were used as a proxy for measuring product non-compliance they do not measure the precise extent of non-compliance, since each notification relates to many products. Moreover, only products presenting a serious risk are notified on RAPEX. Consequently, no products presenting formal non-compliance are included in these statistics, which further underestimates the real dimension of product non-compliance.

However, it is also true that the increase in the number of notifications may not only represent more products posing a safety risk, but also an increase in the effectiveness of MSAs in identifying these products, thereby increasing the level of consumers' and users' protection. Similarly, the rising number of RAPEX notifications may also be due to various external factors.

Some **data provided in national reports** can also be used as proxies for product non-compliance. The following indicators have been taken into account:

- Number of product-related accidents/user complaints;
- Number of corrective actions taken by economic operators;
- Number of inspections resulting in findings of non-compliance;
- Number of inspections resulting in restrictive measures taken by MSAs;
- Number of inspections resulting in the application of penalties.

Where possible, analysis of these data contributed to widening the overview, allowing for a possible comparison with information extracted from RAPEX. However, as explained below, there are a number of limitations and gaps on data retrieved from the national reports (e.g. they do not provide data for all EU Member States nor all sectors relevant to the Regulation; they only cover the period from 2010 to 2013; and the data provided are not always reliable and comparable). Therefore, to provide reliable information to the greatest extent possible, only the sectors where information on the above-mentioned indicators was reported by at least 15 Member States was considered. As a result, we have collected information **on nine out of 30 sectors**, although not all indicators are available for each sector.[35] Moreover, the group of Member States varies, depending on the indicator and sector considered.

4.3.1.2 Data gaps in the assessment of implementation

As far as the assessment of **implementation** is concerned, the main difficulties encountered while performing the desk research related to the differing levels of detail in the information provided by Member States. Since the countries encountered several **difficulties in reporting data on available resources** in terms of both budget and staff, information was only partially or not available at all for a large number of Member States for the following reasons:

- Data on resources were **only available for some MSAs or for some sectors** in 15 Member States;[36]
- Data on resources were presented as **estimates of the total budget** as information was not disaggregated for market surveillance activities alone (Spain) or the national market surveillance framework comprised numerous and very different authorities (UK), meaning that data were not aggregated;

35 Sectors excluded for which **less than 15 MS** report information on the relevant indicators: cosmetics, construction, aerosol, simple pressure vessels, transportable pressure equipment, lifts, cableways, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, explosives, appliances burning gaseous fuels, electrical equipment under EMC, electrical and electronic equipment under RoHS and WEEE and batteries, chemical, motor vehicles and tyres, recreational craft, marine equipment, non-road mobile machinery, fertilisers, other consumer products under GPSD.

36 BE, BG, CY, CZ, EE, EL, HU, IE, IT, LU, LV, MT, PT, RO and SK.

- Data on resources **were not available** due to the indirect federal administration, as there are numerous administrative units that perform market surveillance activities in Austria, for example;

- Data on resources **were not reported** by four Member States.[37]

Additional limitations related to the fact that some Member States[38] reported **financial data expressed in the national currency**, requiring conversion to euros. Similarly, other Member States,[39] while requested to provide information on available staff in terms of full-time equivalents (FTEs)),[40] reported **data in terms of staff numbers**. Consequently, **data on resources were incomplete.** Due to these limitations, the information provided should be interpreted carefully.

Finally, **the breakdown by product sector emerged as a critical factor.** The desk research was structured according to the reference list of 30 product sectors provided by the EC in its '*Template for drafting a national market surveillance programme pursuant to Article 18(5) of Regulation (EC) No 765/2008*'[41]. All Member States followed the classification suggested by the EC except Germany and Lithuania. Germany provided aggregated information on market surveillance activities performed during 2010-2013 and relating to the Product Safety Act. It transposed 12 European Directives included in the list of sectors covered by the Regulation.[42] The German national programme provides detailed information only for activities performed in sectors 18 and 19, while for other sectors data are aggregated. Lithuania did not adopt the EC template as it launched a study on national market surveillance in 2013 to assess how well its market surveillance system was functioning. However, this study did not include information on market surveillance controls and inspections performed on products covered by the Regulation.

4.3.1.3 Data gaps in national programmes

As far as national programmes are concerned, there is **a lack of harmonisation in the programme year of reference**. Most of the programmes analysed refer to 2015, but for some Member States, the programmes which referred to that year were not available. As a result, the national programmes referring to previous years (i.e. the Czech Republic's national programme refers to 2013[43]) and/or covering two or three years (i.e. Germany's programme covered 2014 to 2017, Ireland and Slovakia covered 2014 and 2015; Portugal's programme covered 2012 and 2013; while the Netherlands covered 2015 and 2016) were considered. Lithuania required the review of six sector-specific programmes as the general programme was not available, while the Romanian national programme covered 2016, since programmes for previous years were not available.

37 DE, HR, LT and SI.
38 For example, CZ, DK, and EE.
39 For example BG, EE, MT, RO, and SI.
40 A full-time equivalent is "*a unit to measure employed persons that makes them comparable although they may work or study a different number of hours per week. The unit is obtained by comparing an employee's average number of hours worked to the average number of hours of a full-time worker or student. A full-time person is therefore counted as one FTE, while a part-time worker gets a score in proportion to the hours he or she works*". http://ec.europa.eu/eurostateuropa.eu/eurostat/statistics-explained/index.php/Glossary:Full-time_equivalent_(FTE)
41 In its version made available to MS for drafting market surveillance reports. The most recent, updated version of the template can be found at http://ec.europa.eu/DocsRoom/documents/20141 (Publication date: 18/11/2016).
42 Aerosol dispensers, simple pressure vessels, personal protective equipment, appliances burning gaseous fuels, equipment and protective systems intended for use in potentially explosive atmospheres, recreational craft, lifts, pressure equipment, machinery, low voltage, toys, noise emission in the environment by equipment for use outdoors, other consumer products under GPSD.
43 In the case of CZ, the 2013 national programme was analysed; as for 2015, only a few, sector-specific national programmes were available.

Moreover, **information was not always complete and harmonised.** In some cases, Member States did not follow the EC template when drafting national programmes,[44] thus reporting different information than that recommended. In other cases,[45] Member States only provided sector-specific data (i.e. corresponding to 'Section 2' in the EC template), without reporting all relevant information on the general market surveillance organisation and infrastructure. In such cases, we tried to gain an understanding of the implementation of market surveillance at the national level by 'abstracting' information from the sectoral programmes.

4.3.1.4 Data gaps in national reports

An initial, serious limitation of national reports related to **gaps in data available on market surveillance activities,** across sectors and Member States over the entire period 2010-2013. For example, data on accidents, penalties and restrictive measures in each sector are never available for more than 16, 18 and 20 Member States respectively. Moreover, when they are available, **they are hardly comparable**, having a very high variance. For instance, in the number of inspections performed, the resulting variance seems to stem from the different national interpretations of what constitutes an inspection (e.g. six Member States[46] include 'visual inspections', Denmark states that an important element of its market surveillance are inspections at trade fairs, while France lists 'inspections on advertising' among its activities. Moreover, Italy only reports the number of inspections ordered by the Ministry of Health, thereby excluding inspections performed by other MSAs on their own initiative). This made a thorough evaluation of the Regulation's effectiveness and efficiency very difficult, and any comparisons between countries and sectors unlikely to be reliable.

Moreover, **some national reports do not include all sectors** listed in the EC template.[47] For instance, Austria excluded the marine equipment sector since it is not relevant for the country. Similarly, Denmark does not perform market surveillance in the cableway sector as the few ski slopes in the country have drag lifts. Lack of coordination within a Member State might be another reason for sector exclusion, inasmuch as the central authority responsible for market surveillance could not obtain the necessary information from sector-specific MSAs.[48] Against this background and according to the methodology used to structure the desk research, the main limitations on data availability related to **sector coverage**,[49] in particular:

- **All or almost all sectors** were covered by Bulgaria, the Czech Republic, Denmark, Finland, France, Hungary, Latvia, Malta, Poland, Romania, Sweden and Slovenia;
- **More than two-thirds of the sectors** were covered by Austria, Belgium, Cyprus, Estonia, Greece, Ireland and Portugal;
- **About half of the sectors** were covered by Italy, Luxembourg and Slovakia;
- **Less than half of the sectors** were covered by Spain and Croatia.

44 CZ, DE, FR, LT, LU and, UK.
45 BE, EL, HR, HU and IT.
46 BG, EE, EL, HU, LU and PT.
47 GROW.B1 (2016). Summary of MS' assessment and review of the functioning of market surveillance activities according to Article 18(6) of Regulation (EC) No 765/2008:. http://ec.europa.eu/DocsRoom/documents/15241?locale=en
48 Ibid.
49 LT does not provide information on market surveillance activities in specific sectors, while the UK only has detailed information on four sectors: toys, electrical appliances and equipment under LVD, cosmetics and childcare articles.

The sectors **most frequently excluded** by the national reports are:

- Efficiency requirements for hot-water boilers fired with liquid or gaseous fuels and non-road mobile machinery, which were only covered by nine Member States;
- Marine equipment, recreational craft, and noise emissions for outdoor equipment were covered by 14, 17 and 17 Member States respectively.

Table 4-52 provides a complete overview of geographical and sectoral coverage as per the national reports.

In addition to the sectors included in the reference list, a number of national reports also covered other product areas considered as relevant, in particular:

- Cigarette lighters, leather, products imitating foodstuffs, packaging, liquid fuels and wheeled tractors (BG);
- Offshore products and food contact materials (DK);
- Steel for the reinforcement of concrete and metal scaffolding (EL);
- Control equipment in the road transport sector (IT);
- Plant-protection products and packaging waste management (PT);
- Equipment for TV sets and precious metals (SE);
- End-of-life vehicles and passenger cars (UK).

4.3.1.5 Data gaps related to the market analysis and the CBA

The gaps of the **market analysis** related to:

- **Data consistency and availability**: some products included in the EC template are not covered by the NACE and/or PRODCOM classifications;
- **Time frame**: currently available Eurostat statistics – and namely SBS – used for the analysis at the sectoral level do not cover the entire time frame required by the ToR, namely 2008-2015 for all EU-28 Member States.

Given that the national reports were the main source of information for **mapping costs and benefits**, data gaps largely correspond to those listed above, and derive precisely from:

- **Low availability of general and sectoral data**, as some Member States did not provide the information corresponding to a number of sectors and/or indicators, or they provided qualitative rather than quantitative data (see Table 4-52 for an overview of sectoral and geographical coverage provided by national reports);
- **Questionable data**: some Member States reported values that do not seem reliable. For instance, the Bulgarian national authorities reported a budget available to MSAs in relative terms amounting to an average of 47.2% of the total national budget, while the

Czech authorities reported values a budget available to MSAs around 92.6% of the total national budget;

- **Unstructured data**: some Member States provided data aggregated to correspond to multiple sectors, thereby compromising the analysis at sector level. Other Member States did not aggregate data at the national level, providing information only for some national MSAs;

- **Unavailability of data about costs incurred by MS authorities** for surveillance activities before 2008. These costs might allow for assessment of the costs deriving from the new obligations introduced by the Regulation.

- **Unavailability of data about product compliance in the Single Market and injuries caused by product non-compliance.** A potentially ineffective market surveillance might lead to relevant costs for economic operators, related to a lower product compliance and to unfair competition, as well as to reduced safety and user trust. There are no databases on this, except the European Injury Data Base (IDB). However, the IDB data currently available are produced voluntarily by Member States and do not clearly mention if notified injuries are caused by product non-compliance or by improper consumer use. Therefore, we used an online survey and targeted interviews to measure in a qualitative way if the measures taken by MSAs are proportionate to their objectives and effective in ensuring product compliance and a level playing field for businesses.

4.3.2 Data gaps in the field research

Some difficulties were encountered while performing the field research. In some cases, **respondents felt overburdened** by the many requests for information (e.g. public consultation, targeted surveys and interviews) despite the careful stakeholder targeting performed jointly with the EC.

As for the targeted surveys, the information requested was very detailed and stakeholders expressed the need for an **extended deadline** in order to provide more complete information. This implied a rescheduling of activities (e.g. interviews) that were specifically aimed at investigating issues emerging from the targeted surveys. Furthermore, the analysis revealed **gaps in the contributions received from economic operators and civil society associations**, as only four economic operators, three civil society associations and 12 industry associations participated. Consequently, these categories are under-represented in the targeted surveys' results, although they were consulted extensively through interviews in the final phase of the study.

As for the **interviews**, a general lack of stakeholder willingness to participate was detected. In particular, it was difficult to identify the right person to interview for the case studies.

4.3.3 Solutions to the problems encountered

The table below provides an overview of all problems encountered and solutions proposed.

Table 4-4 - Problems encountered and mitigation measures

Problems encountered	*Mitigation measure*
Lack of data on product non-compliance	RAPEX data and information from the national reports have been used to provide at least an idea of the dimension of the phenomenon.
Lack of data on levels of overall resources available to MSAs: • Data on budget are only available for a few sectors, or are presented as estimates; • Impossible to disaggregate data on budget only related to market surveillance; • Existence of too many authorities.	These data were cross-checked through the interviews. In case of persisting limitations, these data were not included in the analysis.
Data expressed in national currency instead of euros	We used the European Central Bank average exchange rate for each year over the period 2010-2014.
Data expressed in terms of staff number instead of FTEs	We considered staff numbers as proxies for FTEs.
Lack of harmonisation in the programme year of reference	We assumed that national programmes are still comparable irrespective of the year of reference.
Information not always complete and harmonised since some MS did not follow the EC template at all and others only reported sector-specific information	We extrapolated information to gather the overall picture of market surveillance implementation at the national level.
National reports do not include data for all product sectors covered by the Regulation	Some hypotheses have been made concerning the correspondence between the EC template and NACE/ PRODCOM classifications, in order to obtain reliable sources of data for the analysis at both product and sector level.
Currently available Eurostat statistics do not allow for the time-frame coverage requested by the ToR	We have only selected the years with the highest availability of data, namely 2012-2014.
Lack of data on Germany	A case study was conducted on Germany.
Low quality of data for the CBA provided in the national reports that could not be solved by data gathered through the targeted surveys, which are not complete.	10 interviews were performed to collect data for the CBA.

5. STATE OF PLAY

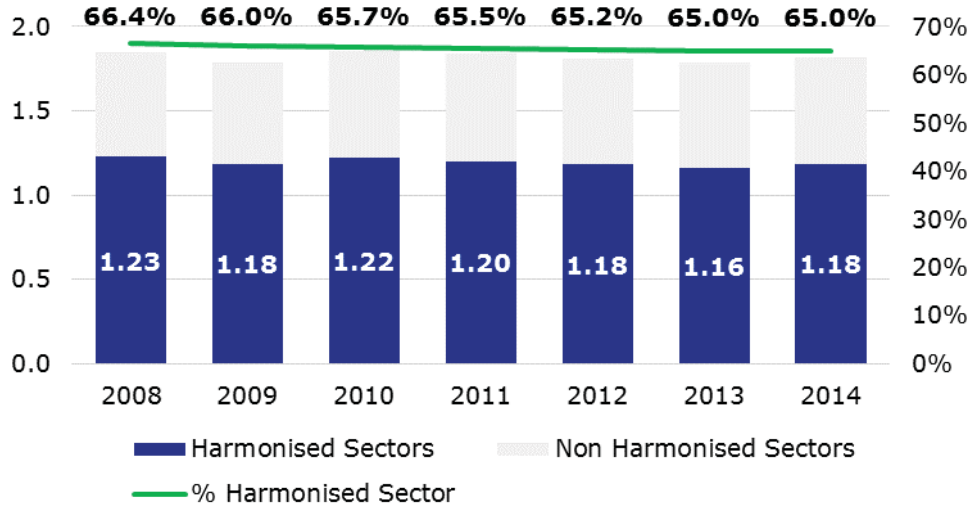
5.1 Market analysis

The market analysis was performed to estimate the value and volume of the products included in the scope of Regulation (EC) No 765/2008 (see Annex for tables of correspondence between the sector in scope of the Regulation and statistical classification used, i.e. NACE). This analysis has also been used to assess whether the extent of market surveillance activities is sufficient, given the market dimension.

5.1.1 Analysis at sectoral level

As shown in the figure below, from 2008 and 2014, around **1.2 million enterprises** were operating within harmonised sectors, representing more than 65% of the total number of active enterprises in the manufacturing economy (around 1.8 million).

Figure 4-1 - Number of enterprises in harmonised sectors vs. overall manufacturing sectors (2008-2014, EU-28), millions, NACE Digit-2

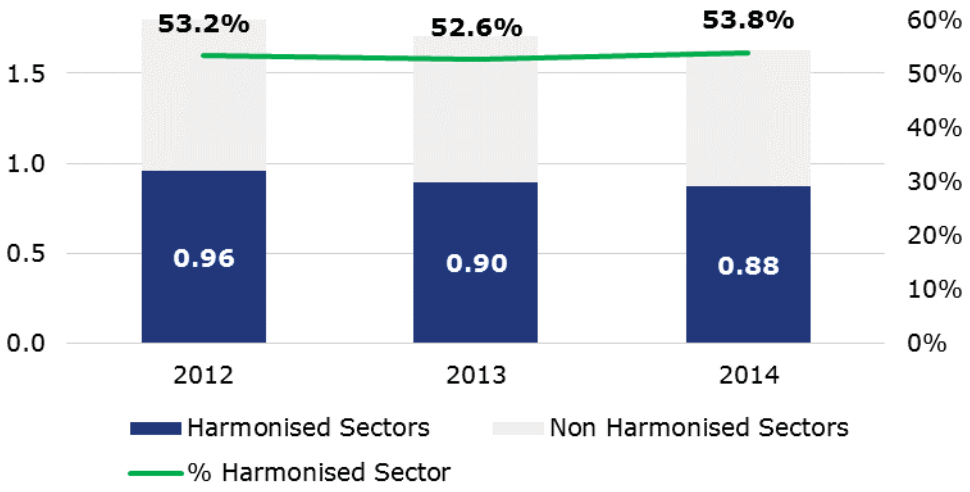


Source: Authors' elaboration on SBS (2016)

It is important to emphasise that since data are available at NACE division level (Digit 2 – NACE code), all **results should be considered as an upper estimate,** since some divisions might contain one or more classes for which there are no harmonised product rules.

A more precise estimate is available for 2012-2014; during this period, Eurostat provides data at NACE group level (Digit 3 – NACE code). In this case, the number of enterprises operating within the harmonised sectors is **0.91 million** (53% of the total number of enterprises active in the manufacturing sectors).

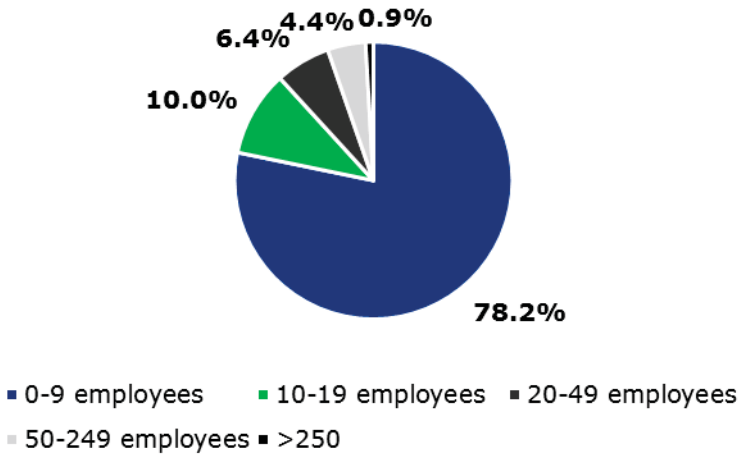
Figure 4-2 - Number of enterprises in harmonised sectors vs. overall manufacturing sectors (2012-2014, EU-28), millions, NACE Digit-3



Source: Authors' elaboration on SBS (2016)

It is very important to underline that around **78%** of the enterprises operating within the harmonised sectors **are micro-enterprises** (i.e. with less than 9 employees) and **16.4% are small enterprises** (i.e. with less than 50 employees).

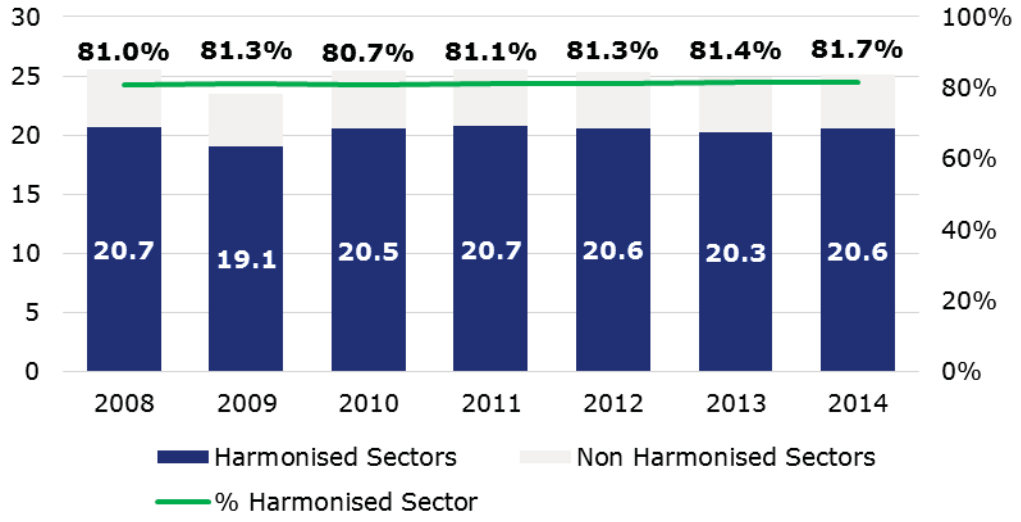
Figure 4-3 - Size of enterprises operating in harmonised manufacturing sectors (2012-2014, EU-28)



Source: Authors' elaboration on SBS (2016)

Furthermore, more than 20 million people are employed in the harmonised sectors at the EU-28 level (i.e. around 81% of all people employed in the manufacturing sectors), with a quite insignificant variation over the period considered.

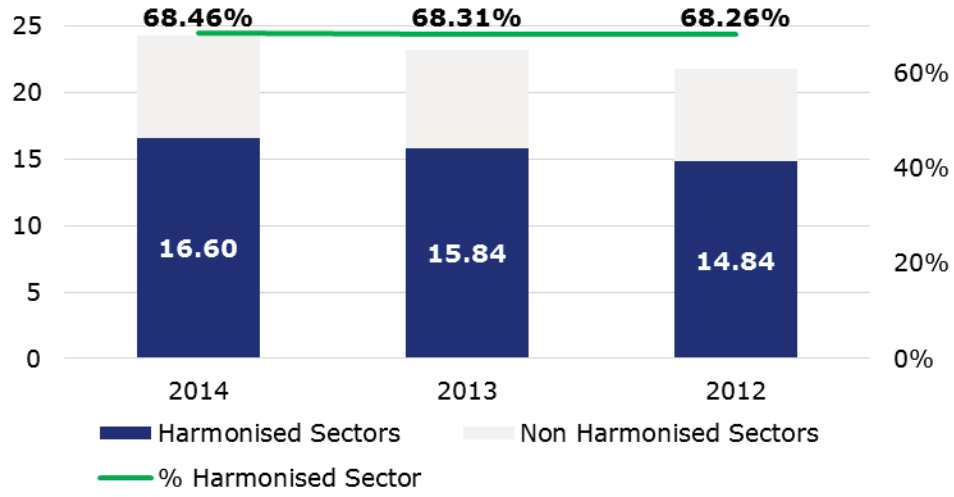
Figure 4-4 - Number of employees: harmonised sectors vs. overall manufacturing sectors (2008-2014, EU-28), millions, NACE Digit-2



Source: Authors' elaboration on SBS (2016)

In this case, a better estimation is achieved by using available data at NACE Digit-3: 15.8 million people are employed in the harmonised sector, which correspond to 68.4% of all those employed in the manufacturing sectors.

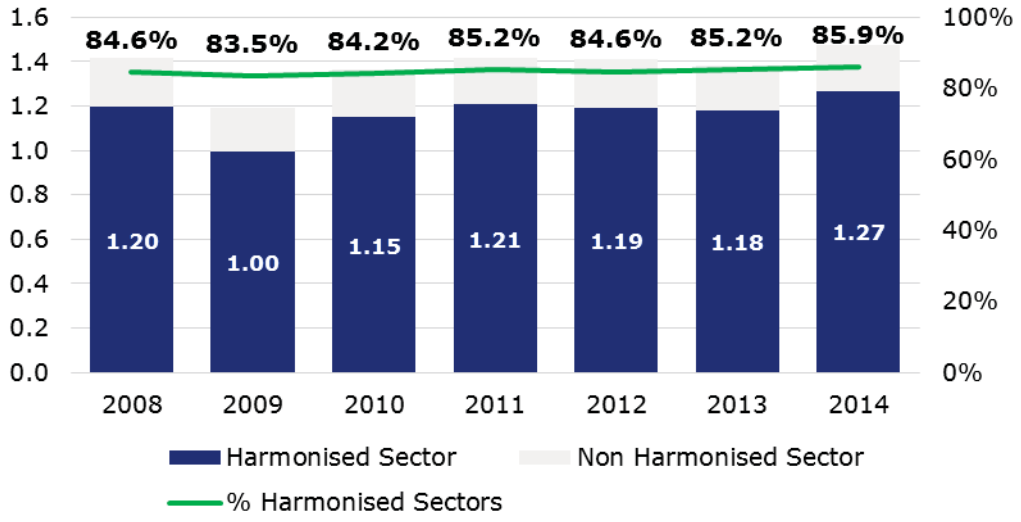
Figure 4-5 - Number of employees: harmonised sectors vs. overall manufacturing sectors (2012-2014, EU-28), millions, NACE Digit-3



Source: Authors' elaboration on SBS (2016)

The importance of harmonised sectors is more evident if wealth creation (i.e. value added and turnover) is considered. In particular, **the value added produced in harmonised sectors increased by 6% during the period 2008-2014** (i.e. rising from €1.2 to 1.27 €billion) and its contribution to the overall value added of the manufacturing sectors increased from 84.6% in 2008 to 85.9% in 2014 (Figure 4-6).

Figure 4-6 - Value added at factor cost: harmonised sectors vs overall manufacturing sectors (2008-2014, EU-28), €billion, NACE Digit-2



Source: Authors' elaboration on SBS (2016)

In addition, considering the period 2012-2014, **micro and SMEs operating in harmonised sectors contributed to 32% of the overall value added produced in the manufacturing economy** (i.e. 373 billion out of €1,164 billion).

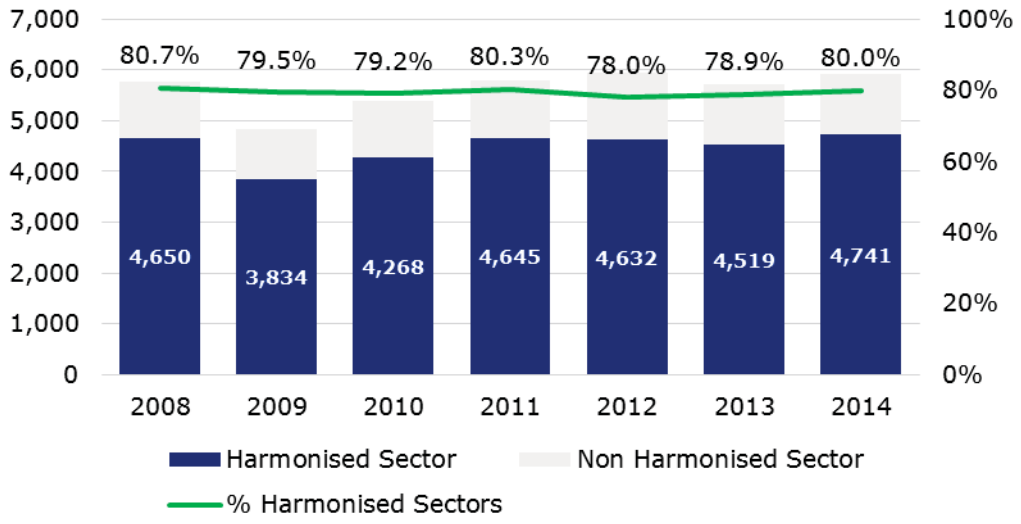
Table 4-5 - Value added at factor cost per size of enterprises: harmonised sectors vs. overall manufacturing sectors (2011-2013, EU-28)

Size of enterprises	*Harmonised sectors*		*Manufacturing*		*a/b*
	*Total **(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%

Source: Authors' elaboration on SBS (2016)

Finally, relevant results also emerged in terms of turnover. As shown in the figure below, enterprises operating within harmonised sectors contribute to around 80% of the total value of market sales in manufacturing sectors (€4,469 billion out of €5,620 billion which corresponds to the overall turnover produced within the manufacturing sectors).

Figure 4-7 - Turnover: harmonised sectors vs. overall manufacturing sectors (2008-2014, EU-28), €b



Source: Authors' elaboration on SBS (2016)

If the size of enterprises is considered, micro and SMEs active in harmonised sectors accounted for 27% (i.e. 3% plus 24%) of turnover generated within the entire manufacturing economy (€1,238 billion out of €4,564 billion).

Table 4-6 - Turnover per size of enterprises: harmonised sectors vs. overall manufacturing (2011-2013, EU-28)

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%

Source: Authors' elaboration on SBS (2016)

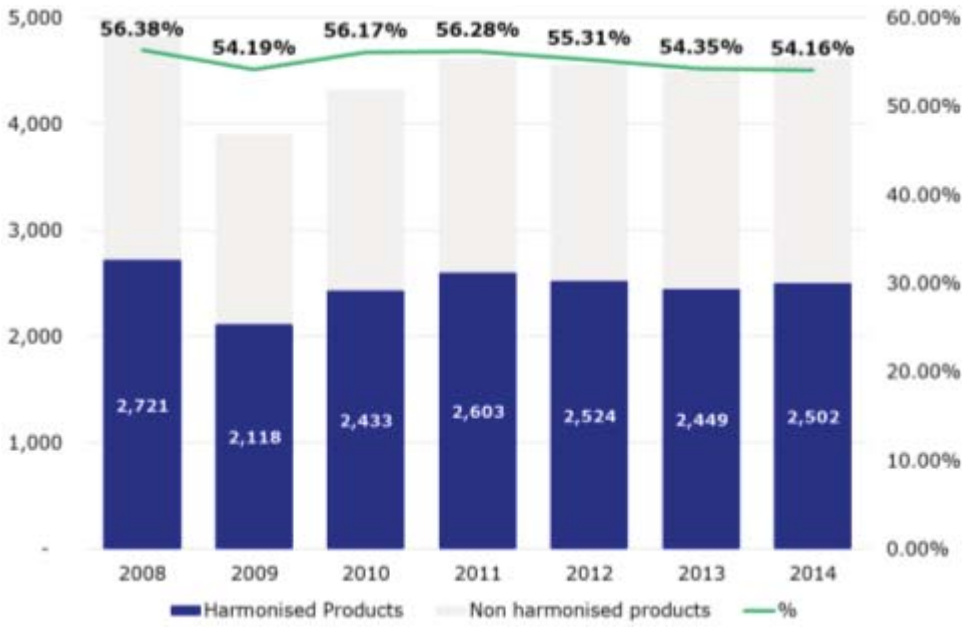
5.1.2 Analysis at product level

We have identified 1,850 harmonised products, representing around 46% of all products (around 4,000) included in the PRODCOM list.

The analysis at product level has been performed over the period 2008-2015.

In particular, the research, on average, **value of harmonised products** traded within the EU Internal Market was **€2,478 billion during the period 2008-2014** (Figure 4-8 and Figure 4-9).

Figure 4-8 - Value of harmonised products within the EU-28 (2008-2014), €bn



Source: Authors' elaboration on PRODCOM – statistics by product, Eurostat (2016)

The value of harmonised products corresponds to around 69% of the overall value of manufacturing products traded. This value has been computed considering the following values for the identified harmonised products (Figure 4-9):

Value of sold production – Value of extra EU exports + Value of extra EU imports.

To identify the economic sectors in which harmonised product rules are more relevant, the NACE codes used so far have been aggregated using the International Standard Industrial Classification of All Economic Activities (ISIC rev 4).[50]

The analysis shows (Table 4-7) that 80% of harmonised products (€1,818 billion) are traded within the following sectors:

Basic metals and fabricated metal products (NACE codes 24 and 25)

- Chemicals and chemical products (NACE code 20);
- Rubber and plastics products, and other non-metallic mineral products (NACE codes 22 and 23);
- Computer, electronic and optical products (NACE code 26);
- Machinery and equipment (NACE code 28);

50 http://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF (page 44).

- Transport equipment (NACE codes 29 and 30).

Table 4-7 - Value of harmonised products per sector (ISIC rev 4/NACE rev.2)

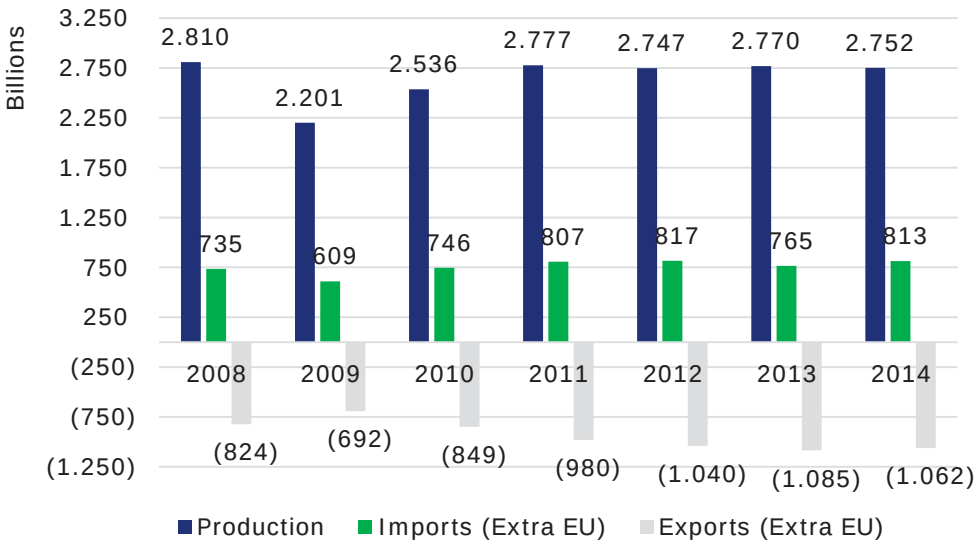
ISIC rev 4	*NACE rev 2*	*Average value (€b) 2008-2014*	*%*
Manufacture of textiles, apparel, leather and related products	13 to 15	120.40	4.9%
Manufacture of wood and paper products, and printing	16 to 18	:	:
Manufacture of coke, and refined petroleum products	19	:	:
Manufacture of chemicals and chemical products	20	362.47	14.6%
Manufacture of pharmaceuticals, medicinal chemical and botanical products[51]	21	103.16	4.2%
Manufacture of rubber and plastics products, and other non-metallic mineral products	22 + 23	324.72	13.1%
Manufacture of basic metals and fabricated metal products, except machinery and equipment	24 + 25	459.96	18.6%
Manufacture of computer, electronic and optical products	26	242.03	9.8%
Manufacture of electrical equipment	27	165.76	6.7%
Manufacture of machinery and equipment n.e.c.	28	309.13	12.5%
Manufacture of transport equipment	29 + 30	323.79	13.1%
Other manufacturing, and repair and installation of machinery and equipment	31 to 33	67.28	2.7%
Total		**2,478.69**	**100%**

Source: Authors' elaboration on PRODCOM (2016)

Furthermore, **30% of the value of harmonised products** (€756 billion on average over the period considered) is related to **goods imported from non-EU countries** (green bars in Figure 4-9).

51 Pharmaceutical products are not considered as falling within the scope of Regulation (EC) No 765/2008 except as far as border-control provisions are considered. Nevertheless, this NACE sector is included because it encompasses other product categories falling within the Regulation, such as medical devices.

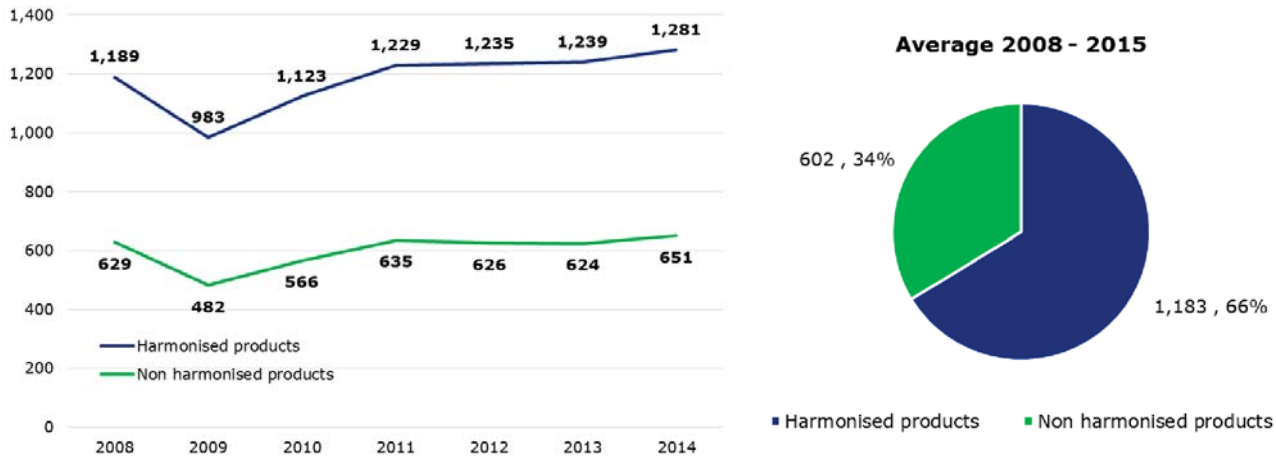
Figure 4-9 - Trade in harmonised products: sold production and trade with non-EU countries (2008-2014, EU-28), €b



Source: Authors' elaboration on PRODCOM – statistics by product, Eurostat (2016)

The relevance of harmonised products also emerges if **intra-EU imports** are considered. Eurostat statistics on international trade in goods[52] show that products for which harmonised product rules exist represent 66% (Figure 4-10) of the value of the overall intra-EU imports of manufacturing goods (€1,183 billion). Annex 8.14 provides the value of intra-EU imports of harmonised products per Member State.[53]

Figure 4-10 - Value of intra-EU imports: harmonised products vs. non-harmonised products (annual value and annual average 2008-2015, EU-28, €b)



Source: EU trade since 1998 by SITC, Eurostat (2016)

52 EU trade since 1988 by SITC:, http://ec.europa.eu/eurostat/web/international-trade-in-goods/data/database
53 The value of extra EU trades (used in Figure 9) is only available at EU28 level from PRODCOM database.

5.2 Implementation of the Regulation

This section is mainly descriptive and summarises the current situation in terms of structures relevant to implementation of Regulation (EC) No 765/2008, in particular: the organisation of market surveillance at the national level, market surveillance activities to detect non-compliant products, the existing coordination and cooperation mechanisms within/among Member States, and the measures taken against non-compliant products.

5.2.1 Organisation of market surveillance at the national level

5.2.1.1 Organisational models

According to Article 16(1) of the Regulation, "*Member States shall organise and carry out market surveillance as provided for in this Chapter [i.e. on General requirements]*". The Regulation 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 organised differently at the national level in terms of sharing competences and powers between MSAs. Table 4-8 summarises the organisational structures in place in all EU Member States, as resulting from the national programmes and based on the classification provided by the European Parliament (2009).[54]

54 European Parliament (2009), *Effectiveness of Market Surveillance in the Member States. Directorate A: Economic and Scientific Policies*, IPOL/A/IMCO/ST/2009-04.

Table 4-8 - Organisational structures for market surveillance in the EU-28 Member States

MS	*Organisational structure for market surveillance*
AT	Market surveillance is performed by *Land* or federal authorities depending on the legal provisions that apply. Federal authorities perform market surveillance in all the sectors covered by the New Approach, with a few exceptions, which is where the *Lands* are responsible. For instance, they are responsible for market surveillance in the pyrotechnics and explosives for civil use sectors. Finally, other national agencies carry out inspections in sectors such as radio and telecommunication equipment under R&TTE, and fertilisers.
BE	The Belgian Interministerial Economic Commission within the Federal Public Services coordinates market surveillance at the national level. Various federal government departments, agencies and institutes are responsible for market surveillance implementation.
BG	The Bulgarian State Agency for Metrological and Technical Supervision (DAMTN) is the main authority responsible for market surveillance of products covered by the New Approach Directives, except for medical devices and health-related products, the responsibility for which falls under the Executive Agency for Medicines (IAL) and the Regional Health Inspectorate (RZI). The Consumer Protection Commission (KZP) is responsible for consumer protection and for surveillance in the aerosol dispenser, tyre labelling, other products under GPSD, and textile and footwear labelling sectors, while the Technical Control Inspectorate (KTI) is responsible for agricultural and forestry machinery and the Regional Inspectorates for the Environment and Water (RIOSV) are responsible for fluorinated greenhouses gases and ozone-depleting products.
CY	Cyprus has a semi-decentralised market surveillance structure, whereby ministries and their departments are competent for a number of sectors covered by the Regulation. The Ministry of Labour, Welfare and Social Insurance and the Ministry of Transport, Communications and Works are responsible for the largest number of sectors (eight each).
CZ	The Czech Trade Inspection Authority carries out surveillance in 19 sectors.[55] Other authorities have sector-specific market surveillance responsibilities in the remaining sectors. For instance, the Ministry of Health performs controls on cosmetic products and the Rail Authority carries out market surveillance for cableway products.
DE	Germany has a regional market surveillance structure, as each of its 16 *Lands* is responsible for implementing market surveillance. Each has a competent ministry per sector. However, market surveillance responsibilities for some sectors are managed at the federal level.[56]

55 Toys, transportable protective equipment, construction products, aerosol dispensers, simple pressure vessels and pressure equipment, transportable pressure equipment, machinery, lifts, noise emissions for outdoor equipment, personal protective equipment, appliances burning gaseous fuels, measuring instruments, non-automatic weighing instruments and pre-packaged products, electrical equipment under EMC, radio and telecom equipment under R&TTE, electrical appliances and equipment under LVD, recreational crafts, marine equipment, other consumer products under GPSD, textile and footwear labelling.

56 Construction products, cableways, electrical equipment under EMC, radio and telecom equipment under R&TTE, electrical and electronic equipment under RoHS and WEEE and batteries, other chemicals (detergents, paints, persistent organic pollutants, fluorinated greenhouse gases, ozone- depleting substances, etc.), tyre labelling, marine equipment, motor vehicles, fertilisers.

MS	*Organisational structure for market surveillance*
DK	Denmark has a decentralised market surveillance structure as activities are divided between 11 authorities, each having expertise in a particular area. This structure, aimed at ensuring strong technical and specific skills, also implies that activities are managed in different ways depending on the competent authority and sector.
EE	Estonia has a semi-decentralised structure with seven MSAs established under four ministries. However, the Technical Regulatory Authority is the main authority responsible for carrying out market surveillance in 18 sectors.
EL	There are 10 MSAs. Eight are represented by the competent ministries and two are national agencies: the National Organisation for Medicines and the National Telecommunications & Post Commission (EETT). The Ministry of Economy, Development and Tourism and the Ministry of Development and Competitiveness are the main authorities as they are responsible for market surveillance of 13 and seven sectors, respectively.
ES	Market surveillance activities are coordinated by the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN). As Spain is organised into autonomous communities, the autonomous community authorities have executive powers in the field of consumer products. For the other sectors, national or regional authorities are responsible for market surveillance. SOIVRE (the Official Service of Surveillance, Certification and Technical Assistance of Foreign Trade) is involved in performing controls at the borders, checking products before their arrival to Customs' offices.
FI	There are nine MSAs. Market surveillance is generally carried out at the national level. However, exceptions are market surveillance of a number of products for professional use (PPE, machinery, cableways, non-road mobile machinery) where 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 areas carry out activities at the regional level.
FR	The Directorate-General for Competition, Consumer Affairs and Fraud Repression (DGCCRF) and the Directorate-General for Customs and Indirect Taxation (DGDDI) are responsible for market surveillance activities with cross-sectoral competences. However, other institutions contribute to market surveillance by performing specific checks or on-site services, such as the Directorate-General for Companies for Measuring Instruments, the Directorate-General for Risk Prevention, the Directorate for Maritime Affairs, and the National Agency for the Safety of Medicinal and Health Products.
HR	Market surveillance is organised according to the sectoral competences of six ministries. On 1 January 2014, the Ministry of the Economy took over the main market surveillance tasks – namely the protection of consumers, product safety and pressure equipment and the tasks of the mining and electricity inspectorate. Other relevant authorities are the State Office for Metrology (responsible for measuring instruments, non-automatic weighing instruments and pre-packaged products), the Ministry of the Interior (pyrotechnics), the Croatian Regulatory Authority for Network Industries - HAKOM (radio equipment and telecommunications terminal equipment), the Ministry of Agriculture (fertilisers) and the Ministry of Health (cosmetic products, toys and chemical products).

MS	Organisational structure for market surveillance
HU	Hungary has a decentralised market surveillance structure, made up of 14 MSAs. Market surveillance in a number of sectors is managed at national level by the competent agencies (e.g. National Media and Infocommunications Authority, Hungarian Trade Licensing Office) or by the competent government office. In most sectors, market surveillance activities are carried out at the regional level.[57]
IE	Overall, 19 government departments and state agencies are in charge of market surveillance. The Health and Safety Authority carries out surveillance in 11 sectors, although for some of these it is not the only responsible authority.
IT	Italy has a decentralised market surveillance structure, with eight ministries carrying out surveillance activities, helped by several national agencies and Customs depending on the sectors. Product safety controls within national borders are assigned to the Guardia di Finanza, while Customs are responsible for product checks at the border.
LT	The state non-food inspectorate performs market surveillance activities in 18 sectors covered by the Regulation, while 10 other MSAs (ministries or national agencies) share surveillance duties for a number of sectors covered by the Regulation.
LU	Market surveillance is mainly managed by the Institute for Standardisation, Accreditation, and the Safety and Quality of Products and Services (ILNAS). Like France, several ministerial departments and administrations are nonetheless responsible for specific market surveillance activities. The Ministry of Health, for instance, is responsible for the implementation of specific Directives in the field of health.
LV	There are 11 different authorities subordinated to seven different ministries. In addition, some market surveillance activities are performed by the Customs Board of the State Revenue Service and the State Police.
MT	Malta has a centralised market surveillance structure. In 2013, the Malta Competition and Consumer Affairs Authority (MCCAA) was set up, replacing the existing Malta Standards Authority and the Consumer and Competition Division. The former comprises the Regulatory Affairs Directorate, responsible for the transposition of European technical regulations and Directives into Maltese law, and the Market Surveillance Directorate (MSD-TRD), which is the sole MSA for Malta for non-food and non-medicinal products.
NL	There are six MSAs under different ministries, each performing surveillance on a different set of products covered by the Regulation. They are the Social Affairs and Employment Inspectorate (I-SZW), Human Environment and Transport Inspectorate (ILT), the Netherlands Radio-communications Agency (AT), Verispect B.V., Health Care Inspectorate (IGZ), and the Netherlands Food and Consumer Product Safety Authority (NVWA).
PL	Poland has 10 MSAs, some of which carry out market surveillance activities for a number of sectors while others have a specific area of competence. The Office of

57 Personal protective equipment, aerosol dispensers, simple pressure vessels and pressure equipment, machinery, explosives for civil uses, chemicals under REACH and other chemicals, motor vehicles, and fertilisers.

MS	Organisational structure for market surveillance
	Competition and Consumer Protection (OCCP) supervising trade inspection, for instance, manages surveillance activities related to 14 sectors,[58] while the National Sanitary Inspection controls products in the cosmetic sector.
PT	Six authorities are responsible for the mainland's market surveillance, while two MSAs (i.e. Regional Inspection of Economic Activities of the Azores - IRAE Açores - and Regional Inspection of Economic Activities of Madeira - IRAE Madeira) are responsible for market surveillance in the autonomous regions. In mainland Portugal, the authority for food and economic security performs activities and inspections in all sectors concerned by the Regulation, while the remaining five authorities carry out market surveillance in the other sectors covered by the Regulation (e.g. the National Communication Authority deals with products under the R&TTE). The Tax and Customs Authority, which is not considered an MSA, is responsible for border controls.
RO	Romania has 14 MSAs with sector-specific competences. These comprise 11 national agencies and institutions, the Ministry of Health and the Ministry of Agricultural and Rural Development and the State Inspectorate for Construction.
SE	Market surveillance is decentralised at sectoral level and is carried out by 16 MSAs affiliated to a total of seven ministries, each competent for a specific area of products, and 290 municipalities.
SI	There are nine MSAs – 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 – subordinated to six ministries. The TIRS is the main authority in charge of the supervision of 15 sectors covered by the Regulation.
SK	Slovakia has a centralised market surveillance system in which the Slovak Trade Inspectorate is the main authority in charge of consumer protection for non-food products in the internal market. Other authorities, such as the Slovak Metrological Inspectorate and the National Labour Inspectorate, perform market surveillance related to specific products. Market surveillance for cosmetic products is enforced at both national and regional level, as the Public Health Authority of the Slovak Republic together with 36 Regional Public Health Authorities are the responsible authorities. Interestingly, products are divided into two groups – consumer products and products used by businesses – which means that some product categories fall under the responsibility of two different MSAs, depending on their final users.
UK	MSAs operate at national or regional level depending on the sector of competence. More than 200 UK local authorities (Trading Standards in Great Britain and District Councils in Northern Ireland) are responsible for ensuring the safety of consumer and construction products. The Health and Safety Executive (HSE) in Great Britain and the Health and Safety Executive for Northern Ireland (HSENI) are in charge of market surveillance related to the safety of goods for workplaces and linked aspects. Other national agencies are responsible for supervision in other sectors.

58 Personal protective equipment, packaging and packaging waste, pressure equipment, GPSD, measuring instruments, machinery, products under Low voltage Directive, pyrotechnic articles, non-automatic weighing instrument, toys, simple pressure vessels, eco-design products, gas burning appliances, energy labelling.

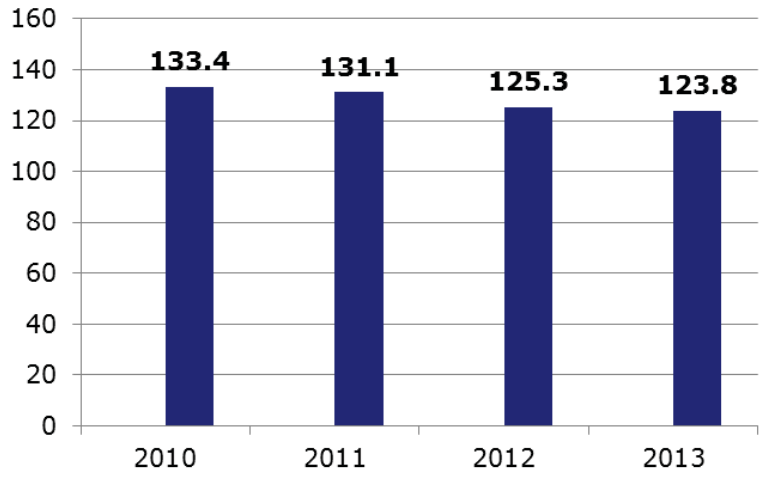
5.2.1.2 Resources available to MSAs at the national level

According to Article 18(3) of the Regulation, "*Member States shall entrust market surveillance authorities with the powers, resources and knowledge necessary for the proper performance of their tasks.*"

5.2.1.2.1 Financial resources available for market surveillance activities

Data on the **total budget available to MSAs in nominal terms,** as reported in Figure 4-11, indicate that the overall amount available at the EU level declined annually between 2010 and 2013. The figures refer to 18 EU Member States, excluding Austria, Cyprus, Estonia, Greece, Croatia, Luxembourg, Slovenia and the United Kingdom which have not included these data in their national reports. Moreover, Hungary only reported values since 2011, and Sweden reported incomplete data for 2010 and 2011. Therefore, they were not considered as the lack of data for 2010 and 2011 would have created a different perspective on the 2010-2013 trends.

Figure 4-11 - Total budget available to 19 MSAs in nominal terms during 2010-2013, €m



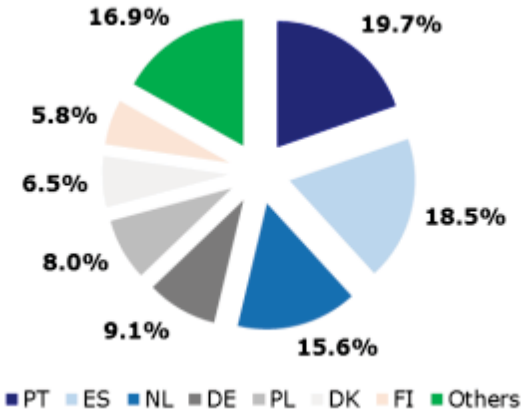
Source: Authors' elaboration on national reports

As suggested by the study's Steering Committee, the declared budget should reflect all financial resources assigned to market surveillance and enforcement activities, including related infrastructures and projects and measures aimed at ensuring economic operators' compliance with product legislation. These measures range from communication activities (consumer/business information and education) to enforcement, and should 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. However, national reports do not always specify the methodology used to measure costs and types of costs included. As a result, some inconsistencies appear across countries and throughout the years for which data are available (2010-2013).

At the national level, during 2010-2013, information analysed shows that:

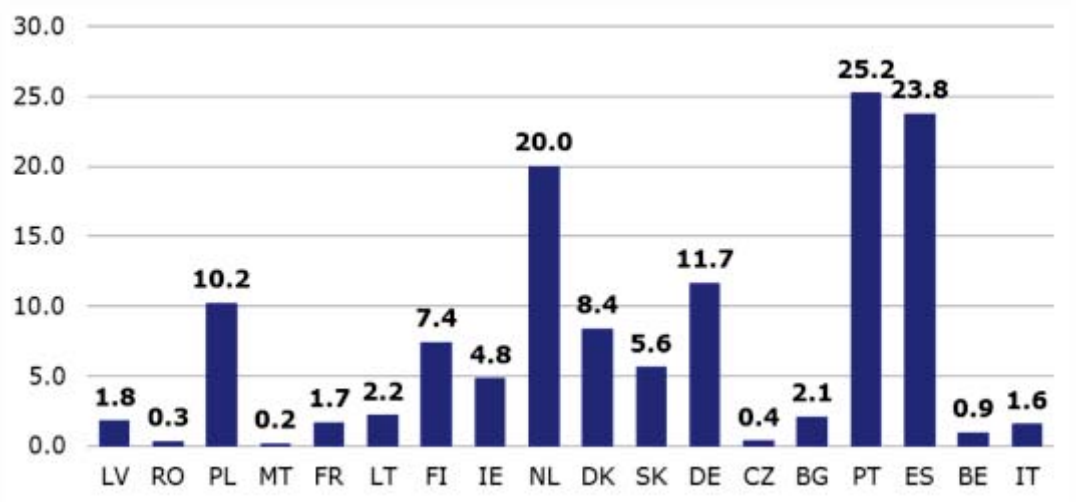
- More than 80% of the total budget available to the 18 MSAs reporting data in nominal terms is concentrated in seven Member States (Figure 4-12);
- More than half of the Member States providing data had an available annual budget of less than €10 million (Figure 4-13);
- Only three countries (Portugal, the Netherlands and Spain) declared an annual budget allocated to market surveillance activities equal to or greater than €20 million (Figure 4-13).

Figure 4-12 - Contribution of each MS to the total budget available in nominal terms to MSA at EU level from 2010-2013



Source: Authors' elaboration on national reports

Figure 4-13 - Annual budget available to MSAs in nominal terms, average 2010-2013, €M

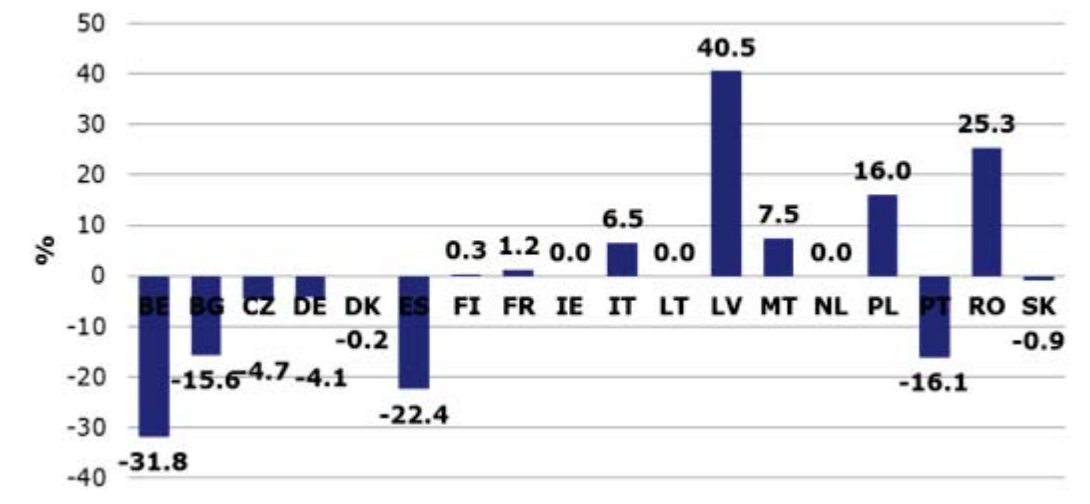


Source: Authors' elaboration on national reports

As shown in Figure 4-14, over the period considered the total budget allocated annually to market surveillance activities increased in eight Member States[59] and decreased in seven.[60] In other countries (Ireland, the Netherlands and Lithuania) the budget remained stable over the period 2010-2013. The magnitude of reduction and increase in the total budget available to national MSAs also differs. On a three-dimension scale (0-10% – limited, 10-30% – moderate, 40-50% – high) the variations in 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 the Member States, i.e. in 12 out of 18.

Figure 4-14 – Variation (%) in the average annual budget available to MSAs in nominal terms 2010-2013, €M



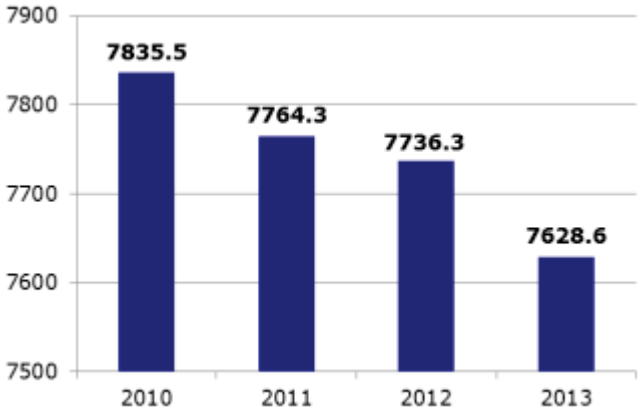
Source: Authors' elaboration on national reports

5.2.1.2.2 Human resources available for market surveillance activities

The **staff resources available to MSAs (FTE units)** are relevant for measuring enforcement costs incurred by MSAs. A reduction in number can also be observed here (Figure 4-15), potentially as a result of the budget decrease discussed above. Consequently, the costs incurred by MSAs to enforce the Regulation in terms of FTEs were lower in 2013 compared to 2010. The analysis considered 19 Member States, since data on the other were not available over the entire period; as stated before, Hungary did not provide all the necessary data.

59 FI, FR, IT, LT, LV, MT, PL, RO, SE.
60 BE, BG, CZ, DE, ES, PT, SK.

Figure 4-15 – Total staff resources available to MSAs (FTE units) during 2010-2013 at EU level[61]



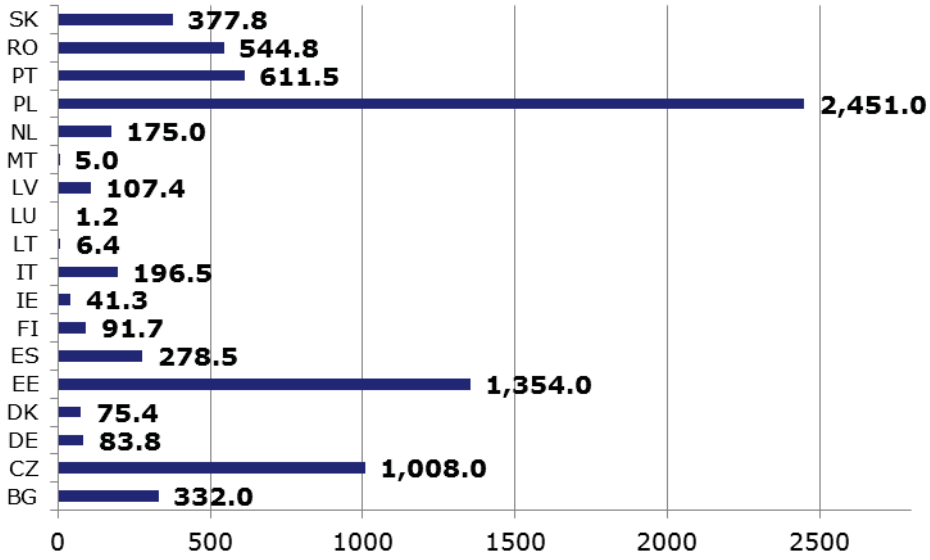
Source: Authors' elaboration on national reports

The analysis at the Member State level of the **total number of staff resources** available to MSAs (FTE units) revealed the following:

- On average, 7,741 staff resources (FTEs) were available for the MSAs of 18 EU Member States during the period 2010-2013 (Figure 4-15);
- 86.3% of staff resources (6,679) were based in seven Member States (Poland, Estonia, Czech Republic, Portugal, Romania, Slovakia and Bulgaria, Figure 4-17 and Figure 4-18);
- More than 30% of total staff resources were based in one country (Poland, Figure 4-17 and Figure 4-18);
- There were significant 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 most countries.

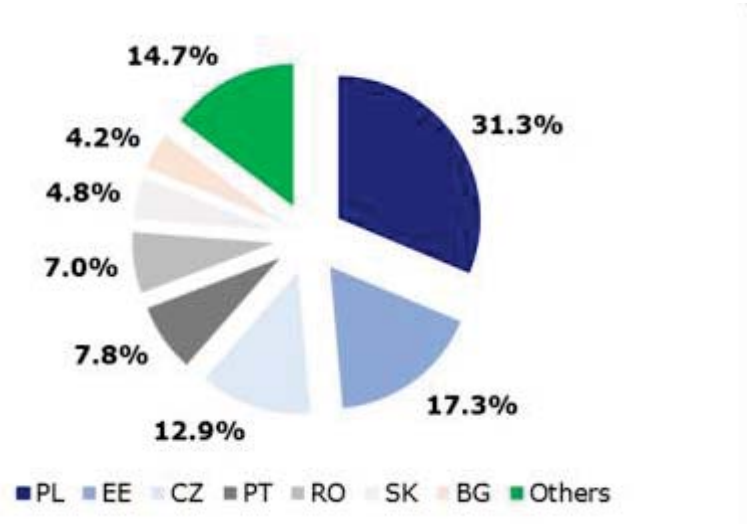
61 The analysis includes: BG, CZ, DE, DK, EE, ES, FI, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE and, SK; the other MS have not provided complete and reliable data.

Figure 4-16 – Total staff resources available to MSAs at country level (average 2010-2013), FTEs



Source: Authors' elaboration on national reports

Figure 4-17 – Total staff resources available to MSAs (FTE units) per country over 2010-2013



Source: Authors' elaboration on national reports

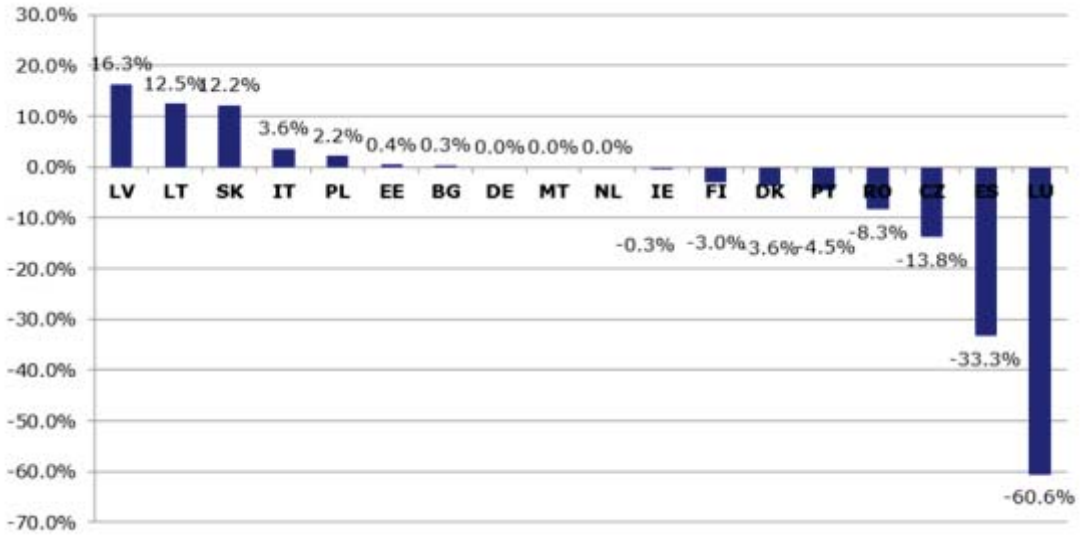
The highlights of the analysis concerning the **variation** in total staff resources available to MSAs (FTE units) over the period 2010-2013 include (Figure 4-18):

- 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).

Figure 4-18 – Variation in total staff resources available to MSAs (FTE units) over 2010-2013

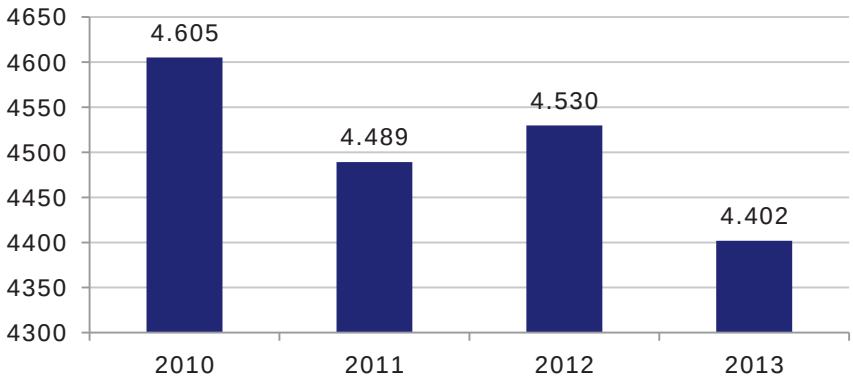


Source: Authors' elaboration on national reports

While at the EU level the budget available for market surveillance activities experienced 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 (falling one year, rising in the next, then falling again) which could be translated into fluctuating staff costs during this period (Figure 4-19). In this case, only 16 Member States provided completed data and were included in the analysis.[62]

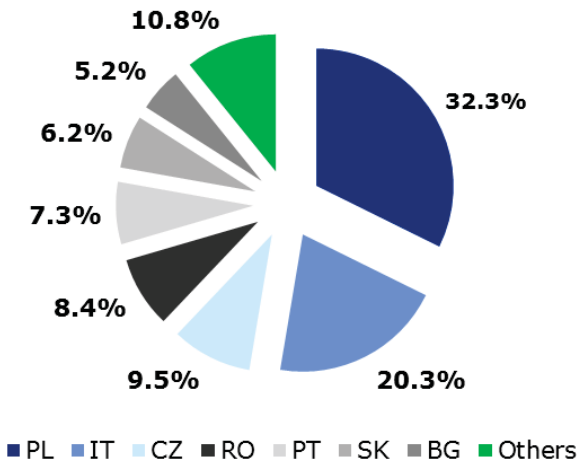
62 BE, BG, CZ, DK, EE, ES, FI, IE, IT, LT, LU, LV, PL, PT, RO, SK.

Figure 4-19 - Total number of inspectors available to MSAs (FTE units) over 2010-2013 at EU level



Source: Authors' elaboration on national reports

Figure 4-20 - Total number of inspectors (FTE units) available to MSAs per country over 2010-2013



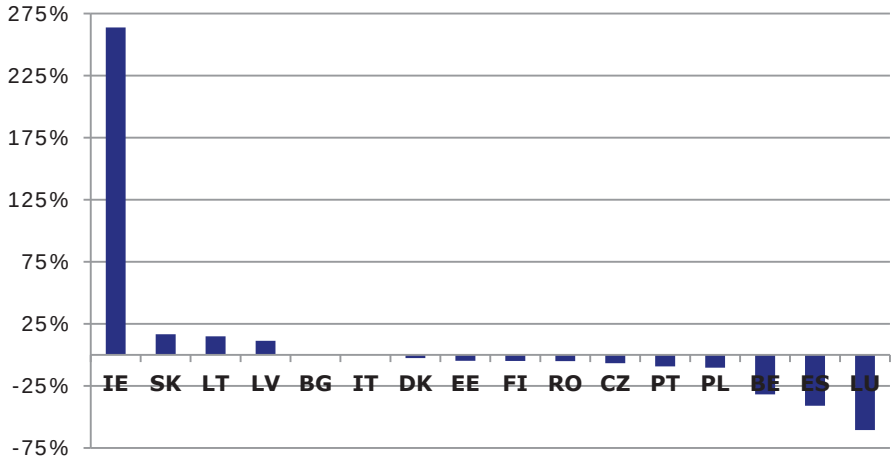
Source: Authors' elaboration on national reports

Regarding the total number of inspectors (FTE units) available to MSAs over 2010-2013 at the country level, the following data emerged:

- On average, 4,506 inspectors were available to the 16 Member States considered for inspection activities (Figure 4-19);
- The majority (90%) of inspectors (4,019) were based in six Member States - Poland, Italy, Czech Republic, Romania, Portugal and Slovakia (Figure 4-20);
- 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 for instance, in Luxembourg and Lithuania (included in the 'Others' category in Figure 4-20) only 4.6 and 21.74 FTEs, respectively, were allocated to market surveillance activities, while Poland involved 5,822 FTEs.

Figure 4-21 - Variation in total number of inspectors (FTE units) available to MSAs per year, during 2010-2013



Source: Authors' elaboration on national reports

At the country level, analysis of the change in the number of inspectors available to MSAs annually reflects the following:

- In most Member States (10 out 16) the number of inspectors fell;
- Six countries (Bulgaria, Italy, Denmark, Estonia, Finland and Romania) had relatively stable trends, with the increase or decrease in the number of inspectors no higher than 5% of the number of inspectors available to MSAs in 2010;
- A significant increase (263.8%) was registered in Ireland.

With the exception of two Member States (Ireland and Poland), the overall trend in the total inspectors available to MSAs during the four years considered tends to be aligned with that for the total staff available to MSAs.

5.2.1.2.3 Technical resources

In relation to technical resources in particular, **many MSAs**[63] **do not have their own laboratories for product testing** in a large number of sectors (i.e. more than 20), and thus outsource these activities to accredited laboratories. However, some MSAs do have in-house test laboratories. Based on the available data, MSAs in Germany and Bulgaria have test facilities for most sectors covered by the scope of the Regulation (i.e. 27 and 18 sectors,

63 Based on the information collected through the targeted surveys and directly requested to IMP-MSG representatives: CY, EE, FI, HR, IE, LU, LV, PL, RO, SE, and SI.

respectively). Table 4-9 below presents an overview of test laboratories available in each Member State.

Table 4-9 – National MSA laboratories across Member States[64]

MS	*Number of **sectors** where **MSAs** have own test laboratories*	*Number of **sectors** where **MSAs do not** have own test laboratories*	*Number of **sectors** for which **no info** was available*
DE	27	0	6
BG	18	14	1
CZ	13	19	1
NL	12	12	9
PL	10	23	0
HR	7	22	4
LU	6	26	1
EE	5	21	7
RO	5	28	0
UK	4	19	10
CY	3	23	7
SE	3	28	1
FI	2	24	7
LV	1	26	6
SI	1	32	0
DK	0	18	15
IE	0	33	0

Source: Targeted surveys

There are also **differences across sectors**. For instance, the electrical equipment under EMC, radio and telecom equipment under R&TTE – RED, cosmetics and toys are sectors where in-house laboratories are available, although only in a few Member States (i.e. either 8 or 7). In contrast, very few MSAs have in-house laboratories in the PPE, construction products, aerosol, simple pressure equipment, and lifts sectors.

64 No adequate information was available for AT, BE, EL, ES, FR, HU, IT, LT, MT, PT, and SK. The reference list of sectors is that provided in Table 4-1.

Table 4-10 - National MSA laboratories across sectors[65]

Sector	*Number of **MS** where **MSAs** have test laboratories*	*Number of **MS** where **MSAs do not** have test laboratories*	*Number of **MS** for which **no info** was available*
2. Cosmetics	8	6	14
18.Electrical equipment under EMC	8	10	10
19.Radio and telecom equipment under R&TTE - RED	8	11	9
3.Toys	7	12	9
17.Measuring instruments	7	11	10
15.Explosives for civil uses	6	10	12
20.Electrical appliances and equipment under LVD	6	13	9
21.Electrical and electronic equipment under RoHS and WEEE and batteries	6	11	11
22.Chemicals	6	10	12
12.Noise emissions for outdoor equipment	5	11	12
31.Biocides	5	11	12
4.PPE	4	16	8
9.Machinery	4	14	10
10.Lifts	4	15	9
13.Equipment and protective systems intended for use in potentially explosive atmospheres	4	11	13
14.Pyrotechnics	4	13	11
1.Medical devices	3	13	12
5.Construction products	3	15	10
8.Transportable pressure equipment	3	13	12

65 The following sectors were not considered as too many data were missing: 26.Marine equipment, 27.Motor vehicles and tractors, 28.Non-road mobile machinery, 29.Fertilisers, 30.Other consumer products under GPSD. The reference list of sectors is that provided in Table 4-1.

Sector	*Number of **MS** where **MSAs** have test laboratories*	*Number of **MS** where **MSAs do not** have test laboratories*	*Number of **MS** for which **no info** was available*
11.Cableways	3	13	12
25.Recreational craft	3	13	12
6.Aerosol dispensers	2	16	10
7.Simple pressure vessels and pressure equipment	2	15	11
16.Appliances burning gaseous fuels	2	14	12
23.Eco-design and energy labelling	2	12	13
32.Textile and footwear labelling	2	13	13
33.Crystal glass	2	12	14
24.Tyre labelling	1	13	14

Source: Targeted surveys

The Annex gives a complete overview per individual Member State and per sector of available test facilities.

5.2.2 Market surveillance activities

5.2.2.1 Approaches to market surveillance

All Member States have both proactive and reactive approaches to market surveillance.

Proactive market surveillance refers to activities that are specifically planned, organised and implemented by MSAs under their own enforcement powers. Proactive surveillance can relate to targeting either economic operators (based on criteria such as history of non-compliance, results of audits, market share, and distribution of products and/or users) or products. According to Article 18(5) of the Regulation, the proactive planning of market surveillance is shared with the EC and other MSAs via national programmes. This exchange of information can facilitate cooperation and sharing resources between MSAs in different Member States while helping to avoid the duplication of activities. **Reactive market surveillance** is normally triggered by an outside event and in relation to a specific suspected offence.

While both types of approaches are used, Member States refer to different **criteria to select a particular sector as a priority**, as reported in the table below.

Table 4-11 - Criteria as the basis for proactive and reactive approaches in market surveillance[66]

Proactive approach	*Reactive approach*
• Risk assessment to determine product/ sectoral priorities of market surveillance (14) • Planned monitoring campaigns (8)[67] • Sectoral market surveillance programmes and specific strategies (5) • Monitoring of complaints from consumers/ users, economic operators and public organisations (4) • Monitoring of RAPEX and ICSMS (3) • Experience gained from previous market surveillance activities (3) • Legislative changes (3) • Results of laboratory tests from previous years (2) • EU market surveillance campaigns (2) • Market research (1)	• Notifications received via RAPEX and ICSMS (19) • Customs' checks or notifications (11) • Complaints received from consumers/users, economic operators and public organisations (9) • Accident reports (8) • Media news (6) • Notifications from other national or international authorities (3) • Reports from competing enterprises, from consumers' associations (2) • Knowledge gained from coordination meetings (1) • Requests for investigation of suspect or hazardous non-compliant products (1)

Source: National programmes

In particular, as provided by Article 19(1),[68] **risk assessment** is at the core of proactive surveillance in several Member States.[69] In light of the lack of resources, risk assessment helps MSAs to prioritise sectors and control initiatives. Some Member States, for instance, carry out regular surveillance activities on mass products or on products targeting sensitive classes of consumers. Consequently, sectors such as toys, plant protection products and electrical appliances are given a high priority due to the significant number of consumers/users involved and their vulnerability (children or untrained users).

5.2.2.2 MSAs' powers of inspection

According to Article 19(1) of Regulation (EC) No 765/2008, MSAs shall "*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*".

In general, all Member States have the power to perform:

66 The numbers in brackets represent the number of MS expressly citing the criterion – in their national programmes - as a basis for proactive or reactive surveillance.

67 Market surveillance campaigns are also tools for implementing proactive market surveillance. These campaigns can be conducted at the national level or jointly with other MS Joint market surveillance campaigns are strongly recommended as they improve the effectiveness of national efforts in the Single Market and can reduce costs. To encourage joint market surveillance campaigns, the EC offers financial support for actions that fulfil certain requirements and which are selected under the relevant grant procedures.

68 Stating that MSAs "*shall take account of established principles of risk assessment, complaints and other information*", when deciding to take enforcement measures.

69 AT, BE, DK, EE, IE, NL, PL, RO, SE, SI, SK, and UK.

- **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 necessary however to verify the conformity of the product, for example, regarding the correct application of the conformity assessment procedure, the compliance with the applicable essential requirements, and the contents of the EU declaration of conformity";[70]

- **Physical checks of the products**, aimed at verifying basic characteristics of the goods either *in situ* or at commercial, industrial, and storage premises, workplaces or other premises where the products are in use;[71]

- **Inspections of business premises**;

- **Product testing** through laboratory examination, aimed at verifying product compliance with basic health and safety requirements.

However, there are **other powers of inspection** that are attributed differently to national MSAs (and across sectors within the same Member State) as they are based on different national legislative frameworks.

- *Carry out sector inquiries*: based on the information available, this power is granted in most Member States and in the majority of sectors. Irish MSAs are granted this power for the lowest number of sectors (i.e. only in five: medical devices, cosmetics, measuring instruments, electrical and electronic equipment under RoHS and WEEE and batteries, and chemicals). In eight Member States,[72] this power is granted in all sectors (see also Table 4-35 in Annex).

- *Do mystery shopping:* this is the least common power among MSAs and across sectors, since it is only available to 10 of the MSAs and on average is granted in seven sectors in just 11 Member States. The Member States granting it most are the Czech Republic (in 30 sectors), Latvia, Slovenia (in 26 sectors each), and Finland (in 25 sectors). The personal protective equipment sector has the highest coverage by Member States, although only 11 of them grant this power in the sector (see also Table 4-36 in Annex).

- *Request information/cooperation by any possible natural or legal person:* based on the available data, this power is generally granted to half of the MSAs in more than 14 sectors. In particular, in the Czech Republic, Estonia, Poland and Romania it is granted in all sectors, while in Belgium, Lithuania, Luxembourg and Slovenia it is granted in almost all sectors (i.e. more than 30 sectors). In Ireland, this is applied in a limited way (only in five sectors), but there are no Member States where this power is not granted at all (see also Table 4-37 in Annex).

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70 COM(2016)1958 final. *The 'Blue Guide' on the implementation of EU product rules*. http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=7326

71 WELMEC (2007), Market Surveillance Guide. http://www.welmec.org/fileadmin/user_files/publications/WELMEC_5.2_Issue_2_final.pdf

72 CZ, EE, HR, LT, LU, PL, RO and SI.

- *Seize and detain products:* based on available information, this power is granted in 14 sectors in a significant number of Member States[73] and in five of them[74] it is available to MSAs in more than 30 sectors; in 12 Member States[75] it is granted in fewer than seven sectors. Personal protective equipment is the sector covered most, with 17 Member States granting this power. In Bulgaria and Ireland, it is not granted in 26 and 29 sectors, respectively (see also Table 4-38 in Annex).[76]

- *Seize documents:* the distribution of this power is similar to the previous one. Based on the information available, it is granted in 14 sectors in more than 12 Member States.[77] In the personal protective equipment and lifts sectors it is granted by the highest number of Member States (i.e. 16). In Bulgaria and Ireland, this power is granted in the lowest number of sectors, i.e. eight and five, respectively (see also Table 4-39 in Annex).[78]

- *Take samples for free:* based on available information, this power is granted in 14 sectors in more than 10 Member States. Those with the highest number of sectors in which MSAs can use it are Estonia, Germany, Poland and Slovenia (granting it in 32, 28, 32 and 29 sectors, respectively). The sectors covered most are toys, radio and telecom equipment, electrical appliances and equipment under LVD, chemicals and crystal glass, where this power is granted in 14 Member States (see also Table 4-40 in Annex).

- *Make use of test reports by MSAs in other EU countries:* as previously noted, the average number of Member States granting this power is 10. Ireland is the only Member State where this power is not granted in a particularly high number of sectors (i.e. 30 out of 33),[79] while MSAs in the Czech Republic, Estonia, Lithuania, Luxembourg and Slovenia can use it in more than 28 sectors. The sectors covered most are toys, machinery, measuring instruments, radio and telecom equipment under RTTE - RED, electrical appliances and equipment under LVD, with 14 Member States granting it (see also Table 4-41 in Annex).

Table 4-12 below presents an overview of the abovementioned powers of inspection granted to MSAs at the national level.

73 i.e. 14 MS: CY, CZ, DE, DK, EE, FI, HR, LU, LV, NL, PL, RO, SI and UK.
74 CZ, EE, LU, PL and RO.
75 AT, BG, EL, ES, FR, HU, IE, IT, LT, MT, PT and SK.
76 In particular, in Bulgaria this power is granted in sectors 2. Cosmetics, 10. Lifts, 17. Measuring instruments, 22. Chemicals, 29. Fertilisers, 31. Biocides. In Ireland, it is granted in sectors 1. Medical devices, 2. Cosmetics, 17. Measuring instruments, 22. Chemicals.
77 CY, CZ, DE, DK, EE, FI, HR, LU, NL, PL, RO, SE SI and UK.
78 In particular, in Bulgaria this power is granted in sectors 6. Aerosol dispensers, 10. Lifts, 11. Cableways, 17. Measuring instruments, 24. Tyre labelling, 30. Other consumer products under GPSD, 32. Textile and footwear labelling, 33. Crystal glass. In Ireland, it is granted in sectors 1. Medical devices, 2. Cosmetics, 17. Measuring instruments, 21. Electrical and electronic equipment under RoHS and WEEE and batteries, 22. Chemicals.
79 In particular, it is granted only in the medical devices, cosmetics and measuring instruments sectors.

Table 4-12 - MSAs' powers of inspection

Powers	*Number of MSAs having this power in more than 14 sectors*	*Number of sectors where this power is granted in a significant number of MS*[80]
Carry out sector inquiries	16	16 sectors (in more than 14 MS)
Do mystery shopping	10	7 sectors (in more than 11 MS)
Request information/ cooperation by any possible natural or legal person	14	15 sectors (in more than 13 MS)
Seize and detain products	14	14 sectors (in more than 12 MS)
Seize documents	13	14 sectors (in more than 12 MS)
Take samples for free	13	14 sectors (in more than 10 MS)
Make use of test reports by MSAs in other EU countries	12	14 sectors (in more than 10 MS)

Source: Targeted surveys

5.2.2.3 Customs and control of imported products

According to Article 27 of Regulation (EC) No 765/2008, external- border-control authorities controls Authorities are endowed with the following main tasks:

- Carrying out appropriate checks on the characteristics of products;
- Suspending the release of a product for free circulation in the internal market when the product: (a) displays characteristics which give cause to believe that the product, when properly installed, maintained and used, it 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; and (c) the CE marking has been affixed to the product in a false or misleading manner;
- Ensuring efficient cooperation and exchange of information among external- border-control authorities controls Authorities.

Although Customs are responsible for targeting shipments and carrying out physical checks of goods before they gain access to the national market, the final decision on the safety and compliance of products is to be taken by MSAs.

The case of **France** is particularly relevant as Customs are an MSA in their own right. Depending on the applicable legislation, French Customs may take samples of products, have them tested in a laboratory and decide, depending on the results, on the appropriate follow-up,

80 The reference list of sectors is that provided in Table 4-1.

thereby enhancing the overall efficiency of market surveillance procedures.[81] The coordination between French MSAs and French Customs is particularly relevant in light of the role played by the latter, as explained.

Based on the available data, all Customs except the Dutch Customs, have the power to **request businesses to provide information and exhibit documents** on products presented for release. Moreover, according to Articles 197 and 198 of Regulation 952/2013 (the Union Customs Code), Customs are **authorised to destroy products** in and **to recover from economic operators the costs borne to store/destroy products** in all Member States for which information is available. Finally, only six Customs authorities can recover the costs **of testing non-compliant products**.[82] As a potential consequence of this, the guarantees provided are not always sufficient to cover possible costs linked to market- surveillance checks.[83]

Table 4-13 - Customs' powers[84]

MS	*Request business to provide info and exhibit documents on products presented for release for free circulation*	*Recover costs to test products found to be non-compliant*	*Destroy products*	*Recover costs borne to store or destroy products*
AT	√		√	√
BE	√		√	n.a.
BG	√	n.a.	√	√
CY	√		√	√
CZ	√		√	√
DE	√[85]		√[86]	√
DK	√[87]		n.a.	n.a.
EE	√	√	√	√
ES	√	n.a.	√	√
FI	√	√	√	√

81 Panteia and CESS (2014), Good Practice in Market Surveillance Activities related to Non-Food Consumer Products sold Online, Annexes, p. 39.

82 EE, FI, IT, MT, PL and SK.

83 This question received a very low share of responses (i.e. nine). More in detail, Customs in Finland, Latvia and Sweden state that guarantees are sufficient, Customs in Austria, Cyprus, France and Italy deem that they are insufficient, while Customs in Germany and Luxembourg declare that no guarantees exist.

84 A blank cell means Customs do not have the relevant power; 'n.a' means 'information is not available'. No information was available for: EL, IE, LT, SI and UK.

85 Only in cases where the declarant has a legal obligation.

86 Customs may decide to destroy goods where release for free circulation is not allowed by MSAs AND the goods are not placed under a Customs procedure other than free circulation or are re-exported. Customs supervise destruction of goods where it is carried out by the importer (on his own initiative or following a decision from the MSA).

87 Only when required by the MSAs.

MS	*Request business to provide info and exhibit documents on products presented for release for free circulation*	*Recover costs to test products found to be non-compliant*	*Destroy products*	*Recover costs borne to store or destroy products*
FR	√		√	√
HR	√		√	√
HU	√		√	√
IT	√	√	√	√
LU	√		√	√
LV	√		√	√
MT	√	√	√	√
NL			√	√
PL	√	√	√	√
PT	√	n.a.	√	√
RO	√		√	√
SE	√		√	√
SK	√	√	√	√

Source: Targeted surveys

As shown in Table 4-34 in Annex similarly to the situation for the MSAs, **half of Customs[88] do not have in-house testing laboratories**. Only Croatian Customs own in-house laboratories to test products in all sectors covered by the Regulation, followed by Estonian and French Customs, which respectively cover eight and seven sectors, respectively.

Table 4-14 - Availability of test laboratories for Customs authorities' across Member States[89]

MS	*Number of sectors where **Customs have** own test laboratories*	*Number of sectors where **Customs do not** have own test laboratories*
HR	33	0
EE	8	0

88 For which information was available: AT, BE, BG, CY, CZ, DE, DK, ES, LT, LU, LV, PL, RO and SE.

89 No information was available for EL, HU, IT, MT, SK, PT, RO, SI and UK. The number of sectors covered by the table may not add up to 33 due to data availability. The reference list of sectors is that provided in Table 4-1.

MS	*Number of sectors where **Customs have** own test laboratories*	*Number of sectors where **Customs do not** have own test laboratories*
FR	7	22
FI	2	31
NL	1	32
AT	0	33
BE	0	33
BG	0	33
CY	0	33
CZ	0	33
DE	0	33
DK	0	33
ES	0	33
LT	0	33
LU	0	33
LV	0	33
PL	0	33
RO	0	33
SE	0	33

Source: Targeted surveys

If the sector dimension is taken in consideration, the available information indicates that test laboratories are not available in Customs in most Member States. In-house laboratories in the majority of sectors (i.e. 20) are only available in one Member State (Table 4-14).

Table 4-15 - Customs authorities' laboratories across sectors[90]

Sector	*Num. of MS where **Customs have** own test laboratories*	*Number of MS where Customs **do not** have own test laboratories*	*Number of MS for which **no info** was available*
2.Cosmetics	4	15	9

90 The reference list of sectors is that provided in Table 4-1.

Sector	*Num. of MS where **Customs have** own test laboratories*	*Number of MS where Customs **do not** have own test laboratories*	*Number of MS for which **no info** was available*
3.Toys	4	15	9
32.Textile and footwear labelling	3	16	9
4.PPE	2	16	10
5.Construction products	2	16	10
9.Machinery	2	16	10
19.Radio and telecom equipment under R&TTE - RED	2	17	9
20.Electrical appliances and equipment under LVD	2	16	10
21.Electrical and electronic equipment under RoHS and WEEE and batteries	2	16	10
22.Chemicals	2	16	10
29.Fertilisers	2	16	10
30.Other consumer products under GPSD	2	16	10
31.Biocides	2	16	10
1.Medical devices	1	17	10
6.Aerosol dispensers	1	17	10
7.Simple pressure vessels and pressure equipment	1	17	10
8.Transportable pressure equipment	1	17	10
10.Lifts	1	17	10
11.Cableways	1	17	10
12.Noise emissions for outdoor equipment	1	17	10
13.Equipment and protective systems intended for use in potentially explosive atmospheres	1	17	10
14.Pyrotechnics	1	17	10
15.Explosives for civil uses	1	17	10

Sector	*Num. of MS where **Customs have** own test laboratories*	*Number of MS where Customs **do not** have own test laboratories*	*Number of MS for which **no info** was available*
16. Appliances burning gaseous fuels	1	17	10
17.Measuring instruments	1	17	10
18.Electrical equipment under EMC	1	17	10
23.Eco-design and energy labelling	1	17	10
24.Tyre labelling	1	17	10
25.Recreational craft	1	17	10
26.Marine equipment	1	17	10
27.Motor vehicles and tractors	1	17	10
28.Non-road mobile machinery	1	17	10
33.Crystal glass	1	17	10

Source: Targeted surveys

5.2.3 Coordination and cooperation mechanisms

Member States are requested to establish coordination mechanisms between their MSAs (Article 18(1)), and cooperation mechanisms with authorities from other Member States (Article 24) and third countries (Article 26).

As for coordination between national MSAs, **most Member States have a permanent, ad-hoc body** responsible for cooperation and coordination between national MSAs.[91] The coordination body's members are usually **MSA representatives**.[92] Overall, there are **no uniform working practices, and the frequency of meetings** also varies substantially. For instance, in Austria, Cyprus and Lithuania, coordination councils usually meet twice a year, in Denmark three times a year, and in the Netherlands and Sweden five times a year. The Spanish Market Surveillance Committee convenes every 40 to 60 days, while in Poland meetings are held at least once a year. Member States report that coordination bodies are **mainly responsible for**:

- Ensuring and strengthening coordination and cooperation among different MSAs, with Customs Authorities and other national authorities responsible for border controls;[93]
- Ensuring the exchange of information between relevant institutions;[94]

91 AT, BG, CY, DE, DK, EE, EL, FI, FR, HR, IE, IT, LU, LV, NL, PL, RO, SE, SI, and UK. HU and LT did not report on the existence of any permanent body to ensure coordination between MSAs. Where this is not the case (i.e. BE, CZ, ES, SK), there exist different coordinating bodies/working groups or ad-hoc bilateral agreements to enhance cooperation, further discussed below.

92 DE, EE, HR, IE, LU, NL, PL, RO and SE. The remaining MS did not provide any information.

93 AT, DE, DK, EE, HR, LV, and PL.

- Setting market surveillance priorities and strategic objectives, and discussing proposals for improving market surveillance;[95]

- Promoting the establishment of a common approach to market surveillance (e.g. by planning coordinated actions among different inspection bodies, organising exchanges of experience and best practice, and incentivising debate among MSAs);[96]

- Monitoring conformity assessment procedures and planning inspections.[97]

In some Member States, coordination bodies fulfil additional tasks. More specifically, the Austrian coordination body **gathers information** from businesses and consumers about their market surveillance priorities. In Latvia, it focuses on ensuring a clear **division of competences** among MSAs to prevent duplication of activities. Finally, the Polish coordination body **reports on the findings of inspections and maintains public registers** of non-compliant products.

Besides more structured forms of coordination, there are several additional mechanisms at the national level which have the same purpose, such as:

- Ad-hoc bilateral agreements;[98]

- Fora for deeper cooperation and/or dialogue;[99]

- Working groups for the direct exchange of information and experience;[100]

- Regular contacts to coordinate market surveillance activities;[101]

- Joint actions on specific product categories.[102]

Within the same Member State, **almost all MSAs cooperate with Customs** on an ad-hoc basis, through regular dialogue or joint surveillance actions.[103] A few Member States have

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94 DE, EE, LV, PL, and SE.
95 DK, EE, FI, LU, NL, and SE.
96 AT, DK, EE LV, NL, PL, SE, and SI.
97 FI, PL, and SI.
98 BE, CZ, EE, RO, and SK.
99 Fora appear to be a good working tool especially for the UK, where different ones exist, such as: the sub-group of the Market Surveillance Co-ordination Committee (MSCC), which focuses on border controls; the Product Safety Focus Group, acting as the contact point between local authorities, regions, central government and other stakeholders; and the National Trading Standards Board (NTSB), which involves a group of experienced local government heads of trading standards.
100 CZ, EE, FI, SE, SI, SK, and UK. Estonia, for instance, set up an expert working group for borderline products under the Health Board, while Sweden established the permanent 'Forum for Customs-Related Issues'. Finland set up the 'Mativa Network', which meets twice a year and focuses specifically on cooperation related to RAPEX and ICSMS systems. In the UK, the HSE (Health and Safety Executive) Product Safety Team is responsible for enforcing the legislation on workplace goods.
101 BE, NL and SE report that some departments hold regular meetings on surveillance of some product categories. In CY and SI, MSAs frequently exchange communications on daily matters by phone, official letters or electronically. EL created a specific integrated information system presenting multiple information such as names and data of the registered test laboratories, registered products and names of inspectors, annual budgets for inspections allocated by national legislation, risk assessments and planning of costs.
102 BG, CZ, EL, ES, HU, LT, NL and SI.
103 A regular dialogue between Customs and MSAs in Greece is ensured through the exchange of information sheets providing information on product compliance and provide guidance for releasing/suspending products for/from free circulation. Also, the Consumer Protection and Health Board exchanges information on an ongoing basis, and difficulties encountered during inspections are discussed in annual meetings between MSAs and Customs. Information exchange is based on risk analysis to provide an expert assessment of products for Customs' inspection. Similarly, the German MSAs create product-risk profiles in collaboration with

opted to **establish a permanent body** dedicated to cooperation with Customs.[104] Other Member States have introduced **bilateral cooperative agreements**.[105] In some cases, there is cooperation between MSAs and Customs through **regular participation in working groups** at both national and EU levels.[106] Notably, to ensure a close link between all the authorities involved, cooperation mechanisms have been established between French Customs and MSAs. These can be used during inspections carried out by Customs in order to access information collected on the market by MSAs, and vice versa. Moreover, a cooperation protocol exists between Customs and the national MSA (DGCCRF, Directorate-General for Competition, Consumer Affairs and the Combating of Fraud). This protocol specifies the frequency of meetings between the two authorities during which annual control plans are developed. More importantly, the protocol clearly establishes geographical and sectoral competences. By knowing who to address for which purposes, the regional, local and central units of both Customs and the DGCCRF can quickly approach the relevant unit, making the market surveillance activities quicker and more responsive.

As for cooperation with other countries (pursuant to Articles 24 and 26), the majority of Member States[107] engage in some form of **cooperation with other EU countries**, notably by means of joint actions, i.e. specific market surveillance projects carried out simultaneously between MSAs in different countries. However, joint actions co-funded by the EU de facto require external support for the coordination of the MSAs involved and management of the budget. Only a few[108] Member States participate in **cooperation initiatives on market surveillance involving third countries**, although cross-country communication and cooperation is considered useful by nearly all public authorities (PAs).[109]

AdCO groups (Administrative Cooperation Groups) are a relevant example of cross-country coordination mechanisms. They are supported by the EC and involve MSA representatives in

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Customs in order to help the latter to decide on whether to defer the placing of a product on the market and to inform the MSAs. In both Poland and Romania, MSAs support Customs through training courses. An interesting form of cooperation has been set up in Poland since 2011, whereby all Customs appoint product safety coordinators, who are responsible for monitoring the correct and uniform application of market surveillance regulations and cooperation with MSAs to improve the effectiveness of joint actions. Furthermore, Polish Customs usually cooperate with MSAs in the drafting of position papers on new EU legislative proposals. Information on the type of cooperation with Customs was not available for FR, HU, LU, LV and PT.

104 This is the case in Belgium, where an ad-hoc unit, made up of representatives from MSAs and the General Administration of Customs and Excise (AGDA), meets several times a year to discuss potential improvements to market surveillance. For instance, improvements such as checklists to assist Customs' monitoring and a table breaking down the responsibilities among MSAs have resulted from these meetings. Similarly, the UK has established an Intelligence Hub, which acts as a single point of contact for the liaison between all MSAs, Her Majesty's Revenue and Customs (HMRC) and the Border Force for the border controls of unsafe and/or non-compliant products entering the country. The National Clearance Hub, which is responsible for the Customs clearance of products entering the UK, also acts as a single point of contact for importers and other enforcement agencies for freight clearance queries. In Sweden, the Market Surveillance Council also involves the National Board of Trade and the Customs authorities.

105 DK, EL, ES, FR, NL, MT, RO, SI, and SK. For instance, cooperation agreements between Customs and MSAs are implemented systematically in Spain. The Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) is usually engaged in activities relating to the promotion of consumer and user rights regarding goods and services. However, it acts as an MSA and undertakes actions only in cases where Customs authorities request support on the basis of Articles 27 to 29 of the Regulation. Interestingly, there is also another control body, i.e. the Official Service Inspection, Supervision and Regulation of Exports – SOIVRE, operating in Spain. This body is in charge of monitoring a series of products (e.g. through documentary checks, inspections and testing) before they reach Customs' offices. Specific product categories (i.e. toys, textiles, shoes, some personal protective equipment, some electrical products and wood products and their derivatives) must receive formal approval (in the form of a safety certificate) from SOIVRE before Customs can let them entering the country.

106 In particular, in Poland and Sweden, Customs participate jointly with MSAs in the EC Expert Working Group on product safety and compliance checks for imported goods. Furthermore, Sweden has set up a permanent working group for cooperation, the 'Forum for Customs-Related Issues'. This Forum is convened twice a year and is open to all authorities in the Market Surveillance Council, the Swedish coordination body comprising the 16 national MSAs. It has the task of drawing up the national market surveillance plan and promoting cooperation and efficiency in market surveillance activities.

107 AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, IE, IT, LT, LV, MT, NL, PL, PT, RO, SI, and UK.

108 AT, CZ, EE, EL, ES, FI, RO, and UK.

109 i.e. by 56 out of 77 public authorities responding to the question.

a given sector. AdCOs meet regularly to discuss issues in their area of competence and to ensure efficient, comprehensive and consistent market surveillance.[110] Thus, they enable flexible and efficient cooperation between Member States.[111] They are the most frequently used mechanism for market surveillance cooperation related to product categories subject to Union harmonisation legislation.[112]

RAPEX and ICSMS are key tools provided by the Regulation to allow for cross-border exchange of information and possible collaboration between MSAs. According to what was stated in national programmes, **all Member States make use of RAPEX** and **most of them utilise ICSMS**, in accordance with Articles 22 and 23, respectively.

As regards **existing databases for monitoring accidents related to products**, only Bulgaria, Greece, Hungary and Liechtenstein seem to have no national databases to collect data on injuries.[113] The EU Injury Database systems are the most widespread mechanisms for gathering injury information across Europe, as they are available in 16 EU Member States[114] plus Iceland and Norway.

5.2.4 Measures on non-compliant products

5.2.4.1 Restrictive measures

As shown in the table below, which is based on RAPEX data, **the most frequently imposed restrictive measures are withdrawal, recall and ban.** The data show that the use of restrictive measures has grown over the two periods by an impressive 52%. Interestingly, the most significant increases have been registered in the most 'coercive' measures (i.e. seizure, withdrawal, destruction). The use of other measures, such as requests for information or corrective actions, has actually declined.

Table 4-16 - Average number of RAPEX notifications on measures undertaken by Public Authorities (PAs) over 2005-2009 and over 2010-2015

Measure	*'05-'09*	*'10-'15*	*Average Δ%*	Total
Recall	184.4	288	56%	2,648
Withdrawal	428.2	803	88%	6,959
Destruction	11.8	18	55%	169
Ban	242	236	-2%	2,627
Seizure	10	27	167%	210

110 http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups/index_en.htm
111 Four MSAs (DE, FI, 2 SE), the German coordinating authority.
112 COM(2013) 76 final. Product Safety and Market Surveillance Package - Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee. 20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU.
113 No information was reported in national programmes, therefore source for this data is DG JUST (2015). Draft - *Mapping injury and accident databases for market surveillance of products in the EU – Survey Results*.
114 AT, CY, DK, EE, FI, IE, IT, LT, LV, LU, MT, NL, PT, RO, SE, and UK.

Corrective actions	21.2	16	-27%	199
Information	16	2	-91%	89
Total	**913.6**	**1,389**	**52%**	**12,901**

Source: Authors' elaboration on RAPEX database

The national reports do not appear to confirm the data from RAPEX, since overall **MSA restrictive measures** showed a slight fall, averaging -0.33% over the period 2010-2013, although such measures increased in R&T under R&TTe and in the toy sector. However, as noted, data from national reports demonstrated a number of limitations in terms of sectoral and geographical coverage, and covered a smaller time frame when compared to RAPEX. In this case, the low number of both sectors (3) and Member States (19) covered might explain this trend.

Table 4-17 – Number of MSA restrictive measures in three sectors[115]

Sector	*2010*	*2011*	*2012*	*2013*	*Average Δ%*
Electrical appliances under LVD	344	117	82	70	-20%
R&T under R&TTE	877	769	784	952	2%
Toys	1,277	1,433	1,430	1,450	3%
Total	**2,498**	**2,319**	**2,296**	**2,472**	**-0.3%**

Source: Authors' elaboration on national reports

As for **measures undertaken by economic operators**, on average, measures increased between the two periods. From 2005-2009 to 2010-2015, the most significant increase (by nearly 124%) was registered in the average number of notifications relating to product destructions.

Table 4-18 - Average number of RAPEX notifications on measures undertaken by economic operators over 2005-2009 and over 2010-2015

Measure	*'05-'09*	*'10-'15*	*Average Δ%*	Total
Recall	225.8	334.7	48.2%	**3,137**
Withdrawal	334	332.7	-0.4%	**3,666**
Destruction	15.8	35.3	123.6%	**291**

115 Data for 19 MS: AT, BG, CY, CZ, DK, EE, EL, FI, FR, HU, IE, LU, LV, PL, PT, RO, SE, SI and SK.

Measure	*'05-'09*	*'10-'15*	*Average Δ%*	Total
Ban	10.8	15.8	46.6%	**149**
Information	28.8	3.3	-88.4%	**164**
Total	**615.2**	**721.8**	**17.3%**	**7,407**

Source: Authors' elaboration on RAPEX database

Data from national reports partly confirm data from RAPEX. **Indeed, corrective actions taken by economic operators increased slightly** over time, showing a +4% rise at the end of the period. They also grew in the toy sector, but fell in radio and telecommunications equipment under R&TTe.

Table 4-19 - Corrective actions taken by economic operators[116]

Indicator/sector	*2010*	*2011*	*2012*	*2013*	*Average Δ%*
Measuring instruments	415	557	463	515	6%
R&T under R&TTE	734	790	689	588	-5%
Toys	1,116	1,474	1,902	1,517	9%
Total	**2,264**	**2,821**	**3,054**	**2,620**	**4%**

Source: Authors' elaboration on national reports

Table 4-20 presents an overview of the **measures undertaken by both economic operators and PAs per category of product**, comparing the periods 2006-2009 and 2010-2015. If single product categories are considered, the number of notified measures has diminished over time for the majority of these (e.g. notifications of withdrawals diminished for 17 product categories from 2006-2009 to 2010-2015). However, if measures are considered across sectors, the number of notifications always increased over the period, with the exception of 'other' measures. The following sectors were particularly the subject of restrictive measures: chemicals, clothing, textiles and fashion items, communication and media equipment, construction products, jewellery, laser pointers, motor vehicles, pressure equipment/vessels, protective equipment, pyrotechnic articles. For instance, **construction products** and **jewellery** were particularly subjected to higher levels of withdrawals, with increases of 3,167% and of 389%, respectively, from one period to the other. Similarly, notifications of bans related in particular to the **protective equipment** sector showed an increase of 1,167% from 2006-2009 to 2010-2015. **Overall, the number of notified measures rose by 20% only falling in the toy sector**.

From this analysis, it can be concluded that **product non-compliance increased consistently from 2006-2009 to 2010-2015**. Nonetheless, as previously mentioned, these data could be

116 Data for 20 MS: AT, BE, BG, CY, DK, EE, EL, FI, FR, HU, IE, IT, LU, LV, MT, PL, RO, SE, SI and SK.

interpreted in two opposing ways, inasmuch as an increase in RAPEX notifications may also imply that MSAs have become more effective in finding – and thus correcting – non-compliance.

Table 4-20 - Annual average number, total number and percentage increase of notified measures taken by both PAs and economic operators per product category

	Withdrawal				*Ban*				*Recall*				*Other*[117]				*Total*			
	06-09	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*
Chemical products	19	30	257	63	6	13	100	111	5	6	59	14	6	8	71	42	36	57	487	60
Childcare articles and equipment	53	32	405	-38	18	12	143	-33	29	23	255	-22	12	6	84	-52	112	73	887	-35
Clothing, textiles and fashion items	106	400	2,825	278	17	57	409	225	46	150	1,083	225	12	22	180	80	181	629	4,497	246
Comm. and media equip.	2	7	54	225	0	1	9	439	5	9	76	71	1	2	17	24	9	20	156	111
Construction products	0	7	41	3167	0	1	4	100	-	6	35	n/a	0	1	9	439	1	14	89	1945
Cosmetics	47	44	452	-8	18	13	153	-28	15	10	122	-33	6	14	109	123	87	81	836	-7
Decorative articles	12	12	119	0	2	3	27	14	9	4	64	-54	1	5	33	574	25	24	243	-2
Electrical appliances and equipment	109	101	1,040	-8	34	27	299	-22	77	71	735	-8	13	9	105	-33	234	207	2,179	-11
Food-imitating	23	16	187	-33	6	5	56	-19	7	5	59	-31	3	2	24	-8	39	28	326	-29

117 Other measures include notifications of: imports rejected, information and appropriate warnings, corrective actions, suspension of sales, seizure and confiscation, fines and destruction. Please consider that these data were not homogenous across the years.

	Withdrawal				*Ban*				*Recall*				*Other*[117]				*Total*			
	06-09	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*
products																				
Furniture	9	7	78	-25	3	3	28	19	6	6	60	-12	2	0	8	-78	20	16	174	-19
Gadgets	3	2	21	-38	1	1	6	-33	2	0	9	-81	1	1	8	-33	6	3	44	-49
Gas appliances & components	6	3	43	-41	5	3	36	-41	4	5	45	19	2	0	10	-83	17	11	134	-31
Hand tools	2	1	12	-78	1	0	3	-67	1	-	3	-100	1	0	6	-86	5	1	24	-82
Hobby/sports equipment	16	16	164	0	6	7	65	29	16	12	138	-22	4	2	29	-59	42	38	396	-11
Jewellery	5	23	159	389	1	2	15	167	1	3	22	204	0	1	9	136	7	29	205	321
Kitchen/ cooking accessories	8	6	65	-31	2	3	26	80	3	4	35	48	1	1	8	-33	13	13	134	0
Laser pointers	8	11	98	48	1	2	17	389	1	3	22	204	4	4	42	0	13	21	179	58
Lighters	19	16	174	-15	8	4	55	-45	7	2	39	-70	4	2	28	-57	38	24	296	-36
Lighting chains	19	19	193	0	7	7	68	-4	14	11	122	-19	1	2	16	48	41	39	399	-5
Lighting equipment	59	42	488	-28	21	5	113	-75	43	34	373	-22	4	2	25	-48	126	83	999	-34
Machinery	17	11	132	-36	6	2	36	-74	13	9	105	-33	5	2	30	-71	42	23	303	-46
Motor vehicles	11	3	60	-75	5	0	21	-89	11	118	755	944	105	31	606	-70	131	153	1442	16
Other	7	27	189	278	1	5	35	574	5	12	94	123	2	4	29	151	15	48	347	224

	Withdrawal				*Ban*				*Recall*				*Other*[117]				*Total*			
	06-09	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*
Protective equipment	9	16	130	71	0	3	19	1167	6	10	83	71	2	2	18	4	17	30	250	80
Pyrotechnic articles	-	14	84	-	0	1	6	-	0	0	2	-33	-	-	-	-	1	15	92	2870
Recreational crafts	1	-	5	-100	0	-	1	-100	1	2	14	63	4	0	18	-96	7	2	38	-73
Stationery	7	2	37	-75	1	-	4	-100	3	0	14	-95	1	0	4	-78	12	2	59	-83
Toys	290	267	2,758	-8	82	72	762	-12	131	107	1,164	-19	36	40	384	9	539	485	5,068	-10
Total	867	1,134	10,273	31	251	252	2,516	0	463	623	5,590	34	234	162	1,910	-31	1,815	2,172	20,289	20

Source: Authors' elaboration on RAPEX database

5.2.4.2 MSAs' powers of sanction

According to Article 41 of Regulation (EC) No 765/2008, "*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 […].*"

Penalties are imposed on economic operators by MSAs or by a court and **should act as powerful deterrents for non-compliance**. They may be either administrative or criminal, depending on the seriousness of the offence. **Administrative sanctions** are imposed in cases of infringements of administrative law and include both restrictive measures and monetary sanctions. **Criminal sanctions**, such as imprisonment, are usually imposed in cases of serious infringements and by means of a judicial procedure. As provided for by Article 41 of the Regulation, **all Member States foresee the use of penalties for product non-compliance**.[118] More specifically, they all apply administrative sanctions for non-compliance, while 24[119] recur to criminal law for the enforcement of market surveillance in non-food product sectors. In case of serious infringements, **imprisonment is envisaged** in 21 Member States.[120]

The following table presents a synthesis of penalty mapping set at the national level for product non-compliance. The complete overview is presented in the Annex.

Table 4-21 - Types of penalties and Member States where these are applied

Penalty	*Administrative*	*Criminal*
Definition	Administrative penalties are imposed in cases of infringements of administrative law; they include both restrictive measures and fines	Criminal penalties can be imposed in cases of serious infringements by means of a judicial procedure
Member States	28	24
	All EU MS	AT, BE, BG, CY, CZ, DE, DK, EE, FI, FR, HR, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SI, SK, UK

Sources: National programmes and reports, EC-SOGS N620[121]

As the result of the mapping provided in the Annex, **the level of penalties differs across Member States and sectors.** As for the **administrative sanctions**, for instance, fines for breaching the national legislation on medical devices may vary from €30 to €1,500 in Lithuania and reach €1,802,776 in the Czech Republic. In the toy sector, fines in Romania and Sweden range respectively from €330 to €2,200 and from €500 to €500,000. As for

118 According to the Blue Guide: "*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: (a) take any action to bring the product into compliance with the applicable requirements laid down in the Union harmonisation legislation; and/or (b) withdraw the product; and/or (c) recall the product; and/or (d) 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*".

119 AT, BE, BG, CY, CZ, DE, DK, EE, FI, FR, HR, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SI, SK and UK.

120 AT, BE, BG, CY, CZ, DE, DK, EE, FI, FR, HR, IE, IT, LT, LU, MT, NL, PL, SE, SI, UK.

121 http://ec.europa.eu/DocsRoom/documents/6266/attachments/1/translations

construction products, there is no maximum level for monetary sanctions in the Netherlands, while every year Sweden establishes a fixed amount to be paid in case of non-compliance. Infringements regarding measuring instruments are fined up to €50,000 in Germany, €24,000 in Poland and €7,500 in Bulgaria. The variance is particularly high even for **criminal sanctions**. When looking at the medical device sector, Bulgaria does not foresee any criminal prosecutions for non-compliance, Denmark only sets criminal fines, while imprisonment is set from a six-month period in Ireland to up to four years in Cyprus. It is not possible to be imprisoned for breaching the legislation on toy safety in Croatia, although criminal monetary sanctions are available, while Estonia foresees a maximum period of three years in detention. For non-compliance in the measuring instruments sector, imprisonment is not foreseen in Bulgaria, but is in Malta and the UK.

According to data available from the national reports, **application of sanctions and penalties experienced a positive trend,** rising by 34% from 2010 to 2013. This variation was related in particular to an increase in measures taken in the radio and telecommunications equipment under R&TTe and in the toy sector.

Table 4-22 - Applications of sanctions/penalties in three sectors covered by the Regulation[122]

	2010	*2011*	*2012*	*2013*	*Δ%*
Measuring instruments	436	454	415	329	-25%
R&T under R&TTE	163	315	324	328	101%
Toys	1,900	1,814	2,580	2,692	42%
Total	**2,499**	**2,583**	**3,319**	**3,349**	**34%**

Source: Authors' elaboration on national reports

Similarly, **the criteria for setting the amounts of penalties differ** from one Member State to another (e.g. dangers to health and safety in France and Croatia, the seriousness of the offence in Finland and the Netherlands, the Court's decision in the UK).[123]

Furthermore, as shown in Table 4-23, in some countries MSAs have specific **sanctioning powers**. In particular they may:

- *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. In Estonia, Romania and Slovenia this power is more diffused, being granted in almost all sectors, except for biocides in Slovenia (see also Table 4-42 in Annex).

- *Impose administrative economic sanctions (without resorting to national courts):* this power is granted in all sectors by five Member States,[124] while Ireland is the country where MSAs have this power in fewer sectors. Indeed, Irish MSAs can impose

122 Data for 19 MS: AT, BG, CY, CZ, DK, EE, EL, FI, FR, HU, IE, LU, LV, PL, PT, RO, SE, SI and SK.
123 Targeted surveys.
124 CZ, EE, LT, RO, SI.

sanctions without resorting to the courts in only two sectors: medical devices and electrical and electronic equipment under RoHS and WEEE and batteries. The sectors covered most are aerosol dispensers and electrical and electronic equipment under RoHS and WEEE and batteries, where this power is available to 15 MSAs (see also

- Table 4-43 in Annex).

- *Impose compensation for consumers/users of non-compliant products:* this power is not particularly widespread, since only Slovenia grants it in all sectors.[125]Electrical appliances and equipment under LVD is the most-covered sector, although in only six Member States (see also Table 4-44 in Annex).[126]

- *Impose provisional measures pending investigations:* this power is available in more than 30 sectors in five Member States,[127] while in Ireland it is granted in only four sectors[128] and Romania does not grant it at all. In five sectors[129] it is granted by 15 Member States, which is the highest coverage for this power (see also Table 4-45 in Annex).

- *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. The sectors covered most are toys, personal protective equipment, machinery, noise emissions for outdoor equipment, and electrical appliances and equipment under LVD. In Estonia and Slovenia, it is granted in all sectors (see also Table 4-46 in Annex).

- *Recover from economic operators the costs borne to test products found to be non-compliant:*[130] a large number of MSAs for which information could be gathered can make use of this power in the majority of sectors.[131] In 13 Member States this power is granted in more than half of all sectors. Toys, personal protective equipment, simple pressure vessels, machinery and lifts are the sectors covered most, with 16 Member States making this power available to MSAs (see also Table 4-47 in Annex).

- *Sanction economic operators which do not cooperate:* this is the **most common power of sanction** among MSAs, as 15 Member States grant it to MSAs in more than 14

125 In Slovenia, MSAs have the powers to impose compensation for consumers, established in the Consumer protection law in Article 37(c) (OJ RS No. 98/04, 114/06 – ZUE, 126/07, 86/09, 78/11, 38/14 and 19/15). The compensation is imposed on a case-by-case basis. In many cases, MSAs recur to court experts to assess and justify the amount to be refunded by the economic operator.

126 DE, ES, FI, PL, SE and SI.

127 BG, CZ, EE, LT, SI.

128 Medical devices, cosmetics, measuring instruments, electrical and electronic equipment under RoHS and WEEE and batteries.

129 Medical devices, toys, personal protective equipment, measuring instruments, electrical and electronic equipment under LVD.

130 For instance, in the UK the legislation allows MSAs to recover from economic operators the 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 charges 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.

131 For instance, in Croatia, on the basis of the national Law on Administrative Procedure, MSAs can require by administrative decision that economic operators pay for testing costs only where these products were found to be non-compliant. In Slovenia, MSAs have the powers to request economic operators to pay for test costs according to Art. 17 of the Act on technical requirements for products and the conformity assessment (OJ RS, No. 17/2011) (1) stating that MSAs may take product samples for free in order to carry out checks and tests necessary to assess conformity. If the product is not in conformity, the costs incurred shall be borne by the economic operator. The cost recovery is imposed on case-by-case basis. In many cases, MSAs recur to court experts to assess and justify the amount to be paid by the economic operator.

sectors. Six Member States apply it in more than 30 sectors[132] and the most-covered sector is toys, with 18 Member States making it available to MSAs (see also Table 4-48 in Annex).

- *Shut down websites:* this is **the least-adopted sanction**, both across sectors and among Member States. In fact, based on the available information, only Latvian MSAs have this power in more than 14 sectors (see also Table 4-49 in Annex).

- *Remove or require to remove illegal content from a website:* only eight Member States confer MSAs with the power to remove illegal content from websites in more than 14 sectors.[133] Furthermore, only 11 sectors out of 33 are in some way covered by this power across the EU. Toys and electrical appliances and equipment under LVD are the most covered sectors, with 10 Member States granting this power.

Table 4-23 below presents an overview of the abovementioned powers of inspection.

Table 4-23 - MSAs' powers of sanction

Powers	*Number of MSAs having this power in more than 14 sectors*	*Number of sectors where this power is granted in a significant number of MS*
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	1	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 the costs borne to test products found to be non-compliant	13	16 sectors (in more than 12 MS)
Sanction economic operators which do not cooperate	15	15 sectors (in more than 13 MS)
Shut down websites	1	7 sectors (in more than 1 MS)
Remove or require to remove illegal content from a website	8	11 sectors (in more than 7 MS)

Source: Targeted surveys

132 BG, CZ, EE, LU, RO and SI.
133 BG, CZ, FI, LU, LV, NL, SI and UK.

Additional differences in the penalty framework also depend on the **procedure to impose economic sanctions.**[134]

First, based on the available data, **not all MSAs can impose administrative fines without resorting to the courts** (for instance in Malta, Ireland and Finland). In Austria, an administrative court intervenes in cases where the non-compliant economic operator disagrees with the sanction imposed by the MSA and appeals against it. In Malta and Finland, MSAs can only impose restrictive measures and cannot recur to administrative monetary sanctions given that only the court has the power to impose fines. Please refer to case study 5 in Annex for more information.

Secondly, the conformity assessment procedures, the evaluation procedures preceding the imposition of sanctions, and the administrative process often require a considerable amount of work and resources.[135]

Thirdly, **the amount of effort and the resources necessary to impose sanctions may not always be coherent with the monetary value of the fines imposed**.[136]

5.3 Figures on non-compliance

As already noted, RAPEX is used to notify products that pose serious risks to consumer health.[137] In an attempt to identify any differences in the number of notifications before and after the Regulation came into force, where relevant, data have been divided into two time frames, 2006-2009 and 2010-2015, respectively. The table below presents **the average number of RAPEX notifications per category of products, per year,** divided into two periods, i.e. 2006-2009 and 2010-2015, where 2010 marks the year of the Regulation's entry into force.

Table 4-24 - Annual average of RAPEX notifications by product category for the periods 2006-2009 and 2010-2015

Product category	*2006-2009*	*2010-2015*	*Average Δ%*
Chemical products	24.5	49.83	103%
Childcare articles and children's equipment	72	62.17	-14%
Clothing, textiles and fashion items	154.5	512.67	232%
Communication and media equipment	7.25	13.50	86%
Construction products	0.75	9.33	1,144%
Cosmetics	66.75	75.83	14%
Decorative articles	18.5	15.17	-18%

134 37% of MSAs report that this procedure is burdensome to a large extent, 34% to a small extent, while 29% of them do not consider it as burdensome.
135 Three MSAs (2 CY, SE), one AdCO member (medical devices).
136 As underlined by a Finnish MSA.
137 Since 2005, only products posing serious risks have been notified. Since 2013, both PAs and economic operators started to report information about actions undertaken against products presenting a lower level of risk. In 2015, these notifications still represented a very small percentage (6%) of total notifications.

Electrical appliances and equipment	158.5	181.33	14%
Food-imitating products	30.25	22.33	-26%
Furniture	12.5	13.00	4%
Gadgets	4.25	2.00	-53%
Gas appliances and components	9.5	8.33	-12%
Hand tools	3.5	0.83	-76%
Hobby/sports equipment	29.75	32.67	10%
Jewellery	6.5	32.67	403%
Kitchen/cooking accessories	10.25	10.17	-1%
Laser pointers	9.25	16.67	80%
Lighters	27	23.17	-14%
Lighting chains	31.75	31.83	0%
Lighting equipment	77	56.50	-27%
Machinery	22.5	20.17	-10%
Motor vehicles	154.75	183.17	18%
Other	10.75	41.83	289%
PPEPPE	13.25	32.17	143%
Pyrotechnic articles	0.5	14.83	2,866%
Recreational crafts	6.5	4.33	-33%
Stationery	7.5	2.17	-71%
Toys	393.75	458	16%
Total	**1,209.25**	**1,927.5**	**59%**

Source: Authors' elaboration on RAPEX database

Overall, these trends are consistent with those reflected in the national reports. As reported therein, MSAs' inspection activities resulting in a **finding of non-compliance registered a positive average annual growth** over the period 2010-2013 (13%), rising from 11,945 in 2010 to 18,316 in 2013. This growth was due in particular to greater non-compliance in the eco-design and energy labelling sector and in the pyrotechnics sector – the latter also registering the highest increase in RAPEX notifications. Discrepancies between the two sources (e.g. an increase in the annual average number of RAPEX notifications in the PPE sector and a decrease in the annual average findings of non-compliance in the same sector) can be explained by the limitations, previously discussed, of data provided by national reports.

Table 4-25 - MSAs' findings of non-compliance[138]

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%**

Source: National reports

At the **Member State level**, the highest numbers of notifications per year over 2010-2015 came from Hungary, Spain, Germany, Bulgaria and the UK. These were also among the major notifying countries over 2005-2009. Those experiencing the largest variations over the two periods are Luxembourg, Malta and Romania,[139] which also have the lowest average number of notifications per year over the period 2005-2009. Overall, **the average number of notifications has increased from one period to another in most Member States**, with very few exceptions (i.e. Belgium, Greece, Ireland, Poland and Slovakia).

Table 4-26 - Average number of RAPEX notifications per year, per Member State, from 2005 to 2015[140]

MS	*'05-'09*	*'10-'15*	*Average Δ%*	*MS*	*'05-'09*	*'10-'15*	*Average Δ%*
HU	123.4	233.7	89%	SE	21.8	43.0	97%
ES	121.2	210.5	74%	PT	24.4	41.7	71%
DE	158.0	199.7	26%	PL	57.6	38.0	-34%
BG	53.4	170.2	219%	DK	13.6	32.2	137%
UK	84.4	119.8	42%	LV	9.4	26.0	177%
CY	35.2	115.7	229%	SI	18.0	21.7	20%
FR	56.2	114.8	104%	MT	5.2	21.5	313%
FI	55.4	85.0	53%	RO	5.0	18.8	277%

138 Data for 21 MS: AT, BE, BG, CY, CZ, DK, EE, EL, FI, FR, HU, IE, IT, LU, LV, PL, PT, RO, SE SI and SK.
139 It should be noted that the lower level of notifications in Romania over the period 2005-2009 might also be due to its later entry into the EU in 2007.
140 It should be noted that data for BG, HR and RO may experience higher variations given that they entered the EU after 2005.

EL	107.4	75.8	-29%	EE	15.8	17.7	12%
NL	37.8	60.3	60%	AT	13.8	17.3	26%
CZ	38.4	57.3	49%	IE	21.6	17.2	-21%
IT	24.4	53.5	119%	HR	-	14.3	n/a
SK	82.4	48.3	-41%	BE	10.4	9.8	-5%
LT	30.0	44.3	48%	LU	1.0	5.5	450%

Source: Authors' elaboration on RAPEX database

When looking at the **notified products' country of origin** (Table 4-27), it can be seen that notifications increased in 2010-2015 with respect to 2006-2009 for all major countries of origin. Over the period 2010-2015, around **80% of total notifications were related to products from 12 countries**, half of which are EU Member States (DE, ES, FR, IT, PL, UK) and one is Turkey. The **majority of notified products came from China,** equalling 59% of total RAPEX notifications over the period 2010-2015. However, between 2010 and 2015, a considerable number of products notified also came from Turkey (402), Germany (380), the USA (298) and Italy (243).

When looking at the **trends** in the number of notifications over the two periods, a remarkable increase was experienced by products imported from India, Turkey and the USA.

Table 4-27 - RAPEX notifications by products' country of origin

	2006-2009			*2010-2015*		
Country of origin	*Notifications*	*Annual average*	*% of total*	*Notifications*	*Annual average*	*% of total*
China	2,952	738	54%	6,862	1,143.7	**59%**
Turkey	108	27	2%	402	67	**3%**
Germany	271	67.75	5%	380	63.3	**3%**
United States	121	30.25	2%	298	49.7	**3%**
Italy	212	53	4%	243	40.5	**2%**
France	107	26.75	2%	196	32.7	**2%**
United Kingdom	88	22	2%	174	29	**2%**
India	44	11	1%	170	28.3	**1%**
Japan	98	24.5	2%	167	27.8	**1%**
Poland	87	21.75	2%	155	25.8	**1%**
Taiwan	79	19.75	1%	119	19.8	**1%**

Spain	58	14.5	1%	111	18.5	**1%**
Other	1,232	308	23%	2,288	381	**20%**
Total	**5,457**	**1,364.25**	**100%**	**11,565**	1,927.5	**100%**

Source: Authors' elaboration on RAPEX database

6. ANSWERS TO THE EVALUATION QUESTIONS

6.1 Effectiveness

This section focuses on the analysis of the effectiveness of the Regulation in achieving its specific and strategic objectives, as defined in its intervention logic, and the reasons behind the results achieved. Evaluation questions have been aggregated accordingly.

6.1.1 Achievement of the specific objectives

EQ of reference

EQ 1. *Are the results in line with what is foreseen in the impact assessment for the Regulation, notably as to the specific objectives of (i) enhanced cooperation among Member States/within Member States, (ii) uniform and sufficiently rigorous level of market surveillance, (iii) border controls of imported products?*

EQ 2. *How effective was the measure as a mechanism and means to achieve a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security? What have been the quantitative and qualitative effects of the measure on its objectives?*

EQ 3. *How effective was the measure as a mechanism and means to achieve a level playing field among businesses trading in goods subject to EU harmonisation legislation? What have been the quantitative and qualitative effects of the measure on its objectives?*

6.1.1.1 Cooperation and coordination

The current framework of existing cooperation and coordination arrangements is varied as well as complex.

As for **coordination between national MSAs**, various coordinating tools are used, such as ad hoc, permanent bodies for coordinating market surveillance activities and related meetings, committees, working groups, fora, informal arrangements, information systems and websites.

The great majority of Member States, with only a few exceptions,[141] have set up **formal mechanisms**, establishing an **ad hoc permanent coordinating body**. However, the **frequency of the body's coordination meetings** varies, ranging from two – in Austria, Cyprus and Lithuania - to more than five times a year – in Spain. In addition, the body's responsibilities are not uniform, and span from merely operative – e.g. monitoring of conformity assessment procedures – to more strategic, such as setting market surveillance priorities (DK, EE, FI, LU, NL and SE), or ensuring a clear division of competences between national MSAs to avoid duplication of activities (LV). The German coordination body (Zentralstelle der Länder für Sicherheitstechnik – ZLS) analysed in case study 2 is particularly relevant as it is in charge of strategic tasks to avoid overlapping among Land MSAs.[142]

141 i.e. BE, CZ, ES, SK.

142 For instance, ZLS creates product risk profiles to be applied throughout the country, or even enforces market surveillance measures when a case involves several Länder, thus allowing a uniform approach in a highly decentralised organisation of market surveillance.

Nonetheless, it is worth mentioning that coordination and cooperation mechanisms among MSAs in Germany were already in place before the entry into force of the Regulation, thus probably impacting positively on the way the Regulation has been further implemented by German Authorities.

Another interesting example of a particular coordination mechanism is represented by the Italian Medical Device Registration database. Although not yet fully merged with databases on product non-compliance, it allows for information sharing between economic operators and public healthcare agencies (see case study 1 in Annex).

In general, the pre-existence or the absence of an internal cooperation mechanism may be a relevant element of differentiation to be taken into consideration.

In addition to structured arrangements, there are also **informal mechanisms** for coordinating market surveillance activities, such as ad hoc bilateral agreements, fora, working groups, regular contacts, and joint actions. These mechanisms have proven to be effective, allowing, for instance, **to focus on specific market surveillance issues** such as border controls (as it is the case of MSCC in the UK, of a working group in Estonia, and of a forum in Sweden) or the use of RAPEX and ICSMS (as for the Finnish MATIVA network), or **to share experience and knowledge** on specific product categories – as it occurs in Belgium, the Netherlands and Sweden.

Finally, Member State authorities rely also on **information systems** such as ICSMS and RAPEX to exchange information and coordinate market surveillance activities, as well as on **websites** to communicate with economic operators and citizens both within and among Member States. Yet, their use is not at full potential. For instance, very few Member States use institutional websites as the most common tool to alert users on hazards,[143] despite the fact that the effectiveness and inclusiveness of a reporting system is crucial in ensuring stakeholders' involvement and cooperation in market surveillance. As proof, *'European organisations representing the interests of consumers, SMEs and other businesses have not yet been systematically involved in European efforts to improve market surveillance*'.[144] Next to this, the study identified many practical **difficulties in setting up a reporting system aimed at exchanging information between all authorities and economic operators**.[145]

Moreover, statistics[146] and information gathered from stakeholders[147] show that **the use of ICSMS by both MSAs and representatives from the private sector is still limited, or that some Member States do not even use ICSMS at all**.[148] Even within Member States, there is a great variance between MSAs in their use of the system.[149] This hampers the possibility to avoid duplication of effort, which is the case when the system is properly used, as shown by the German practice analysed in case study 2.[150] A number of MSAs indeed report on the

143 AT, BG, CZ, EE, NL, PL, RO, SI, and UK.
144 COM(2013) 76 final.
145 Ibid.
146 No information was found for LT and PT in national market surveillance programmes. Information on Member States' use of ICSMS has been complemented with ICSMS-AISBL (2015). IMP-ICSMS N024. Graph: *Level of use of ICSMS by all EU/EEA Member States (1. half of 2015)*, p.2.
147 Two European industry associations, a Danish industry association, a large Italian product manufacturer/ authorised representative, a large Spanish holding company, a Hungarian civil society association.
148 Such as BG, LT, MT, PT, RO. Source: ICSMS-AISBL (2015). IMP-ICSMS N024. Graph: *Level of use of ICSMS by all EU/EEA Member States (1. half of 2015)*, p.2
149 Source: ICSMS-AISBL (2015). IMP-ICSMS N024.
150 Germany represents a particularly positive case, in light of the fact that ICSMS was designed in Germany and then spread at the European level. Before starting a non-compliance case, German MSAs check on the tool as to whether a product has already been filed in the system.

duplication of work due to the filling-in of both ICSMS and internal/national databases,[151] which create disincentives to use ICSMS, due to compatibility issues. Further frequent issues concern the lack of adaptations to insert sector-specific information into ICSMS[152] and the impossibility to update information on the progress of the case.[153] The **low user-friendliness** to ease data entry,[154] inability to find **instructions about how to use** ICSMS[155] and **linguistic barriers**[156] are also reported as minor issues that could be improved.

As for RAPEX, its use has **significantly increased over the years**, both in terms of the number of notifications and follow-up actions (see case study 4). Moreover, the number of follow-ups outweighed the number of total notifications from 2014, thus possibly indicating that RAPEX **is increasingly recognised and used as an information tool** for enforcing market surveillance. However, **the use of RAPEX across Member States differs**, indicating that some Member States are more proactive while others are more reactive in dealing with notifications (see Figure 4-50). Yet, there are doubts on the full use of RAPEX when considering that the number of notifications made in the system is not proportionate to the size of the national markets.[157] For instance, Cyprus notifies on average more than Poland, Sweden and Romania.[158] Additional obstacles to the use of RAPEX is the perceived redundancy of having different notification procedures and communication tools. As proof, some MSAs think that ICSMS, RAPEX and the safeguard clause should be integrated within a single information system to reduce double work and inconsistencies.[159]

The sub-optimal use of information systems to exchange information also hampers **cooperation between Member States** – this is mainly based on the use of those systems and on European-level initiatives (namely expert groups, AdCOs and joint actions).

Besides the sub-optimal use of information systems, cooperation between Member States faces additional challenges. Even if the majority (77%) of MSAs and Customs consulted state that they cooperate with authorities based in other Member States and the large majority of MSAs declare to notify other Member States (75%),[160] most of **MSAs (78%) responding to the survey rarely restrict the marketing of a product following the exchange of information on measures adopted by another EU MSA against the same product**. Also, the possibility for MSAs and Customs to **make use of test reports drafted by MSAs in other EU countries** seems to be limited.[161] As shown in case study 4, for instance, while some countries used to rely completely on risk assessments provided by other Member States, others prefer to repeat the risk assessment on notified products. Input provided by some stakeholders and case study 4 suggest that the main obstacles to a full follow-up of RAPEX notifications across Member States consist of:

151 20 MSAs (AT, CH, CY, DE, ES, 5 FI, LT, LV, 3 NL, PL, 4 SE) and the Estonian and the Lithuanian coordinating authorities.
152 13 MSAs (AT, CH, 4 DE, 2 FI, LV, 3 SE, UK).
153 A Danish MSA.
154 Three MSAs (DE, LT, UK).
155 Four MSAs (DE, FI, LT, SE).
156 Four MSAs (BG, CH, LT, SE).
157 As regards RAPEX: http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/reports/docs/rapex_annual_report_2015_en.pdf
158 RAPEX database, average of data over the period 2005-2015.
159 Three MSAs (DE, PL, SE) and one AdCO chair.
160 41 MSAs (2 AT, 2 BE, BG, 2 CY, DE, 2 DK, ES, 6 FI, 2 IT, 4 LT, LU, 2 LV, 5 NL, PL, 9 SE) and eight AdCO members (electromagnetic compatibility, explosives for civil use, gas appliances, measuring instruments, medical device, noise, pyrotechnic articles, recreational craft). Source: targeted surveys.
161 Overall, the possibility of using test reports drafted by other EU MSAs is recognised only in BG, CZ, DE, EE, FI, LT, LU, LV, SI, and UK for a considerable number of sectors (i.e. more than 20).

- The lack of risk assessment data and test reports, making it impossible to assess the quality of checks performed by other MSAs;

- The lack of power to make use of test reports provided by other EU countries: as shown in Table 4-12, only 12 MSAs out of 28 have this power in more than 14 sectors. This causes duplication of testing costs and lengthy follow-up procedures;

- Possible disagreements between Member States on appropriate measures to be taken against the same non-compliant product;

- Language barriers;

- Difficulties in understanding the description of adopted measures when these are too generic.

As for EU-level arrangements, participating in AdCO work proves to be essential for coordinating actions[162] and keeping an eye on what MSAs in other Member States do, as well as learning from each other.[163] However, **not all MSAs participate in this form of administrative cooperation**.[164] Furthermore, according to the feedback received by AdCO Chairs, many Member State representatives participating in the meetings do not get actively involved in common discussions and activities. In light of this, the EC has increased its support for these groups, underlining that the chairpersons bear a remarkable burden when organising meetings and that many MSAs cannot attend due to budgetary constraints. Interestingly, however, the **number of AdCO groups has increased** with respect to the period previous to the implementation of the Regulation, rising from 'more than 10'[165] to the current 28.[166] This could possibly indicate an incentive to cooperate on sectoral market surveillance issues due to the introduction of the Regulation. In addition, from the interviews with business representatives it emerged that the cooperation mechanisms in place are not effective in identifying non-compliant products on the market because of limited financial, human and technical resources.

Finally, only few[167] Member States participate in cooperation initiatives on market surveillance **involving third countries**, as reported in the national programmes.

In conclusion, **coordination and cooperation mechanisms are significantly developed,** consisting of an impressive number of initiatives, and all stakeholders recognise them as useful.[168] However, these mechanisms **have not reached a level that can be considered satisfactory, especially considering those existing among Member States.** In particular, **despite the necessary tools being in place to ensure cross-border market surveillance cooperation**, they are not used effectively.

162 29 MSAs (BG, 2 CH, CY, 4 DE, 2 DK, 3 FI, IT, 2 LT, 2 LV, LU, 5 NL, 4 SE, UK), based on the targeted surveys.
163 31 MSAs (AT, BG, 2 CH, CY, 2 DE, 6 FI, 2 IT, 3 LT, 2 LV, 4 NL, PL, 6 SE), based on the targeted surveys.
164 8 MSAs (CY, 2 FI, 2 LT, 2 LV, SE), based on the targeted surveys.
165 SEC(2007) 173, p.34.
166 http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups_en
167 AT, CZ, EE, EL, ES, FI, RO, and UK.
168 45 out of 47 participants to the targeted survey find it useful (2 coordinating authorities, 39 MSAs and 4 Customs).

Based on the analysis undertaken **there is still a need for higher** level **and more transparent cooperation and exchange of information**, consistent with what was also suggested by some stakeholders.[169]

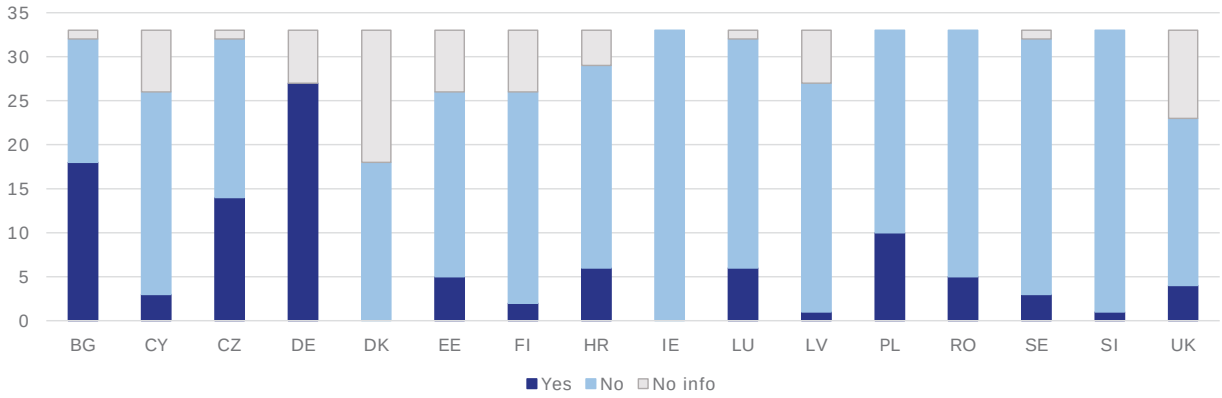
6.1.1.2 Uniform and sufficiently rigorous level of market surveillance

Member States need efficient and well-functioning (i.e. uniform and sufficiently rigorous) market surveillance systems to ensure the effective and efficient enforcement of the legislation and to reduce the number of non-compliant products circulating on the market. Nonetheless, **a satisfactory level of uniformity and rigorousness of market surveillance has not been achieved yet.**

As resulting from the analysis of national reports, there are significant differences across Member States.

Firstly, the **organisation** of market surveillance is different across Member States, in terms not only of level of centralisation of the organisational model, but also in terms of available resources (financial, human, and technical). Although data available from national reports, as discussed in the limitations to the study, are not fully reliable in their precise values, the big picture of a **high level of heterogeneity in the available resources** can be considered reliable, as also confirmed by additional stakeholder input and presented in section 5.2.1.[170] For instance, as shown in the figure below, **the availabilities of laboratories for product testing widely very across Member States**, though a widespread lack can be traced.

Figure 4-22 – MSAs' availability of in-house laboratories for product testing in 33 sectors covered by the Regulation[171]



Source: Authors' elaboration on multiple sources

The availability of resources seems to influence the depth of market surveillance controls. For instance, based on the figure below, Cyprus, Finland, Ireland and the UK perform a lot more physical checks on the product than testing, and also have few in-house

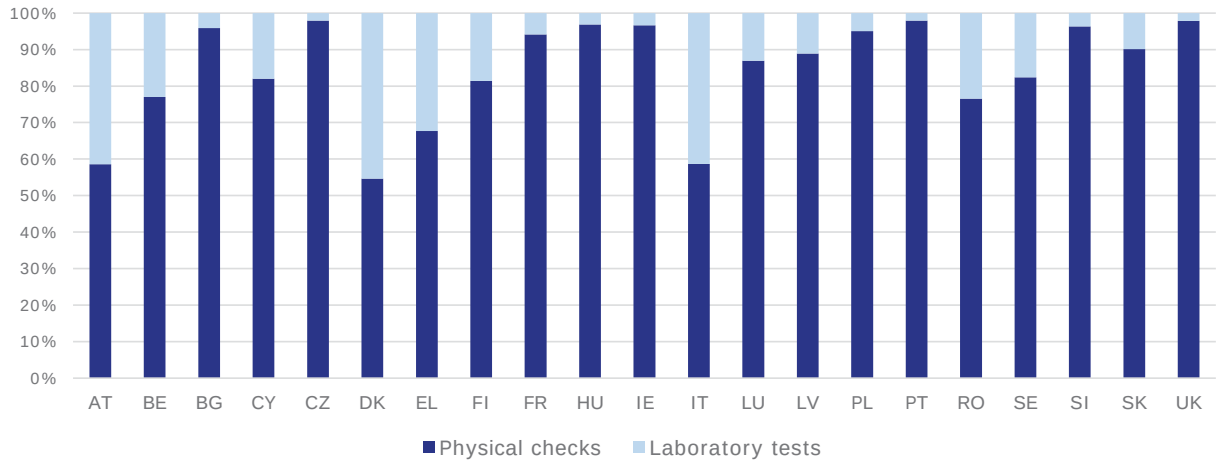
169 13 stakeholders (nine MSAs, three AdCO members, and one Custom Authority) suggest need for higher level of cooperation, 8 (MSAs) for higher transparency. Source: targeted surveys.

170 In the context of interviews, six interviewees from the Ministry of Health and Social Services (ES), the Ministry of Economic Development (IT), ISPRA (IT), REACH – CLP Unit (IT), the Ministry of Economy, Development and Tourism (EL) and a large French economic operator reported this issue, while all German interviewees (three MSAs and one Customs authority) perceive available resources as sufficient.

171 12 Member States have been excluded due to lack of information.

laboratories. In addition, as discussed under section 6.2.1, some Member States give higher importance to administrative aspects than to technical aspects, when checking compliance.

Figure 4-23 –Share of physical checks and of laboratory tests performed on total inspections, average 2010-2013[172]

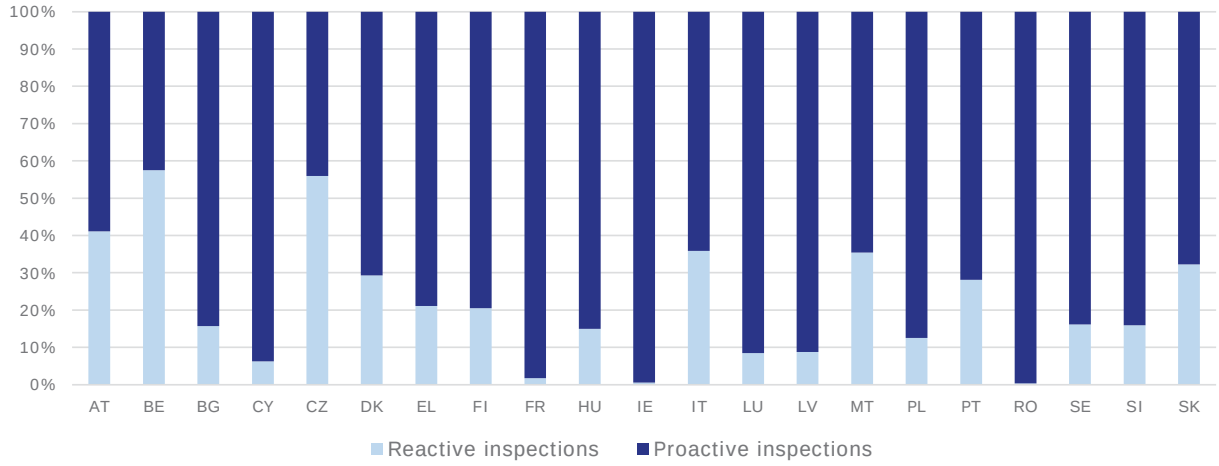


Source: Author's elaboration on data from national reports

Therefore, the **intensity of enforcement activities varies across countries**. As based on the figure above, there are some Member States (i.e. AT, DK, EL, IT) that seem to perform a higher number of laboratory tests – thus involving more in-depth enforcement – instead of merely checking formal compliance.

A second element of differentiation is represented by MSAs' **strategies of market surveillance**. As shown in the figure below, the level of proactivity varies from one Member State to the other.

Figure 4-24 – Average of reactive vs proactive MSAs' inspections between 2010 and 2013



Source: Author's elaboration on data from national reports

172 Data for DE, EE, ES, HR, LT, MT and NL are excluded as incomplete/unreliable. These data also do not include all sectors covered by the Regulation.

As a further proof, in order to assess to which extent market surveillance activities are proportionate to the dimension of the national market, **the total number of inspections carried out by MSAs has been compared to the number of enterprises active in the harmonised sectors per Member State**. The correlation between the two variables – though positive – is very low (i.e. 0.15), thus showing that MSAs' activities and efforts are not related to market dimensions. Moreover, its value varies considerably across Member States, as shown in the table below. These results further show the **lack of uniformity of market surveillance activities across Member States**.

Table 4-28 – MSAs' average number of inspections per average number of manufacturing enterprises[173]

MS	Index	MS	Index	MS	Index
IE	824%	FI	67%	HR	16%
LU	447%	EL	56%	SE	13%
EE	208%	RO	56%	SK	10%
AT	148%	PT	39%	PL	9%
HU	104%	BE	35%	CZ	9%
LV	82%	FR	23%	UK	5%
CY	81%	DK	22%	IT	3%
BG	73%	DE	19%	NL	1%
SI	70%				

Source: Author's elaboration of data from national reports and Eurostat SBS

As the table shows, subject to a number of important caveats due to limitations of the methodology used and the comparability of data provided by Member States, Ireland has the highest ratio (842%) whereas the Netherlands have the lowest (1%). The number of market surveillance inspections is remarkable also in Luxembourg, Estonia, Austria and Hungary. On the contrary, market surveillance controls do not seem proportionate with respect to the number of enterprises in the Czech Republic, the United Kingdom and Italy. It is stressed that the methodology only takes into account the number of manufacturing enterprises (excluding retailers) and disregards the number or the value of products available in the different countries. It is to be considered that these wide differences are also due to the differing interpretations of what an inspection is, thus impacting on the way Member States report data. For instance, the Irish, Belgian and Slovenian national reports include 'controls (including checks on the Internet) or other forms of contacts (mail, telephone)' in the number of inspections, which explains the resulting high index. Similarly, Bulgaria, Greece, Portugal, Hungary, Luxembourg and Estonia – the last three having an index greater than 100% - include 'visual inspections' in the definition of inspection. Denmark states that an important element of its market surveillance is inspections at trade fairs, while France lists 'inspections on advertising' among the activities. Italy – which has a very low index – reports only the number of inspections ordered by the Ministry of Health, therefore not including inspections performed by other MSAs on their own initiative. Moreover, as remarked under section 4.3.1, data on market surveillance activities presented in the national reports suffer a number of

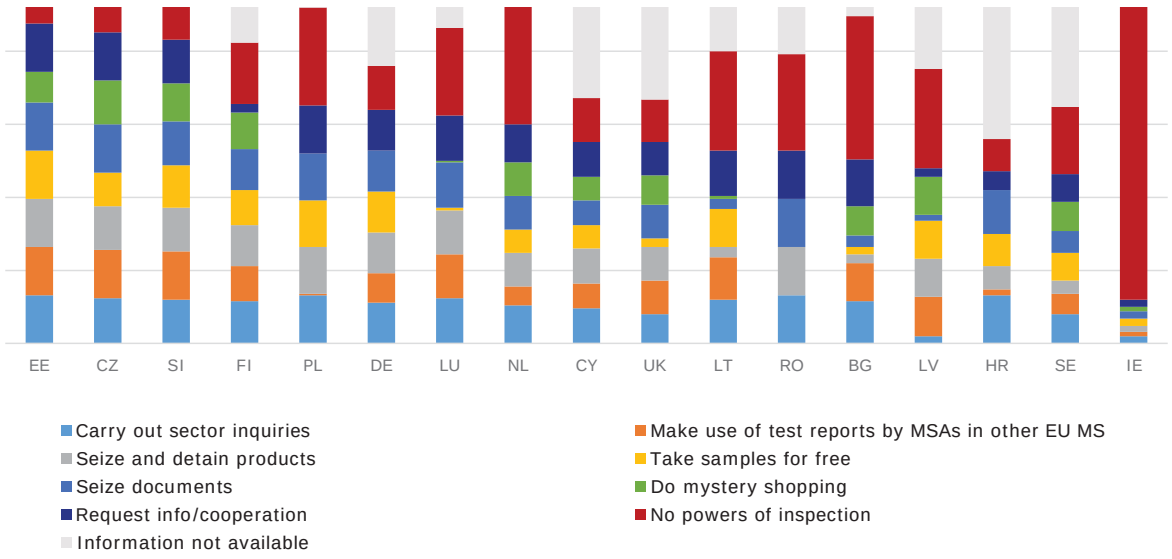
173 More precisely, the average number of inspections carried out at the national level over the period 2010-2013 as provided by the national reports has been compared to the average number of enterprises in the harmonised sectors over the period 2012-2014 as provided by Eurostat SBS. However, as already discussed, it is to be considered that data from national reports have a number of limitations in terms of Member States providing data, sector and timeframe coverage. As a consequence, some Member States (ES, LT, MT) have been excluded from the analysis due to lack of data. Moreover, it is to be considered that market surveillance is performed on products, but the relevant manufacturing enterprises do not necessarily have to be based in the same Member State. In addition, retailers can also be inspected; therefore, the number of enterprises used for the index is smaller than the businesses that could be subject to market surveillance controls and therefore only partly reflect the actual market dimension in the relevant Member State.

limitations, therefore, despite any definition of the term 'inspection', the number of inspections performed shall also be considered with caution.

Differentiation has been assessed also in terms of **powers of inspection**, which are **differently attributed to national MSAs (and across MSAs within the same Member State)** as they are established by different national legislative frameworks. Whereas core powers such as performing documentary and visual checks, physical checks on products, inspection of business's premises and product testing, are common to most Member States, additional powers can be granted to MSAs depending on the Member State and the sector considered, **thus making the approach to inspections heterogeneous across Member States and sectors**. The same picture applies to Customs that can have different powers depending on the Member State considered. For instance, the power to destroy products and to recover the related costs from economic operators is granted to Customs in some countries, but not all.

Based on information reported in Table 4-12 - MSAs' powers of inspection and in more detail in Annex, the following figure displays the extent of inspection powers in a sample of Member States for which relevant information was available. The analysis shows that inspection powers are widely and equally distributed across sectors in the Czech Republic, Estonia and Slovenia. On the contrary, MSAs in Bulgaria, Ireland, the Netherlands and Poland lack inspection powers in a number of sectors.

Figure 4-25 – Extent of inspection powers in 17 EU Member States, considering 33 sectors covered by the Regulation[174]



Source: Authors' elaboration on various sources

Differences in the allocation of powers are also evident when looking at powers related to **online trade**, which as the following box shows, represent a specific issue where a more uniform market surveillance approach would be required across Member States.

174 AT, BE, DK, EL, ES, FR, HU, IT, MT, PT and SK are not reported due to lack of data. The height of the bars equals the sum of each of the 33 sectors covered by the Regulation where a given power is granted.

Box 4-1 – Market surveillance of online sales

Online sales have become an important issue for market surveillance. The analysis undertaken highlights the following specificities as relevant to understand the challenges market surveillance faces in the case of online sales:

- Online sales are characterised by a high number of small consignments, with goods most of the time directly delivered to consumers;
- The number of existing web outlets is huge;
- Even though a web outlet is shut down, it is very easy to create a new web outlet by changing the name and the domain in a short time; as a result, unsafe products withdrawn/banned from the EU market can return on the market through a different website or under a different legal name;
- In many cases, the number of parties and intermediaries determine a complex distribution chain, where especially the role of fulfilment houses[175] and commercial platforms is not clear;
- Economic operators are often located in third countries and Authorities are not informed in advance that products are being imported;
- Online channels can be used to make unsafe, withdrawn products return on the market;
- Consumers are not fully aware of the risks associated with buying products online.

Vis-à-vis these specificities, the majority of stakeholders face specific issues related to online sales[176] and current market surveillance does not seem to be fully effective for online sales for various reasons.

First, specific **powers** of inspections and sanctioning related to online sales are present only in few Member States: most MSAs do not have enough power to deal with products sold online and powers of sanction are generally not extended to those kinds of product (see also Table 4-50 in Annex).

Second, irrespective of the existence of explicit powers, bodies or procedures for online sales, **enforcement activities** are not straightforward: evidence gathered from stakeholders, national programmes and through the case study on online sales (see Annex 8.4) shows that market surveillance on products sold online is particularly challenging for most Member States,[177] due to both the high volumes of products and websites involved (that would require resources that are not available), and the difficulties in inspecting and sanctioning the responsible

175 According to the Blue Guide: *'Fulfilment houses represent a new business model generated by e-commerce. Products offered by online operators are generally stored in fulfilment houses located in the EU to guarantee their swift delivery to EU consumers. These entities provide services to other economic operators. They store products and, further to the receipt of orders, they package the products and ship them to customers. Sometimes, they also deal with returns. There is a wide range of operating scenarios for delivering fulfilment services. Some fulfilment houses offer all of the services listed above, while others only cover them partially. Their size and scale also differ, from global operators to micro businesses.*'

176 80% (n=67) of respondents to the targeted surveys encountered issues related to online trade with three large consumer associations based in different Member States (BE, DE, IT) encountering difficulties in performing their activities due to online trade.

177 AT, BG, CY, CZ, DE, DK, EE, ES, FI, HR, IS, IT, LT, NL, NO, PL, RO, SE. As reported in both national programmes and in contributions received to the public consultation and targeted surveys.

economic operator given the complex (and sometimes invisible) distribution chain,[178] with products most of the time directly delivered to consumers.

Third, in some cases, in light of the already-mentioned complex distribution chain, the same **identification of the responsible economic operator** is challenging,[179] and even when authorities have the power to shut down websites, this might take several months and the action is ineffective since, as described above, sellers can change name and domain in a short time.

Difficulties are exacerbated in **the case of cross-border online sales**, where action, which should be particularly fast, as some stakeholders underlined,[180] is lengthy and costly due to jurisdictional constraints and becomes basically irrelevant when third countries are involved. Indeed, tackling websites outside of the EU is substantially impossible and would represent a waste of resources: communication (see the section below on 6.1.1.3 Border control of imported products) and response by economic operators, even when clearly identified, are very limited, and cooperation with Authorities from different countries (especially if non EU-countries) is not always fast and effective (see Annex 8.4). Moreover, border controls of goods sold online are particularly difficult since there is no previous information about shipments, Authorities are not informed in advance that products are being imported, and often there are no electronic declarations.[181]

Despite some Member States (e.g. Estonia, the Netherlands, Romania and Slovenia) having tailored strategies to tackle online sold products, **the current market surveillance approach to online sales is still conducted in a fragmented and uncoordinated way.**[182]

As a result, non-compliance of products sold online is a real issue, especially when e-commerce popularity has increased amongst consumers[183] and when 78% of participants to the targeted survey reported that there are non-compliance issues related to online trade. Controls effectively performed are considerably less than those that are necessary, as highlighted by some stakeholders[184] and in the case study on online sales. As a consequence, the incentive for economic operators to be compliant is also low, considering the low risk of being caught and effectively punished.[185]

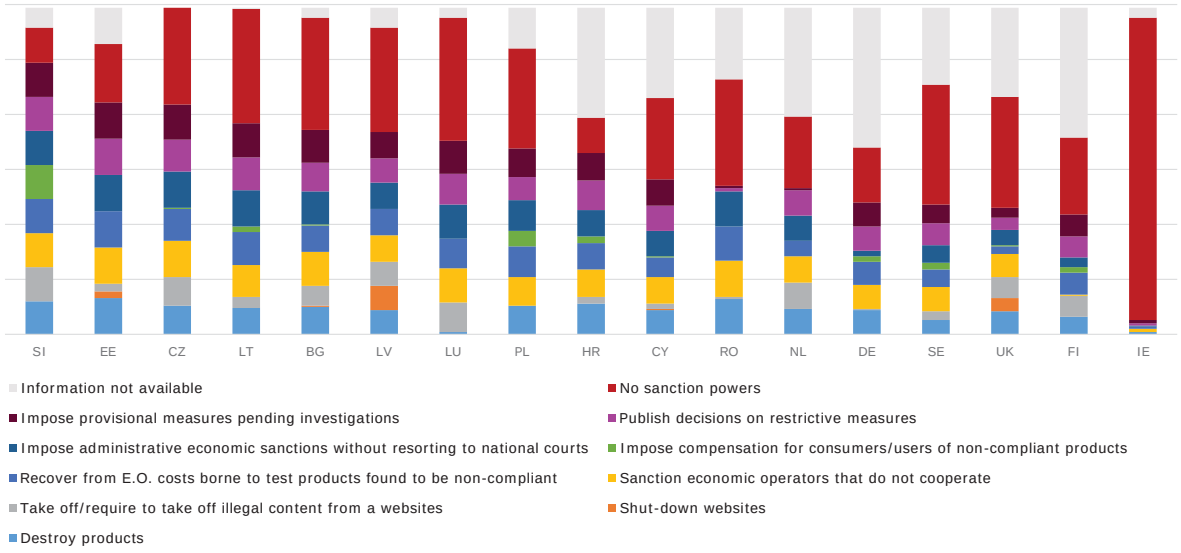
In light of this, the current level of protection and legal support to consumers is lower if compared to that for products marketed through other distribution channels.[186]

Similarly, the figure below – based on information reported in Table 4-23 and detailed in Annex – represents the extent of **sanctioning powers** in 17 EU Member States, considering the 33 sectors covered by the Regulation. The analysis shows again that sanctioning powers

178 As highlighted by an AdCO member (Medical Devices), only a very small share of products sold through fulfilment houses is checked (especially when coming from third countries) as they are delivered directly to consumers.
179 Six MSAs (AT, DK, 3 FI, SE), three AdCO members (measuring instruments, noise, pyrotechnic articles).
180 Five MSAs (2 FI, 2 SE, UK).
181 As stated by an interviewee from the Netherlands Food and Consumer Product Safety Authority.
182 As also underlined in COM(2013)76 final.
183 Source: PANTEIA (2014), *Good practice in market surveillance activities related to non-food consumer products sold online*.
184 Three MSAs (2 FI, NL), one AdCO member (recreational craft).
185 Four MSAs (CY, FI, 2 NO), eight economic operators (ES, 3 FR, 3 NL, UK), 11 industry associations (7 BE, ES, NL, 2 UK), two consumer organisations (BE), one international organisation from the UK, a Belgian trade union, two citizens from Germany and from the UK, three others (2 BE, FR). Source: public consultation.
186 COM(2013) 76 final. Product Safety And Market Surveillance Package – Communication From The Commission To The European Parliament, The Council And The European Economic And Social Committee. 20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0076:FIN:eng:PDF and Panteia and CESS (2014).

are widely distributed across sectors in the Czech Republic, Estonia and Slovenia, though with differences for some powers such as those related to online sales (shut down websites and remove/require to remove illegal content from a website) and impose compensation for consumers/users of non-compliant products. Irish MSAs are, once again, the ones lacking sanctioning powers in the highest number of sectors.

Figure 4-26 - Extent of sanctioning powers in 17 EU Member States, considering 33 sectors covered by the Regulation[187]



Source: Authors' elaboration on various sources

These differences highlight that while **some powers of inspection and powers of sanctions are uniformly attributed across Member States**, others are not, with considerable differences that lead to different models of enforcement power across the EU.

Thirdly, a **high level of heterogeneity can also be traced in the level of sanctions and related procedures**, as presented in detail in the specific case study undertaken and in the analysis of the penalty framework presented in the Annex. The mapping performed shows that the level of penalties differs both among Member States and across sectors. Similarly, procedures for imposing sanctions differ. In some Member States, MSAs can directly impose administrative monetary sanctions together with restrictive measures. In other Member States, MSAs are instead obliged to recur to Courts, even to impose administrative monetary sanctions. As result of these differences, **the current system of penalties and sanctioning powers does not provide sufficient deterrence**, as also confirmed by stakeholders.[188] In addition, stakeholders underlined that the existence of different methodologies and core elements to set penalties at the national level represents an issue in the internal market, and their harmonisation a priority.[189] Also, in terms of rigorousness of the system, it is worth underlining that penalties are not sufficiently high to prevent non-compliant behaviour,[190] so that the consequences of placing a non-compliant product on the market are mild if compared

187 AT, BE, DK, EL, ES, FR, HU, IT, MT, PT and SK are not reported due to lack of data. The height of the bars equals the sum of each of the 33 sectors covered by the Regulation where a given power is granted.
188 52% of respondents to the Public consultation state deterrence is not sufficient, while 38% of them think it is sufficient only to a moderate extent.
189 According to 77% of respondents to the public consultation.
190 According to 64% of respondents to the public consultation.

to the costs of respecting compliance rules. Therefore, the probability of being sanctioned is very low and does not ensure the right incentives to sell only compliant goods,[191] given that market surveillance is very fragmented at the national level.

Finally, a **heterogeneity exists in the system of monitoring and reporting** set up by the Regulation, i.e. the national reports. As discussed, the Regulation aims at creating a framework for market surveillance controls and sets up a monitoring system (through Article 18(5)) to supervise how and to what extent these controls are performed. However, as thoroughly discussed under section 4.3.1, national reports are not uniform or comparable across Member States, and present a significant number of gaps and inconsistencies. These issues reflect the existing differences in the organisation models – which make it, for instance, difficult to collect and/or aggregate data on market surveillance activities – but also differences in market surveillance approaches – e.g. the different interpretations of what an inspection is.

The heterogeneity existing across Member States in the implementation of the Regulation allows the conclusion 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 the inference that **market surveillance might also be more rigorous** in some Member States than in others. Potential effects are a less effective deterrence power and an unequal level playing field among businesses in some Member States, thus also potentially generating imbalances in the level of product safety across Europe. Some stakeholders, for instance, highlighted the need for a higher level of cooperation among EU MSAs to effectively increase deterrence.[192]

Nonetheless, if stakeholders' input is considered, according to more than half of respondents to the targeted surveys,[193] the current system of market surveillance controls does **not generate serious discrepancies within and across Member States**. However, as presented in the consultation in Annex, the opinion changes according to the stakeholder category considered. The majority of economic operators and civil society (53%) think that discrepancies exist across Member States, while the majority of MSAs and Customs (62%) think they do not exist.[194] But in light of the picture presented above, this opinion could be interpreted as resulting from a lack of full awareness of enforcement authorities of the situation existing in other EU Member States, rather than from real uniformity. This interpretation is also confirmed by the fact that most **MSAs (78%) rarely restrict the marketing of a product following the exchange of information on measures adopted by another EU MSA against the same product**, thus implying a 'lack of confidence' in other Member States' rigorousness on controls. In addition, despite declaring that there are no discrepancies in uniformity and rigorousness of market surveillance controls, MSAs and Customs express opinions on the effects of these discrepancies in terms of product safety reduction, influence on market behaviour and obstacles to free circulation of goods. A further

191 Four MSAs (CY, FI, 2 NO), eight economic operators (ES, 3 FR, 3 NL, UK), 11 industry associations (7 BE, ES, NL, 2 UK), two consumer organisations (BE), one international organisation from the UK, a Belgian trade union, two citizens from Germany and from the UK, three others (2 BE, FR). Source: public consultation.

192 Three MSAs or Customs Authorities (2 DE, CZ), a Swedish economic operator, seven industry associations (4 BE, NL, ES, FR), three consumer organisations (2 BE, DK), a Belgian trade union.

193 58 % declared to be not aware of any discrepancies across EU Member States in terms of uniformity and rigorousness of controls (total number of respondents = 118). A Belgian civil society association reports that only six MS are actively engaged in verifying the energy-efficiency labelling. A Danish MSA makes the example of controls over dangerous hover boards: many MS did not take any action, despite notifications via RAPEX, ICSMS and AdCO.

194 Respectively, 16 economic operators and civil society representatives and 66 MSAs and Customs.

evidence of the perceived low rigour of market surveillance recognised univocally by all stakeholders is the **incapacity of the Regulation to deter rogue traders**.[195]

To conclude, the differences identified in the implementation at the national level allow the inference that **market surveillance is not uniform across Member States**. As for its **rigorousness**, the serious lack of data and inhomogeneity of national reports do not allow for a thorough assessment, except if based on stakeholders' perceptions, on the discrepancies in the penalty framework and in the 'lack of confidence' of enforcement authorities in other MSAs' risk assessments. However, the low usability of data of national reports is already a finding in itself of a drawback of the Regulation in the achievement of its objectives, inasmuch as the major evidence on its functioning (i.e. the effectiveness of market surveillance controls) is hard – if not impossible – to retrieve.

6.1.1.3 Border control of imported products

Overall, stakeholders claim that **powers attributed by the Regulation to Customs are adequate**,[196] and the **procedures** for the control of products entering the EU market foreseen by Articles 27 to 29 of the Regulation are **clear, easy to apply and still relevant**.[197]

However, **checks of imported products** seem to be not sufficient.[198] Border control is indeed one of the most challenging tasks for market surveillance nowadays, in light of the increasing importance of EU trade with third countries and particularly with China. Evidence of this lies in the fact that the large majority of products notified on RAPEX come from China – as presented in Table 4-27. The share of non-compliant products imported from China accounted for an annual average of 54% of total RAPEX notifications over the period previous to 2010, this average even increasing up to 59% in 2010-2015. These data were confirmed by **more than half of respondents to the public consultation experiencing** non-compliance of products imported from non-EU countries. In addition, not only extra-EU, but **also intra-EU trade** deserves attention from a market surveillance perspective, as it represents a large share of overall EU trade. As presented in Table 4-27, 14% of total RAPEX notifications over the period 2010-2015 related to products imported from six EU Member States (DE, ES, FR, IT, PL, UK). In addition, **imported products are often bought online**,[199] this making enforcement even more challenging (for more information on online sales please refer to case study 3 in Annex 8.4).

The main difficulties related to controls of imported products are due to a **lack of jurisdiction** of MSAs outside of their Member State,[200] and to a **lack of direct communication** between MSAs and businesses,[201] particularly – again – in the context of online sales.[202] As a consequence, **businesses are not willing to collaborate** with MSAs' requests for corrective

195 As confirmed by 83% and 89% of economic operator/civil society representatives (n=15, n=16) for checks of MSAs and checks of Customs respectively – and by 75% of MSAs and Customs (n=64).

196 As declared by Customs in BE, BG, CY, CZ, EE, FI, DE, HU, IT, LU, LV, MT, NL, PL, RO, SE and SK. Source: targeted surveys.

197 According to Customs answering the targeted surveys, procedures are clear (95% n=20), easy to apply (76% n=16) and relevant (86% n=18).

198 According to the majority of stakeholders answering to the targeted surveys. When breaking down the results by stakeholder category, all Customs have a positive opinion on the adequacy of performed checks, while MSAs and AdCO members are divided between those stating that checks are adequate and those reporting the contrary. When asked about difficulties in performing market surveillance or controls of imported products in a particular sector, MSAs, Customs and AdCO members most frequently mention the machinery sector, toys, electrical appliances and equipment under LVD, chemicals, biocides, PPE and construction products.

199 Based on the results of the public consultation, 14% of respondents report that most of them are sold online, 56% say that some of them are sold online and 18% think that only a few are supplied online.

200 67% of respondents to the public consultation.

201 79% of respondents to the public consultation.

202 83% of respondents to the public consultation.

actions, for information/documentation or for paying penalties for non-compliance.[203] As discussed in case study 3, other issues specifically inherent to online sales relate to products directly mailed to consumers, to the high number of intermediaries and to the low level of consumers' awareness concerning the risks of buying products online, as described in detail in Box 1. Moreover, **despite the fact that the necessary tools are in place to ensure cross-border market surveillance cooperation** (e.g. RAPEX, ICSMS and the safeguard clause procedure), they are not used effectively, as discussed previously. Moreover, as shown in Table 4-12, only 12 MSAs out of 28 have the power to make use of test reports from other EU countries in more than 14 sectors.

To conclude, the Regulation is effective when looking at the existing coordination and cooperation within and among Member States, though some adjustments are needed particularly in the use of the information tools (i.e. RAPEX, ICSMS). Border controls of imported products present no implementation problems and Customs' powers as provided for by the Regulation are adequate; however, results are not satisfactory (i.e. more than half of notified products are imported). Finally, the uniformity and rigorousness of the market surveillance system definitely needs to be enhanced.

6.1.2 Achievement of the strategic objectives

Overall, the **Regulation provides an effective framework** for ensuring the protection of public interests[204] and a level playing field among businesses in the EU.[205] Nevertheless, its implementation suffers a number of shortcomings that hinder the achievement of these objectives. The assessment of the effectiveness of the Regulation in **achieving its objectives** focused on their expected result, i.e. the reduction of non-compliant products on the market. The existence of non-compliant products indeed poses threats to consumers/users and also points to the existence of rogue traders that benefit from lower compliance costs. Overall, the analysis of the information gathered from both the field and the desk research highlights that **the Regulation has not fully achieved its strategic objectives**.

All sources of information indeed converge on the conclusion that **there are still many products in the EU market that do not comply with legislative requirements**, as highlighted already by the 2007 IA for the Regulation and, later on, by the Proposal for product safety and market surveillance package.[206] Interestingly, despite the problem being identified 10 years ago and then regularly through the following years, nothing has changed, despite the entry into force of a Regulation aiming, *inter alia*, at tackling the issue.

As described, **the average number of RAPEX notifications increased by nearly 60% from 2006-2009 to 2010-2015** (rising from an average of 1,209 to 1,928 notifications per year), **even though the Regulation came into force.** In particular, notifications of products in sectors such as **construction, jewellery and pyrotechnics experienced a remarkable growth**, with a percentage increase greater than 400% over the two periods. If compared over the same period, data from national reports on MSAs' findings of non-compliance (Table 4-25) confirm the trends in RAPEX notifications in the electrical appliances equipment and in

203 According to 72%, 67% and 68% of respondents to the public consultation respectively.
204 'Public interests' include: health and safety in general, health and safety at the workplace, protection of consumers, protection of the environment, supported by respectively: 93%, 80%, 84% and 69% of respondents to the targeted surveys.
205 According to 63 public authorities replying to this question in the targeted surveys (equal to 84%) and according to 12 among businesses and industry associations (equal to 71%).
206 SEC(2007) 173, p.19 and SWD(2013) 33 final.

the machinery sector.[207] Moreover, the correlation between RAPEX notifications and findings of non-compliance is positive, though low (on average 0.44 over the period).[208]

In order to better understand these trends, we have verified whether the average number of RAPEX notifications is correlated with the value of harmonised products traded in the internal market over the two periods considered.[209] The aim was to check whether the increase in notifications was not – or at least not only – due to a mere increase in traded products, but actually to an increase in non-compliance at the EU level. **A positive growth in the number of RAPEX notifications is registered** in five product categories (again construction and pyrotechnics, together with textiles, cosmetics and motor vehicles), **despite a reduction in the value of harmonised traded products**. Moreover, as shown in the table below, the annual average value of trade for all harmonised products is almost constant (+0.1%) over the two periods considered, but, as said, the annual average number of notifications increased (+59%). Yet, this result has to be taken with due care given the impossibility to confirm casual links.

Table 4-29 - Annual average value of harmonised traded products and average number of RAPEX notifications by product category over the periods 2006-2009 and 2010-2015

Product category	2006-2009	2010-2015	Δ% traded products	Δ% RAPEX notifications
Chemicals	1,067,897,632,898	1,106,833,111,374	3.6%	103%
Construction	156,586,485,690	128,882,492,028	-17.7%	1,144%
Textiles	104,626,637,224	104,598,300,839	-0.03%	232%
Cosmetics	17,870,226,314	15,421,496,892	-13.7%	14%
Appliances burning gaseous fuels	2,236,818,858	2,062,761,701	-7.8%	-12%
Machinery	278,111,694,212	271,828,263,683	-2.3%	-10%
Motor vehicles and tractors	338,802,673,379	329,544,444,282	-2.7%	18%
Simple pressure vessels and pressure equip.	243,498,460,356	248,009,349,724	1.9%	-
Personal protective equip.	33,664,105,623	35,624,391,429	5.8%	143%
Pyrotechnics	2,314,375,580	2,302,762,034	-0.5%	2,866%
Recreational craft	6,185,094,424	5,755,650,303	-6.9%	-33%

207 Electrical appliances: finding of non-compliance +2%, RAPEX notifications: +3% over 2010-2013. Machinery: finding of non-compliance +2%, RAPEX notifications: +16% over the 2010-2013 period.

208 Due to lack of data, the following MS are not included: ES, HR, LT, MT, NL and UK. Moreover, only a few sectors are covered, namely: biocides, crystal glass, eco-design & energy efficiency, electrical appliances and equipment under LVD, machinery, measuring instruments, non-automatic weighting instruments and pre-packed products, noise emissions for outdoor equipment, personal protective equipment, pyrotechnics, radio and telecomm equipment under R&TTE, textile & footwear labelling, and toys.

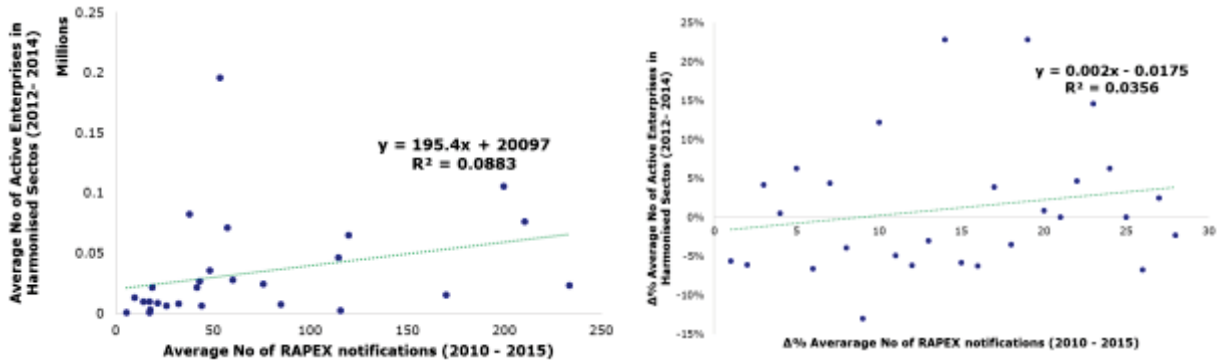
209 Since the product categories included in RAPEX slightly differ from the classifications used for the market analysis, only the product categories for which a reconciliation was possible were examined.

Product category	2006-2009	2010-2015	Δ% traded products	Δ% RAPEX notifications
Toys	9,359,483,585	12,004,549,187	28.3%	16%
Total	**2,261,153,688,142**	**2,262,867,573,475**	**0.1%**	**59%**

Source: Authors' elaboration on PRODCOM (2016) and RAPEX database

As described, **the average number of notifications has increased from one period to another in most Member States**, with very few exceptions. Also in this case, the possible link to the number of enterprises active in the harmonised sectors at the national level has been examined. As previously, the check aimed at assessing whether the increase in notifications was not – or at least not only – due to a mere increase in traded products, but actually to an increase in non-compliance at the national level. Although a positive correlation exists, it seems not to be statistically significant, thus further confirming that the increase in the number of notifications is not related with changes to the market structure.

Figure 4-27 - Correlation between RAPEX notifications and number of active enterprises in harmonised sectors by Member State



Source: Authors' elaboration on PRODCOM (2016) and RAPEX database

As already described, **the average number of notifications has increased from one period to another in most Member States**, with very few exceptions. Also in this case, the possible link to the number of enterprises active in the harmonised sectors at the national level has been examined. Although a positive correlation exists, it seems not to be statistically significant, thus further confirming that the increase in the number of notifications is not related with changes to the market structure.

Similarly, **the number of restrictive measures imposed by MSAs** in reaction to non-compliant products has increased.[210] Interestingly, as shown in Table 4-16, the most significant increases have been registered in the most coercive measures (i.e. seizure, withdrawal, destruction), while other measures such as requests for information or corrective actions have even decreased. This could indicate that not only non-compliance has increased, but that **its seriousness has worsened**, requiring MSAs to take 'decisive' measures. Similar conclusions can be drawn on the measures undertaken by economic operators to correct non-compliance. As shown in Table 4-18, since the entry into force of the Regulation, the most

210 RAPEX database

significant increase has been registered in the average number of notifications relating to product destructions. Moreover, Table 4-20 displays that **non-compliance does not affect all sectors equally, thus differently impacting on the level playing field**. The number of notified restrictive measures has diminished over time for the majority of sectors. However, the overall number of restrictive measures increased over the period. This means that there are some product categories particularly subject to restrictive measures, whose increase largely outweighs the decrease in the number of restrictive measures experienced by the other sectors.[211] It is worth mentioning that **textiles, construction, motor vehicles and pyrotechnics,** as shown in Table 4-29, registered the highest number of RAPEX notifications despite a reduction in their traded values, this further confirming a possible increase in product non-compliance in these sectors. The **toy sector** represents an exception, given that it registered **a lower number of restrictive measures**. This could effectively be an indicator of increased compliance given the large attention devoted to toys in market surveillance activities[212] – in light of the target group involved (i.e. children) – and since it is known to be the sector with the highest number of RAPEX notifications. [213]

Although data provided by national reports are partial in terms of sector, Member State and time coverage, the analysis performed allows the conclusion that, overall, **product non-compliance is increasing in Europe.** This is also in line with the results of the analysis based on RAPEX data. **These data are widely confirmed by stakeholders' perceptions** on trends in non-compliance. Most stakeholders do not perceive a substantial variation in the dimension of product non-compliance considering the period 2010-2015, despite the entry into force of the Regulation.[214]

Moreover, as already discussed, the Regulation has been implemented in different ways across Member States, in terms of powers of sanction/inspection attributed to MSAs, resources and level of penalties. These discrepancies diminish the Regulation's effectiveness in achieving a level playing field, inasmuch as they **influence regulatory/ administrative costs to businesses across Member States** (e.g. preparing documents and information requested by MSAs/Authorities in charge of EU external border controls in implementing surveillance measures).[215] Similarly, these discrepancies **influence market behaviour** (e.g. decision of companies to enter the EU market via certain Member States).[216] For example, according to an EU industry association, the impact of unfair competition due to rogue traders could be equivalent to -10% of the turnover of a lawful manufacturer, depending on product categories and countries. Specifically for engineering products, the drop in market share due to unfair competition could reach as much as -20%.

The above considerations allow to conclude that **the Regulation has not been capable** of fully achieving a high level of protection of public interests and a level playing field for businesses across the EU in light of the significant discrepancies in its implementation and of the dimension of product non-compliance, which did not vary (or even increase) since its

211 The following were particularly subject to restrictive measures: chemicals, clothing, textiles and fashion items, communication and media equipment, construction products, jewellery, laser pointers, motor vehicles, pressure equipment/vessels, protective equipment, pyrotechnic articles.

212 As discussed, Member States are used to prioritise market surveillance strategies focusing on mass products or on products targeting sensitive classes of consumers.

213 As also reported by an interviewee from an EU industry association.

214 26% (n=21) of respondents to the targeted survey state that the level of product non-compliance increased in the last five years whereas 25% (n=20) state it diminished. The remaining 49% state it did not change in the last five years.

215 According to 11 economic operators and industry associations answering to the targeted surveys (equal to 73% of respondents).

216 According to 10 economic operators and industry associations answering to the targeted surveys (equal to 71% of respondents) and to 26 Public Authorities (equal to 63% of respondents).

entry into force. As mentioned, these aspects negatively influence the capacity of the Regulation to achieve its objectives inasmuch as:

- **An unequal implementation of the Regulation creates disparities in the level of enforcement, and thus of protection of public interests across the EU**. Similarly, the increase in the number of non-compliant products signals that the protection of public interests has not improved with respect to the years previous to the entry into force of the Regulation.

- **An unequal implementation also creates disparities in the level of enforcement and thus differences in the burden of controls borne by economic operators**, which in some Member States and in some sectors is higher than in others. In addition, the increase in the number of non-compliant products signals that there are rogue traders that can still benefit from lower compliance costs, this further hindering the achievement of a level-playing field within the internal market.

6.1.3 Enabling factors

EQ of reference

EQ 4. *Are there specific forms of the implementation of the Regulation at Member State level that render certain aspects of the Regulation more or less effective than others, and – if there are – what lessons can be drawn from this?*

EQ 5. *To what extent has the different implementation (i.e. discrepancies in the implementation) of the initiative in Member States impacted on the effectiveness of the measures on the objective?*

As described, **the Regulation has been differently implemented across the EU.**

The first element of differentiation between Member States is their national organisation of **market surveillance structures**. Based on the information provided in Table 4-8, three types of organisational models can be identified:[217]

- **Centralised,** where activities are carried out by one or few MSAs. This model is applied in Bulgaria, the Czech Republic, Luxembourg, Malta, Portugal and Slovakia.

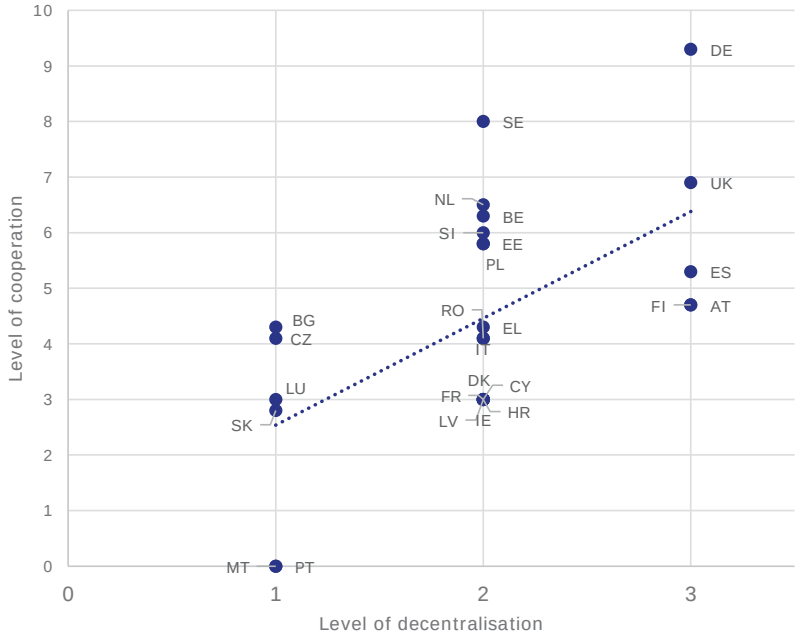
- **Decentralised at the sectoral level**, where several MSAs operate and have different competences, depending on the sector where they perform market surveillance activities. This model is adopted in Belgium, Cyprus, Croatia, Denmark, Estonia, France, Greece, Ireland, Italy, Latvia, Lithuania, Poland, the Netherlands, Romania, Slovenia and Sweden.

- **Decentralised at the regional/local level**, where numerous MSAs have enforcement responsibilities on specific geographical areas of competence. Austria, Finland, Germany, Hungary, Spain and the United Kingdom follow this organisational structure.

217 European Parliament (2009), Effectiveness of Market Surveillance in the Member States. Directorate A: Economic and Scientific Policies. IPOL/A/IMCO/ST/2009-04; 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; National market surveillance programmes from EU Member States.

Each Member State organises market surveillance in a way that best suits its particular cultural and legal framework or legal system, so that there is no 'one size fits all'. As discussed in 0, the lack of structured data on product non-compliance and on market surveillance activities makes the establishment of a causal link between the national organisation and the effectiveness of enforcement action not straightforward. **Organisational models influence how market surveillance is performed**,[218] resulting in differences across the EU. For instance, as shown in the figure below, Member States with a centralised structure need to rely on fewer and simpler cooperation tools. In contrast, the more a Member State is decentralised, the more it needs to set up numerous and complex cooperation mechanisms.[219]

Figure 4-28 – Existing correlation between the level of decentralisation of market surveillance and the complexity of cooperation tools within a Member State[220]



Source: Author's elaboration of information from national programmes

The results of case studies 1 and 2 allow the inference that **crucial elements for the effectiveness of decentralised models** are a clear attribution of tasks among authorities and to each MSA (i.e. that market surveillance is not just one 'among other tasks' that a MSA has to perform in its daily activities – this also impacting on cost-effectiveness), the existence of a

218 PROSAFE (2013). *Best Practices Techniques in Market Surveillance*, p.16. http://www.prosafe.org/library/knowledgebase/item/best-practices-techniques-in-market-surveillance

219 The figure compares two qualitative indexes. The 'x' axis measures **the degree of decentralisation** of a national market surveillance structure based on the three models identified: 1=centralised; 2=decentralised at sectoral level; 3=decentralised at local/regional level. The 'y' axis measures **the degree of cooperation** within the single Member State, taking into consideration the cooperation mechanisms/tools described in section 5.2.1. Each cooperation mechanism/tool has been assessed on the basis of three dimensions: the *scope* of its activities related to market surveillance, its *duration over time* and its *coverage* (i.e. in terms of stakeholders' representativeness). Each of these dimensions has been given a rating from 0 to 1, and the overall value of each mechanism results from the sum of the values of its dimensions. Therefore, a permanent ad hoc body for coordinating market surveillance activities rates 3, since it is permanent (duration=1), it involves all relevant stakeholders (coverage=1) and its scope of activities is the widest (scope=1). A bilateral agreement instead rates 1.1 (coverage=0.1; scope=0.1; duration=0.9). The level of cooperation within a Member State results from the sum of the values of each cooperation mechanism in use therein.

220 HU and LT have not been taken into consideration due to lack of data on existing cooperation mechanisms. The correlation between the two variables is quite significant, equal to 0.6760. It is to be noted that the coordination mechanisms used for this graph are those cited in Member States' national programmes, therefore not all coordination tools actually existing at the national level might have been taken into account.

coordination board, the possibility for each MSA to have direct contacts with Customs, the visibility (to the public) of identity and contacts of relevant competent authorities. As far as the **sector-decentralised model** is concerned, formal channels and procedures for coordination are essential to have coherent policy approaches in different sectors. The crucial aspect for the **local-decentralised model** is to have a strong coordination body granting not only coherent policy approaches in different regions, but also coordination of investigations via a common database and a tool for common decision making.

A second element of differentiation is represented by available **resources**. As discussed, financial, human and technical resources **vary greatly across Member States.**

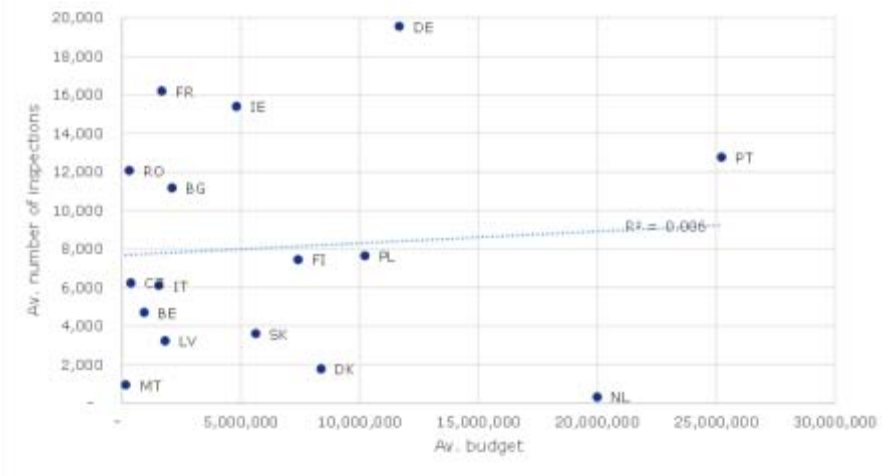
As presented in Figure 4-12, more than 80% of the total **budget available** for market surveillance is concentrated in seven Member States,[221] meaning that there are significant differences in terms of budget availabilities to implement the Regulation's provisions across Member States. Overall, the budget available for market surveillance decreased between 2010 and 2013 (Figure 4-13), though variations at the national level did not follow a common trend. Budget indeed increased in nine Member States,[222] decreased in seven[223] and remained stable only in two.[224] Possibly as a consequence of budget reduction, the number of **inspectors** also decreased (see Figure 4-19) and is very concentrated at the EU level, with 90% of them based in only six Member States[225] (see Figure 4-20) Finally, as presented in Table 4-9, only Germany and Bulgaria have MSAs with their own testing facilities for the majority of sectors covered by the scope of the Regulation (i.e. 27 and 18 sectors respectively).

This picture suggests a diffused lack of resources for MSAs, as also widely confirmed by stakeholders.[226] In general, this is indicated as one of the **main bottlenecks** to market surveillance implementation[227] and effective deterrence.[228]

In this context, we verified whether **MSAs' resources show a small positive correlation to the number of inspections performed** at the national level.[229] As shown in the figure below, the correlation is equal to 0.08, possibly due to the lack of reliability and completeness of data from the national reports. As a consequence, we can only suppose that **differences in the levels of available resources influence the inspections performed at the national level, but it is not possible to conclude on a direct causal relationship.**

221 DE, DK, ES, FI, NL, PL, PT, SE. The following: AT, CY, EE, EL, HR, LU, SI, and UK are excluded due to lack of data.
222 FI, FR, IT, LT, LV, MT, PL, RO, SE.
223 BE, BG, CZ, DE, ES, PT, SK.
224 IE, NL.
225 CZ, IT, PL, PT, RO, SK.
226 Lack of financial resources: 121 respondents to the Public consultation (equal to 70% of those answering the question); lack of human resources: 123 respondents to the Public consultation (equal to 72% of those answering the question); Lack of technical resources: 87 respondents to the Public consultation (equal to 52% of those answering the question). In the context of interviews, 6 interviewees from the Ministry of Health and Social Services (Spain), the Ministry of Economic Development (Italy), ISPRA (Italy), REACH – CLP Unit (Italy), the Ministry of Economy, Development and Tourism (Greece) and a large French economic operator also reported this issue.
227 Data from national reports. BG, CZ, EE, EL, ES, IE, LT, LV, MT, PL, PT, and SI.
228 Three MSAs, three economic operators (FR, PL, UK), two industry associations (BE, FR) and an international organisation. Source: public consultation.
229 Since the total budget as indicated in the national reports refers to the overall resources available to MSAs, it was not possible to provide an estimation of the average cost per inspection at the national level and of the average cost per FTE at the national level, since the allocated budget does not cover only market surveillance-related activities.

Figure 4-29 - Average annual budget available to MSAs in nominal terms vs average number of inspections performed (2010-2013)[230]



Source: Author's elaboration on data from national reports

The different levels of resources, however, have implications on the way MSAs perform their tasks and therefore deserve consideration.[231] For instance, MSAs' **market knowledge in order to target checks is perceived as sufficient only in certain cases,**[232] as some sectors (e.g. chemicals, construction) require specific skills.[233] As discussed in the previous section, **this could result in a higher level of non-compliance**. For instance, chemicals and construction are among the sectors with the highest number of RAPEX notifications (see Table 4-24) and of restrictive measures imposed by MSAs (see Table 4-20), despite a reduction in their traded values (for construction, see Table 4-29). As confirmed by an MSA from Sweden, some Member States cannot afford chemical analyses and therefore they just perform formal checks on chemicals. Moreover, based on the available information, the only MSAs with their own in-house laboratories for product testing are in the construction (3 MSAs) and in the chemical (6 MSAs) sector respectively (see Table 4-10). Testing products is more costly and time consuming than simple documentary checks, since it often involves test laboratories and an officer who is usually able to check only a few products per week (excluding the follow-up activities).[234] **The excessive costs of testing have been reported as the most likely explanation for the low level of surveillance in some sectors** and they are, therefore, another possible explanation for the data gaps in the national reports. As mentioned, national reports do not always include data on market surveillance activities for all sectors. The reasons for these gaps are many, as discussed: some sectors are not relevant for the concerned Member State (e.g. marine equipment in Austria) or in some cases it was impossible to collect data due to the high number of authorities involved. However, the major issue in other sectors excluded from national reports (e.g. lifts, recreational craft and

230 Some MS (i.e. AT, CY, EE, EL, ES, HR, HU, LT, LU, SE, SI, UK) have been excluded from the sample due to lack/unreliability of data from the national reports.

231 PROSAFE (2013). Best Practices Techniques in Market Surveillance. p.19.

232 Data from national reports of BG, CY, DK, HR, EE, IT, LT, PL, SK, and UK. 92% of respondents to the public consultation either agree or strongly agree (55% and 37% respectively) with the following statement: *'MSAs should have more knowledge about the relevant sector'* (total number of respondents: 218, of which 51 MSAs, 10 coordinating authorities, 62 economic operators, 47 industry associations, 4 international organisations, 6 consumer organisations, 3 academic/law firms, 1 trade union, 4 consumers/citizens, 13 others). Data from the targeted surveys do not fully confirm this point, although they might be biased by respondents' identity. The question '*Do you usually perceive to have sufficient market knowledge to target checks to be carried out?*' was only asked to MSAs and Customs, which answered 'yes' in 71% of cases (n=51, 39 MSAs and 12 Customs).

233 Data from targeted surveys, seven MSAs.

234 PROSAFE (2013). Best Practices Techniques in Market Surveillance. p.19.

pressure equipment) is that **inspections and testing of the related products are so costly that MSAs usually perform or consider to perform only documentary checks**, thus further confirming an unequal enforcement of market surveillance across sectors and across Member States.[235] Figure 4-22 and Figure 4-23 presented above support this evidence, showing how **the higher or lower availabilities of laboratories for product testing seems to confirm a tendency to perform more or less laboratory tests at the national level**.

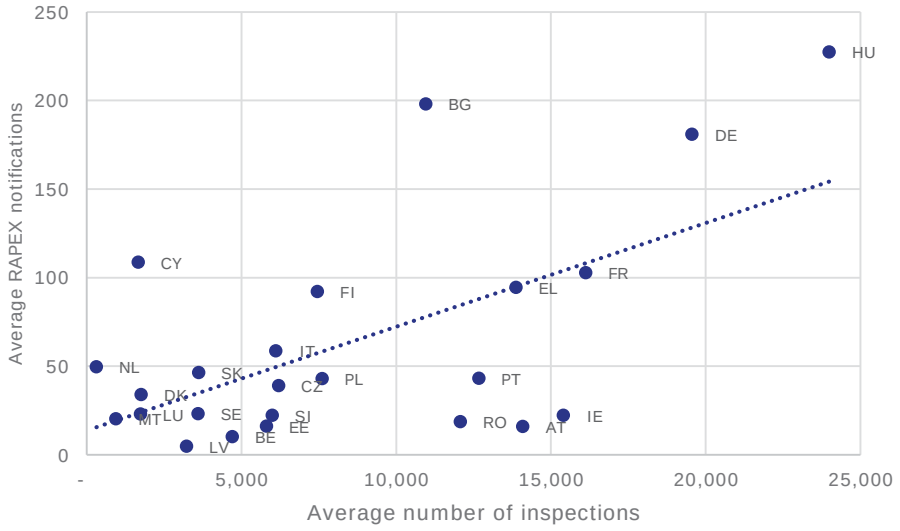
The availability of resources also influences MSAs' criteria for prioritisation of monitoring and enforcement activities.[236] For instance, **MSAs and Customs determine the 'adequate scale'**[237] of controls first on the basis of financial and human resources rationalisation,[238] and then of product risk level.[239] However, the Regulation requires Member States to give MSAs all the resources they need 'for the proper performance of their tasks'.[240] This would imply that first MSAs determine their targets in terms of controls, and sufficient resources would be given as a consequence. This may actually explain the low number of controls. Interestingly, the German Product Safety Act defines the adequate number of products to be tested by means of a 'sample rate' (i.e. 0.5 products per thousand inhabitants per year, as an indicative target for each Federal State).[241] The establishment of a clear benchmark makes it easier to calculate the number of MSA working hours and staff needed to perform such tests. However, the measure of adequate scale also depends on product features (i.e. whether it is a serial or single product). Moreover, in some Member States such as Italy, MSAs' resources are not linked to specific objectives or targets, except for special financial allocations assigned by the MISE (the coordinating authority) to specific projects – as discussed in case study 1. In general, however, each Italian MSA can set its own priorities and is free to allocate resources and to focus on self-established issues, although the MISE organises meetings to provide strategic orientations, European guidelines and general updates every 6 months.

As shown in Figure 4-29 above, differences are traced also in MSAs' **strategies for market surveillance.** In general, proactive market surveillance is more cost-efficient than reactive market surveillance, because the required resources can be defined in advance.[242] However, not all market surveillance activities can be planned ahead. In order to avoid duplication, a MSA should check ICSMS and any other appropriate platforms (e.g. national database) to see if the same product has already been assessed. Once again it can be concluded that **market surveillance is not uniform across the EU,** being also strategically influenced by the level of resources, which is different from one Member State to another.

In addition, **the relationship between the number of inspections and the number of RAPEX notifications** has been considered (see Figure 4-30 below). Interestingly, the correlation between the two is positive and quite significant (i.e. 0.61). These data confirm that the number of inspections performed at the national level is an enabling factor to detect non-compliance, and that human and technical resources available at the national level might play a relevant role in the effective enforcement of market surveillance.

235 Confirmed by the coordinating authorities of EL, FI, IT, NL and a Swedish MSA.
236 Data from national programmes: MT, PL.
237 Based on Article 19 of the Regulation, *'Market surveillance authorities shall 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.*'
238 Ten MSAs (AT, CY, DK, 3 FI, LV, 2 SE, UK) and one AdCO member (pyrotechnic articles).
239 Eight MSAs (CY, EE, 4 FI, LT, NL) and three AdCO members (construction products, explosives for civil use and recreational craft).
240 Regulation (EC) No 765/2008, Article 18(3).
241 Article 26 of the Product Safety Act, available at: https://www.gesetze-im-internet.de/englisch_prodsg/englisch_prodsg.html#p0023.
242 European Commission (2017), *Good Practice for Market Surveillance*. p.8. http://ec.europa.eu/DocsRoom/documents/21081

Figure 4-30 – Average number of inspections and average number of RAPEX notifications (2010-2013)[243]



Source: Author's elaboration of data from national reports and RAPEX database

Powers attributed at the national level and the **role of Customs** in enforcing the Regulation influence the effectiveness of border control. For instance, based on the available data, 16 Member States do not have in-house testing laboratories for any (or almost any) sectors.[244] The lack of laboratories, resulting in the impossibility for Customs to perform more in-depth and time-efficient controls, hinders potential improvement in border controls. However, in some Member States where Customs do not have laboratories, this shortcoming is compensated by MSAs having their own laboratories in some sectors.[245] On the one hand, this assures that testing is performed. On the other hand, the intervention of two different authorities (i.e. MSAs and Customs) could make procedures slower. According to data provided in the national reports, over the period 2010-2013, **Customs were particularly proactive** in Luxembourg and Croatia as they prompted on average, respectively, 45% and 37% of the total inspections performed. Similarly, they had a considerable role in triggering controls in Belgium, Poland and Bulgaria (they induced 22%, 17% and 15% of total inspections, respectively).

Furthermore, **controls are expected to be tougher in Member States where Customs act as MSAs**, such as in Finland, France, Latvia and Malta.[246] If Customs have MSA powers, there is a substantial extension of their area of competence and a significant need for in depth expertise.[247] While Customs powers are essential for the control of traded products, the introduction of Regulation 765/2008 highlights the need for cooperation between Customs and MSAs and with other EU Customs[248] as a crucial element for enhancing market

243 ES, HR, LT and UK have been excluded due to lack of data.
244 AT, BE, BG, CY, CZ, DE, DK, ES, FI, LT, LU, LV, MT, NL, PL, SE.
245 Based on the available information, in BG, CZ, DE, LT, NL, PL and SE. For more detailed information, please refer to Annex.
246 This being confirmed by two German and one Swedish MSAs and two Dutch Customs authorities responding to the targeted surveys.
247 Swedish Board for Accreditation and Conformity Assessment.
248 Dutch Customs and Swedish Board for Accreditation and Conformity Assessment.

surveillance on imported products.[249] In this respect, there are notable **differences across Member States**.

Overall, it seems these discrepancies are being allowed by **the general requirements set in the Regulation**,[250] as further discussed below.

This lack of specificity reveals **the obligations of Member States** as regards organisation (Article 18(3)). The Regulation foresees that Member States shall entrust MSAs with the **powers, resources and knowledge** necessary for the proper performance of their tasks. However, without setting any minimum criteria or thresholds, this results in a wide variety of implementation forms, especially in terms of endowments of powers and resources. As discussed in the previous sections, these are not always sufficient to grant an effective enforcement. The same considerations can be drawn for Article 19, stating that MSAs shall perform 'appropriate checks of products on an adequate scale'. As discussed, the 'intensity' of market surveillance and the types of checks performed vary across Member States, thus further deepening the differences in the enforcement levels.

Article 18(5) and Article (6) require a **periodical update of national programmes and a review of the functionality** of market surveillance activities every four years, but it does not mention any timing for update, neither does it provide any specific methodologies for the review. Article 18(5) therefore does not foresee the provision of **structured information** from Member States to the EC relating to market surveillance activities, which is particularly evident in light of all the data limitations of national programmes and reports described in section 4.3.1. This lack of harmonisation makes the national programmes and reports **not immediately comparable across countries**, which is a missed opportunity for Member States to benchmark and learn from each other's experiences. In practice, as further discussed below in section 6.3, it is a missed opportunity for market surveillance harmonisation.

As discussed below, the Regulation **does not include specific provisions related to the principles of cooperation between Member States**. This clearly impacts on the existing cooperation mechanisms and tools, which, as described in the previous sections, are many and different, but could be improved. Finally, the Regulation is **not specific enough to set a minimum and/or a maximum level of penalties**, or any principles to define them. As discussed, this results in wide differences in the minimum/ maximum amounts within and across Member States, which lower the enforcement deterrence power.

An additional enabling factor has been identified in the (lack of) cooperation with between enforcement authorities and businesses. Among the main reasons for product non-compliance in the internal market, there seems to be **a lack of economic operators' knowledge**[251] on the relevant legislative requirements to be complied with, as well as a **deliberate choice to exploit market opportunities at the lowest cost**,[252] possibly due to low incentives to comply with the existing rules. This issue was particularly emphasised by some stakeholders participating to the public consultation, highlighting how violations are often due to

249 PROSAFE (2013). Best Practices Techniques in Market Surveillance. p.90.

250 44% of respondents to the targeted surveys state there is a need for additional guidance on the Regulation. Total number of respondents to the question *'Is there a need for any additional guidance on any areas of the Regulation?'* = 118. Yes = 52 (35 MSAs, 6 coordinating authorities, 5 Customs, 2 economic operators, 4 industry associations). No = 66 (33 MSAs, 7 coordinating authorities, 14 Customs Authorities, 2 civil society associations, 2 economic operators, 8 industry associations).

251 According to 57% of respondents to the public consultation (n=136). Confirmed by OECD (2000*). Reducing the risk of policy failure: challenges for regulatory compliance.* Also confirmed by an EU industry association.

252 According to 49% of respondents to the public consultation (n=117). Confirmed by OECD (2000*). Reducing the risk of policy failure: challenges for regulatory compliance.* Also confirmed by two EU industry associations.

complexity or complicated interplay among rules,[253] especially for SMEs, which are hardly able to understand bureaucratic requirements.[254] As mentioned in section 6.4.2, an EU industry association claims that the interplay between the GPSD and the Regulation leads to extreme legal uncertainty 'which economic operators and enforcement authorities are increasingly unable to understand and to apply properly in the remit of their respective obligations'. As a further proof, the UK adopts an approach to sanctions that sees prosecution as a 'failure of the enforcement' and that is therefore based on the collaboration between economic operators and MSAs, setting compliance as a common goal and helping economic operators in understanding and correcting non-compliance. Several stakeholders[255] expressed a need for a **higher level of information flow from MSAs to businesses** and more practical guidance for economic operators. In the context of the interviews, an EU industry association suggested giving economic operators that are willing to comply the opportunity to do so before imposing sanctions, while another EU industry association suggested organising educational campaigns targeting economic operators.

6.2 Efficiency

EQ of reference

EQ 6. *What are the regulatory (including administrative) costs for the different stakeholders (businesses, consumers/users, national authorities, European Commission)?*

EQ 7. *What are the main benefits for stakeholders and civil society that derive from the Regulation?*

EQ 8. *To what extent have the market surveillance provisions been cost effective?*

EQ 9. *Are there any significant differences in costs (or benefits) between Member States? If so, what is causing them?*

This section first describes how different stakeholders are directly or indirectly impacted by the Regulation, secondly it provides an overview of the costs for the different stakeholders, and finally it presents a qualitative analysis of the cost-effectiveness of the Regulation, as well as differences across Member States.

6.2.1 Costs of the Regulation

6.2.1.1 Costs for Member States

The EU harmonisation legislation is mainly based on standards adopted by a recognised Standardisation Body in accordance with a request made by the European Commission and cited in the OJEU. Within this framework and in line with Regulation (EC) No 765/2008 Member States have the following obligations:

253 Also stated by the Swedish Board for Accreditation and Conformity Assessment and by an EU industry association.
254 Also confirmed by an interviewee from an EU industry association.
255 An MSA from Norway, seven industry associations (2 BE, ES, DK, FI, NL, UK), two economic operators (IT, SE), a Belgian consumer organisation, one academic/law firm from the UK. Also confirmed by an EU industry association.

- Organisational obligations:
    - Provide the necessary infrastructures, resources and powers to perform market surveillance;
    - Establish market surveillance programmes and communicate them to the European Commission;
    - Establish complaint procedures and monitoring of accidents;
- Information obligations:
    - Inform the European Commission on responsible authorities and their specific areas of competence;
    - Inform the public on responsible authorities and contact possibilities;
- Surveillance obligation:
    - Perform appropriate checks: documentary/physical, and laboratory checks;
    - Request documentation and enter premises;
    - Cooperate with economic operators to eliminate risks;
    - If necessary, destroy/render products inoperable when they pose a serious risk;
- Cooperation obligations:
    - Exchange of information;
    - Mutual assistance;
    - Participation in administrative cooperation;
    - Possibility to develop cooperation with third countries.

However, **unavailability of data about costs incurred by Member State Authorities** for surveillance activities before 2008 did not allow for the assessment of the additional costs deriving from the new obligations introduced by the Regulation.

With respect to organisational, information and cooperation obligations a qualitative analysis can be found in Sections 0 and in the first two case studies presented in the annexes.

To answer to the evaluation questions related to the efficiency, this section focuses on the costs related to surveillance obligations for which data included in the national reports might be considered as the best source of information.

To estimate the regulatory costs for national authorities related to surveillance obligations the following four indicators have been selected:

- Budget available to MSAs in nominal terms;
- Budget available to MSAs in relative terms (% of the total national budget);
- Staff available to MSAs (FTE units);
- Number of inspectors available to MSAs (FTE units).

The main highlights of the analysis show the **costs at Member State level**:

- The budget allocated to Market Surveillance Activities:
  - On average, is €7.5 m per each Member State in nominal terms,[256] representing around 0.1-1.33%[257] of total national budget;
  - Decreased by 7% over the period 2010-2013 (from €7.8 m to €7.5 m);
- Human resources allocated to MSAs
  - More than 280 FTEs[258] were involved on average at Member State level over the period 2010-2013 in inspection activities. The number of inspectors decreased by 4.4% (i.e. reduced from 288 to 275) over the period considered;
  - MAs can count on average on more than 415[259] FTEs in order to perform market surveillance activities each year; however, the number of FTEs available decreased by 2.6% over the period 2010-2013.

However, from the data presented in the national reports a lack of a structured approach clearly emerged:

- Some countries, such as France, **declared in the report only financial resources concerning a specific activity** (i.e. testing capacity on state-owned laboratory);
- Other countries, such as Ireland and Italy, **provided information only related to specific sectors;**
- Some others, such as Estonia, could not indicate separately the financial resources allocated to market surveillance, since market surveillance is only a part of their MSA activities.

Therefore, the figures presented so far, extracted from the national reports, probably represent a lower estimate of costs at national level for market surveillance.

256 Not all EU-28 Member States provided reliable data for this indicator. Therefore, figures do not include AT, CY, EE, EL, HR, HU, LU, SI, UK. The average for Sweden is computed considering only data for 2012 and 2013 because some authorities did not provide any figures for some sectors for 2010 and 2011.
257 The figures refer to 10 MS that provided reliable data, precisely: DK, EE, ES, FI, IT, LV, MT, PL, SE, SK.
258 The figures refer to 16 MS that provided data, precisely: BE, BG, CZ, DK, EE, ES, FI, IE, IT, LT, LU, LV, PL, PT, RO, SK.
259 The figures refer to 18 MS that provided data: BG, CZ, DK, EE, DE, ES, FI, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SK. For Sweden, the average is computed considering only data for 2012 and 2013 because some authorities did not provide any figures for some sectors for 2010 and 2011.

Within this framework, an estimation of the costs related to surveillance obligations is only possible for a limited number of countries (15) that provided completed and reliable data regarding the above mentioned indicators (Table 4-30).

Specifically, the analysis compared the average nominal budget to the number of inspections and the number of tests performed. It emerged that:

- Member States follow different approaches in:
  - Performing market surveillance activities;
  - Reporting data to the EC;
- Each Member State performed each year around 7,500 inspections and 770 tests in laboratories on average over the period 2010-2013;
- Even if the nominal budget for the countries considered remained virtually constant, the yearly number of inspections increased by 21% while the yearly average number of tests in laboratories decreased by 7%.

Table 4-30 – MSAs' average number of inspections per average number

MS	Nominal budget (Av. '10-'13) €	Δ% 2010 - 2013	Number of inspections (Av. '10-'13)	Δ% '10-'13	Average cost of inspections €	Num. of tests performed in laboratories (Av. '10-'13)	Δ% '10-'13	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: Author's elaboration of data from national reports

As shown for inspections and tests, the fact that every Member State defines its own market surveillance approach creates a high variation in the ways the different sectors are controlled and managed. Moreover, fragmentation throughout the Internal Market may interfere with Authorities' early action and produce additional costs for businesses.

Different approaches may also reduce the efficiency of the market surveillance when responsibilities of national authorities are not primarily related to market surveillance of non-food products within the meaning of the Regulation, creating overlapping and duplication of activities. To give an example, the toy sector in Italy is indicated as controlled by the Guardia di Finanza, by Chambers of Commerce, by Customs, and by the Carabinieri NAS. The Ministry of Economic Development (MISE) acts as a 'filter' redirecting – for instance – Customs' requests regarding specific product issues to the relevant Ministry, since the system as it is designed does not grant an immediate contact between the different actors involved, nor does it create synergies across them for overlapping sectors.

6.2.1.2 Costs for economic operators

As stated previously, the Regulation under the scope of the study provides a framework for the market surveillance of products and controls on products from third countries.

Therefore, the only **direct costs** for economic operators **deriving** from the Regulation are related to **information obligations** pursuant Article 19. Specifically, "*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, and, where it is necessary and justified, enter the premises of economic operators and take the necessary samples of products. They may destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary. Where economic operators present test reports or certificates attesting conformity issued by an accredited conformity assessment body, market surveillance authorities shall take due account of such reports or certificates*."

Concerning the costs incurred by businesses, only two industry associations and one company replied to the targeted survey question on costs for economic operators related to the application of the Regulation. As for public authorities, even if the number of responses is sufficient (around 25 authorities answered the question related to costs for economic operators), their informative power is low: the answers do not appear to be robust since they have a very high variance.

In this context, we integrated results from the survey with **10 targeted interviews** with businesses and business associations in order to understand the nature and magnitude of the costs for businesses deriving from the Regulation.

During the interviews it emerged that costs related to information as established in Article 19 of the Regulation are perceived as not significant.

However, a potential ineffective **market surveillance might lead to additional and more significant costs for economic operators, related to** a lower product compliance, including for those from outside Europe, **to unfair competition**, and to a reduced safety and user trust.

For business associations involved in the study, the internal market constitutes an indispensable, stable and important economic area where companies are asked to comply with health and safety conformity requirements offering a high level of protection.

From stakeholders' perspective, the implementation of the approach introduced with the NLF is a 'learning by doing' process where some **across-the-board inconsistencies** still remain and the current enforcement mechanism is not able to create a level playing field for business that are selling products in the Internal Market. This **is creating additional costs for economic operators**, especially SMEs.

From the discussion with some business associations, it emerged that additional costs are generated by:

- The concept of 'appropriate' applied to checks foreseen by the Regulation (cf. Article 19(1)) leads – in some cases – to discrepancies in market surveillance practices within the EU due to the concomitant-wide leeway for interpretation and transposition; this creates unbalances in costs, especially for SMEs;

- MSAs have limited financial, human and technical resources that limit their capacity to control the entire market and reduce thoroughness of the performed controls; a low enforcement programme and a low risk of detection of infringements can discourage compliant behaviour and increase unfair competition;

- Member States give greater importance to administrative aspects than to technical aspects – in some cases, manufacturers are requested to translate the product-specific documentation in different languages, English not always being accepted as 'lingua franca' and generating additional information obligation and administrative burden;

- Economic operators give greater importance to user safety regulation than other technical aspects (e.g. standard level on noise for machineries). This creates potential opportunities for free riding and increases costs for businesses that are willing to comply with all rules

- Communication among MSAs and manufacturers of the products is not effective when they are not both based in the MSA's country; hence the risk is that MSAs prefer to contact the local distributors that do not always have the right information. Thus, communication between businesses supplying products in the Internal Market and MSAs might be laborious and beset with delays. As product cycles are becoming shorter and shorter, the delay in these procedures for demonstrating and controlling product compliance is reflected in additional burdens (costs) for businesses (especially SMEs). However the use of an IT database collecting all technical product specifications raises issues related to intellectual property protection. Instead, there is a need for more cooperation between industry and authorities. In this way, MSAs can take advantage of manufacturers' technical knowledge and may be in a better position to identify non-compliant products on the market and set appropriate priorities for market surveillance activities.

- The identification of non-compliant products might be reinforced by more effective cooperation between industry and authorities. In this way, MSAs can take advantage of manufacturers' technical knowledge and may be in a better position to identify non-compliant products on the market and set appropriate priorities for market surveillance activities;

- In some cases product non-compliance is related to a lack of awareness about product legislation based on EU harmonised rules. Knowledge among SMEs and especially micro businesses about harmonised rules applicable to industrial products is not always high;

- As online trade is becoming increasingly relevant, the absence of a specific regulation poses serious compliance challenges for suppliers and manufacturers.

All issues contribute to the framework in which **the level playing field is not completely ensured** and in which ineffective controls and checks lower businesses' willingness to comply with the rules, and discriminate businesses that abide by the rules against those who do not.

6.2.2 Benefits of the Regulation

In terms of **benefits** the following have been considered:

- Direct benefits:
  - Cost savings for business;
  - Improved safety and trust for end-users;
- Indirect benefits:
  - New market opportunities for businesses.

Cost savings result from the simplification of pre-existing regulatory provisions. They relate to lower administrative, operational and external costs in comparison to the situation before 2008.

Benefits for businesses have been investigated through the online survey with individual companies as well as through 10 interviews with businesses associations.

During interviews, business' associations were asked whether their industry had benefited from cost savings since the entry into force of the Regulation. **The majority of the associations did not report cost savings** as a result of the implementation of the Regulation in terms of administrative and operational tasks if compared to the situation prior to 2008.

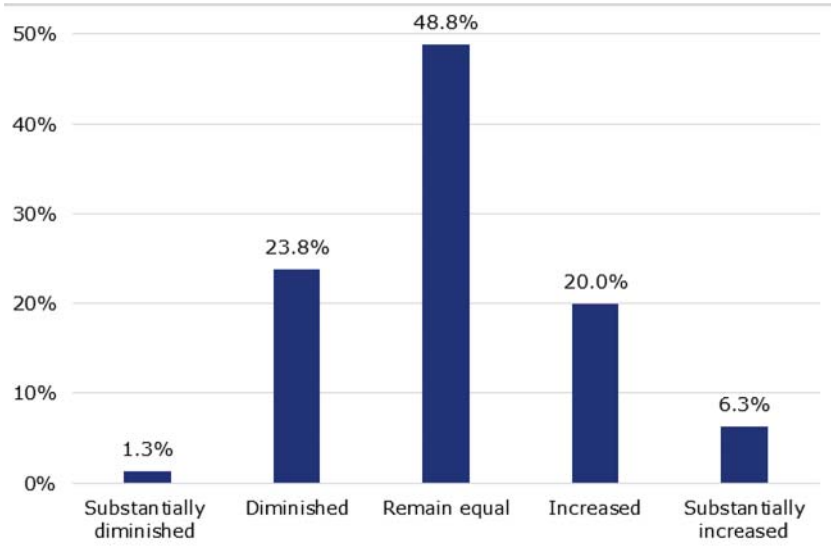
The Regulation is expected to induce benefits also in terms of **improved safety** and provision of information along the value chain. This relates to the obligation of making the information available to public authorities and third parties and to the incentive of complying with the EU's standard product rules. In this case, benefits would translate into improved safety due to better communication on the technical performance of the products and into increased users' trust.

Businesses' association were asked:

- Whether in their opinion the level of product compliance had diminished in the last 5 years;
- Which are the sectors more affected by non-compliance;
- Whether market surveillance activities are sufficient to deter rogue traders in their sector in their Member State.

Most **stakeholders involved did not perceive a substantial variation in product non-compliance** considering the period from 2010 to 2015 (Figure 32); however the number of stakeholders that perceived an increase in product non-compliance is higher than the numbers of the stakeholders that perceived that product non-compliance had reduced. This seems to be also confirmed by the increased number of notifications and corrective measures taken by the MSAs in the last few years.

Figure 4-31 - Perceived level of product non-compliance in the last five years (80 responses)

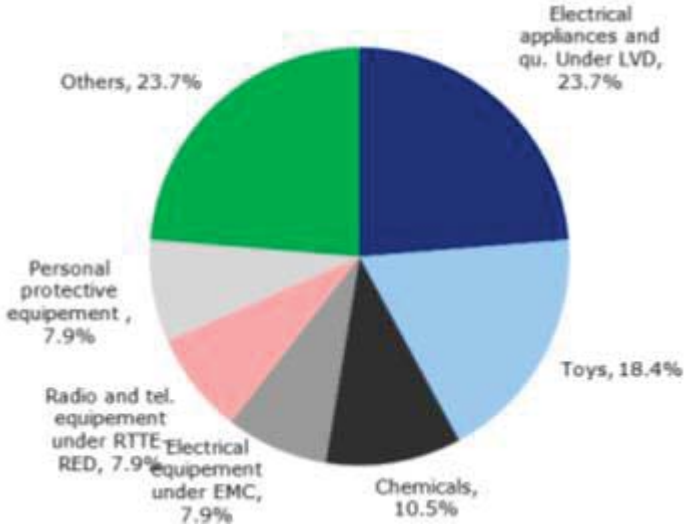


Source: Author's elaboration of data from online targeted survey

The analysis of responses to the survey highlights also that 'Toys', 'Chemicals' and 'Electrical appliances under the Low Voltage Directive' seem to be the sectors were the product non-compliance is more problematic (Figure 4-33).

However, only for toys and chemicals is this perception confirmed by the indicators used to measure product non-compliance in the internal market.

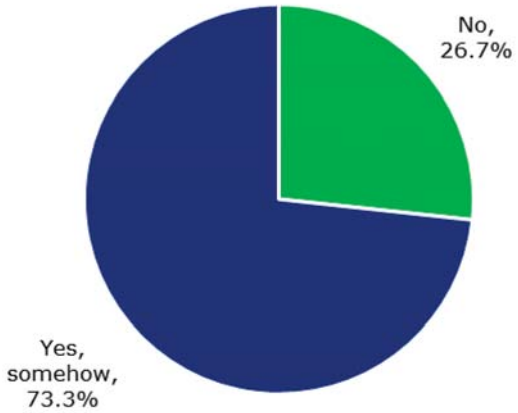
Figure 4-32 - Sectors heavily affected by product non-compliance (34 responses)



Source: Author's elaboration of data from online targeted survey

Market surveillance activities are perceived as not sufficient to deter rogue traders. However these findings are related to a low number of total received answers (Figure 4-33).

Figure 4-33 - Do you think that market surveillance activities are sufficient to deter rogue traders in your sector in your Member State? (15 responses)



Judging from the figures presented above, it might appear that **the Regulation is not producing the envisaged benefits and that the problem related to product non-compliance still remains**. However, it is not possible to measure how this has impacted safety and uniform protection of consumers across the EU. No data are available about injuries caused by product non-compliance. An exception is represented by the IDB but the currently available IDB data are produced voluntarily by Member States and do not clearly mention if notified injuries are caused by product non-compliance or improper use by consumers.

The Regulation aimed at ensuring a level playing field for businesses. This can create benefits in terms of increased turnover, reduced barriers to trade and increased competition for economic operators in the home and EU markets, thus also benefitting end-users.

However, as shown so far, the Regulation demonstrated a reduced capacity to achieve its strategic objectives. Interviewed stakeholders had mixed views with regard to the ability of the Regulation to ensure a level playing field for business. Therefore, the Regulation is perceived to have introduced more costs for manufacturers than benefits.

6.2.3 Cost-effectiveness of the Regulation

The cost- effectiveness of the Regulation is related to the extent to which the **desired results** (i.e. increased product compliance and increased cooperation and exchange of information among the EC, the Member States, the MSAs and Custom authorities) and **impacts** (i.e. increased protection of consumers across the EU and contribution to ensuring a level playing field for businesses) **have been achieved at a reasonable cost** (i.e. resources allocated to market surveillance activities).

Within this framework, it emerged that the Regulation has a limited cost effectiveness due to:

- A partial achievement of both expected results and impacts;
- Resources allocated seems not correlated to the size of surveyed markets.

6.2.3.1 Results and impacts of the Regulation

It has been showed that, after the entry into force of the Regulation, **product non-compliance increased consistently from 2006-2009 to 2010-2015**:

- The use of **restrictive measures** has grown by an impressive 52% (Table 4-16). In addition, the most significant increases have been registered in the most 'coercive' measures (i.e. seizure, withdrawal, destruction);
- **MSAs' restrictive measures** remained broadly unchanged (i.e. -0.33%);
- **Measures and corrective actions undertaken by economic operators** on average have increased. From 2005-2009 to 2010-2015, the most significant increase (by nearly 124%) has been registered in the average number of notifications relating to product destructions (Table 4-18).

In terms of cooperation and exchange of information, there are no uniform working practices across Member States and, as emerged from interviews with business representatives, the cooperation mechanisms in place are not effective in identifying non-compliant products on the market and in ensuring a level playing field for businesses.

Furthermore, section 6.1.1 analysed in detail to which extent the Regulation achieved both its specific and strategic objective that clearly reflect a reduced cost-effectiveness.

6.2.3.2 Cost of market surveillance activities and size of surveyed markets

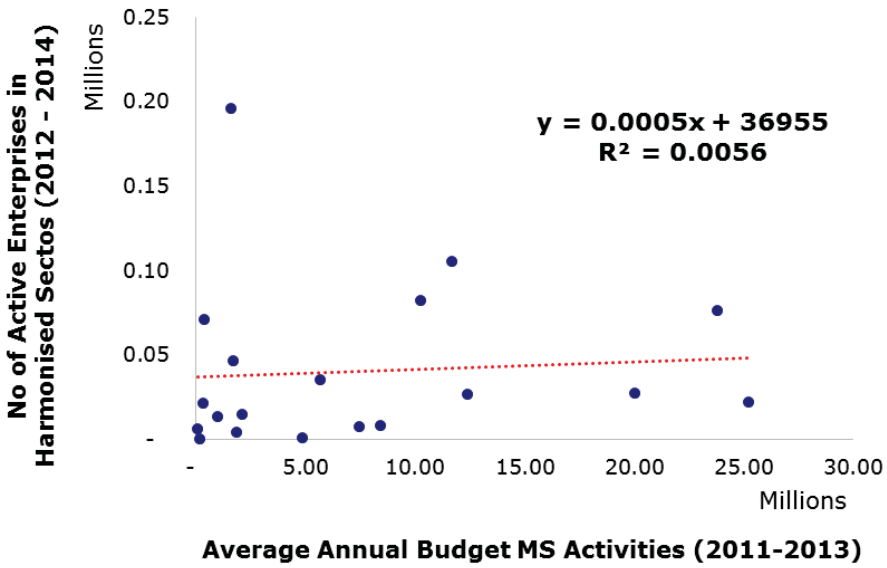
The limited cost-effectiveness of the market surveillance provisions also emerged from the comparison between the **financial resources allocated to surveillance activities at national level and the size of the local market for harmonised products**.

Specifically, the following dimensions have been compared:

- The average annual budget available to MSAs in nominal terms to the average number of enterprises active in the national market;
- The variation of the nominal budget available to MSAs to the variation of the number of enterprises active in the national market.

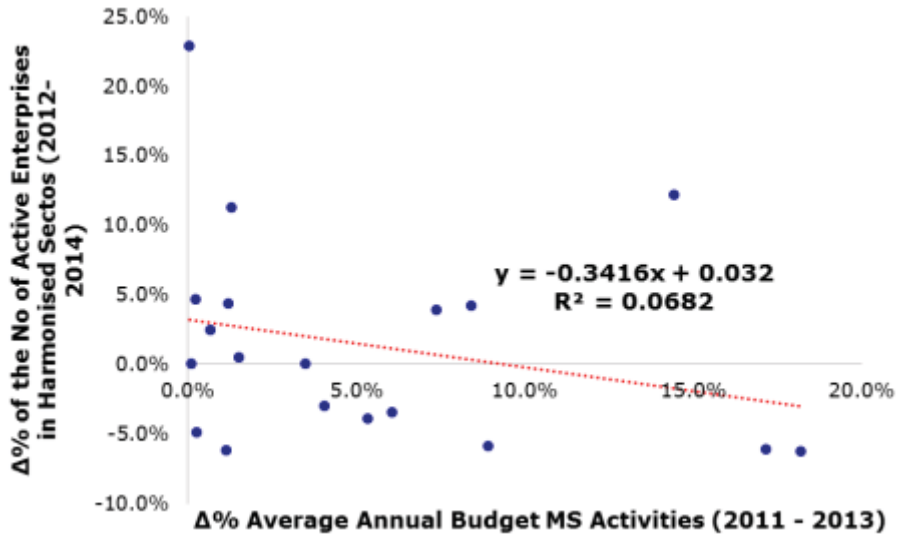
The results of these comparisons show that neither the average annual budgets allocated to MSA activities (Figure 4-34) or their variation over the period 2011-2013 (Figure 4-35) are correlated with the number of enterprises active in the harmonised sectors.

Figure 4-34 - Average annual budget available to MSAs in nominal terms vs average number of enterprises active in harmonised sectors



Source: Authors' elaboration on data from national reports and SBS (2016)

Figure 4-35 - Average annual budget available to MSAs in nominal terms vs average number of enterprises active in harmonised sectors (percentage variation)



Source: Authors' elaboration on data from national reports and SBS (2016)

The **differences** in the budgets allocated to MSA activities might be related to the fact that Member States have different organisational models requiring different levels of financial resources. However, another possible explanation might be sought in the different approaches followed by MSAs in reporting data concerning the used financial resources as well as the performed activities.

6.3 Relevance

EQ of reference

EQ 10. *To what extent are market surveillance provisions of the Regulation still relevant in the light of, for instance, increasing online trade, the increase in imports from third countries, shortening product life, increasing budgetary constraints at national level, etc.?*

EQ 11. *To what extent do the effects of the market surveillance provisions satisfy (or not) stakeholders' needs? How much does the degree of satisfaction differ according to the different stakeholder groups?*

EQ 12. *Is there an issue on the scope (i.e. all EU product harmonisation legislation) of the measure or some of its provisions?*

EQ 13. *Is the concept of lex specialis still a suitable interface between the market surveillance provisions in the Regulation and those in other (notably sector) legislations?*

This section presents the answer to the evaluation questions in two main blocks. First, it looks at the relevance of the Regulation in terms of its general scope and nature; second, it looks at whether the Regulation meets stakeholders' needs, with a focus on needs related to new/emerging issues.

6.3.1 Relevance of the scope of the Regulation

The **scope** of the Regulation is considered clear and adequate by 71% of stakeholders,[260] but **not clear and adequate by 29%**[261] of them. Considering that MSAs are those implementing the Regulation and economic operators are those subject to market surveillance, the latter percentage is to be considered quite relevant and an **indication of a problem in the scope** that should be taken into consideration.

The same fact that some Member States included additional sectors within their national reports, as mentioned,[262] is an indication of some confusion on the scope of application of the Regulation (so that an MSA suggested that the Regulation should mention more clearly the sectors it applies to). Moreover, input gathered from stakeholders confirms that it is not always straightforward for economic operators to understand whether a product is subject to market surveillance and specific requirements or not, thus resulting in a 'good faith' non-compliance. The request from the majority of stakeholders (78%) for MSAs to provide information on product requirements in addition to enforcement, or support to companies through guidance on how to interpret product requirements, and in general terms to increase cooperation with the private sector,[263] has to be interpreted in the light of this picture. In perspective, difficulties in understanding the Regulation's scope might be exacerbated by technological developments, including 3D printing, and new kinds of products, such as apps and intangible products.

Next to this, some stakeholders, while considering the current scope clear, suggest to enlarge it to additional sectors.[264]

Also when looking at the specific items covered by the Regulation through its **definitions**, some points have to be underlined. Even though definitions are considered clear and appropriate,[265] a few stakeholders suggest they are **not complete and up to date**,[266] and might need some **adjustments** to further improve clarity and enhance implementation and enforcement capacity for all stakeholder categories. For instance, the current definitions do not consider the specific needs related to online sales, so that some stakeholders suggest to include specific definitions,[267] such as that of 'fulfilment house',[268] and to revise the definition

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260 Nine coordinating authorities, 37 MSAs, 13 Custom authorities, 3 economic operators (ES, IT, SE), 12 industry associations (AT, 8 BE, DK, EL, ES).

261 Three coordinating authorities (DE, DK, FI), 22 MSAs (BE, CH, 6 DE, DK, ES, 4 FI, IS, LT, 3 LV, NO, PL, SE), 3 Custom authorities (DE, FI, RO), one civil society association and one economic operator from Belgium.

262 Belgium also includes cigarette lighters, leather, products imitating foodstuffs, packaging, electrical equipment, liquid fuels and wheeled tractors. Denmark includes off-shore and food contact materials. Greece includes steel for the reinforcement of concrete and metal scaffolding. Portugal includes plant protection products, packaging waste management and information on the misuse of the CE marking. Sweden includes equipment for TV sets and precious metals. The UK includes end-of-life vehicles, passenger cars and products under the EU Timber Regulation.

263 For instance, 87% of respondents to the public consultation agree that MSAs should provide information on product requirements in addition to enforcement or support to companies through guidance on how to interpret them (78%). Finally, agreements between businesses and authorities are considered effective by 54% of respondents.

264 A Finnish authority suggested end-of-life vehicles; an Austrian MSA, software; a Polish MSA, civil aviation products for recreational use; a Finnish MSA, drones; a German MSA ring transformers and smart meters.

265 Source: targeted surveys. On average, 93% of respondents (51 out of 55) state definitions are appropriate and 93% that definitions are clear (100 out of 107).

266 Source: targeted surveys. On average 82% of respondents (34 out of 41) evaluate definitions as complete and up to date, while 18% of them (7 out of 41) state they are incomplete and outdated.

267 Nine MSAs (DE, DK, 3FI, LT, NL, PL SE), one AdCO member (electromagnetic compatibility), three Member State coordinating authorities (DE, DK, LT) and a Belgian industry association.

268 It is not always clear when fulfilment houses have to be considered as hosts and are thus not liable for product non-compliance - or when they act as proper distributors. According to Article 14 of Directive 2000/31/EC on hosting, *'Where an information society service is provided that consists of the storage of information provided by a recipient of the service, Member States shall ensure that the service provider is not liable for the information stored at the request of a recipient of the service, on condition that: (a) the provider does not have actual knowledge of illegal activity or information and, as regards claims for damages, is not aware of facts*

of 'EU importer'.[269] Similarly, the distinction between the definitions of 'making available on the market' and 'placing on the market' is not completely clear in the context of imported goods and online sales.[270] The interpretation of 'placing on the market' provided in the Guide in this regard is reported by some stakeholders to be unsatisfactory.[271] On the same lines, the Regulation is not completely clear in the definition of 'product' – currently not listed under Article 2 – and does not include the concepts of 'second-hand good', 're-used good' and 'by-products'.[272] As regards 'recall', a Swedish MSA states that the definition should be extended in order to refer also to situations where the manufacturer offers to remedy the fault (rectification), accept return and supply of another product (exchange) or accept return of the product and pay compensation (return). There is also the need to better define the concept of 'risk'.[273]

The concept of *lex specialis* is deemed to be a suitable interface to address sector specificities of market surveillance and it causes no difficulties in implementation according to the vast majority of stakeholders consulted.[274] Despite the generally positive views about the concept of *lex specialis*, some issues have been raised. In more detail, some stakeholders[275] underline that the scope of market surveillance rules in sector-specific legislation is not always clear, as it is not straightforward to assess which provisions of the Regulation apply and which articles of the sector-specific legislation are covered by the *lex specialis* principle. These interpretation problems often result in an excessive administrative burden and in legal uncertainty,[276] so that some MSAs suggest having a uniform market surveillance regulation for non-food sectors,[277] containing all market surveillance provisions at the EU level for all sectors,[278] or anyhow some adjustments. Yet, the idea of a joint Regulation is not shared by all, and some other stakeholders[279] find such merging for non-food products not appropriate.

6.3.2 Relevance of the Regulation to stakeholders' needs

6.3.2.1 Relevance to strategic objectives

Overall, **the Regulation meets stakeholders' needs.**[280] The framework for market surveillance provided is generally appreciated, being considered as useful in defining national market surveillance programmes and policies for controlling imported products.[281] The Regulation is considered relevant to meet the needs related to the free movement of goods and the protection of consumers, and – to a lower extent compared to the first ones – to a level

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or circumstances from which the illegal activity or information is apparent; or (b) the provider, upon obtaining such knowledge or awareness, acts expeditiously to remove or to disable access to the information'.

269 Eight MSAs (DE, DK, FI, LT, 2 NL, SE, UK), a Lithuanian and a Danish coordinating authority, one AdCO member (electromagnetic compatibility), an industry association from Belgium.

270 Five MSAs (AT, DE, DK, FI SE), a Danish, the Turkish and the Romanian coordinating authorities, four Customs Authorities (BE, BG, EE, FR).

271 Five German MSAs.

272 The Finnish coordinating authority, a Swedish MSA, a Swedish Customs. A by-product is something produced in an industrial or biological process in addition to the principal product.

273 As stated by an interviewee from the Swedish Board for Accreditation and Conformity Assessment (SWEDAC).

274 70% (n=48) of respondents replying to the survey.

275 An AdCO member (pyrotechnic articles), seven MSAs (2 BE, 2 DE, 2 FI, NO).

276 Romanian and Slovenian coordinating authorities.

277 Five MSAs (4 DE, LV).

278 Two Danish coordinating Authorities and one Latvian MSA.

279 Three German MSAs and one German coordinating Authority, one Danish MSA (stating that it is useful to keep the sector-specific regulation for construction products).

280 According to 73% of respondents to the targeted survey.

281 49% of stakeholders (23 MSAs, 7 Customs authorities, 5 coordinating authorities and 3 AdCO members -construction products, measuring instruments, recreational craft) think it is useful in defining their national policies to a large extent, 46% consider it to be useful to a small extent (28 MSAs, 5 Customs authorities and 6 coordinating authorities), and only 5% declare it not to be useful (3 MSAs and one Customs authority).

playing field (see Annex). There is a smaller but still very positive consensus that the framework provided by the Regulation contributes to the protection of the environment.[282]

The relevance of the Regulation is also confirmed by **the dimension of the internal market for non-food products**, as presented in section 5.1.[283] In this context, market surveillance is fundamental both to ensure that users are protected from non-compliant (and potentially) dangerous products and to ensure a level playing field for businesses across the EU. Without a Regulation setting out the minimum requirements for market surveillance, some Member States may apply less stringent provisions, allowing the entrance of non-compliant products into the EU market. Alternatively, different market surveillance practices could result in unbalanced surveillance to the detriment of economic operators and to the level playing field.

6.3.2.2 Relevance to specific objectives

The analysis undertaken on the effectiveness of market surveillance highlighted that the main challenges in enforcing market surveillance refer to cooperation and coordination arrangements and to the uniformity and rigorousness of the system and drive to the conclusion that market surveillance could be enhanced through further exchange of information and cooperation.

In light of this, **provisions related to cooperation** (under Articles 24, 25, and 26) together with provisions requesting the use of tools to exchange information (under Articles 22 and 23, as well as 17), are particularly relevant to enhance market surveillance enforcement, yet encountering some implementation issues that might need to be addressed. As discussed in case study 4, RAPEX and ICSMS are not used at their full potential as there are some cross-border cooperation gaps.

Along the same lines, the **provisions on market surveillance programmes and reports** (as per Article 18(5)) are also useful,[284] and represent a tool for cooperation between MSAs. Nonetheless, limitations to this study and feedback from stakeholders highlight room for improvement. Being the main source of information for monitoring market surveillance, the quality and comparability of the information provided is far from being sufficient, thus limiting any proper assessment of the functioning of market surveillance and making their consultation very burdensome,[285] if not useless, as already remarked. Reasons behind their limited informative power can be related to:

- The administrative burden associated to the drafting on a yearly basis *vis-à-vis* market surveillance activities that do not change every year[286] (making the administrative burden sometimes higher than the benefits);

282 70% of respondents to the targeted survey (54 out of 78) stating that the framework is adequate to the protection of the environment.

283 As discussed in section 5.1, over the period 2008-2014, around 1.2 million enterprises were operating within harmonised sectors, representing more than 65% of the total number of active enterprises in the manufacturing economy. The value added produced therein totalled €1,269 billion in 2014. Moreover, approximately 30% of the value of harmonised products (€678 billion) is related to goods imported from non-EU countries.

284 76% of respondents to the targeted surveys. Various benefits have been highlighted by stakeholders. National programmes are considered to be an opportunity to define market surveillance strategies and to inform consumers; they push MSAs to improving the effectiveness and efficiency of market surveillance activities, since they help in verifying and monitoring implemented activities; they are useful to avoid overlapping of market surveillance actions, working as a tool for cooperation between MSAs; they even contribute to ensuring a level playing field in Europe, since they allow Member States to acknowledge the differences in the enforcement actions and possibly to eliminate them.

285 They are separate documents and do not always include relevant information.

286 Four MSAs (3 FI, SE), two Member State coordinating authorities (EE, FI).

- The generality of the requirements, which hinders the harmonisation of programmes across Member States;[287]

- The too lengthy procedure for providing the EC with the programmes and the publishing process of the documents,[288] which makes it difficult for Member States to learn from each other's experiences and to enhance collaboration (since when all the programmes are published – or sent to other Member States – in late autumn, the period they refer to is already over).

As regards the controls of products entering the community market (i.e. Articles 27 to 29), the **powers attributed by the Regulation to Customs are adequate**,[289] and the **procedures** for the control of products entering the EU market foreseen by Articles 27 to 29 of the Regulation are **clear, easy to apply and still relevant**.[290]

6.3.2.3 Relevance to new needs

Some issues emerge when looking at needs related to specific dynamics such as increasing online trade, increasing imports from third countries, shortening product life, and increasing budgetary constraints at national level. These dynamics had been raised in the inception phase of the study and have been then verified with stakeholders, to check whether additional phenomena had to be integrated into the analysis, which was not the case.

The Regulation appears to be **only partially relevant to new dynamics, with specific reference to online trade and increasing budgetary constraints**.

As shown, market surveillance on products sold online is particularly challenging, and the Regulation does not seem to be able to properly address related specificities. Specifically, the Regulation **does neither include specific provisions covering online sales, nor does it provide for definitions that account for its specificities**. As mentioned above, the same definitions of 'making available on the market' and 'placing on the market' do not consider the complex distribution chains of online sales, as also highlighted by some stakeholders when discussing both import from third countries and online sales.[291] Also, when considering the economic operators involved in the online sales supply chain, the Regulation does not reflect the latter complexity, for example leaving a grey area on whether fulfilment houses, which according to various stakeholders represent an increasing concern,[292] should be subject to market surveillance.[293] Moreover, in the case of e-commerce, other parties, such as the commercial platforms where products are sold, **should be punishable** when selling non-compliant products.[294] The overall limited relevance of the Regulation to online sales is also underlined by stakeholders.[295]

287 Five MSAs (BE, 2 DE, FI, SE), one AdCO member (medical devices) and three coordinating authorities (2 DK, SI).
288 Three MSAs (LV, NL, SE), two AdCO members (recreational craft).
289 As declared by Customs in BE, BG, CY, CZ, EE, FI, DE, HU, IT, LU, LV, MT, NL, PL, RO, SE, SK. Source: targeted surveys.
290 According to Customs answering the targeted surveys, procedures are clear (95% n=20), easy to apply (76% n=16) and relevant (86% n=18).
291 Five MSAs (AT, DE, DK, FI SE), a Danish, the Turkish and the Romanian coordinating authorities, 4 Customs Authorities (BE, BG, EE, FR).
292 Four MSAs (3 DE, NL), two AdCO members (electromagnetic compatibility, medical devices), and two EU industry associations.
293 These facilities are often regarded as logistics service providers rather than economic operators as defined in the Regulation, and this makes them difficult to sanction.
294 According to a Finnish MSA.
295 47% of survey respondents stated that the Regulation is not able to address specific issues deriving from the increase in online trade.

Yet, it is worth underlining that problems with market surveillance on products sold online can hardly be addressed by means of legislative measures only. Evidence gathered suggests indeed that the cost-effectiveness of proper rules and procedures would not be achieved unless accompanied by proper information and communication campaigns enhancing consumers' awareness of the risks related to products sold online.

A large share of stakeholders[296] has also challenged the relevance of the Regulation **to the needs related to budgetary constraints at national level**.

As discussed, market surveillance activities are indeed influenced **also by budgetary constraints,** several Member States identifying the **lack of financial and human resources** as one of the main bottlenecks hindering market surveillance implementation and enforcement.[297] Despite the increase in non-compliant products, the total **budget available to MSAs** in nominal terms at EU level[298] decreased during the period 2010-2013, representing around 0.1-1.33%[299] of the total national budget. Furthermore, neither the average annual budget allocated to market surveillance activities nor its variation over the period 2011-2013 are correlated with the number of enterprises active in the harmonised sectors. The lack of resources makes, for example, market surveillance measures lengthy, *vis-à-vis* a market that requires fast reaction, as in the case of online sales, already discussed, and the shortening of the product life cycle. Moreover, as discussed, budgetary constraints hamper the participation of many MSAs to AdCO groups, thus limiting the possibilities for cooperation.

Whereas the organisation of market surveillance is under the responsibility of Member States, the Regulation could both define minimum criteria for deploying resources to market surveillance and further streamline arrangements for the exchange of information and best practices, to further favour cooperation and reduce the burden for national authorities.

6.4 Coherence

EQ of reference

EQ 14. *To what extent are the market surveillance provisions coherent internally?*

EQ 15. *To what extent are the market surveillance provisions above still coherent with other Union legislation on market surveillance on non-food products?*

EQ 16. *To what extent are these provisions coherent with wider EU policy?*

6.4.1 Internal coherence

The objective of this analysis is to assess whether the market surveillance provisions of the Regulation are coherent within themselves.

The scope of Regulation (EC) No 765/2008 covers:

296 48% of survey respondents (all public authorities) stated the Regulation is not able to address specific issued deriving from increase in budgetary constraints.
297 Data from national reports of BG, CZ, EE, EL, ES, IE, LT, LV, MT, PL, PT, and SI.
298 Not all EU-28 Member States provided reliable data for this indicator. Therefore, figures do not include AT, CY, EE, EL, HR, HU, LU, SI, UK.
299 The figures refer to 10 MS that provided reliable data, precisely: DK, EE, ES, FI, IT, LV, MT, PL, SE, SK.

1. The rules for the organisation and accreditation of conformity assessment bodies;
2. The rules for market surveillance of products;
3. The control on products from third countries;
4. The general principles for CE marking.

For this purpose, the Regulation defines, among others:

- *Market surveillance,* consisting of all the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Community harmonisation legislation;
- *Public Authorities,* including **'market surveillance authority(ies)', namely the authorities 'of a Member State responsible for carrying out market surveillance on its territory';**
- *Product,* defined as '**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**'. This definition is restricted to '**products covered by Community harmonisation legislation'**. It is to be noted that this definition is not listed under Article 2 – Definitions, but under Article 15(4) – Scope;
- *Community harmonisation legislation* is defined as 'any Community legislation harmonising the conditions for the marketing of products';
- *Public interests*: although there is no definition for this term, the text of the Regulation indicates that public interests concern health and safety in general, health and safety at the workplace, protection of consumers, protection of the environment and security.

Moreover, the definitions refer to actors – manufacturer, authorised representative, importer and distributor – and processes of 'making available' and 'placing' on the market of products, as well as to restrictive measures such as 'withdrawal' and 'recall'. They are in line with the scope of the Regulation.

Article 16 of the Regulation establishes the obligation of Member States to organise and carry out market surveillance of harmonised products **in accordance with specific requirements**, relating, among others, to the product risk and the obligation to inform the public, the Commission and the other Member States of the measures taken to reduce such risks. Further **obligations of Member States** are, for instance, to designate national MSAs and to inform the Commission thereof; to establish appropriate communication and coordination mechanisms between MSAs; to set up adequate procedures in order to follow up on complaints or reports on issues relating to risks, monitor accidents and harm to health potentially caused by those products; to verify that the corrective action has been taken; to entrust MSAs with the powers, resources and knowledge necessary for the proper performance of their tasks; to notify of dangerous products and related measures in RAPEX and ICSMS system; to establish, implement and *periodically update* their market surveillance programmes. To this purpose, Member States may cooperate with all relevant stakeholders. However, **there is no mention of the timing for updating the programmes**. Moreover, the

Regulation requires Member States to periodically evaluate the functioning of their surveillance activities. The reviews shall be performed every four years and the results shall be communicated to the other Member States and the European Commission and be made available to the public. The Regulation **does not provide any specific methodology** to be followed by the Member States to review and assess the functionality of the surveillance activities, though information about possible technical guidance is included in Article 38.[300]

Requirements for MSAs are set in terms of performing appropriate product checks on an adequate scale; r**equiring** economic operators to make relevant documentation and information available; where necessary and justified, **entering the premises of economic operators** and taking samples of products; **destroying or rendering inoperable products** presenting a serious risk where necessary; **cooperating with economic operators**; **alerting users** to identified hazards relating to products; **informing economic operators** of any measures restricting the free circulation of products.

Article 20 makes reference to products presenting a serious risk, for which Member States shall ensure rapid intervention. To this purpose, the Regulation indicates that **Member States shall perform appropriate risk assessments**, taking into account the nature of the hazard and the likelihood of its occurrence. If a product presenting a serious risk has been made available on the market, Member States shall notify the European Commission of any voluntary measures taken and communicated by an economic operator as per Article 22(2). **However, the Regulation does not make reference to any specific risk assessment methodologies,** but a reference to technical guidelines is made in Article 38.[301]

The limitations under Article 21 refer to restrictive measures, which shall be based on proportionality and necessity. These measures and the remedy actions shall be communicated to the economic operators involved, to the Member State concerned and to the European Commission. This communication shall be done 'without delay' but **there is no indication of a maximum deadline.** The Regulation states that the economic operator shall have the opportunity to be heard within 10 days, unless such consultation is not possible because of the urgency of the measure. **However, the Regulation does not provide the date from which 10 days are to be calculated.**

Article 23 states that the European Commission shall **develop and maintain a general archiving and exchange of information system**, using electronic means, on issues relating to market surveillance activities, programmes and information on non-compliance with Union harmonisation legislation. Member States shall provide the European Commission with information at their disposal (and not already provided under Article 22) regarding, in particular, identification of risks, results of tests carried out, provisional restrictive measures, contacts with the economic operators concerned and justification for action or inaction.

Articles 24 to 26 refer to international cooperation via exchange of information and resources sharing between national MSAs, between Member States and the European Commission and the relevant Community agencies, and with third countries. In this regard, Member States shall ensure efficient cooperation and exchange of information on market surveillance programmes and products presenting risks. Cooperation consists in providing information or documentation, in carrying out investigations or any other appropriate measures and in

300 However, non-binding guidance was elaborated at expert group level.

301 The EC drafted, however, a guidance on risk assessment in collaboration with Member States, which has been published last year. Available at: http://ec.europa.eu/DocsRoom/documents/17107/attachments/1/translations

participating in investigations initiated in other Member States. The Regulation **does not include provisions related to the principles of cooperation between Member States** (i.e. spontaneous and/by request provision of information, fullest availability for cooperation, reciprocity basis, including in the case of negative response/no information). As discussed this is an issue for the consistent implementation of the Regulation, which has impacts on the achievement of its objectives.

Section III covers the control of products entering the Community market. The designated Member States' authorities in charge of this task shall have the powers and resources necessary for the proper performance of their tasks. The **external border control authorities** shall suspend the release of a product for free circulation in the Community market, whenever the case, and shall immediately notify national MSAs of any such suspension. Where MSAs find that the product in question does not present a serious risk to health and safety, that product shall be released. In accordance with Article 28, a suspended product is released if the external border control authorities have not been notified of any actions taken by the MSAs within three working days. Based on Article 29, if products presenting a serious risk are declared for a **Customs procedure** and the MSAs do not object, the endorsements shall also be included in the documents used in connection with that procedure. Inoperable products presenting a serious risk may be destroyed where deemed necessary and proportionate.

Chapter V refers to Community Financing. Among the eligible activities we identified:

- The drawing up and updating of contributions to guidelines in the fields of – among others – market surveillance;

- The making available of technical expertise for the purpose of assisting the European Commission in its implementation of administrative cooperation, including the financing of AdCOs, market surveillance decisions and safeguarding clause cases;

- The performance of preliminary or ancillary work in connection with the implementation of the conformity assessment, metrology, accreditation and market surveillance activities;

- Activities carried out under programmes of technical assistance, cooperation with third countries, market surveillance and accreditation policies and systems among interested parties in the Community and at international level.

Chapter VI – Final Provisions – covers the issuance of technical guidance for the implementation of the Regulation (Article 38) and the application of penalties (Article 41). As mentioned, Member States shall perform **reviews and assessments over the functionality of the surveillance activities**, as well as risk assessments to identify if products present serious risks. The technical guidance shall consider providing a methodology for these two processes. Finally, Member States shall set the **penalties** for economic operators, which may include criminal sanctions, applicable to infringements of the 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 under the Regulation. In this regard, a Finnish MSA indicates that penalties for infringements regarding the CE marking (with reference to

Article 30(6)[302]) shall be 'proportionate to the seriousness of the offence'. However, he states that **since non-compliance with rules on the CE marking concerns only formal requirements and not safety, the Regulation should not name them as 'penalties'.** In addition to this, the Regulation does not provide a minimum and maximum level of penalties. As discussed, this caused discrepancies in the level of sanctions and penalties for infringements of the Regulation across the EU.

Overall, **the Regulations' provisions appear to be coherent within themselves** in that roles and responsibilities of all relevant stakeholders involved, and processes are clearly defined and in the scope of the Regulation.[303] **The issues identified relate to the general character of the Regulation's requirements, which allow for different implementations at the national level.** As discussed in section 6.1.2, this heterogeneity impacts on the Regulation's achievement of its strategic objectives.

6.4.2 External coherence

In order to evaluate the external coherence of the Regulation, we analysed to which extent its provisions are coherent with other Union legislation on market surveillance on specific non-food products (i.e. the GPSD) and with harmonised sectoral legislations.

The **General Product Safety Directive (GPSD)** aims to ensure that only safe products are made available on the market. It applies to all non-food consumer products in the absence of specific provisions with the same objective in EU legislation governing the safety of the products concerned.[304] Thus, it has the effect of a safety net as it covers consumer products not covered by more specific provisions of EU product safety legislation.

The definitions of the GPSD are not always aligned with those of the Regulation. For instance, the definitions of 'distributor', 'withdrawal', 'recall' are different from one piece of legislation to the other, while the definitions of 'serious risk' and 'dangerous products' are set in the GPSD and not in Regulation 765/2008, though the latter widely refers to these concepts. In this regard, clarifications are needed on how to apply these concepts to products that are rarely dangerous but can still have non-conformities that imply a high risk (e.g. lifts).[305] Further, Article 18 of the GPSD states that Member States shall notify the party concerned about restrictive measures and indicate the remedies available. The parties concerned shall, whenever feasible, be given an opportunity to submit their views before the adoption of the measure. However, there is no deadline for hearings, as indicated by Regulation 765/2008.

Moreover, the boundary between the GPSD and the Regulation is not always clear,[306] despite the existing Commission's Guidelines. Therefore, **the two legislations sometimes seem to overlap**, 'leading to extreme legal complexity which economic operators and enforcement

302 Article 30(6) where it states that *'Without prejudice to Article 41, Member States shall ensure the correct implementation of the regime governing the CE marking and 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'.*

303 As confirmed also by four coordinating authorities (EE, HR, RO, TR), 14 MSAs (BE, CY, DK, IS, IT, 4 LT, NL, PL, 2 SE, UK), 4 Customs (CZ, CY, IT, LV), two EU industry associations, a Swedish company (equal to 62% of respondents to this question in the targeted surveys).

304 Article 1(2) of the General Product Safety Directive.

305 SE MSA.

306 Three coordinating authorities (2 DE, FI), eight MSAs (2 BE, CY, 2 DE, DK, ES, LV), two EU industry associations, one Swedish Customs authority.

authorities are increasingly unable to understand and to apply properly in the remit of their respective obligations, leading to diverging interpretations on both sides and to uncertainty'.[307]

As mentioned, the external coherence has also been assessed with respect to **each sectoral legislation** covered by the scope of the Regulation. **No coherence issues** have been found with the majority of legislations, whose interface with Regulation 765/2008 is clear in light of the *lex specialis* principle. Rather, some **complementarities** have been spotted, although they **do not raise any concerns with respect to overall coherence**.

The following table shows, for the remaining sectoral legislations, the **coherence issues** identified with respect to the definitions and penalties set down in each of them. For instance, in the case of lifts, 'recall' is not feasible, and the definition of 'placing on the market' in the Lifts Directive is different from the definition provided in Regulation 765/2008. Moreover, for sectors such as the lifts sector, the definition of 'putting into service' is fundamental, but – though set out in the relevant legislation – it is currently missing from the Regulation.[308]

Nonetheless, these inconsistencies **mainly regard misalignments in the terminology** provided in different legislative texts and do not seem to hamper the application of the Regulation; issues have also not been reported by stakeholders in this respect. As proof, product non-compliance in the internal market is not due to ambiguity in the rules.[309]

Table 4-31 – Consistency issues between the Regulation and some sectoral legislation

Sectors	*Definitions*	*Issue*	*Penalties*	*Issue*
Medical devices	• Manufacturer • Authorised representative • Placing on the market • Putting into service	Inconsistent	No reference about applicable penalties for substantial non-compliance.	Inconsistent
Personal protective equipment[310]			No reference about applicable penalties for substantial non-compliance.	Inconsistent
Construction products			No reference about applicable penalties	Inconsistent
Transportable pressure equipment			Article 14(7) refers to penalties only in respect to the failure to implement the rules governing the Pi marking.	Inconsistent
Lifts	Placing on the market	Inconsistent		
Cableways	European specification	Inconsistent	No reference about	Inconsistent

307 An EU industry association.
308 AdCO chair contributing to the targeted survey.
309 According to 51% of respondents to the public consultation (n=121).
310 Recently redrafted: Regulation (EU) 2016/425.

	(instead of European harmonised standards)		applicable penalties	
Noise emissions for outdoor equipment	Different definition in respect to 'marking'	Inconsistent	No reference about applicable penalties	Inconsistent
Gas appliances (Directive 2009/142/EC)			No reference about applicable penalties	Inconsistent
Pre-packaged products	No definitions provided	Inconsistent		
Measuring containers	No definitions provided	Inconsistent		
Units of measurement	No definitions provided	Inconsistent		
Motor vehicles, Directive (Directive 2007/46/EC)	Manufacturer	Inconsistent		

6.5 EU added value

EQ of reference

EQ 17. *What is the additional value resulting from the market surveillance provisions at EU level, compared to what could be achieved by Member States at national and/or regional levels?*

EQ 18. *To what extent do these provisions support and usefully supplement market surveillance policies pursued by the Member States? Do the provisions allow some sort of 'control' by the EU on the way national authorities carry out market surveillance?*

As described in the previous sections, there are no issues on the EU added value provided by the Regulation in terms of its objectives. It is clear, indeed, that by its same nature, the Regulation provides EU added value in terms of **harmonisation of market surveillance** if compared to what could be achieved by different pieces of national legislation, and that stakeholders recognise this value.[311]

According to stakeholders, the Regulation has the potential to:

- Contribute to the establishment of a level playing field;[312]
- Improve the free movement of goods;[313]

311 25 MSAs, four coordinating authorities, nine Customs authorities, four industry associations (3 BE, AT). Source: targeted survey.
312 10 MSAs, two coordinating authorities, two EU industry associations, an Italian and a Swedish economic operators. Source: targeted survey.

- Enhance efficiency and effectiveness of market surveillance activities.[314]

Stakeholders also state that the Regulation has stimulated **transparency and unambiguous interpretation of rules**.[315] By setting common requirements, the Regulation **contributed to uniform safety levels across the EU**.[316]

Moreover, the Regulation has **improved cooperation** among actors involved in market surveillance activities.[317] By clarifying the role of Customs, for instance, "*the Regulation has enhanced their channels and opportunities of collaboration with other EU authorities*".[318] In this regard, stakeholders positively assess **the role of the RAPEX and ICSMS system** as valuable tools that increase and enhance the exchange of information and open for possibilities of collaboration between Member States. Moreover, **the framework provided by the Regulation is useful to define national market surveillance and control of imported products policies**.[319] Interestingly, a Finnish MSA declares that the Regulation brought an additional benefit in this sense thanks to its comprehensiveness, *"which could not be achieved by small countries".*

Nonetheless, it is more interesting to look at to what extent the **specific content** of the Regulation is capable of bringing EU added value. In this respect, the analysis performed enables the identification of some provisions that bring more EU added value than others.

The analysis undertaken for effectiveness, highlights that **cooperation and coordination** among authorities in a Member State and across Member States are fundamental to assure effectiveness of market surveillance measures, even more considering that intra-EU trade represents 66% of the value of the overall imports of manufacturing goods (Figure 11). Therefore, understanding whether provisions of the Regulation related to this objective have provided EU added value is particularly important.

The EU added value of the Regulation mainly stems from provisions envisaging common information systems, **which are managed by the European Commission, favouring administrative cooperation, and enhancing collaboration between Customs and MSAs.**

As for information systems, all Member States make use of RAPEX and most of them utilise ICSMS to exchange information and coordinate market surveillance activities. As shown in previous sections and presented in detail in case study 4, the use of RAPEX has significantly increased over the years, in terms of both the number of notifications and follow-up actions (even though with the limitations described), thus showing the EU added value of such a system that allows for an information sharing that would not be possible otherwise (even though the Regulation in fact extended the use of RAPEX).

As regards ICSMS, the EU added value is more limited, especially considering that a number of MSAs highlight the possible duplication with other pre-existing internal/national databases (see section 6.1.1).

313 Four MSAs. Source: targeted survey.
314 Five MSAs, a Slovakian Custom authority, two industry associations, an Italian economic operator. Source: targeted survey.
315 14 MSAs, a Finnish Custom authority, three coordinating authorities. Source: targeted survey.
316 EU and DK industry association, Swedish company. Source: targeted survey.
317 6 MSAs, Slovak and Swedish Custom authority, to Danish coordinating authorities, an EU industry association. Source: targeted survey.
318 Swedish Customs. Source: interview.
319 According to 95% of answers received to this question, and namely by 11 coordinating authorities, 54 MSAs and 16 Customs.

Provisions related to administrative cooperation are also providing EU added value. The role of **EU level working groups and initiatives** supporting administrative cooperation (i.e. AdCOs) is worth mentioning: the presence of EU-level working groups and related initiatives enables a sharing of information and good practices that would not be possible otherwise, thus responding to a need of an increased exchange between Member States.

Finally, the enhanced collaboration between MSAs and Customs also reflects the EU added value of related provisions that create an incentive to collaborate that would not exist otherwise.

On a different note, the EU added value provided by provisions related to **collaboration between Member States** is not as straightforward. Whereas stakeholders consulted confirm a high level of collaboration, evidence of a non-complete recognition of national practices of market surveillance when dealing with cross-border non-compliance (see again section 6.1.1.) limits their EU added value.

Similarly, and connected, the EU added value linked to provisions dealing with **market surveillance organisation at national level** is limited. In this case, the picture emerging is still one of a highly fragmented and uncoordinated system, largely due to the adaptation of market surveillance organisation at national level to national governance models that are independent from the Regulation. In this respect, it seems that the Regulation has not provided minimum guidance to have a more homogenous market surveillance system but instead rather too general requirements.

Last, but far from being least, it is worth recalling the EU added value of provisions on **national programmes and reports**. In this case, it seems that an important opportunity has been lost. Whereas in principle the existence of a system to gather information from Member States provides EU added value in terms of an EU monitoring of the enforcement of market surveillance, once again the lack of clear guidance on how to draft national documents and interpret their contents makes these documents largely irrelevant when seeking a reliable picture, with all the limitations in terms of follow-up action that have clearly emerged in this study.

7. CONCLUSIONS

7.1 Effectiveness

The evaluation analysed the effectiveness of the Regulation in meeting its specific and strategic objectives, and looked into enabling factors.

As for the effectiveness in meeting specific objectives, the evaluation concluded that the Regulation has been only partly effective in achieving them.

The **problems** related to the achievement of specific objectives are many.

Although **coordination and cooperation mechanisms are significantly developed,** and recognised as useful, they **have not reached a level that can be considered satisfactory, especially considering those existing among Member States.** In particular, despite the necessary tools (i.e. RAPEX and ICSMS) being in place to ensure cross-border market surveillance cooperation, they are not used effectively. This hampers the possibility to avoid duplication of effort, which is the case when the system is properly used. More significantly, MSAs do not fully benefit from the advantages of these systems as they rarely restrict the marketing of a product following the exchange of information on measures adopted by another EU MSA against the same product. Also, the possibility for MSAs and Customs to make use of test reports drafted by MSAs in other EU countries seems to be limited. As for EU level arrangements, although participating in AdCO proves to be essential for coordinating actions and learning from best practices, not all MSAs participate in this form of administrative cooperation, also due to lack of resources.

Based on the analysis undertaken there is still need for higher level and more transparent cooperation and exchange of information.

As the level of **uniformity and rigorousness of market surveillance, the evaluation concluded that the Regulation has not been fully effective.** Uniformity and rigorousness have not been achieved yet, due to the significant differences across Member States in the implementation of the Regulation. These differences are related to the organisation of market surveillance at the national level, the availability of resources (financial, human and technical), the strategies of market surveillance, the powers of inspection and of sanctions, the level of sanctions and the systems of monitoring and reporting, i.e. the national reports. The general character of the Regulation's requirements is likely to have allowed these different implementations.

The heterogeneity existing across Member States in the implementation of the Regulation allows inferring 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. As for its **rigorousness**, the serious lack of data and inhomogeneity of national reports do not allow for a thorough assessment, except if based on stakeholders' perceptions, on the discrepancies in the penalty framework and in the 'lack of confidence' of enforcement authorities in other MSAs' risk assessments.

As for **border controls**, although **powers attributed by the Regulation to Customs are adequate**, and the **procedures clear, easy to apply and still relevant**, the **checks of imported products** seem to be insufficient.

The main difficulties related to controls of imported products are due to a lack of jurisdiction of MSAs outside their Member State, and to a lack of direct communication between MSAs and businesses, particularly in the context of online sales. Moreover, despite the fact that the necessary tools are in place to ensure cross-border market surveillance cooperation (e.g. RAPEX, ICSMS and the safeguard clause procedure), they are not used effectively, as discussed.

As for its strategic objectives of strengthening the protection of public interests through the reduction of the number of non-compliant products on the Internal Market and of ensuring a level playing field among economic operators providing a framework for market surveillance and controls of products**, the evaluation also concluded that the Regulation is not fully effective**. This conclusion is based, first, on the evidence of an increasing number of non-compliant products covered by harmonisation legislation (as demonstrated by the rising number of RAPEX notifications and of restrictive measures taken by MSAs, see sections 0 and 0). On the one hand, the increasing product non-compliance threatens the achievement of a high level of protection of public interests for as long as these products present risks to consumers and end-users. On the other hand, a level-playing field among businesses trading goods subject to EU harmonisation legislation risks not being achieved as long as there is still the possibility for rogue traders to disregard legal requirements and sell non-compliant products.

Moreover, as already discussed, the Regulation has been implemented in different ways across Member States. These discrepancies diminish the Regulation's effectiveness in achieving a level playing field, inasmuch as they create disparities in the level of enforcement that influence regulatory/administrative costs to businesses across Member States and market behaviour. Ultimately, this impacts a lower protection of public interest – due to increasing non-compliant products – and to the achievement of a level playing field.

Finally, the evaluation identified a number of **enabling factors**, related to the different national implementations, which made the implementation of the Regulation more or less effective, eventually impacting on the achievement of its objectives.

The level of decentralisation of market surveillance structures, for instance, impacts on the level of existing cooperation and collaboration between national MSAs. The more a Member State is decentralised, the more it will need numerous and complex coordination mechanisms.

Resources, which, overall, are scarce and varied across Member States, are certainly a second enabling factor. It is sufficient to think that the lack of resources is considered as one of the main bottlenecks to market surveillance implementation and effective deterrence. The different levels of resources have implications on the way MSAs perform their tasks. For instance, MSAs' market knowledge in order to target checks is not sufficient in sectors that require specific skills. Moreover, the excessive cost of testing is the most likely explanation for the low level of surveillance, which in some sectors is limited to mere documentary checks. Similarly, resources also influence MSAs' criteria for prioritisation of monitoring and enforcement activities, impacting on the 'adequate scale' of controls (foreseen by Articles 19 and 24). Along the same lines, resources influence strategies for market surveillance, which could be proactive rather than reactive.

Powers attributed at the national level and the role of Customs in enforcing the Regulation influence the effectiveness of border control. Controls are indeed expected to be tougher in Member States where Customs act as MSAs. While Customs powers are essential for the

control of traded products, the introduction of Regulation 765/2008 highlights the need for cooperation between Customs and MSAs and with other EU Customs as a crucial element for enhancing market surveillance on imported products. In this respect, there are notable differences across Member States.

Overall, it seems that these discrepancies are being allowed by the general requirements set in the Regulation. This lack of specificity relates to Member States' obligations as regards organisation, powers, resources and knowledge necessary for MSAs to perform their tasks properly. Article 18(5) on national reports and programmes is also general, as it does not foresee the provision of structured information from Member States to the EC relating to market surveillance activities, which is particularly evident in light of all the data limitations highlighted in the study. Moreover, the Regulation does not include specific provisions related to the principles of cooperation between Member States. This clearly impacts on the existing cooperation mechanisms and tools, which, as described in the previous sections, are many and different, but could be improved. Finally, the Regulation is not specific enough to set a minimum and/or a maximum level of penalties, or any principles to define them. As discussed, this results in wide differences in the minimum/ maximum amounts within and across Member States, which lower the enforcement deterrence power.

An additional enabling factor identified is the (lack of) cooperation between enforcement authorities and businesses. Among the main reasons for product non-compliance in the internal market seems to be a lack of economic operators' knowledge on the relevant legislative requirements to be complied with, as well as a deliberate choice to exploit market opportunities at the lowest cost, possibly due to low incentives to comply with the existing rules.

7.2 Efficiency

The efficiency of the Regulation has been assessed in terms of costs incurred by different stakeholders, benefits produced, and the extent to which the desired effects (results and impacts) have been achieved at a reasonable cost. Furthermore, significant differences between Member States have also been considered.

The Regulation introduces costs for Member States and economic operators. Costs for Members States are related to organisational, information, surveillance and cooperation obligations embedded in the Regulation. Costs for economic operators are related to information obligations as defined in Article 19 of the Regulation.

The unavailability of data on costs incurred by Member States Authorities in charge of market surveillance before 2008 did not allow for the measurement of additional costs deriving from the new obligations introduced by the Regulation.

However, data included in the national reports provide information about costs incurred in performing market surveillance on harmonised products.

The main highlights of the analysis show that at Member State level:

- The budget allocated to Market Surveillance Activities:

- On average, is €7.5 m per Member State in nominal terms,[320] representing around 0.1-1.33%[321] of total national budget;

- Decreased by 7% over the period 2010-2013 (from €7.8 m to €7.5 m);

- Human resources allocated to MSAs:

  - More than 280 FTEs[322] were involved on average at Member State level over the period 2010-2013 in inspection activities. The number of inspectors decreased by 4.4% (i.e. reduced from 288 to 275) over the period considered;

  - MAs can count, on average, on more than 415[323] FTEs in order to perform Market Surveillance activities each year; however the number of FTEs available decreased by 2.6% over the period 2010-2013.

Costs incurred by MSAs **vary considerably from one Member State to another**. These differences might be related to the fact that Member States have different organisational models requiring different levels of both human and financial resources. However, another possible explanation might be sought in the different approaches followed by MSAs in reporting data concerning the used financial resources as well as the performed activities.

The fact that Member States define their own market surveillance approach creates a high variation in the ways the different sectors are controlled and managed. Moreover, fragmentation throughout the Internal Market may interfere with the Authorities' early action and produce additional costs for businesses (for instance, multiple evaluations and validations in order to allow them to place a product in the Market).

With respect to costs for economic operators, **information costs are perceived as not significant but some across-the-board inconsistencies** still remain; also the current enforcement mechanism is not able to create a level playing field for businesses that are selling products in the Internal Market. This might reduce businesses' willingness to comply with the rules and discriminate businesses that abide by the rules against those who do not.

In terms of **benefits**, there is no evidence of cost savings for businesses as a result of the implementation of the Regulation as regards administrative tasks, operational tasks if compared to the situation prior to 2008.

Furthermore**, the expected improved safety** is not confirmed by RAPEX notifications and by the statistics on the implemented restrictive measures at national level.

An increase in RAPEX notifications and surveillance measures may also imply that MSAs have become more effective in finding – and thus correcting – non-compliance. However this underlines that the Regulation is still not able to increase businesses' willingness to comply with the rules, thereby discriminating businesses that abide by the rules against those who do not.

320 Not all Member States provided reliable data for this indicator. Therefore figures do not include AT, CY, EE, EL, HR, HU, LU, SI, UK. For SE the average is computed considering only data for 2012 and 2013 because some authorities did not provide any figures for some sectors for 2010 and 2011.
321 The figures refer to 10 MS that provided reliable data, precisely: DK, EE, ES, FI, IT, LV, MT, PL, SE, SK.
322 The figures refer to 16 MS that provided data, precisely: BE, BG, CZ, DK, EE, ES, FI, IE, IT, LT, LU, LV, PL, PT, RO and SK.
323 The figures do not include: AT, BE, CY, EL, FR, HR, HU, SI, UK. For SE the average is computed considering only data for 2012 and 2013 because some authorities did not give any figures for some sectors for 2010 and 2011.

The limited cost-effectiveness of the market surveillance provisions is confirmed by the fact that the average annual budgets allocated to MSA activities nor their variation over the period 2011-2013 are correlated with the size of the market (i.e. number of enterprises active in the harmonised sectors).

Efficiency gains might be achieved by more effective cooperation between industry and authorities. In this way, MSAs can take advantage of manufacturers' technical knowledge, and may be in a better position to identify non-compliant products on the market and set appropriate priorities for market surveillance activities.

The analysis of the efficiency of the Regulation has been limited by the evident poor quality of data included in the national reports, both in terms of completeness and comparability. This definitely shows the need for an in-depth reflection about the **monitoring mechanisms in place** that should allow the EC to get an updated and realistic picture on the implementation of the Regulation within the scope of this evaluation.

7.3 Relevance

The relevance of the Regulation has been assessed in terms of its scope (including its definitions and concept of *lex specialis*) and in view of stakeholders' needs, including those related to new/emerging issues.

The analyses highlighted that the **scope** of the Regulation raises some problems. A quite high percentage of stakeholders (even though not the majority) indeed find the scope of the Regulation not fully clear. Some confusion on the scope of the Regulation has also emerged from the analysis of national reports (adding sectors not in the scope of the Regulation), and considering input from economic operators. The analysis also underlined that difficulties in understanding the Regulation's scope might be exacerbated by technological developments introducing new forms of products.

As for the Regulation's **definitions**, the evaluation highlighted some points to consider. Although these are generally clear and appropriate, they are not fully **complete and up to date,** especially when considering the need to also cover online sales, but also with reference to the definitions of 'making available on the market' *vis-à-vis* 'placing on the market', 'product' in relation to the concepts of 'second hand good', 're-used good' and 'by-products', of 'recall', or the definition of 'risk'.

The assessment of the relevance of the Regulation focused also on the concept of ***lex specialis***, concluding that the concept results are a suitable interface to address market surveillance in specific sectors, with not specific difficulties in implementation. Some issues though have emerged as regards a lack of clarity in the scope of market surveillance rules in sector-specific legislation.

Looking at the relevance of the Regulation to **stakeholders' needs,** the analysis concluded that the Regulation is relevant to some extent, as it is relevant overall when considering the current needs associated with its general and specific objectives, but it becomes less relevant with looking at the needs related to new/emerging dynamics**.**

Indeed, the framework it provides results in being useful overall in defining national market surveillance programmes and policies, and in meeting the strategic objectives of the Regulation. It also results in meeting the relevant needs of cooperation and exchange of

information. With specific reference to the provisions on market surveillance programmes and reports, though, the quality and comparability of the information provided is far from sufficient, making their consultation very burdensome if not useless. Finally, the results are relevant when referenced to the needs of border controls.

However, when moving to the relevance of **emerging issues**, the Regulation is not as relevant, especially with reference to increasing online trade and budgetary constraints at national level. As for online trade, the Regulation neither includes specific provisions covering online sales, nor does it provide for definitions that account for its specificities, as already mentioned. As for budgetary constraints, the Regulation does not properly account for the relation between the lack of resources and the related lengthy processes to enforce market surveillance, and the dynamics of the market that require a fast reaction.

7.4 Coherence

Coherence of the Regulation has been evaluated at two levels: internal coherence of the provisions of the Regulation within themselves, and external coherence of the Regulation with the GPSD and sectoral legislations in its scope.

As for **internal coherence**, overall the market surveillance provisions of the Regulation are consistent within themselves and in the scope of the legislation. Furthermore, the roles and tasks of all the different stakeholders concerned by the Regulation are well defined and no duplication of activities has been traced. The analysis – supported by stakeholders' opinions – has not identified any overlaps or contradictions between the Regulation's provisions within the scope of this study. However, some areas for improvement have been identified. In this respect, there are areas where further guidance and clarity would be beneficial. For instance, the Regulation does not provide any specific methodology to be followed by the Member States when reviewing and assessing the functionality of the surveillance activities. Similarly, the Regulation does not include provisions related to the principles of cooperation between the Member States (i.e. spontaneous and/by request provision of information, fullest availability for cooperation, reciprocity basis, including in cases of negative response/no information). At present, provisions about the implementation of market surveillance are too general, thus allowing for significant differences in the implementation of the Regulation in terms – for instance – of communication and collaboration tools existing within/among Member States, endowments of powers and resources, and the 'adequacy' of checks, as already discussed under section 7.1.

As for **the external coherence of the Regulation with the GPSD, some issues have been traced**. More specifically, the definitions provided in the GPSD are not always aligned with those of the Regulation. Moreover, the boundary between the GPSD and the Regulation is not always clear, **the two legislations sometimes seem to overlap**, and the differences between mutual scopes should be further defined. A low number of stakeholders suggested improving the overall coherence of the Regulation by merging it with the GPSD. This would allow significant simplification and increased legislative certainty, as the convergence would solve some inconsistencies in terms of definitions and concepts between the two Regulations. A similar but less radical solution would be to at least clearly exclude all products covered by specific Union legislation from the scope of the GPSD.

Finally, the coherence of the Regulation with sectoral directives is safeguarded to a sufficient extent by the existence of the *lex specialis* provision. Nonetheless, also in this case, there exist discrepancies and shortages in the definitions and terminology provided in the different

legislations. Although not hindering the implementation of the Regulation, they still cause inconsistencies and diminish the overall clarity of the framework for market surveillance.

7.5 EU added value

The EU added value of the Regulation in terms of **harmonisation, transparency and unambiguous interpretation of rules** is widely recognised by stakeholders. Moreover, the framework provided **by the Regulation is useful to define national market surveillance and control of imported products policies.**

However, the analysis focused on assessing the EU added value as per the **specific provisions** of the Regulation. In this respect it appears that some of them achieve a higher EU added value when compared to others.

The EU added value of the Regulation mainly stems from provisions envisaging common **information systems for cooperation and coordination, favouring administrative cooperation, and enhancing collaboration between Customs and MSAs.**

On a different note, the EU added value provided by provisions related to **collaboration between Member States** is not as straightforward, due to an incomplete recognition of national practices of market surveillance when dealing with cross-border non-compliance, despite a general positive opinion expressed by stakeholders. Similarly, and connected, the EU added value linked to provisions dealing with **market surveillance organisations at national level** is limited, mainly because the Regulation does not provide minimum guidance to have a more homogenous market surveillance system. Finally, it is worth recalling provisions in **national programmes and reports**. Although they could provide significant EU added value in terms of monitoring the enforcement of market surveillance, the lack of clear guidance on how they should be drafted and interpreted makes these documents largely irrelevant.

8. ANNEXES

8.1 Stakeholder consultation

In line with the Commission's Better Regulation Guidelines,[324] the first section of this Annex sets out a brief summary of the consultation strategy performed within the context of this Evaluation Study. It provides details on how the consultation was conducted, by presenting each consultation tool. Furthermore, a brief summary explains the actions undertaken to meet the EC minimum standards for stakeholder consultation. The second section presents the results of the main findings of the analysis.

8.1.1 The Consultation strategy

The overall process of stakeholder consultation for the Evaluation of the Regulation (EC) No 765/2008 began in June 2016 and continued up to February 2017. The consultation collected inputs from a wide range of stakeholders through different tools, namely:

- A public consultation;
- Five targeted consultations based on online surveys;
- Interviews.

The public consultation and the five targeted consultations were conducted ahead of the interviews, as the latter were aimed at complementing and triangulating the information collected and at clarifying any issues emerged.

As for the **geographical coverage** of the stakeholder consultation, all EU Member States, together with Iceland, Norway, Switzerland and Turkey, were involved in the consultation.

8.1.1.1 Public consultation

The public consultation was launched on 28 June and closed on 31 October 2016. It consisted of an online questionnaire available in 23 official languages of the EU. The consultation collected stakeholders' opinion on several issues:

- The relevance, reasons and consequences of the problem of product non-compliance in the Internal Market for goods;
- The options available to tackle the problem;
- The impact of those options;
- The issue of subsidiarity;
- Whether action at EU level would produce clear benefits with respect to those created at the Member State level in terms of scale and effectiveness.

324 European Commission, SWD(2015) 110 final. Better Regulation Guidelines.

The great majority of questions were **closed questions**, in order to avoid an excessive burden for respondents and to ease the comparison of the answers received in the analysis phase. The questionnaire also had a very **general character**, so that potentially anyone willing to contribute could do so.

Overall, **239 stakeholders** contributed to the public consultation, and namely:

- 64 MSAs or Customs authorities, from AT, BE, CH, CY, CZ, DE, DK, EE, ES, FI, HR, IE, IS, IT, LT, NL, NO, PL, PT, SE, SI, UK;
- 74 economic operators from AT, BE, BG, CZ, DE, ES, FI, FR, HU, IE, IT, NL, PL, PT, SK, SE, UK;
- 12 Public Authorities (PA) from AT, DE, DK, ES, IS, LT, PL, RO;
- 53 industry associations from BE, CH, DE, DK, EL, ES, FI, FR, IT, NL, PT, RO, UK;
- 6 consumer organisations from BE, DK, UK;
- 4 International organisations (AT, FI, UK);
- 4 academic/law firms (DE, HU, UK);
- 2 Trade Unions (BE, FR);
- 6 consumers/citizens (AT, DE, ES, UK);
- 14 others (from AT, BE, DE, FR, NL, PL, SE, SK, TR, other third country).

8.1.1.2 Targeted surveys

For the purpose of the study, **five targeted surveys based on online questionnaires** were launched, involving:

- Member State coordinating authorities in charge of the implementation of the Regulation;
- MSAs in charge of the enforcement of the Regulation, including AdCO representatives;
- Customs authorities;
- Economic operators, and industry associations;
- Consumer and user associations.

The targeted surveys were launched on 26 October and closed on 20 December 2016 and ran on the EY online survey tool (eSurvey). The deadline was initially planned to be the beginning of December, but it was postponed following several requests from stakeholders to be given more time to contribute and after formal agreement with the Steering Group.

The questionnaires **were drafted in five EU languages** (DE, EN, FR, IT and RO) and they consisted **mainly of closed questions**, in order to ensure higher response rates, with some open-ended questions to allow participants to contribute with more detailed views, opinions or advice. The survey was organised into sections corresponding to the evaluation criteria.

Questions were customised to differently address each category of stakeholder taking into account their different level of engagement and experience with the Regulation. In detail, they aimed at:

- Gathering quantitative data, especially those related to the market and cost-benefit analysis;
- Providing preliminary information for answering the evaluation questions;
- Identifying the most relevant aspects of the evaluation to be further addressed through interviews.

Overall, **119 stakeholders** were involved in the targeted surveys up to 20 December 2016, in particular:

- 54 MSAs (from AT, BE, CY, DK, ES, FI, DE, IE, IT, LT, LU, LV, NL, PL, SE, UK);
- 13 MS coordinating authorities (FI, DE, DK, EE, HR, FI, LT, RO, SE, SI);
- 19 Customs authorities (AT, BE, BG, CY, DE, EE, FI, FR, DE, HR, HU, IT, LU, LV, MT, NL, PL, RO, SK, SE);
- 4 economic operators (BE, ES, IT, SE);
- 3 civil society associations (BE, HU);
- 12 industry associations (AT, BE, DK, EL, ES);
- 14 AdCO representatives (medical devices, radio equipment, lifts, pressure equipment, electromagnetic compatibility, 2 measuring instruments, 2 noise, recreational craft, gas appliances, construction products, pyrotechnic articles, explosives for civil use).

8.1.1.3 Interviews

The field research also consisted of **interviews**, aimed at:

- Investigating in detail the specific topics and issues that have emerged from the analysis of the targeted consultations as well as from the desk research (e.g. to examine specific problems encountered in the implementation of the Regulation at the national level, or any best practices signalled), by discussing them with involved national and EU stakeholders;
- Gaining a better understanding of the consequences of current practices, or the most important/emerging issues, by involving stakeholders active in the market (e.g. representatives of consumer associations and industry associations);

- Understanding the different perspectives and viewpoints through discussions with different stakeholders;
- Triangulating the information and data collected through the consultations.

Interviews involved **relevant stakeholders** concerned by the Regulation, including MSAs, Customs, selected representatives from organisations of stakeholder categories (e.g. industry and SMEs, consumers) and individual enterprises for the CBA.

39 interviews have been performed.[325] More in detail:

- 9 (out of 10 planned) general interviews to further investigate the most relevant issues emerged from the desk and field research;
- 20 targeted interviews aimed at building up the five case studies;
- 10 for collecting additional data for the CBA.

Overall, the following stakeholders have been involved:

- 18 MSAs (AT, CY, 2 DE, DK, ES, EL, 2 FI, 2 FR, IE, 2 IT, NL, MT, SK, UK);
- Three coordinating authorities (DE, IT, SE);
- Five Customs (BG, DE, FI, IT, NL);
- Ten economic operators (7 BE, DE, IT, UK);
- Three EU-level industry associations.

8.1.2 Minimum standards for stakeholder consultation

While conducting the consultations, the evaluation team ensured to respect the standards listed in the "Better Regulation Guidelines" of the European Commission, which aim to guarantee that all relevant stakeholders have the opportunity to express their opinions. The table below presents the five Minimum Standards and actions to ensure compliance.

Minimum Standards	*Actions for compliance*
Clear content of the consultation process ('Clarity'): All communication and the consultation document itself should be clear, concise and include all necessary information to facilitate responses	• All stakeholders consulted were first informed about the objectives of the evaluation study. Moreover, stakeholders have been always provided with the accreditation letter signed by the EC, detailing the background and the implementation process of the analysis and authorising the evaluation team to request for data; • Targeted surveys and interviews were drafted specifically for each stakeholder category, so as to provide them with relevant questions only; • All stakeholders involved through the interviews received the interview guidelines in advance, in order to have the chance of

325 The number of interviews foreseen was 40, but a relevant interviewee refused to be involved.

Minimum Standards	*Actions for compliance*
	preparing their answers and collect the information needed.
Consultation of target groups ('Targeting'): When defining the target group(s) in a consultation process, the Commission should ensure that all relevant parties have an opportunity to express their opinions	• The stakeholders to be targeted were defined in a joint effort with the EC. This process was aimed at ensuring that the most relevant groups had their say in the consultation process; • Due to the relevance of the study and to the tight schedule, the EC worked very closely in cooperation with the evaluation team to achieve a satisfactory level of stakeholders' involvement. Further, the EC provided the evaluation team with specific contacts (e.g. of AdCO chairs) so as these stakeholders could raise awareness about the study and involve the members of their group in the consultation process, thus triggering a positive "snowball effect"; • In order to ensure a balanced representation of all stakeholders in both terms of geographical and category coverage, targeted interviews were intentionally aimed at involving parties under-represented in the public consultation and targeted surveys, particularly the industry side.
Publication: The Commission should ensure adequate awareness-raising publicity and adapt its communication channels to meet the needs of all target audiences. Without excluding other communication tools, (open public) consultations should be published on the internet and announced at the "single access point"[326]	• Several email reminders were sent to relevant stakeholders in order to remark the importance of their contribution to the study. • In order to ensure the maximum stakeholders involvement, the evaluation team participated to the IMP-MSG Meeting on 21 October 2016 in Brussels, where the objectives of the study and the main contents of the targeted surveys were presented. Further, the evaluation team tried to collect some preliminary feedback from participants. • The evaluation team also participated to the PARS Project Group Meeting on 1 December 2016 in order to raise EU Customs' awareness about the study and to inform them about the ongoing consultation of the project, eventually soliciting them to contribute.
Time limits for participation ('Consultation period'): The Commission should provide sufficient time for planning and responses to invitations and written contributions	• The public consultation ran for almost 14 weeks; • The targeted surveys ran for almost 8 weeks. Following numerous stakeholders' requests and in agreement with the EC, the survey deadline was extended to 20 September 2016. • The interviews were performed over a time frame of 8 weeks. However, they were scheduled well in advance so as to allow stakeholders to find the date and time that best suited their schedules.
Acknowledgement of feedback ('Feedback'): Receipt of contributions should be acknowledged and contributions published. Publication of contributions on the "single access point" replaces a separate acknowledgment if published within 15 working days. Results of (open public) consultations should be published and displayed on websites	• Results of all the consultation tools were thoroughly analysed and included in the report. • The contributions to the public consultation have been published on the EC website if the stakeholders provided their consent to it. • The contributions to the targeted surveys will not be published as the evaluation team guaranteed the confidentiality of information to all stakeholders consulted.

326 "Your Voice in Europe": http://ec.europa.eu/yourvoice/

8.1.3 Report Charts

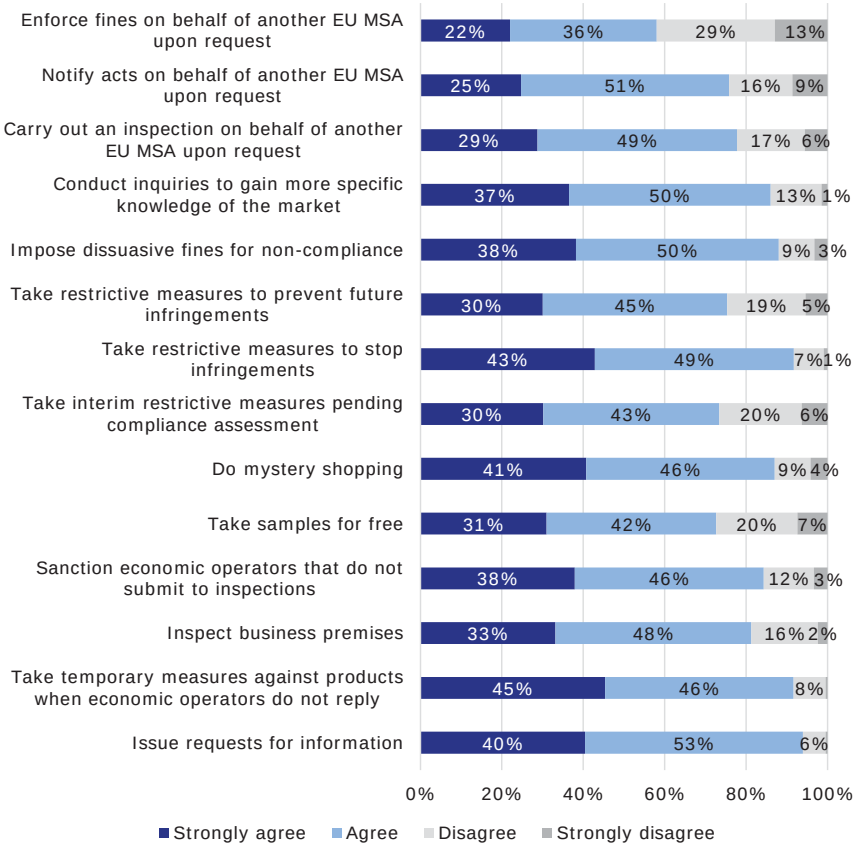
The following sections presents a summary of the most significant results emerged from the targeted surveys and the public consultation. The charts and percentages do not take into account the "no opinion/I do not know" replies, which would bias data. Absolute numbers taking into account all replies are reported in footnote.

8.1.3.1 Effectiveness

8.1.3.1.1 Enforcement powers

One of the issues on which stakeholders have been consulted via the public consultation was **the need for MSAs to be granted particular enforcement powers.** As shown in the following figure, the preferred options are the power to issue requests for information (93%, n=202) and to take temporary measures in case economic operators refuse to collaborate (91%, n=198). Fewer stakeholders see the need for MSAs to enforce fines on behalf of another EU MSAs upon request, though they still represent 55% (n=108) of total respondents.

Figure 4-36 - Powers MSAs need in order to carry out more effective and deterrent action



Source: public consultation[327]

327 *Issue requests for information*: n = 215. In addition, 10% (n=24) of total respondents chose the "no opinion" option; *Take temporary measures against products when economic operators do not reply*: n = 216. In addition, 10% (n=23) respondents chose the "no opinion" option; *Inspect business premises*: n = 214. In addition, 10% (n=25) respondents chose the "no opinion" option; *Sanction*

If the breakdown per specific enforcement power and per stakeholder category is considered, there is a strong agreement among respondents in relation to the **power to issue requests for information**. Overall 94% of respondents agree on this power, despite 25%% (n=3) of PAs disagree.

Similarly, no major differences appear across the categories in relation to the **power to take temporary measures against products when relevant economic operators do not reply to MSAs' requests**. Overall, 91% of respondents agree on the need of this power for MSAs. Interestingly, half of economic operators and industry associations agree with this option (52%, n=34 and 50%, n=24) and even a small share of them strongly agree (respectively 37%, n=24 and 38%, n=18). Also 98% (n=58) of MSAs/Customs either strongly agree or agree. Namely, the strongest support to this power is expressed by civil society representatives as 69% (n=22) of them strongly agree.

As for the **power to inspect businesses' premises**, respondents align independently from the different categories they belong to. The large majority of them (81%, n=174) agree that MSAs should be granted this power. Nonetheless, 29% (n=19) of economic operators and 21% (n=9) of industry associations responding to the public consultation either disagree or strongly disagree on this.

With respect to the **power to sanction economic operators that do not submit to MSAs' inspections of business premises**, there is substantial agreement among the respondents' categories (overall 84% agree). However, a significant part of economic operators (24%, n=16) and PAs (25%, n=3) disagree. MSAs/Customs express the strongest support to this option (53% strongly agree, n=31), immediately followed by civil society representatives (42% strongly agree, n=14).

Overall, the majority of respondents agree on the need for MSAs to be granted with **the power to take samples for free** (73%), especially if MSAs/Customs and PAs are considered (92%, n=59 and 82%, n=10). However, a significant part of economic operators (33%, n=24), and civil society representatives (31%, n=23) disagree.

A very strong agreement is reached by all the respondents on the power to do **mystery shopping** (87%, n=188). Consequently, no significant divergences appear across the categories.

On the contrary, a certain variability appears in the opinions on the power to **take interim restrictive measures on pending compliance assessment**. Even if the majority of respondents agree on this measure, 40% (n=27 and n=19) of economic operators and industry associations are against, as well as 25% (n=3) of PAs.

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economic operators that do not submit to inspections: n = 211. In addition, 11% (n=28) respondents chose the "no opinion" option; *Take samples for free*: n = 216. In addition, 10% (n=23) respondents chose the "no opinion" option; *Do mystery shopping*: n = 216. In addition, 10% (n=23) respondents chose the "no opinion" option; *Take interim restrictive measures pending compliance assessment*: n = 222. In addition, 7% (n=17) respondents chose the "no opinion" option; *Take restrictive measures to stop infringements*: n = 217. In addition, 2% (n=22) respondents chose the "no opinion" option; Take restrictive measures to prevent future infringements: n = 203. In addition, 15% (n=36) respondents chose the "no opinion" option; *Impose dissuasive fines for non-compliance*: n = 217. In addition, 9% (n=22) respondents chose the "no opinion" option; *Conduct inquiries to gain more specific knowledge of the market*: n = 208. In addition, 13% (n=31) respondents chose the "no opinion" option; *Carry out an inspection on behalf of another EU MSA upon request*: n = 198. In addition, 17% (n=41) respondents chose the "no opinion" option; *Notify acts on behalf of another EU MSA upon request*: n = 186. In addition, 22% (n=53) respondents chose the "no opinion" option; Enforce fines on behalf of another EU MSA upon request: n = 186. In addition, 16% (n=38) respondents chose the "no opinion" option.

A wide and strong agreement is found in the option for **MSAs to take restrictive measures against Economic operators to stop infringements**, where overall 92% of stakeholders agree. Only economic operators slightly differ from the average, though 85% (n=55) of them agree.

There is also a wide consensus among respondents in relation to the power **to take restrictive measures against economic operators to prevent future infringements** (64%, n=130). Among the categories, only a small share of economic operators slightly differ from the average, as 21% (n=13) of them disagree.

No substantial differences are reported in relation to **the power to impose dissuasive fines for non-compliance**. The strongest agreement on this issue is expressed by MSAs/Customs (46% of respondents, n=28).

A strong alignment is reported also in favour of the **power to conduct sector inquiries to gain more specific knowledge of the market** (87%, n=181). There are no diverging views on this issue and the highest share of disagreement, equal to 16% (n=7), is expressed by respondents from industry associations.

For the power to **carry out inspection on behalf of another EU MSA**, PAs seems divided, with 55% (n=5) that disagree. Also a significant part of economic operators disagree (30%, n=19), while an impressive 93% (n=42) of industry associations either agree or strongly agree. Finally, 21% (n=6) of civil society representatives and 22% (n=12) of MSAs are against this possibility.

The power to **notify acts on behalf of another EU Member State's authority upon request** is not fully supported by respondents. Except for Industry associations (only 12% disagree, n=5), a significant part among all categories (from 27% of civil society representatives, n=7 to 38% of PAs, n=3) disagree.

The power to **enforce fines on behalf of another EU Member State's authority upon request** encounters a quite low support with respect to previous options (58% overall, n=108). Especially MSAs seem slight against this power (53% either disagree or strongly disagree, n=26), and the other categories disagree from 32% (n=8) of civil society representatives, 39% of economic operators (n=24) and of industry associations (n=16) and 44%of PAs (n=4).

If the results of the **targeted surveys** are considered, 70% of respondents indeed report there is **no need to grant any additional powers to allow MSAs to enter businesses' premises.**[328] Broken down by category, differences in the expressed opinions appear to be relevant. The largest part of respondents from industry associations and MSAs disagree on the need to grant more powers (82%, n=9 and 68%, n=46 respectively). Instead, respondents from companies are perfectly divided as 50% (n=1) of them support the need to grant MSAs more powers to enter businesses' premises.

In addition, 57% of respondents from different categories report that **MSAs have enough powers to effectively detect non-compliance and obtain corrective actions**. Analysed by category, 64% (n=7) of respondents from industry associations believe that there is no need to

328 In this regard a Spanish and two Belgian industry associations state that additional powers are not necessary if not accompanied by more financial and human resources.

grant Authorities in charge with EU external border controls any additional power. However, respondents from companies show more variability in the collected responses, as 50% (n=1) of them do not align with the previous position.

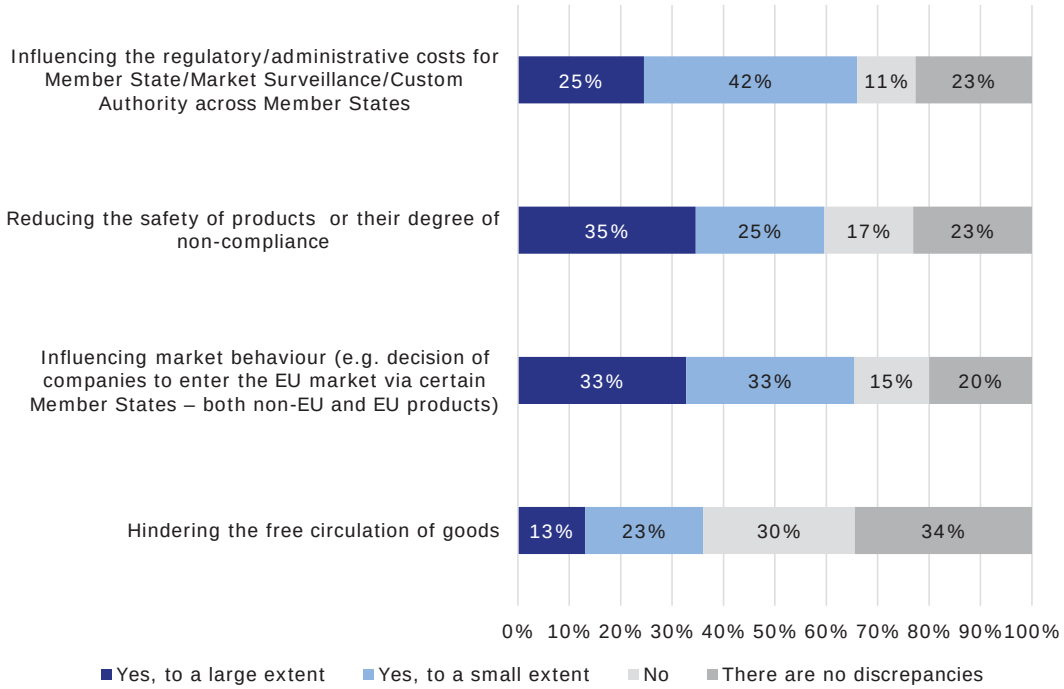
The majority of respondents to the surveys (58%) report not to be aware **of any discrepancies across EU Member States**. Some diverging views appear when responses are analysed by category. The majority of respondents from industry associations (64%, n=7) and from civil society associations (67%, n=2) confirm to be aware of discrepancies across EU Member States. A certain variability also appears in the case of MSAs as 46% (n=31) of them consider to be aware of discrepancies across EU Member States.

8.1.3.1.2 Uniformity and rigorousness of controls

As for the **uniformity and rigorousness of controls by MSAs**, 71% of respondents to the survey report to be not aware of any discrepancies across sectors in their Member State. Analysed by category, the majority of respondents from coordinating authorities (85%, n=11), Custom Authorities (74%, n=14) and MSAs (66%, n=45) share this opinion. However, 67% (n=2) of respondents from civil society associations and 34% (n=23) of respondents from MSAs provide an opposite opinion.

According to respondents to the survey, **discrepancies in market surveillance activities** mainly affect regulatory/administrative costs of businesses across Member States (67%) as well as firms' market behaviour (66%), as shown in the figure below.

Figure 4-37 - Effects of discrepancies in market surveillance activities



Source: targeted surveys[329]

329 *Hindering the free circulation of goods*: n = 61. In addition, 55% (n=76) of respondents chose the "I do not know" option; *Influencing the regulatory/administrative costs of businesses across Member States*: n = 53. In addition, 61% (n=83) of respondents

Opinions provided on possible effects of discrepancies in market surveillance activities vary when responses to the survey are broken down by category.

In relation to the **free circulation of goods**, 75% (n=3) of industry associations consider that such discrepancies do not hinder the free circulation. On the contrary, 42% (n=5) of Custom authorities believe that discrepancies in market surveillance activities affect the circulation of goods from a small to a large extent.

As for **market behaviour**, 75% (n=3) of respondents from industry associations and 70% (n=18) of respondents from MSAs believe that such discrepancies influence market behaviour.

However, the same percentage of respondents from industry associations consider that discrepancies might **reduce the safety of products or their degree of non-compliance** but only to a small extent. Differently, all respondents from civil society associations (n=2) and 45% (n=5) of responding Custom authorities think that the impact is more severe in this sense.

Despite the fact that the majority of respondents consider that discrepancies **influence the regulatory/administrative costs for Market Surveillance/Customs Authorities across Member States**, responses need to be broken down by category to provide a clearer picture. While coordinating authorities and MSAs are in line with this position, 27% (n=3) of Customs Authorities believe that no impact on regulatory/administrative costs is caused by such discrepancies.

8.1.3.1.3 Powers of sanction

52% (n=83) of respondents to the public consultation think that the current framework of market surveillance provides insufficient deterrence, while 48% believe it is sufficient to a significant (10%, n=15) or to a moderate extent (38%, n=59). Interestingly, if compared to other categories, few MSAs or Customs (37%) and PAs (25%) declare that the current framework does not provide sufficient deterrence. Percentage of other categories are higher than 59% in this opinion.

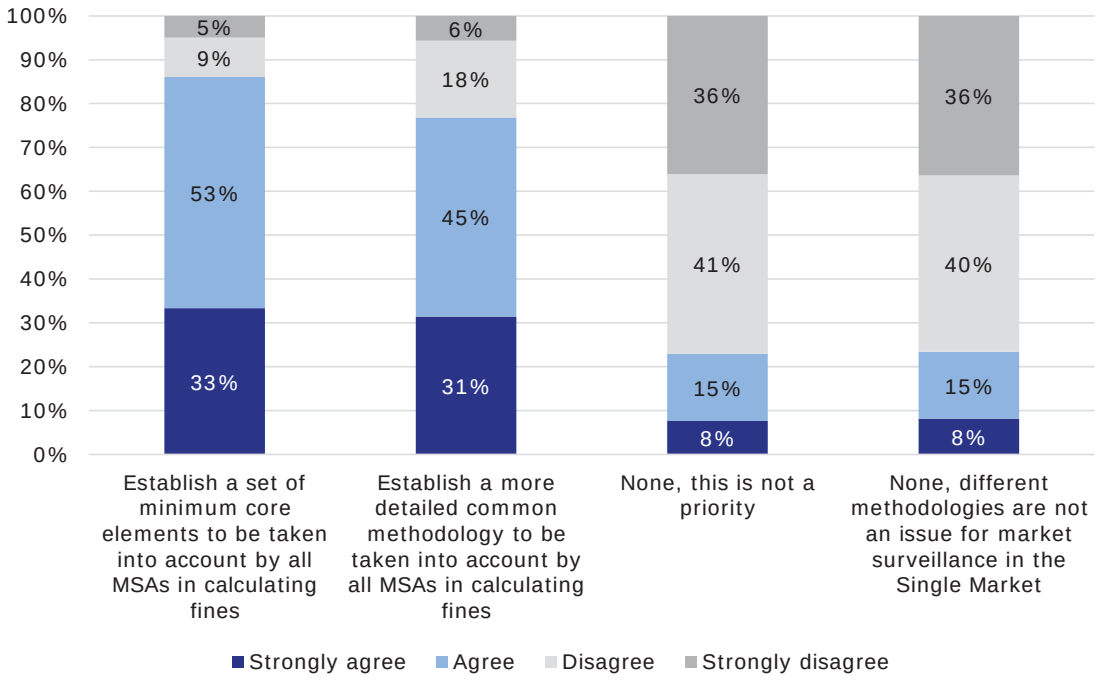
A number of stakeholders indeed state that penalties are not sufficiently high to prevent non-compliant behaviour.[330]

Divergences exist in the methodologies applied by MSAs in different Member States to sanction non-compliant businesses. As shown in the figure below, respondents to the public consultation think it is very important to establish **a set of minimum core elements as well as a more detailed common methodology** to be shared and taken into account by all MSAs in calculating fines. As a proof, only a minority of respondents think this is not a priority and/or that the existence of different methodologies are not an issue in the Internal Market.

chose the "I do not know" option; *Influencing market behaviour*: n = 55. In addition, 60% (n=82) of respondents chose the "I do not know" option; *Reducing the safety of products or their degree of non-compliance*: n = 52. In addition, 62% (n=85) of respondents chose the "I do not know" option.

330 Eight MSAs (CY, 2 DE, 2 FI, LT, NO, PL), two economic operators (AT, FR), five industry associations (2 BE, EL, ES, FR), two consumer organisations (2 BE), a German academic/law firm, a French other.

Figure 4-38 - Measures to be taken to address differences in methodologies to sanction non-compliant businesses



Source: public consultation[331]

If the breakdown per stakeholder category is considered, **a strong agreement on the need to establish a set of minimum core elements** for calculating fines is registered. The only category that significantly disagrees is that of PAs (30%, n=3). Overall 88% stakeholders agree on this matter.

On finding a detailed **common methodology** instead, 'agree' answers drop down to 76%. In this case, 33% (n=17) of MSAs disagree, together with 29% (n=2) of PAs, 24% (n=11) of Industry associations and 18% (n=11) of economic operators.

However the two options of **finding a set of minimum core elements and a more detailed common methodology** are a priority, with only 23% of respondents thinking this is not. PAs stand out with 36% (n=4) of them stating that this is not a priority, followed by 28% (n=12) of Industry associations, 26% (n=13) of MSAs or Customs, 18% (n=10) of economic operators and 14% (n=4) of civil society representatives.

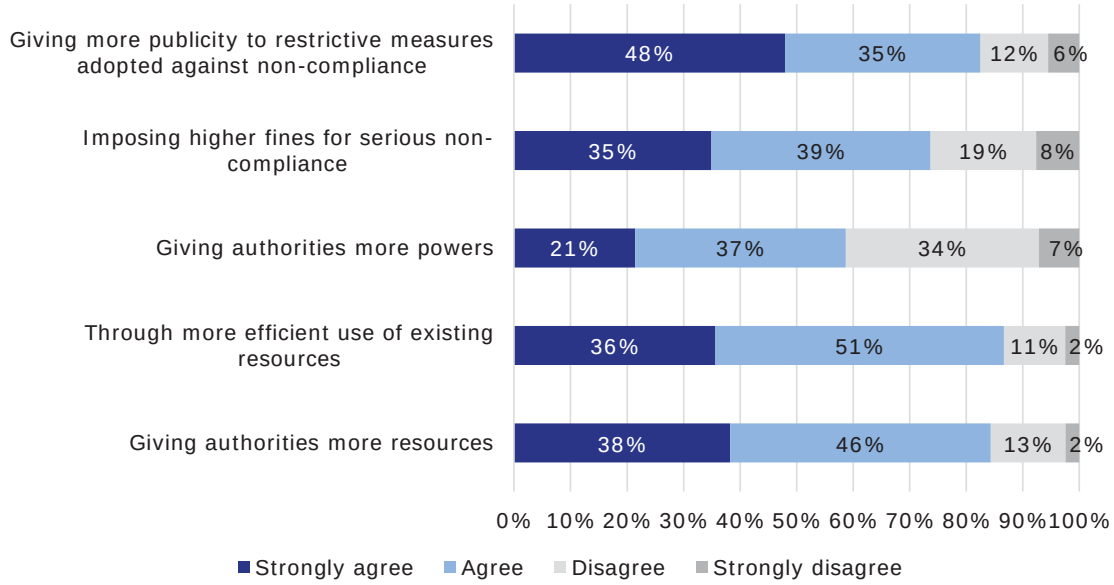
Looking specifically at the **different methodologies existing across Member States for enforcing market surveillance**, it is evident that most of categories consider it is an issue (76% overall). Like in the previous answer, the first category non-aligned with the overall trend is represented by PAs, 40% (n=4) of them considering this not being an issue. Similarly, there is a significant part of MSAs (29%, n=13) and Industry associations (26%, n=11) that do not consider this to be an issue.

331 *Establish a set of minimum core elements to be taken into account by all MSAs in calculating fines*: n = 201. In addition, 16% (n=38) of respondents chose the "No opinion" option; *Establish a more detailed common methodology to be taken into account by all MSAs in calculating fines*: n = 194. In addition, 19% (n=45) of respondents chose the "No opinion" option; *None, this is not a priority*: n = 183. In addition, 23% (n=56) of respondents chose the "No opinion" option; *None, different methodologies are not an issue for market surveillance in the Single Market*: n = 184. In addition, 23% (n=55) of respondents chose the "No opinion" option.

8.1.3.1.4 Solutions to increase the deterrence power of market surveillance

The following figure reports the opinion of stakeholders **on possible solutions to increase the deterrence power of market surveillance**. Giving more publicity to restrictive measures so as to exploit the reputation effect, and a more efficient use of existing resources are the two top options. The least appreciated solution is giving authorities more powers.

Figure 4-39 - Solutions proposed by respondents to the public consultation to increase MSAs' deterrence power



Source: public consultation[332]

If we look at the breakdown per categories, there is a substantial alignment on the **option of giving authorities more resources**, with the overall agreement of 84%. Economic operators represent the category that differs much, considering 29% (n=17) of them disagree. They are closely followed by 29% (n=9) of civil society representatives.

A stronger agreement is registered if the option on **a more efficient use of existing resources** is put forward (87%), with 95% (n=54) of economic operators and 94% (n=44) of Industry associations respectively being in favour of this. On the other hand, the strongest disagreement comes from 36% (n=4) of PAs.

The least appreciated option is definitely to **give authorities more power**, and even if the overall majority of respondents (58%) agree on this option, views change according to the category observed. On the one hand, 70% (n=21) of civil society representatives agree. On the other hand, the majority of Industry associations disagree (56%, n=22), as well as more than 40% of PAs and economic operators (n=4 and n=24).

332 *Giving more publicity to restrictive measures adopted against non-compliance*: n = 217. In addition, 9% (n=22) of respondents chose the "No opinion" option; *Imposing higher fines for serious non-compliance*: n = 209. In addition, 13% (n=30) of respondents chose the "No opinion" option; *Giving authorities more powers*: n = 196. In addition, 18% (n=43) of respondents chose the "No opinion" option; *Through more efficient use of existing resources*: n = 202. In addition, 15% (n=37) of respondents chose the "No opinion" option; *Giving authorities more resources*: n = 204. In addition, 15% (n=35) of respondents chose the "No opinion" option.

About the proposition of **imposing higher fines for serious non-compliance** there is also a substantial agreement (74%) with the only exception of PAs, which are perfectly split on this option (n=6). The other categories anyway for a significant part dislike this option at least in 20% of answers, up to 32% for Industry associations (n=15).

Significant agreement is also registered on the option of **giving more publicity to restrictive measures**, where 83% of four categories out of five agree. The only exception is represented by Industry associations, where only 62% (n=31) of respondents support this option. The highest share of positive answers is from MSAs (90%, n=53) and civil society representatives (94%, n=31).

In order to reduce the level of non-compliant products on the market, stakeholders do not show an overwhelming preference (48% positive, 52% negative) when asked if the responsibility for ensuring product compliance should be left to the businesses. Instead, almost all of respondents (87%) agree that MSAs should provide information on product requirements in addition to enforcement or support to companies through guidance on how to interpret product requirements (78%). Finally, agreements between businesses and authorities are considered effective by 54% of respondents.

When asked if National authorities should focus exclusively on enforcement and leave it entirely up to the businesses to ensure compliance by developing their own approaches, categories are not aligned on considering this measure effective. Only economic operators (59%, n=27) and PAs (70%, n=7) find it effective. The majority of other categories voted for "not effective", for an average of 59.5% (n=around 63).

Overall, the best approach according to stakeholders is that **authorities should also provide support to businesses through guidance on how to interpret product requirements**, justified by 44% of respondents that consider it an effective or very effective (34%) prerogative, with the lowest number of 71% (considering both positive answers) from MSAs.

All the categories also agree that **national authorities should provide information on product requirements**. Every group consider this effective in a range from 80% to 93%, and nearly 30% find it very effective.

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: for only 54% of the sample considered, this measure is effective (of which 19% chose very effective). Numbers are explained by the fact that two categories dislike this measure (75%, n=21 for MSAs and 67%, n=4 for PAs), even if the overall score is positive.

8.1.3.1.5 General description of market surveillance activities and relevant procedures

In light of technological developments and due to the increasing importance of e-commerce, particular attention has to be paid to **online sales and related market surveillance activities**. As a further proof, 80% (n=67) of respondents to the targeted surveys state there are **issues related to online trade,** with three large consumer associations based in different Member States[333] encountering difficulties in performing their activities due to online trade.

333 BE, DE, IT.

More precisely, 88% of MSAs (n=49) and industry associations (n=7) share this opinion. A certain level of opposition is expressed by Custom authorities as 40% (n=6) of them consider that there are no issues/obstacles related to online trade. In opposition with the majority, 75% (n=3) of respondents from companies deny any obstacle/issue related to online trade.

8.1.3.1.6 Customs, controls of imported products

As to specific issues with/obstacles to checks of products imported into the EU carried out by Authorities in charge of EU external border controls, 61% of total respondents to the targeted surveys report none. Broken down by category, the majority of respondents from industry associations and Custom authorities report no obstacles (73%, n=8 and 61%, n=11 respectively). Differently, responses from MSAs on this issue are partially divergent as 50% (n=18) of them consider that there are obstacles to checks of products imported into the EU.

More than half of respondents to the public consultation declare to have experienced non-compliance of products imported from non-EU countries. In particular, 20% of them think that most of these products are non-compliant and 56% think that some of them are non-compliant. In addition, **imported products are often sold online,**[334] this making enforcement even more challenging. Looking at the different categories, 44% (n=4) of PAs believe that most of products imported from non-EU countries are affected by non-compliance, closely followed by 30% (n=13) of respondents among economic operators. Furthermore, 70% (n=31) of industry associations consider that only some of them are affected by non-compliance.

Finally, the majority of respondents to the public consultation from all the categories (70%) consider that **there are non-compliant products in their sector imported from non-EU countries supplied 'online'**. In detail, 21% (n=11) of respondents from MSAs/Customs believe that non-compliance affects most of the imported products from non-EU countries. However, while 18% (n=4) of civil society representatives share this opinion, 23% (n=5) of them totally disagree on this issue. However, also **Intra-EU trade** represents a large share of overall EU trade, inasmuch as 58% of respondents declare that more than 41% of products available in their sector is imported from a different EU Member State.

In general, stakeholders consulted are in favour of the possibility for EU manufacturers or importers to be contacted by MSAs of another EU Member State. The majority of them consider it as a right of MSAs to contact economic operators outside their jurisdiction. Furthermore, most respondents think it would be useful for authorities to discuss non-compliance directly with businesses having the highest level of responsibility and knowledge, thus eventually resulting in the correction of non-compliance in the Single Market. As shown in the figure below, stakeholders outline that the main difficulties faced by MSAs in taking action against non-compliant products traded by businesses located in another EU Member State are represented by online sales (47% agree or strongly agree). Other difficulties to enforcement relate to the lack of businesses' willingness to collaborate with respect to MSAs' requests for corrective actions (57%) or for information/documentation (67%). In addition, 68% of respondents declare that businesses sanctioned do not pay penalties imposed by MSAs.

334 Based on the results of the public consultation, 14% of respondents report that most of them are sold online, 56% say that some of them are sold online and 18% think that only a few are supplied online.

Difficulties in taking actions against non-compliant products traded by businesses located outside the EU are due to different reasons, as presented in the figure below. The main obstacle is represented by sanctioned businesses not paying fines, ignoring requests for corrective actions or not replying to requests for information and/or documentation. Again, online sales are considered an important obstacle to proper enforcement.

Figure 4-40 - Stakeholders' perception of difficulties in taking action against non-compliant imported products

Source: public consultation[335]

About the perception of difficulties in tacking action against non-compliant imported products, the fact that **authorities do not know how to identify and contact businesses located in non-EU countries**, is not felt by stakeholders as a main problem. Every group disagree, although not with significant numbers. Economic operators for example consider this topic irrelevant only in 53% (n=19) of cases.

On the fact that **authorities find it more costly to contact businesses located in non-EU countries**, there is no unique perception. On the one hand, around 70% economic operators and Industry associations agree (n=23 and n=22 respectively), while 58% (n=4) of PAs, 60% (n=9) of Civil society representatives and 73% (n=38) for MSAs disagree.

335 *In particular in the case of goods traded online businesses*: n = 194. In addition, 19% (n=45) of respondents did not reply; *Businesses sanctioned do not pay penalties*: n = 195. In addition, 18% (n=44) of respondents did not reply; *Businesses contacted do not reply to requests for corrective actions*: n = 195. In addition, 18% (n=44) of respondents did not reply; Bus*inesses contacted do not reply to requests for information/documentation*: 192. In addition, 20% (n=47) of respondents did not reply; *Authorities find it more costly to contact businesses located in non-EU countries*: 195195195. In addition, 18% (n=44) of respondents did not reply; *Authorities do not know how to identify and contact businesses located in non-EU countries*: n = 196. In addition, 18% (n=43) of respondents did not reply.

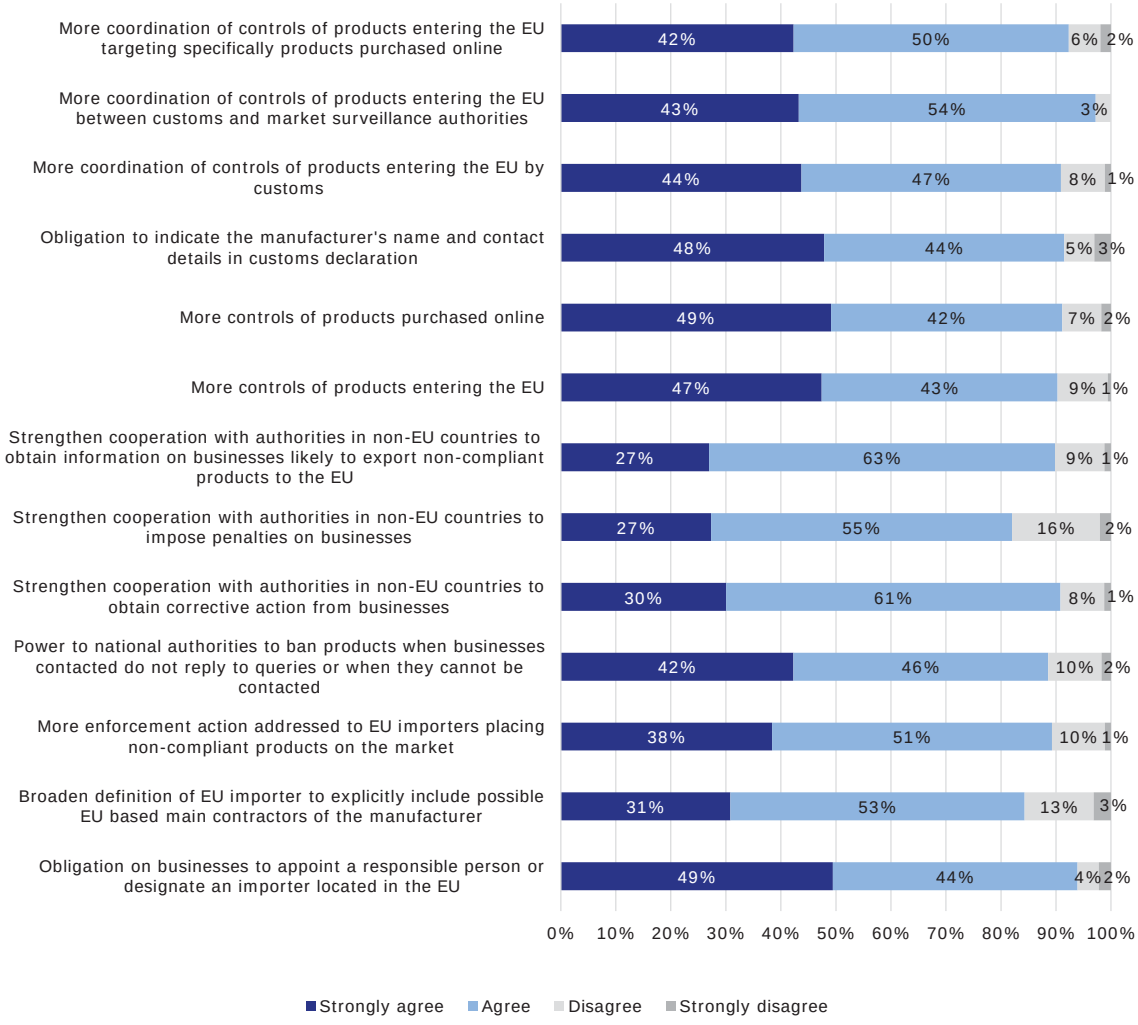
A more clear view can be seen on the perception that **businesses contacted do not reply to requests for information/documentation**. There is agreement on considering it as a problem, according to 65% of stakeholders on average (n= around 77). Similarly, the fact that businesses **do not reply to request for corrective actions**, is perceived as a problem by 72% (n=78) of stakeholders on average with a peak on PAs (100%, n=6).

The perception of difficulties when **businesses sanctioned do not pay penalties** is shared by overall 68% of respondents,[336] with another peak for PAs (100%, n=3) and with the exception of 60% of civil society representatives that disagree, half of them **strongly**. Specifically for difficulties with **businesses trading goods online,** agreement is also shared among stakeholders, but numbers are quite different, starting from the lowest 67% (n=8) of civil society representatives to the highest 100% (n=5) of PAs.

In order to take actions against non-compliant imported products, stakeholders support the idea of a higher level of coordination of controls between Customs authorities and MSAs, the obligation for foreign businesses to appoint a responsible person or importer located in the EU, stronger cooperation between European MSAs and non-EU countries' authorities and more control over specific products purchased online.

Figure 4-41 - Stakeholders' preferences about actions to be taken against non-compliant products traded by businesses located in non-EU countries

336 Number of respondents: Civil society: 10; economic operators: 17; Industry associations: 13; MSAs: 21; PAs: 3.



Source: public consultation[337]

All categories state that an **obligation on businesses to appoint a responsible person or designate an importer located in the EU** is a viable option to help taking action against non-compliant products traded by businesses located in a non-EU country, as 49% strongly agree

337 *More coordination of controls of products entering the EU targeting specifically products purchased online*: n = 156. In addition, 21% (n=37) of respondents chose the "no opinion" option, while 19% (n=46) did not reply; *More coordination of controls of products entering the EU between customs and MSAs*: n = 178. In addition, 11% (n=18) of respondents chose the "no opinion" option, while 18% (n=43) did not reply; *More coordination of controls of products entering the EU by Customs*: n = 176. In addition, 13% (n=21) of respondents chose the "no opinion" option, while 18% (n=42) did not reply; *Obligation to indicate the manufacturer's name and contact details in Customs declaration*: n = 165. In addition, 19% (n=30) of respondents chose the "no opinion" option, while 18% (n=44) did not reply; More controls of products purchased online: n = 169. In addition, 17% (n=27) of respondents chose the "no opinion" option, while 18% (n=43) did not reply; *More controls of products entering the EU*: n = 175. In addition, 14% (n=22) of respondents chose the "no opinion" option, while 18% (n=42) did not reply; *Strengthen cooperation with authorities in non-EU countries to obtain information on businesses likely to export non-compliant products to the EU*: n = 167. In addition, 15% (n=29) of respondents chose the "no opinion" option, while 18% (n=43) did not reply; *Strengthen cooperation with authorities in non-EU countries to impose penalties on businesses*: n = 150. In addition, 23% (n=46) of respondents chose the "no opinion" option, while 18% (n=43) did not reply; *Strengthen cooperation with authorities in non-EU countries to obtain corrective action from businesses*: n = 163. In addition, 17% (n=32) of respondents chose the "no opinion" option, while 18% (n=44) did not reply; *Power to national authorities to ban products when businesses contacted do not reply to queries or when they cannot be contacted*: n = 175. In addition, 13% (n=21) of respondents chose the "no opinion" option, while 18% (n=43) did not reply; *More enforcement action addressed to EU importers placing non-compliant products on the market*: n = 177. In addition, 13% (n=22) of respondents chose the "no opinion" option, while 17% (n=40) did not reply; Broaden definition of EU importer to explicitly include possible EU based main contractors of the manufacturer: n = 159. In addition, 19% (n=36) of respondents chose the "no opinion" option, while 18% (n=44) did not reply; Obligation on businesses to appoint a responsible person or designate an importer located in the EU: n = 180. In addition, 11% (n=17) of respondents chose the "no opinion" option, while 18% (n=36) did not reply.

and 44% agree (n=167 overall). PAs represents the least aligned with 22% (n=2) that disagree.

Broaden definition of EU importer to explicitly include possible EU based main contractors of the manufacturer in the absence of a Civil society representatives responsible person in the EU is also welcomed with no significant deviation from a specific group. Overall 84% agree on this, in range from 78% to 88% considering the single percentage of every category.

In accordance to the previous options, four categories think that more enforcement action addressed to EU importers placing non-compliant products on the market might definitely help, for 89% of respondents, except for PAs (n=6) that are perfectly split.

Strong agreement among all categories also about giving **the power to national authorities to ban products when businesses contacted** do not reply to queries or when they cannot be contacted. From the overall sum of 88% for agree (46%) and strongly agree (42%), groups are allocated between 80% and 92%.

Every category agree on strengthening cooperation with authorities in non-EU countries to perform various activities. In order to obtain corrective action from businesses, four groups are aligned with an overall 91%, except for PAs that agree only in 67% (n=6) of answers. There is substantial agreement also to impose penalties on businesses, but in this case PAs differ significantly from the average –equal to 82%- with a specific percentage of 56% (n=5) on agree and 0% on strongly agree. Finally, there is a strong agreement if the goal is to obtain information on businesses likely to export non-compliant products to the EU, where there is no difference from the overall 90% worthy of note.

All the five categories agree when asked on making **more controls on products entering the EU**, and especially on products purchased online. Overall, 90% of respondents agree on this issue. Analysed by category, 59% (n=32) of MSAs/Customs and 55% (n=22) of civil society representatives express the strongest agreement.

The **obligation to indicate the manufacturer's name and contact details in Customs declaration** is widely accepted by all the sample considered. Considering an overall average of 92%, respondents slightly vary across categories. Only 20% (n=4) of civil society representatives disagree.

On the option of **more coordination of controls of products entering the EU by Customs** (e.g. more exchange of risk information, alignment of measures) all categories are quite aligned on the overall 91%, even if it must be noted of the short distance of Civil society representatives, whose rate of agreement stops at 77% (n=16).

Together with more controls on products, **more coordination of controls on products entering the EU between Customs and MSAs** is broadly needed. Overall, 97% of respondents agree on the need for more coordination especially economic operators as they all (n=45) support this option.

Further coordination of controls is also encouraged in relation **to products purchased online** *(e.g. via a pan-European Task Force of national authorities)*. Also in this case, economic operators widely agree on this opinion (97%, n=35) closely followed by respondents from industry associations (95%, n=39).

Based on respondents' opinion, contacting EU manufacturers or importers located in another EU Member State would be easier through **specific procedures for mutual assistance among authorities of different EU Member States** (91%). Other widely supported options were the possibility to impose stricter obligations on MSAs to respond to requests for mutual assistance (85%) or through granting MSAs the possibility to ask other authorities to sanction businesses located in the latter's country when they refuse to cooperate (85%).

Looking at the **main reasons for product non-compliance**, respondents to the public consultation have provided a ranking (from 1 to 5, 1 being the most important reason) of possible options based on their perception and experience. Above all, there is no a clear distribution of the answers provided, nor significant trends among different groups to be reported.

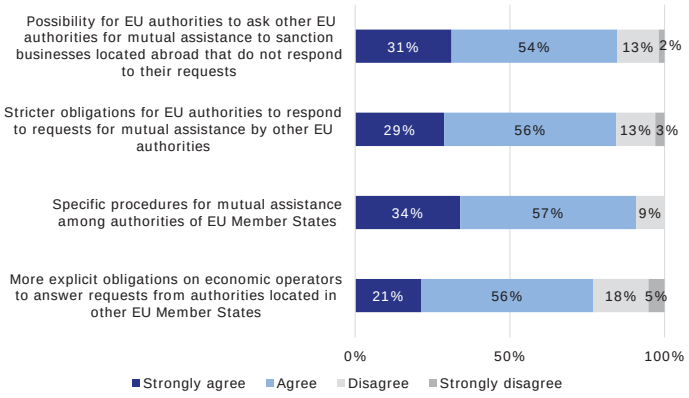
Nearly the majority does not consider non-compliance as a **deliberate choice to exploit market opportunities at the lowest cost**, given the concentration of answers on levels 1 and 2 (48%). A divergent opinion comes from 52% (n=33) of MSAs that chose levels 3 and 4.

A clearer opinion comes when considering the **lack of knowledge**. 57% of respondents chose 1-2, while 43% the remaining, so we can assume that this is perceived as a main reason for non-compliance.

The third option, **a technical or civil society representatives' type of inability to comply with rules**, is seen as a moderate cause: when considering an average of total answers, the result would probably be slightly above level 3. The same conclusion comes from the option **carelessness**, with the only exception of respondents of PAs (n=12), more distributed around level 2.

The last reason, **ambiguity in the rules**, can be considered the first in rank, since 51% of answers are on the two highest levels and 73% from level 3. Also there is a quite similar trends among stakeholders, except for Economic operators.

Figure 4-42 - Possible solutions to ease MSAs' contact with EU manufacturers or importers located in another EU Member State



Source: public consultation[338]

338 *Possibility for EU authorities to ask other EU authorities for mutual assistance to sanction businesses located abroad that do not respond to their requests*: n = 164. In addition, 11% (n=27) of respondents chose the "no opinion" option, while 20% (n=48) did not

8.1.3.1.7 Cooperation with other Member States and third countries

In the targeted surveys, the majority (77%, n=66) of MSAs and Customs state that they cooperate with authorities based in other Member States, while only 23% (n=20) do not. In detail, 85% (n=57) of respondents from MSAs confirm that they usually cooperate while only 47% (n=9) of Custom Authorities act in cooperation with other Customs. Cross-country communication and cooperation is considered useful by nearly all respondents.

According to respondents to the targeted surveys, the **AdCO groups** allow a flexible and efficient form of cooperation between Member States.[339] All (n=13) coordinating authorities confirm that the **MSA in their Member State participates in AdCO activities**. Notably, this opinion is shared by 88% (n=59) of responding MSAs.

As mentioned above, EU MSAs can share information on measures adopted to restrict the marketing of non-compliant products through several means such as RAPEX and ICSMS, the notification procedures, expert groups and AdCOs. However, according to 40% (n=38)[340] of respondents to the public consultation, **MSAs rarely restrict the marketing of a product following the exchange of information about measures adopted by another authority in the EU against the same product**. This occurs "*sometimes*" according to 34%% (n=32)[341] of stakeholders, while a minority declare that it "*very often*" (12%[342], n=11) or "*always*" (6%, n=6[343]) occurs. A minority, 8% (n=8[344]) of respondents thinks that MSAs never exploit information coming from other EU MSAs.

Figure 4-43 - Stakeholders' opinion on 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

reply; *Stricter obligations for EU authorities to respond to requests for mutual assistance by other EU authorities*: n = 167. In addition, 10% (n=23) of respondents chose the "no opinion" option, while 21% (n=49) did not reply; *Specific procedures for mutual assistance among authorities of EU Member States*: n = 174. In addition, 8% (n=18) of respondents chose the "no opinion" option, while 20% (n=47) did not reply; *More explicit obligations on economic operators to answer requests from authorities located in other EU Member States*: n = 174. In addition, 8% (n=18) of respondents chose the "no opinion" option, while 20% (n=47) did not reply.

339 Four MSAs, a Member State coordinating authority.

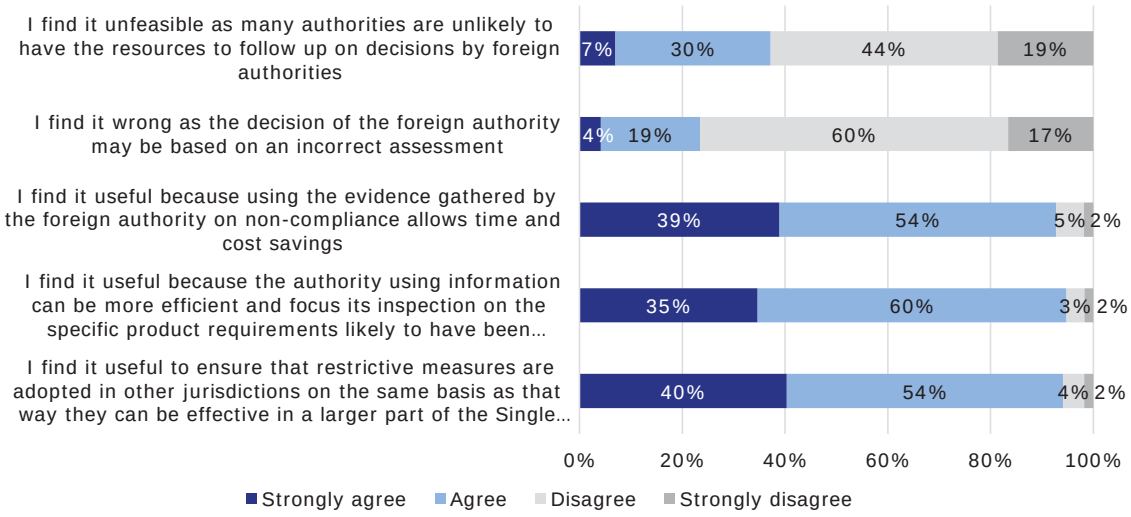
340 Nine MSAs or Custom authorities, four PAs, ten economic operators, ten industry associations, a Belgian trade union, 1 consumer organisation (BE), an English consumer/citizen, two others (BE, SK).

341 13 MSAs or Customs authorities, five economic operators, ten industry associations, an English international organisation, two academic/law firms (DE, UK), a French other.

342 Six MSAs or Customs authorities, two industry associations (BE, PT), a German academic/law firm (DE), two German others.

343 Four MSAs or Customs authorities, a German public authority (DE), an English industry association.

344 A Norwegian MSA, four economic operators (ES, FR, SE, UK), three industry associations (ES, FR, IT).



Source: public consultation[345]

The majority of respondents from the different categories share a positive opinion on the **possibility for a national authority to use information on measures adopted to restrict the marketing of non-compliant products by another EU Member State authority** in order to improve its efficiency and targeted action. Analysed by category, all PAs (n=8) and civil society representatives (n=25) find it useful to ensure that restrictive measures are adopted on the same basis, so as they can be effective in a larger part of the Internal Market. Very few divergent views are provided in the other categories.

Furthermore, the majority of respondents to the public consultation find this possibility as useful because the **MSA using information on measures adopted can be more efficient and focus on the specific product requirements likely to have been infringed**. As in the previous case, all civil society representatives (n=25) and PAs (n=8) responding to this question share this opinion, while few economic operators disagree (12%, n=5).

Almost all the respondents from the different categories also consider that such use of information would be **useful because using the evidence gathered by the foreign authority on non-compliance allows time and cost savings.** Only few economic operators disagree with this opinion (14%, n=6).

Although the majority of respondents disagree with the opinion that **the decision of the foreign authority may be based on an incorrect assessment**, diverging views appear within some categories. More precisely, respondents from the industry associations and economic operators admit the possibility of an incorrect assessment (36% and 37% respectively, n=13 each).

345 *I find it unfeasible as many authorities are unlikely to have the resources to follow up on decisions by foreign authorities*: n = 129. In addition, 26% (n=61) of respondents chose the "no opinion" option, while 21% (n=49) did not reply; *I find it wrong as the decision of the foreign authority may be based on an incorrect assessment*: n = 145. In addition, 18% (n=44) of respondents chose the "no opinion" option, while 21% (n=50) did not reply; *I find it useful because using the evidence gathered by the foreign authority on non-compliance allows time and cost savings*: n = 167. In addition, 10% (n=24) of respondents chose the "no opinion" option, while 20% (n=48) did not reply; *I find it useful because the authority using information can be more efficient and focus its inspection on the specific product requirements likely to have been infringed*: n = 173. In addition, 8% (n=18) of respondents chose the "no opinion" option, while 20% (n=48) did not reply; *I find it useful to ensure that restrictive measures are adopted in other jurisdictions on the same basis as that way they can be effective in a larger part of the Single Market*: n = 171. In addition, 8% (n=20) of respondents chose the "no opinion" option, while 20% (n=48) did not reply.

Finally, the majority of respondents think that such a use of information by a national authority would be unfeasible, as **MSAs are unlikely to have the resources to follow up on decisions by foreign authorities**. However, more than half of economic operators (57%, n=20) do not align with the majority along with a relevant share of respondents from industry associations (47%, n=11).

When asked about ways to increase the effectiveness of market surveillance, most of the respondents to **the public consultation** have suggested **more exchange of information and discussion among EU national authorities prior to final assessment on product non-compliance and corrective action so as to prevent diverging conclusions among authorities.** Broken down by category, nearly all the respondents from the industry associations (n=42) and economic operators (n=46) support this option.

The majority of respondents also believe that effectiveness can be increased by adopting **stricter rules on follow up to restrictive measures adopted by EU authorities**. However, 57% (n=4) of respondents from PAs disagree on this.

Furthermore, most of the respondents suggest the introduction of **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). Namely, almost all the respondents from MSAs/Customs (91 agree on this issue, closely followed by industry associations (83%, n=33).

A great consensus is also reached by respondents on a **procedure for the recognition of national decisions in other EU Member States**. Diverging views are expressed by respondents from PAs as 40% (n=2) of them strongly disagree on such procedure.

On the contrary, a high level of disagreement is expressed by respondents from different categories on the **direct applicability of national decisions in other EU Member States**. Results split by category show a high degree of opposition from PAs (88%, n=5). Nearly half of civil society representatives (n=10) and respondents from economic operators (n=20) also disagree with this opinion.

In addition, the majority of respondents agree on the suitability of **decisions against non-compliant products to be taken by authorities of various EU Member States in close coordination and being applicable simultaneously in all relevant jurisdictions**. The strongest opposition in this case comes from respondents of PAs (51%, n=4) along with MSAs/Customs (42%, n=21).

More than half of respondents from the different categories, also support **the appointment of a lead authority to facilitate coordination of national decisions**. Against the other categories, 86% (n=6) of respondents from PAs disagree on the previous opinion.

Diverging opinions are expressed in relation to the possibility of a **lead authority with powers to adopt decisions against non-compliant products applicable in different Member States** (e.g. subject to consultation with relevant national authorities). Among the different categories, 65% (n=34) of MSAs/Customs disapprove this option.

Half of the respondents also disagree on the possibility for the **Commission to take decisions against non-compliant products supplied in various EU Member States**. The largest

opposition is expressed by respondents from industry associations (59%, n=23) and PAs (51%, n=4).

Finally, the majority of respondents agree on providing **powers to the Commission to check the functioning of market surveillance in Member States**. Looking at the categories, 93% (n=37) of respondents from the industry associations and 87% (n=38) of economic operators support this option.

8.1.3.2 Efficiency

Most of the respondents from the different categories **to the public consultation** agree on the fact that a broader use of electronic means to demonstrate compliance would help **reduce the administrative burden for businesses**. Interestingly, respondents from PAs totally agree with this opinion while low percentages of respondents from industry associations and economic operators disagree (27%, n=11 and 18%, n=9 respectively).

Most of the respondents also believe that a broader use of electronic means to demonstrate compliance helps **reduce the administrative costs of enforcement for authorities**. In detail, civil society representatives (91%, n=19) and PAs (86%, n=6) are the categories that support this opinion the most. On the contrary, 32% (n=11) of respondents from industry associations disagree on this issue.

Furthermore, nearly all the respondents from the different categories agree that the use of electronic means would **provide/allow information to be obtained faster**. Only 10% of respondents from industry associations (n=4) and MSA/Customs (n=4) disagree with the majority.

Similarly, the majority of respondents consider that it would help **provide further information to consumers/end users**. Namely, all (n=6) respondents from the PAs share this opinion. However, 30% (n=10) of respondents from industry associations disagree on this issue.

Based on the experience of many respondents, a broader use of electronic means to demonstrate compliance would help **provide up-to-date information to consumers/end users**. PAs and MSAs/Customs positively support this opinion while 33% (n=11) of respondents from industry associations consider that consumers/end users would not receive up-to date information.

Respondents have also been invited to share their views about different options to better exploit the potential of electronic means for demonstrating compliance. First of all, the majority of respondents show disagreement about a **voluntary decentralised 'Digital Compliance' system**, consisting of information available on the websites of economic operators and notified bodies (on a voluntary basis) and responsible for developing and maintaining such information. In particular, all (n=6) PAs show disagreement on this option. However, respondents from industry associations and civil society representatives are highly divided on this issue as approximately half of them are in favour of these system (n=10 and 20 respectively).

Opinions significantly vary in the case of a **compulsory decentralised 'Digital Compliance' system**. On the one hand, 76% of respondents from industry associations disagree on this option as well as 75% of responding civil society representatives. On the other hand, the

majority of PAs respondents (60%, n=3) agree on a compulsory decentralised system instead of a voluntary one.

Diverging opinions also appear in relation to a **voluntary centralised 'Digital Compliance' system**, established in the form of an electronic repository of information owned and maintained by the European Commission but with the possibility for manufacturers, authorised representatives, notified bodies to upload information regarding conformity of products. The strongest opposition comes from industry associations (71%, n=27) and economic operators (59%, n=27) while the other categories are equally divided.

Half of the respondents from all the categories is in favour of a **compulsory centralised 'Digital Compliance' system owned by the Commission**. In particular, this option is supported by 71% (n=27) of MSAs/Customs and by all PAs (n=6).

In addition, many respondents consider that an **e-labelling system containing the address of the electronic repository would be beneficial** for demonstrating compliance. More precisely, civil society representatives and PAs are the categories expressing the highest support (88%, n=15 and 83%, n=5 respectively).

According to the majority of the respondents, an **e-labelling system containing the product identification and/or manufacturer contact details would be beneficial** for the same scope. Also in this case, civil society representatives and PAs express the strongest support. On the contrary, 36% (n=13) of industry associations disagree on this issue.

The majority of respondents **to the public consultation** also find that **resorting to an automatic identification and data capture system to facilitate access to the repository would be beneficial** in the view of demonstrating compliance. Analysed by category, economic operators show diverging views as approximately half of respondents (53%, n=21) disagree with this option.

As for the resources available for market surveillance activities, the majority of respondents from the different categories agree on the fact that **revenues obtained through sanctions should be allocated to market surveillance activities**. Opinions expressed might diverge when respondents are broken down by category. Most of civil society representatives responding to the specific question, for instance, agree with this option (80%, n=25). However, a significant share of them (19%, n=6) express a completely opposite position. This issue is conflictual also among respondents from PAs, as 30% (n=3) of them strongly disagree on allocating revenues from sanctions to market surveillance activities. 25% of both MSAs/Customs (n=14) and industry associations (n=11) also disagree.

Most of the respondents from the different categories state that **MSAs should not levy administrative fees on operators in their sector to finance controls**. The strongest opposition in this sense is expressed by respondents from the industry associations and by economic operators (73%, n=36 and 51%, n=35 respectively). On the contrary, 64% (n=35) of respondents from the MSAs or Customs is in favour of administrative fees imposed on operators. Diverging views are expressed by respondents from civil society, with the majority of them being against (63%, n=21). Interestingly, few respondents from PAs (25%, n=3) seem to approve the possibility for MSAs to impose administrative fees on operators in their sector to finance controls.

When asked about **Programmes at European level**, the overwhelming majority of respondents from all the categories agreed on the fact that those programmes **should finance sufficient laboratory capacity in each Member State**. Looking at the different stakeholders' categories, nearly the totality of respondents from industry associations and PAs share the previous position (91%, n=39 and 90%, n=10 respectively). However, a significant percentage of economic operators (22%, n=14) disagree with the prevailing opinion on programmes at European level.

Respondents to the public consultation have been asked to reflect upon possible ways to **improve the efficiency in the use of resources for market surveillance activities in their sector**. The majority of respondents from all the categories consider that MSAs **should have more knowledge about the relevant sector** in terms of type and number of economic operators, market trends and other key aspects. Namely, all (n=47) the respondents from the industry associations share this opinion, closely followed by civil society representatives (97%, n=31). Some respondents from PAs and MSAs/Customs do not support the need for improved knowledge for MSAs in their sector of competence (16%, n=2 and 15%, n=9 respectively).

In addition, a large part of respondents from the different categories think that **MSAs should have stronger powers in order to ensure that resources for market surveillance activities are used more efficiently**. Diverging views appear when responses are analysed by category. More precisely, a high percentage of industry associations (46%, n=18) and PAs (45%, n=5) disagree with this opinion, together with 38% (n=23) of economic operators and 36% (n=12) of civil society representatives.

There is a strong agreement among the respondents from all the categories on the fact that **MSAs' inspectors should receive better training**. Significantly, 78% (n=45) of respondents from MSAs/Customs express this position. Looking at the other categories, nearly the totality of economic operators (n=64) and industry associations (n=47) responding to the PC, also share this view. A greater variety of opinions is reported by respondents from PAs.

As for the training received by MSAs' inspectors, the majority of respondents from the different categories consider that **MSAs' inspectors should receive more standardised training across the EU**. Namely, all the respondents from PAs (n=10) agree on this option. A strong consensus is also recorded among respondents from industry associations (96%, n=46), economic operators (86%, n=56) and civil society representatives (91%, n=32). Finally, 18% (n=10) of respondents from MSAs/Customs disagree.

According to the vast majority of respondents from the different categories, **MSAs within a Member State should share more intelligence to use resources more efficiently**. The analysis of answers by category does not show significant diverging views. Only a limited number of respondents from MSAs/Customs and PAs express different opinions (respectively 26%, n=15 and 30%, n=3 disagree).

A very large consensus is also reached by respondents on the fact that **MSAs of different Member States should share more intelligence**. Grouped by category, it is possible to notice that all (n=49) industry associations share this opinion. Very few respondents from the other categories disagree.

In order to increase the efficiency in the use of resources for market surveillance, 88% of respondents from the different categories consider that **MSAs within a Member State**

should better coordinate their action. The analysis of the answers broken by category reveals a very large agreement on the need for better coordination among industry associations (98%, n=48), civil society representatives (93%, n=32) and economic operators (94%, n=60). PAs and MSAs/Customs are less in line with the prevailing position.

Nearly the totality of the respondents from all the categories agree on the fact that **MSAs of different Member States** should better coordinate action. Interestingly, all (n=50) industry associations agree on this issue. Similarly, a very strong agreement is expressed by respondents from the civil society (56%, n=19) and by economic operators (55%, n=35). Only few respondents from the PAs disagree on the need for further coordination among Member States (27%, n=3).

Furthermore, the majority of the respondents from the different categories consider that the **MSAs within a Member State should share capacity of testing laboratories to use resources more efficiently**. Considering the responses grouped by category, only MSAs/Customs and PAs report a relatively high percentage of disagreement (above 27%, n=16 overall). More than 93% of respondents from the other categories agree.

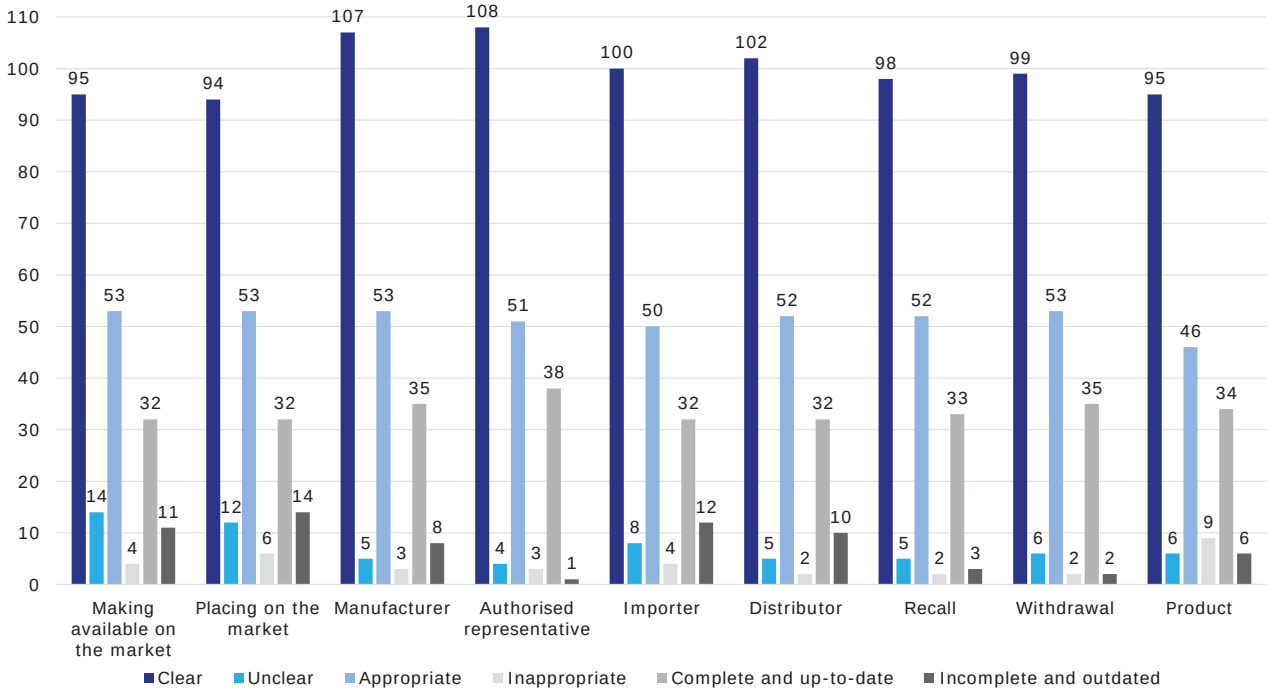
Finally, most respondents from the different categories consider that MSAs **of different Member States** should share capacity of testing laboratories. By comparing the categories, respondents from the industry associations support this position to the largest extent (92%, n=39). Diverging views appeared to be relevant in the case of PAs where half (n=5) of the respondents agrees while the other half disagrees.

8.1.3.3 Relevance

8.1.3.3.1 Definitions

According to the majority of respondents to the targeted surveys, **the definitions** provided in Article 2 of Regulation (EC) No 765/2008 and relevant for market surveillance **are clear**. There is also consensus on the appropriateness of these definitions, whereas **a smaller share of respondents report that they are complete and up-to-date** (as shown in the Figure 4-44 below), this eventually questioning the capacity of the Regulation to answer current stakeholders' needs.

Figure 4-44 - Number of stakeholders' expressing a feedback on the definitions provided in the Regulation[346]



Source: targeted surveys

Responses to the survey may be analysed by definition and respondent category to get a better understanding of the stakeholders' opinions. For instance, the definition of "making available on the market" is considered to be inappropriate, incomplete or unclear by respectively three, eight and seven MSAs out of 94. Conversely, no industry associations express negative opinions on the same concept. The definition "Placing on the market" is considered to be incomplete by 10 MSAs and unclear by two MSAs out of 117 total MSAs responding to this question. As for the concept of "manufacturer", it is generally considered to be clear, except from a notable number of MSAs (27 out of 112) that consider it incomplete and outdated. The definition of "authorised representatives" does not generate any particular concern among stakeholders, given that only three out of 177 consider it as inappropriate (2 MSAs) or incomplete and outdated (1 coordinating authority). Furthermore, nine MSAs indicate the concept of "importer" as incomplete, two of them as inappropriate and three of them as unclear (out of 104 MSAs answering to that point), while all responding industry associations express positive opinions on this definition. As for "distributor", 12 out of 103 MSAs express negative opinions, while the rest of stakeholder categories generally indicated positive views on it. Finally, the definitions of "product", "recall" and "withdrawal" have a uniform very low share of negative opinions across all stakeholders' categories. To conclude with, it is possible to state that there is no significant variability across stakeholder categories regarding definitions, as these are generally perceived as clear.

346 *Making available on the market*: in addition, 6% (n=13) of respondents chose the "I do not know" option. *Placing on the market*: in addition, 6% (n=13) of respondents chose the "I do not know" option. *Manufacturer*: in addition, 5% (n=12) of respondents chose the "I do not know" option. *Authorised representative*: in addition, 5% (n=12) of respondents chose the "I do not know" option. *Importer*: in addition, 5% (n=12) of respondents chose the "I do not know" option. *Distributor*: in addition, 6% (n=14) of respondents chose the "I do not know" option. *Recall*: in addition, 10% (n=21) of respondents chose the "I do not know" option. *Withdrawal*: in addition, 8% (n=18) of respondents chose the "I do not know" option. *Product*: in addition, 8% (n=18) of respondents chose the "I do not know" option.

8.1.3.3.2 Scope of the Regulation

The majority of respondents to the targeted surveys (71%) reported that the current scope of the Regulation is clear. In particular, when analysing the answers per stakeholder category, while all categories are almost aligned on the perception of the scope clarity, only 63% (n=37) of MSAs replying to the question confirm this result.

As for the ***lex specialis*** principle, 70% of respondents to the targeted surveys confirm that it causes **no difficulties of implementation**, though a few stakeholders raised some issues. In opposition to the majority, 31% (n=18) of MSAs consider that the concept of *lex specialis* causes some problems of implementation.

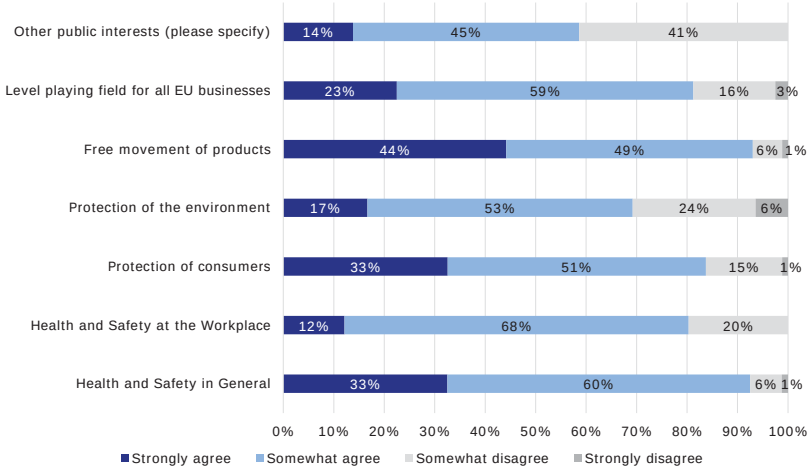
8.1.3.3.3 National reports and programmes on market surveillance

The majority of respondents to the targeted surveys (76%) deem the provisions of Article 18(5) on market surveillance programmes as useful. Broken down by category, both coordinating authorities and MSAs strongly align with this position (89%, n=8 and 74%, n=46 respectively).

8.1.3.3.4 Objectives of the Regulation

When asked about the adequacy of the framework provided by the Regulation in order to achieve its strategic objectives, the great majority of respondents reported that it positively contributes to their achievement, as shown in Figure 4-45 below. In particular, there is a strong consensus that the Regulation promotes the free movements of goods, the health and safety in general and the protection of consumers. Furthermore, according to a Belgian industry association, the compliance checks performed by MSAs contribute to ensure a level playing field in the Internal Market. Interestingly however, a Danish industry association reports that in the case of pyrotechnics articles no free movement of goods exists.

Figure 4-45 - Adequacy of the framework provided by the Regulation to achieve its objectives



Source: targeted surveys[347]

347 *Health and Safety in general*: n = 80; Health and Safety at the Workplace: n = 66; Free movement of products: n = 86. In addition, 19% (n=19) of respondents chose the "I do not know" option; *Health and Safety at the Workplace*: n = 66. In addition, 33% (n=33) of respondents chose the "I do not know" option; *Protection of consumers*: n = 86. In addition, 13% (n=13) of respondents chose the "I do not know" option; *Protection of the environmen*t: n = 78. In addition, 21% (n=21) of respondents chose the "I do not know"

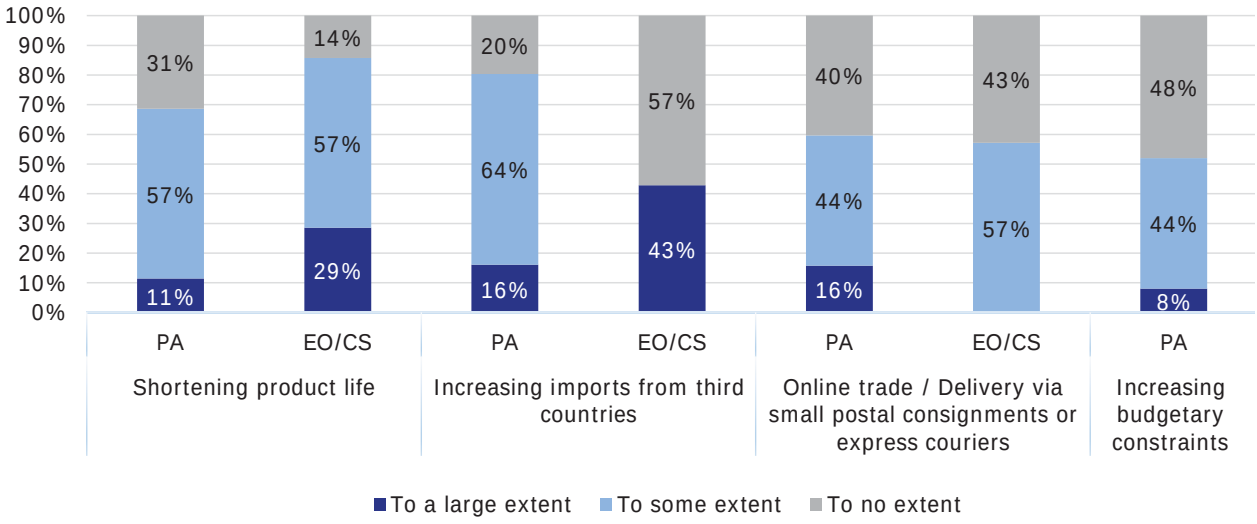
When observing the composition of each listed points in terms of stakeholder category, it is possible to draw some considerations. The totality of industry associations (n=10), companies (n=4) and coordinating authorities (n=11) and the large majority of MSAs (93%, n=49) agree or strongly agree with the idea that the Regulation achieves the objective of protect Health and Safety in general. As for health and safety at the workplace, 23% of MSAs and 20% of coordinating authorities "somewhat disagree" with the statement. As for protection of consumers, no stakeholders' state to strongly disagree, while only 17% (n=2) of coordinating authorities and MSAs (n=10) somewhat disagree, therefore expressing an overall positive perception of the reaching of this goal. In the case of protection of the environment, it is possible to observe an interesting part of MSAs (34%, n=17) and one company out of 4 that disagree or somewhat disagree. No stakeholders disagree with the "free movement of product" point, except from 8% (n=1) of industry associations and 7% (n=4) of MSAs. As for the generation of a level playing field for all EU businesses, the category of industry associations shows 36% (n=4) of disagreement, however no companies (n=4) disagree. Finally, when responding to the "other public interests" option, a higher rate of general disagreement is expressed. In particular, 60% (n=3) of coordinating authorities and 58% (n=11) of MSAs state to disagree or somewhat disagree with the label. Similarly, stakeholders responding to the survey declare that they generally appreciate the framework for market surveillance provided by the Regulation, inasmuch as 49% of stakeholders think it is useful in defining their national market surveillance and control of imported products policies to a large extent, 46% consider it to be useful to a small extent and only 5% declare it not to be useful, for a total of 95% of overall positive answers. Further evidence is provided by **73% of stakeholders reporting that the Regulation currently meets their needs**. In particular, all (n=4) companies and 84% (n=16) of participating Customs and of coordinating authorities (85 n=11) contributed to this figure by answering "yes".

8.1.3.3.5 New dynamics

As for specific issues addressed by the Regulation, **a low share (8%) of public authorities (68%), economic operators and civil society representatives (86%) reported that the Regulation adequately addresses new issues related to increasing general budgetary constraints**, while approximately a half of them (48%) states that it is **not** addressing the issue at all. On the contrary, as shown in Figure 4-46 below, there are different opinions on the role of the Regulation in **addressing the challenges of increasing imported products from third countries**. More in detail, 80% of public authorities report that the Regulation is able to address challenges related to imported products, while only 43% of economic operators share the same opinion and 57% of the last category think that the Regulation does not play any role in this sense. Differently, there is consensus on each respondent category (40% of public authorities and 43% of economic operators and civil society representatives) that the framework provided by the Regulation is **not adequately dealing with issues emerging from online trade**. Finally, 70% of public authorities and 71% of economic operators and civil society representatives confirmed that the Regulation allows authorities to track non-compliant products and ensure corrective action even if the product has a short life.

option; *Free movement of products*: n = 86. In addition, 13% (n=13) of respondents chose the "I do not know" option; *Level playing field for all EU businesses*: n = 19. In addition, 19% (n=13) of respondents chose the "I do not know" option. *Other public interests*: n = 29. In addition, 70% (n=70) of respondents chose the "I do not know" option.

Figure 4-46 - Relevance of the Regulation to new/emerging issues[348]



Source: targeted surveys[349]

As shown in the figure above, the majority of economic operator and civil society associations think that the increasing imports from third countries is an emerging issue that the Regulation is not addressing, while MSAs and Customs mainly think it is addressing it to some extent (64%) and to a large extent (16%), even if 20% of them express a negative opinion concerning the same point. As for online trade, opinions of both public and private stakeholders are similarly in accord in stating that the topic is not addressed by the Regulation or addressed to some extent. Finally, public authorities are particularly concerned when coming to the increase of budgetary constraints.

When asked about **the benefits of having a single European legislation on harmonising market surveillance** instead of several different national legislations, stakeholders report a number of positive achievements of the Regulation. Many respondents to the survey and to the public consultation state that the Regulation contributed to the establishment of a level playing field,[350] while others underline the improvement in the free movement of goods.[351] The simplification of rules[352] is also reported as a benefit, as well as an enhanced efficiency and effectiveness of market surveillance activities.[353] The Regulation is also responsible for

348 Please note that in the figure "PA" stands for "public authorities", "EO" for "economic operators", "CS" for "civil society representatives". Original survey question: *To what extent do you think the Regulation currently addresses specific issues deriving from: Increasing budgetary constraints; Shortening product life impacting the ability of authorities to track non-compliant product and ensure corrective action; increasing imports from third countries; Online trade/Delivery via small postal consignments or express couriers.*

349 *Increasing budgetary constraints*: n = 35; in addition, 47% (n=47) of respondents chose the "I do not know" option. *Shortening product life impacting the ability of authorities to track non-compliant product and ensure corrective action*: n = 46; in addition, 33% (n=18) of respondents chose the "I do not know" option. *Increasing imports from third countries*: n = 56; in addition, 15% (n=18) of respondents chose the "I do not know" option. *Online trade/Delivery via small postal consignments or express couriers*: n = 57; in addition, 15% (n=18) of respondents chose the "I do not know" option.

350 Five MSAs, a Danish and a Finnish coordinating authorities, a Belgian industry association, an Italian and a Swedish economic operators.

351 Four MSAs.

352 Six MSAs, three Custom authorities, three industry associations (3 BE).

353 Five MSAs, a Slovakian Custom authority, two industry associations (BE, DK), an Italian economic operator.

stimulating transparency and unambiguous interpretation of rules,[354] together with cooperation between countries and relevant authorities.[355]

8.1.3.4 Coherence

As for the external coherence, all stakeholders' categories agree on the fact that no serious issues exist. However, few stakeholders report some misalignments between the General Product Safety Directive (GPSD) and the Regulation. More in detail, the boundary between the two are not always clear especially to some MSAs, as they sometimes seem to overlap.[356] Furthermore, few MSAs[357] report that the definitions of the GPSD are not always aligned with those of the Regulation as for instance in the case of "distributor", "withdrawal", "recall".

No other coherence issues have been underlined by any stakeholders' category with regard to sector specific legislation as their interface with the Regulation is clear in the light of the *lex specialis* principle.

8.2 Case study 1: The Italian organisational model of market surveillance: competence sharing among MSAs and among MSAs and Customs

The objective of this case study is to identify critical elements to assess the effectiveness/ efficiency of market surveillance in different types of organisational models. In this respect, Italy can be characterised by a structure that is **decentralised at the sectoral level**, where **competences are shared by various central authorities**. Belgium, Cyprus, Croatia, Denmark, Estonia, France, Greece, Ireland, Latvia, Lithuania, Poland, the Netherlands, Romania, Slovenia and Sweden have similar organisational structures.

The case study assesses, among other issues, the **effectiveness and efficiency of market surveillance**, and the **obstacles** encountered in its enforcement under this type of organisational model.

8.2.1 General organisation

The Italian model of market surveillance is **decentralised at the sectoral level**. The **Ministry of Economic Development (MISE)** is the main national MSA and acts as a coordination body for the different enforcement authorities conducting market surveillance in the field, for relations and negotiations at the EU level, for the use of Rapid Exchange of Information System (RAPEX) and Information and Communication System for Market Surveillance (ICSMS), and for the establishment of *ad hoc* budgets and objectives. The MISE has general responsibilities over all sectors covered by Regulation 765/2008.

8.2.2 Sectoral level

Different ministries are in charge of market surveillance in various sectors within the scope of the Regulation. For instance, the **Ministry of the Interior** is responsible for market surveillance of explosives, while chemicals fall under the responsibility of the **Ministry of Health**. The **Ministry of Infrastructure and Transportation** controls the largest number of

354 14 MSAs, a Custom authority, three coordinating authorities.
355 Seven MSAs, a Custom authority.
356 Three coordinating authorities, eight MSAs, two EU industry associations, a Customs authority.
357 Two MSAs.

product categories. Each ministry organises its own market surveillance enforcement system. For this purpose, ministries can create dedicated units within their organisational structure or rely on external bodies. For example, the Ministry of Health has established the **REACH-CLP Unit**.[358]

Other relevant enforcement bodies are:

- **The Institute for Environmental Protection and Research – ISPRA**, under the Ministry of the Environment. It performs research activities and advises the ministry on environmental issues. It is in charge of enforcing Regulation 765/2008 regarding noise emissions for outdoor equipment.[359] ISPRA autonomously plans its market surveillance activities and carries out controls both on formal and substantial compliance: it checks documents, performs controls on machines during trade fairs and inspects production plants.[360]

- **The Italian Economic and Financial Police – Guardia di Finanza (GdF)**, under the Ministry of Economy and Finance. Its core mission is fighting tax evasion, but it also engages in activities related to IPR (intellectual property rights). Market surveillance activities are undertaken by the Special Unit for the Protection of Markets – Trademarks, Patents and Intellectual Property Group. Its activities are not planned in advance, but mainly based on a reactive approach, depending on the available resources, current needs and suspicions. It exercises its powers on toys, personal protective equipment, low-voltage electronics and electromagnetic compatibility. The Guardia di Finanza operates autonomously within the territory or in collaboration with the Customs Authority. It can also file RAPEX notifications.

- **The Chamber of Commerce, coordinated by Unioncamere**. They manage the action of the individual, regional Chambers and report to the Ministry of Economic Development. Their activities are based on annual bilateral agreements, establishing the number and the sectors of the planned inspections. Inspected sectors vary from year to year and can include toys, textile and footwear labelling, as well as electrical equipment. The Chamber of Commerce can check for the presence of the CE marking and accompanying technical documents and sample tests required by sectoral rules in order to verify that the product conforms to European standards and safety requirements.

- **The Local Health Units (Azienda Sanitaria Locale, ASL)**, under the Ministry of Health. They carry out health and safety inspections in the workplace. Although their core mission is not primarily related to market surveillance, they can sometimes find evidence of non-compliance in plants, machinery, medical devices or personal protective equipment during their inspections.

- **The special unit of the Italian Police Carabinieri, NAS**. It is a law enforcement body under the Ministry of Health, focused on health and safety controls covering several

358 "REACH" stands for 'Registration, Evaluation, Authorisation and Restriction of Chemicals', while "CLP" stands for 'Classification, Labelling and Packaging'.

359 Directive 2000/14/EC on the approximation of the laws of the Member State relating to noise emissions in the environment by equipment for use outdoors.

360 ISPRA organises annual meetings with sectoral representatives and Notified Bodies, in order to mutually exchange information, increase the effectiveness of controls and encourage stakeholders to comply. It also provides a checklist to the Customs Authority to facilitate product controls on its product category at the border.

product categories. In particular, this unit of the Carabinieri monitors activities under the General Product Safety Directives (GPSD), toys, medical devices, plant protection products, as well as health products – all within the scope of the Regulation 765/2008.

There are no financial resources dedicated to market surveillance enforcement, as this is only one among the many tasks expected of the ministries and enforcement bodies.

8.2.3 Customs

The **National Customs Authority** is responsible for product checks at the border and it is mainly active near airports and harbours through its local offices.

Italian Customs check around 4 million import and 8 million export declarations per year. These checks uncover around 250 product non-compliance cases within the scope of Regulation 765/2008, which are then forwarded to MISE. All of this information is entered into the Customs' information system and the Authority establishes the level of control for each incoming product. In order to speed up the process and facilitate the legal circulation of goods, it is also possible to implement controls after products are placed on the market. This 'post-clearance audit' is implemented by all European Customs. In Italy, this process is called the 'blue channel' and allows Customs to perform more accurate controls based on a risk analysis.

The National Customs Agency's activity is based on three pillars:

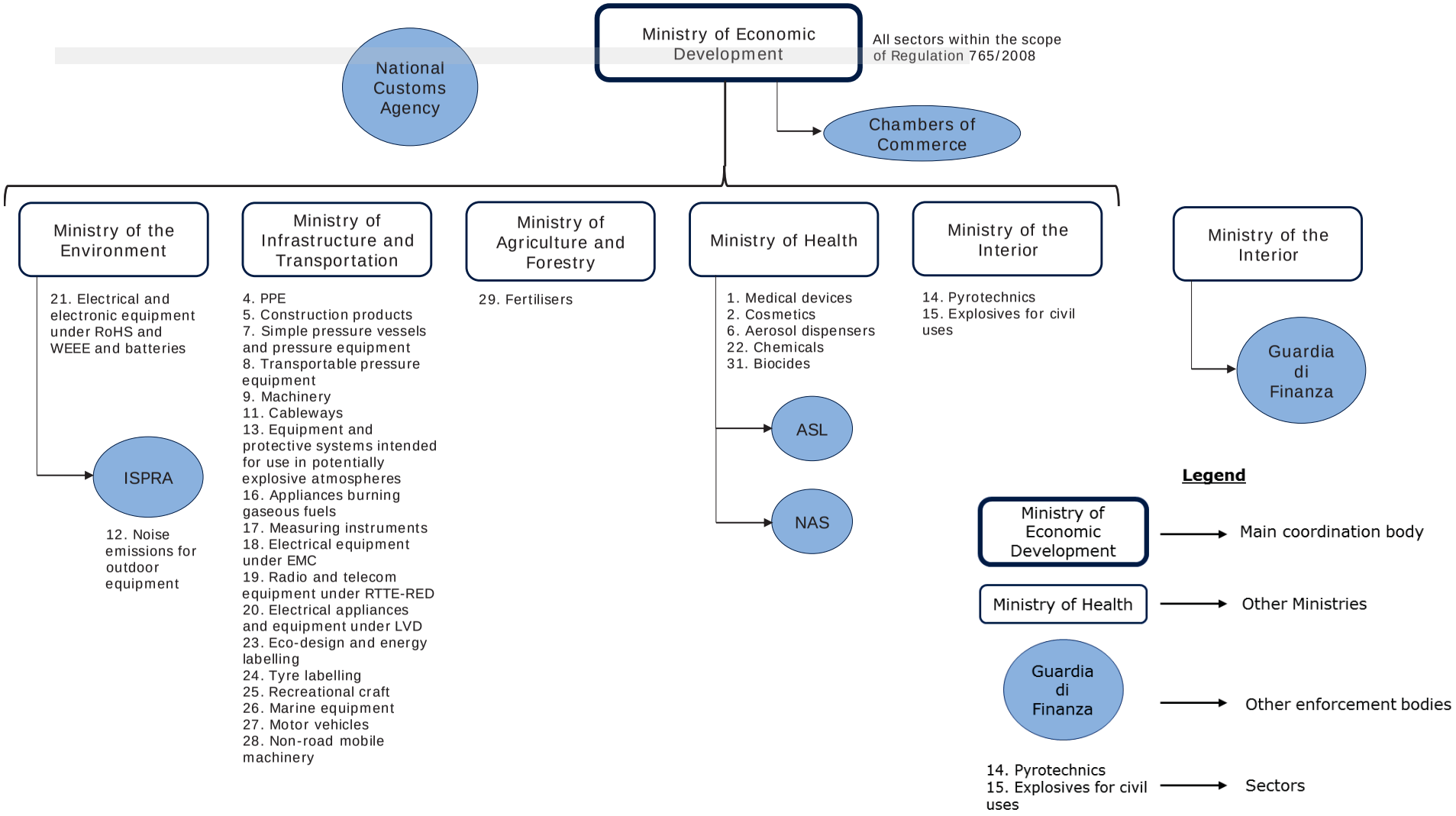
- **Providing information**, through the publication of a Manual on General Product Safety addressing all stakeholder categories. The manual, which dates back to 2005 (revised in 2009), is available[361] on the National Customs Agency website and it can be considered as a best practice in terms of stakeholder information. It addresses not only insiders, but all possible stakeholder categories, ranging from economic operators to citizens, from importers to public officials. It contains operational information, useful links for everyday activities, a glossary and information concerning legislation, technical standards, CE markings, activating procedures, workflow controls and contact points.

- **Conducting training**, which includes the organisation of several workshops open to sectoral associations to enhance cooperation with them. For instance, a collaboration has recently been implemented between the National Customs Authority and Personal Protective Equipment associations to define check lists, training courses and joint projects within the personal protective equipment sector.

- **Engaging in specific actions**, through the implementation of specific projects.

361 Available only in Italian language.

Figure 4-47 - The Italian organisational model of market surveillance[362]



362 **All sectors** within the scope of Regulation 765/2008 are under the responsibility of the MISE. However, surveillance on some specific sectors is implemented by other ministries.

8.2.4 Setting priorities

The **MSA's** resources are normally not linked to specific objectives or targets, except for special financial allocations assigned by the MISE to specific projects. In general, however, each ministry or authority can set its own priorities and is free to allocate resources and focus on self-established issues, although the MISE organises meetings to provide strategic orientations, European guidelines and general updates every six months.

As for **Customs**, specific sectors may be subject to more intensive controls, based on priorities defined by the competent MSAs and/or on risk profiles. Similarly to the situation for MSAs, financial support from the MISE means more laboratory tests can be carried out on imports, such as those leading to the worldwide withdrawal of Mattel's toys from the market in 2007 due the presence of heavy metals in the paints.[363] From that moment on, the MISE continued to finance extra laboratory checks within targeted projects. Risk profiles depend on parameters such as the country of origin, the reliability of the importer or feedback from previous checks.

8.2.5 Internal coordination

The MISE's approach is both proactive and reactive. Proactive surveillance is based on an annual programme establishing priorities and objectives, while reactive surveillance is based on field inspections and notifications from RAPEX and other enforcement bodies.

An example of the autonomy enjoyed by other ministries is the surveillance of chemicals by the Ministry of Health, which has set up a dedicated **REACH-CLP Unit**. Despite its name, the unit aims at covering all product categories relating to chemical substances, such as biocides, plant protection products and electrical equipment – currently under the responsibility of different ministries.[364] The objective is to unify controls within a highly specialised organisational unit working as a single contact point for all chemical products to simplify procedures and controls. Currently, in order to coordinate their activities in the chemical sector, representatives of different ministries, research institutes and regional administrations meet within a technical coordination committee.[365] The committee is organised in working groups dedicated to specific transversal issues, such as training, nanotechnologies or support for enterprises.[366] Furthermore, it is worth pointing out the existence of the Italian **Medical Device Registration database**, implemented by the Ministry of Health in 2007, considered as a best practice in terms of information sharing. All medical devices have to be registered by companies within this database in order to be placed on the Italian market for the first time. It covers more than 500,000 products and allows information sharing between economic operators and public healthcare agencies. The database is available to the public on the Ministry of Health website and contains information both on economic

363 See related article: http://europa.eu/rapid/press-release_IP-07-1234_en.htm?locale=en. Following this case, a number of projects focused on market surveillance in the toy sector have been implemented, such as 'Safe Christmas', "S.T.O.P." (Safe Toys Only Please), 'For a safer market project' and 'Safe Toy'.

364 Biocides and plant protection are managed by the Ministry of Health, electrical products (such as those covered by the ROhS Directive) are under the responsibility of the Ministry of Environment, while fertilisers are assigned to the Ministry of Agriculture.

365 Further relevant information: http://www.reach.gov.it/chi-siamo

366 There is a local REACH-CLP Unit in each Italian Region, mirroring the activity of the central Unit. Every unit appoints its own inspectors, generally two for each Province, with a total of about 400 inspectors in the whole country. They work in a wide range of areas, receiving training from the central unit and having full access to the ECHA (European Chemical Agency) database. There is also a specialised group of 40 inspectors, who receive an intensive and specific training programme in order to be ready to act in case of particularly critical situations (such as urgent notifications from ECHA or in case of toxicological analysis).

operators (i.e. name, fiscal code, and VAT number) and on products (e.g. identification code, type of device, CND classification, and commercial name).

Coordination between the MISE and enforcement authorities, such as the GdF, ASL and Chambers of Commerce, occurs on a case-by-case basis. These authorities are not directly linked to the enforcement of Regulation 765/2008 as they have different core missions. However, while performing their daily activities, such as sanitary inspections for ASL and fiscal checks for the GdF, they can encounter issues related to product non-compliance. Therefore, they perform inspections but cannot take any decisions concerning enforcement measures or penalties for non-compliance. In cases where they identify a suspected non-compliance, they notify the MISE, which will then decide how to react together with the competent ministry.

Coordination between the National Customs Authority and the MISE is based on formal agreements that are published on the Customs Authority's website, as well as on decisions made during meetings, where issues emerging from daily surveillance activities are discussed. The main communication channel between local Customs offices and the MISE is e-mail. When Customs detect a non-compliant product, they refer it to the MISE, which acts as a filter, forwarding the issue to the competent ministry for a decision on whether it is allowed to enter the market or not. At present, databases on product non-compliance are not connected, but the authorities working on particular cases can be granted mutual access to each other's databases. Since the Ministry does not have local offices operating close to Customs facilities, the speed of communication is critical to keep within the three-day limit applied to these decisions.

Another interesting example of collaboration involves Customs and the above-mentioned REACH-CLP Unit within the Ministry of Health. At present, they are involved in implementing the Ticass project, which is focused on gathering information about chemical goods before they enter the country. Product characteristics are registered by the importer in a specific format provided by the Ministry of Health, so that MSAs are rapidly informed about possible critical factors and product traceability is improved. Moreover, the REACH-CLP Unit is planning to extend controls on chemicals at land borders (at the moment chemical checks take place only at airports and harbours), thus increasing law enforcement. In this context, law enforcement bodies at the border, such as the GdF or the Italian Police, will also be required to notify the REACH-CLP Unit about any trucks carrying chemical substances and their destination.

Further, in July 2016, the MISE set up an inter-services conference ('**Conferenza dei Servizi'**), whose objectives are to clarify procedures and legislation underlying controls, to map responsibilities associated with all product categories among different ministries, to define contact points for every possible issue, and to update the Manual on General Product Safety.[367]

367 See earlier in this case. This manual, whose first edition dates back to 2005, is available to the public on the National Customs Agency's website and it could be considered as a best practice in terms of stakeholder information. Indeed, its main feature is the strong informative power as it addresses all possible stakeholder categories, from economic operators to citizens, from importers to public officials. It contains operational information, useful links for everyday activities, a glossary and information concerning legislation, technical standards, CE marking, activation of procedures, workflow of controls and contact points.

8.2.6 Analysis of the effectiveness, efficiency and obstacles

The Italian system is organised in a pyramidal way, with the MISE as the main body responsible for national market surveillance and in charge of coordination. Overall, however, it seems that there are **no formal channels or established standard procedures** through which the different ministries can coordinate their activities. As a consequence, although the MISE may have the formal powers over MSAs' activities, in practice it has no power of control over their budgets and therefore on priority setting. Indeed, it seems that market surveillance, in the context of Regulation 765/2008, is just one of the many tasks that each enforcement body has to deal with on a daily basis. Sectoral decentralisation has led to different product sectors being under the responsibility of the most appropriate ministry or institution, thus providing a **higher level of specific knowledge**. However, this **adds complexity to the management and uniformity of market surveillance** at the national level. In particular, the fact that every ministry internally organises its own market surveillance structure for each product category leads to variation in the ways the different sectors are controlled and managed. Moreover, fragmentation throughout the territory may hinder authorities' response times.

In this context, an overlap of competences may also happen. A critical operational issue is the **integration of Regulation 765/2008 with other sectoral legislation**, given that the primary responsibility for the enforcement of the Regulation is under the MISE, while the enforcement of some sectoral laws is under the responsibility of the relevant ministries. Moreover, some sectors can be controlled by multiple authorities, as in the case of GPSD. Therefore, there may be cases where **products need multiple evaluations and validations** in order to be allowed to enter the market. Overlapping may also occur due the fact that **the core missions of many enforcement bodies** (for instance, GdF, ASL and Chambers of Commerce) **are not primarily related to market surveillance of non-food products within the definition of Regulation 765/2008**. **Further delays may occur as there seems to be no clear division of sectoral responsibilities.** For example, the toy sector is indicated as controlled by the Guardia di Finanza, by Chambers of Commerce, by Customs, and by the Carabinieri NAS. The MISE acts as a 'filter' redirecting queries or cases regarding specific product issues to the relevant ministry because the system, as it is designed, does not factor in direct contact between the different actors involved. This makes it more challenging to create synergies among overlapping sectors.

A joint platform or information system would allow real-time data entry, considerably reduce the duplication of work and speed up responses by the coordination authority to issues encountered by the enforcement bodies in the field. Another related issue is the fact that the MISE has no presence in local Customs' offices, which slows down communication, and makes it harder to respect the established three-day limit for the release of goods. It should be pointed out that central government offices located near or within Customs facilities are rare even within other countries' market surveillance systems.

A further challenge concerns the **disproportionate distribution of the surveillance burden** across EU Member States, which would require more balanced resource allocation at the European level. Italy together with Cyprus, Malta, Greece and Spain handle all border controls along the Mediterranean coast, a considerable cost borne by a handful of countries.

The example shown by projects, such as those previously indicated regarding toys and collaboration with sectoral associations, show that improvements of the current system are possible. This is due to two main reasons: first, they provide the opportunity to improve the

implementation of controls, thanks to better information exchange and availability; second, they provide valuable on-the-job training and boost in-house expertise among Customs officers who are not necessarily specialists in specific product areas.

Despite the above-mentioned drawbacks of sectoral decentralisation, **all interviewees in this case study** deem that **market surveillance enforcement works very well in the country**, also when compared to that of other EU Member States, and **despite a serious lack of resources**. Lack of financial resources is a barrier to in-depth controls over all product categories within the scope of the Regulation. As a consequence, in certain sectors (e.g. construction products) only document and formal compliance checks are performed. As for available human resources, one interviewee underlines the fact that the use of fixed-term contracts within MSAs causes instability from an organisational point of view, and makes it difficult to build on overall expertise gained during employment contracts.

8.2.7 Sources

Interview with the Ministry of Economic Development (MISE)

Interview with ISPRA

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https://www.agenziadoganemonopoli.gov.it//portale

Carabinieri website: http://www.carabinieri.it/

ECHA website: https://echa.europa.eu/

Guardia di Finanza website: http://www.GdF.gov.it/

ISPRA website: http://www.isprambiente.gov.it/en

Ministry of Health website: http://www.salute.gov.it/

MISE website: http://www.sviluppoeconomico.gov.it/index.php/it/

REACH technical committee website: http://www.reach.gov.it/

Unioncamere website: http://www.unioncamere.gov.it/

8.3 Case study 2: The German organisational model of market surveillance: competence sharing among MSAs and among MSAs and Customs

Germany is characterised by a structure **decentralised at the regional/local level**, where competences are shared among various Land authorities. Austria, Finland, Hungary, Spain and the UK have similar organisational structures.

The case study will assess, among other issues, the **effectiveness and efficiency of market surveillance**, and the **obstacles** encountered in its enforcement under this type of organisational model.

8.3.1 General organisation

Germany is a Federal Republic made up of 16 Länder. **The Länder and related ministries are separate from the Federal Government**, both from a policy and financial point of view, each having their own budgets. The Federal Government and Federal Ministries are responsible for the overall legislation (laws and regulations), while the 16 Länder are in charge of the enforcement of this legislation.

Each Land has a high degree of autonomy over several policy areas, including market surveillance, whose related responsibilities are therefore highly decentralised. Every Land manages its own market surveillance system with dedicated MSAs within their ministries, taking into account specific Land-level features such as market structure and relevant industry sectors.

Resources for market surveillance are therefore provided by the Länder themselves. This configuration implies that the budget for the single product category may vary across the Länder and the Federal Government has no influence over this allocation.

Before the entry into force of Regulation 765/2008, German MSAs were not performing market surveillance in some sectors (e.g. construction products), or they were performing it under a different set of rules. As a consequence, MSAs are still building up their market surveillance approach to these sectors, re-organising themselves and learning from experience in well-performing sectors. In contrast, the sectors that were previously regulated by the 'New Approach' already have a very well-functioning market surveillance structure, with dedicated

Land-based authorities and the Working Committee on Market Surveillance AAMÜ[368] acting as the coordination body.

8.3.2 Federal level

At the central level, three Federal MSAs enforce market surveillance in specific product sectors:

- **The Federal Network Agency – BNetzA**, under the Federal Ministry of Economy and Energy, is responsible for market surveillance in two sectors: electrical equipment under the Electro-Magnetic Compatibility Directive[369] and radio and telecommunications equipment under the Radio and Telecommunication Terminal Equipment Directive;[370]

- **The Federal Authority for Maritime Equipment and Hydrography – BSH**, under the Federal Ministry of Transport and Digital Infrastructure, is responsible for the marine equipment sector;

- **The Federal Motor Transport Authority – KBA**, under the Federal Ministry of Transport and Digital Infrastructure, is responsible for motor vehicles.

Three additional Federal agencies are also involved in the context of market surveillance, though they are not responsible for enforcement in individual product sectors, the **Federal Institute for Occupational Safety and Health – BAuA**,[371] the **Federal Institute for Materials Research and Testing – BAM**,[372] and **the Federal Agency for Environment – UBA**.[373]

8.3.3 Land-level

The 16 Länder coordinate their enforcement action through several committees, where representatives from the Land ministries and MSAs regularly meet. Committees are focused on selected sectors. The biggest committee is the **Working Committee on Market Surveillance – AAMÜ**, which covers the largest number of sectors within the scope of

368 Arbeitsausschuss Marktüberwachung.

369 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).

370 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.

371 BAuA is a governmental institution with R&D functions that advises the Federal Ministry of Labour and Social Affairs in all matters of safety and health, especially in work-related fields. In consultation with the Federal Ministry of Labour and Social Affairs, the BAuA participates in national, European and international committees for the formulation of regulations and standards. The Federal Institute collaborates with the institutes which operate within its field of work.

372 BAM is a scientific and technical Federal institute under the Federal Ministry for Economic Affairs and Energy. It tests, researches and advises to protect people, the environment and material goods. According to its founding decree, BAM is responsible for the development of safety in technology and chemistry; for the implementation and evaluation of physical and chemical tests of materials and facilities, including the preparation of reference processes and reference materials; for the promotion of knowledge and technology transfer within its areas of work; for advising the Federal Government, industry, and national and international organisations in the fields of material technology and chemistry.

373 UBA is the central environmental authority. It plays an important role in the enforcement of national and European environmental law, for example in the field of industrial chemicals, plant protection products, medicinal products, and washing and cleansing agents. If a risk to human health or the environment exists, it recommends conditions of use, use restrictions or bans. UBA's specialists also work to improve scientific knowledge about chemicals and their risks, and formulates science-based recommendations for the improvement of environmental and climate protection instruments. It does not only assess environmental health risks to adults and children, but also develops action programmes designed to reconcile environmental and health protection requirements. Its experts also provide advice to municipalities and the Federal States on environmental health issues.

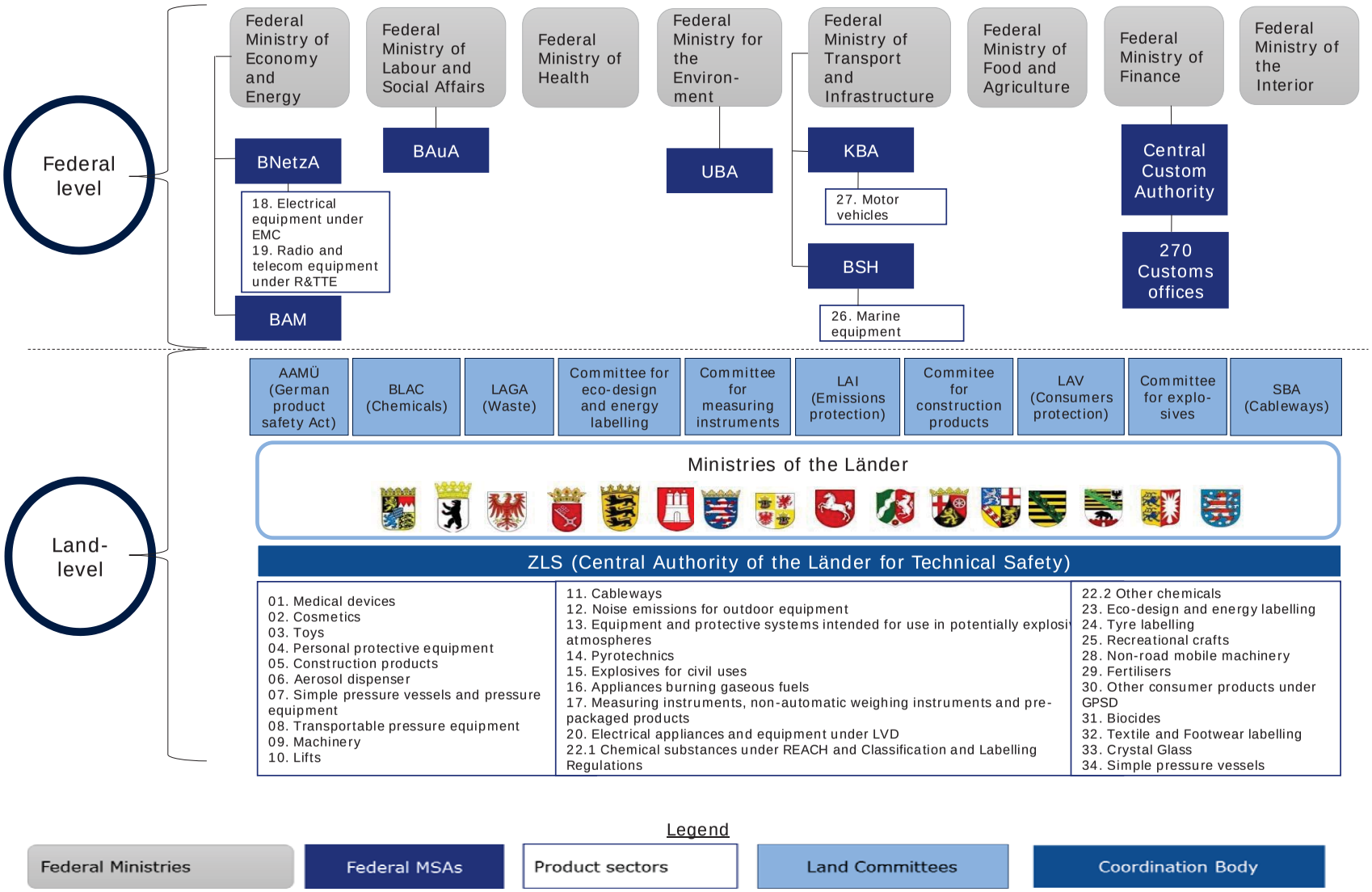
Regulation 765/2008.[374] Other existing committees and related product categories are shown in the figure below.

Another coordination body is the **Central Authority of the Länder for Technical Safety – ZLS.** The ZLS had been set up on behalf of the Länder in order to centralise some market surveillance tasks, such as the creation of product risk profiles and the forwarding of RAPEX notifications, instead of having them repeated for all of the 16 Länder. The ZLS has more operational tasks than the other coordination committees and can even enforce the law under special conditions and following the Länder's requests. For instance, when a market surveillance case involves several Länder or has international relevance, ZLS is allowed to perform market surveillance actions.

The figure below represents the German organisational model of market surveillance.

374 AAMÜ covers the following sectors: equipment and protective systems intended for use in potentially explosive atmospheres, simple pressure vessels, aerosol dispensers, transportable pressure equipment, machinery, lifts, noise emissions for outdoor equipment, electrical appliances and equipment under the Low Voltage Directive (LVD), appliances burning gaseous fuels, personal protective equipment (PPE), toys, recreational craft, other products under GPSD. Source: German Product Safety Act.

Figure 4-48 - The German organisational model of market surveillance



8.3.4 Customs

The **Central Customs Authority** (Generalzolldirektion) is responsible for many fields other than those related to the Regulation (e.g. drugs, weapons, human health, and environment). It also coordinates, manages and supervises the **270 local Customs offices**, which are in charge of border controls.

As for the implementation of Regulation 765/2008, the Central Customs Authority acts as prescribed by Article 27(2)[375] and Article 29(5)[376] on information exchange. It collects information from the ZLS and other coordination bodies or MSAs, in particular with regard to product risk profiles, and distributes this information to local Customs offices. Customs controls are indeed mainly based on risk indicators such as Combined Nomenclature code,[377] product description, consignee, consignor and country of origin/dispatch/export. The Central Customs Authority also provides MSAs and coordination bodies with information extracted from the electronic Customs clearance system (e.g. name and address of importers of certain products).[378]

Relations between Customs and the MSAs are bilateral. On the one hand, if MSAs find high percentages of non-compliant products in some sectors, they inform Customs through land-level coordination committees, asking them to focus on those products. On the other hand, Customs are responsible to inform the MSAs if they have an initial suspicion of a product being non-compliant, although decisions about the non-conformity of a product are ultimately taken by MSAs.

8.3.5 Setting priorities

Although Federal Ministries are responsible for policy-making, they do not set market surveillance priorities, except in those sectors where Federal MSAs are responsible for enforcement (i.e. Electrical equipment under EMC, radio and telecom equipment under R&TTE, motor vehicles and marine equipment). Priorities are set on the basis of information received from the market, by looking at accident data and consumers' complaints, information coming from competitors and press releases on issues related to product safety and, last but not least, information coming from Customs authorities and other Land ministries within coordination committees. Based on this, they identify relevant working fields for the upcoming years. Another important input for setting priorities comes from participation in

375 Article 27(2): 'Where in a Member State more than one authority is responsible for market surveillance or external border controls, those authorities shall cooperate with each other, by sharing information relevant to their functions and otherwise as appropriate.'

376 Article 29(5): 'Market surveillance authorities shall provide authorities in charge of external border controls with information on product categories in which a serious risk or non-compliance within the meaning of paragraphs 1 and 2 has been identified.' Article 29(1): 'Where the market surveillance authorities find that a product presents a serious risk, they shall take measures to prohibit that product from being placed on the market and shall require the authorities in charge of external border controls to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document or, where data processing is carried out electronically, in the data-processing system itself: 'Dangerous product - release for free circulation not authorised - Regulation (EC) No 765/2008'. Article 29(2): 'Where the market surveillance authorities find that a product does not comply with Community harmonisation legislation, they shall take appropriate action, which may, if necessary, include prohibiting the products being placed on the market'.

377 https://ec.europa.eu/taxation_customs/business/calculation-customs-duties/what-is-common-customs-tariff/combined-nomenclature_en

378 All declarations must be electronically filed using the German Customs Administration's ATLAS System (Automatic Rate and Local Customs Clearance System), which makes it easier to check the entered information before submission and to forward it to all the parties involved.

European Joint Actions, which are financed by the European Commission and focused on specific market surveillance topics.

8.3.6 Internal coordination

At the EU level, policy discussions are mainly held by the Federal Government. Nonetheless, collaboration between the Federal and Land level is based on extensive involvement of the Länders' representatives in negotiations at the EU level, so that both the legislative dimension and the enforcement aspects are represented in Brussels within discussion fora that are relevant for market surveillance issues, such as the Consumer Safety Network.[379]

As previously stated, **the 16 Länder coordinate their actions through committees**, each covering specific sectors. Notably, although every Land performs market surveillance in all product sectors covered by Regulation 765/2008, **each of them develops stronger competences in specific product groups** in terms of: higher number of controls and deeper knowledge relating to the specific implementing acts, the relevant standards or test methods.[380] For instance, Baden Württemberg is specialised in electric motors and ventilators, while Hessen is specialised in lights. These decisions on Land 'specialisation' are taken within the committees.

Strong collaboration between Customs and Land MSAs is achieved thanks to the Central Customs Authority having 'permanent guest' status within the coordination committees, thus receiving the minutes of all sessions and participating in meetings in case Customs-related issues are discussed. In contrast, contacts between Customs and Federal MSAs (e.g. BNetzA) are more direct, their units communicating with each other without passing through committees. There are several **formal agreements** between the Central Customs Authority and both Federal and Land MSAs. Moreover, when new EU legislative acts enter into force, it may not be immediately clear to the Customs services which is the appropriate MSA to deal with the new rules. Once 'the right partner' is identified, Customs and the MSA establish and sign a formal agreement to help with market surveillance implementation.

The main platform for information sharing is **ICSMS**.[381] This tool has been developed and adopted at the European level, but it was designed in Germany and it is still used by German MSAs to exchange information and increase the efficiency of market surveillance. Before starting a case, MSAs check to see whether the product has already been filed in the system. This is fundamental in order to prevent duplication of work.

According to all the interviewed stakeholders, **coordination, cooperation and exchange of information work very well** within the German system, also because authorities have been using it since 1993, when Regulation (EEC) No 339/93 – later repealed by Regulation (EC)

379 The Consumer Safety Network is a consultative expert group chaired by the EC and composed of national experts from the administrations of the EU MS, Norway, Iceland and Liechtenstein. Its main areas of discussion are the safety of consumer products, such as lighters and of consumer services, including fire safety in hotels, and the relevant data collection. It meets on average three times a year, usually in cooperation with the General Product Safety Committee meetings. Source: http://ec.europa.eu/consumers/consumers_safety/cooperation_with_stakeholders/index_en.htm

380 As reported by an interviewee from Baden Württemberg Ministry for Environment, Climate Protection and Energy Sector.

381 ICSMS is an information and communication system for the pan-European Market Surveillance. A general information support system set up by the European Commission for the exchange of information between MSAs according to Article 23 of Regulation (EC) No 765/2008. https://webgate.ec.europa.eu/icsms/

No 765/2008 – was applicable. The Regulation became applicable in 2010 and had a wider scope, but cooperation mechanisms were already in place and operating effectively.

A further interesting feature of the German system is represented by the attempt to build an **informal market surveillance network**. Workshops for inspectors are frequently organised, as are events to spread the latest news from Brussels and other relevant information. This helps to keep all inspectors up to date and aligned on how to interpret legislation. It also means inspectors from different institutional levels and sectors have the chance to personally meet and strengthen relations. The people involved tend to know each other and this is very good in developing increased and stronger cooperation among market surveillance actors.

8.3.7 Analysis of effectiveness, efficiency and obstacles[382]

A decentralised market surveillance system requires **highly developed and intense cooperation**, though Germany is used to dealing with decentralisation in several policy areas. Particularly:

- **Substantial resources are likely to be required** to replicate a market surveillance system in 16 Länder. The current allocation of duties at the national level means Länder are responsible for implementing market surveillance as part of their daily tasks using their annual budget.

- **Substantial resources are likely to be required** to ensure the necessary coordination mechanisms (e.g. the establishment of permanent, *ad hoc* coordination bodies such as the ZLS, the organisation of workshops, meetings and events to create an 'informal' network of market surveillance actors). However interviewees stress that **Germany has developed a 'learning economy'** in setting up coordination mechanisms, as decentralisation is based on a well-established 'constitutional principle'.

The German organisational structure establishes a clear division between the 'regulatory' and the enforcement level, mirrored by a respective repartition of resources. An inherent risk of such an approach may be that **high-level policy objectives are not aligned or appropriately shared and implemented in the field**. This misalignment is perhaps compensated by the presence of relevant stakeholders and different authorities in EU-level discussions and committees.

The outcome is a **more tailored response** because market surveillance and enforcement priorities could differ slightly from one Land to another, depending on the regional product portfolio, on the presence of production clusters and on the general market composition (for instance, some Länder may have a strong agricultural tradition, while others are more industrialised). Moreover, although the geographical area where MSAs operate is restricted (i.e. within the Land), they are responsible for a vast array of sectors, thus enhancing their **competences thanks to the role played by the committees**. In any case, all interviewed stakeholders agree that despite this high level of decentralisation, coordination mechanisms in Germany work well, and the level of market surveillance ensures a level playing field for national businesses.

382 Due to lack of data allowing for a proper triangulation, considerations in this section are mainly based on stakeholders' opinions.

Although very complex, **the German organisational structure establishes a responsible authority for each product sector**, which interviewees regard as a strength of the system, because *'tasks are well defined and competences clearly split'*. As proof, **no overlapping occurs** between the Federal and the Land level in terms of market surveillance responsibilities in all sectors covered by the Regulation. Nonetheless, particularly in the case of Customs, **this complexity may make it difficult** for actors internal to the system **to identify the 'right partner'** to deal with market surveillance issues.

Efficiency is further bolstered by a number of coordination tools. The first pillar is represented by the **ZLS**, which is responsible for market surveillance issues with 'cross-Länder' features, such as the development of product risk profiles. In addition, in cases where two Länder make different decisions on similar market surveillance cases, the ZLS is involved in finding a common solution and interpretation. As stated by stakeholders, ZLS ensures a harmonised approach among the 16 Länder. Another pillar of the German coordination strategy is represented by the extensive use of **ICSMS**, which national authorities are very familiar with, as it was first developed in Germany. As already mentioned, ICSMS is crucial to avoiding duplication of work, a possible deficiency of decentralised structures.

Nonetheless, such a thoroughly decentralised system could benefit from some adjustments, particularly in terms of rationalisation of the many different coordination mechanisms in place. Germany is indeed planning to create **a single, general coordination board covering all product categories and ensuring further alignment between the Federal, the Land and the European level**. In order to facilitate this process, ministries have already started to meet on a voluntary basis within this 'Forum for Market Surveillance'. At the moment it still remains a pilot committee, taking place twice a year and organised by the Federal Ministry for Economic Affairs and Energy, though it should be institutionalised by the end of 2017. Moreover, according to one interviewee,[383] '*a centralised system would not be less resource-needing or less time-consuming, as it would in any case need a network of local authorities and an information flow between the two institutional levels'*. Therefore the structures, time and personnel would almost remain the same, and only the responsibilities would be allocated differently.

8.3.8 Sources

Interview with the Federal Ministry for Economic Affairs and Energy

Interview with the Central Customs Authority

Interview with the ZLS

Interview with the Bavarian Ministry for Environment and Consumers Protection

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383 ZLS and the Bavarian Ministry for Economic Affairs and Energy.

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BAUA website: http://www.baua.de/en/Homepage.html

BAM website: https://www.bam.de/Navigation/DE/Home/home.html

German Customs website: https://www.zoll.de/EN/Home/home_node.html

UBA website: https://www.umweltbundesamt.de/en/the-uba/about-us

The German Business Portal: https://www.ixpos.de/IXPOS/Navigation/EN/Your-business-in-germany/Market-entry/Tax-and-duty/duties,t=atlas-system-for-electronic-customs-clearance,did=270836.html

CONCLUSIONS of case studies 1 and 2:

In light of case studies 1 and 2, some general conclusions can be drawn:

- **Crucial elements for the effectiveness of both organisational models:** the importance of clear task assignments among authorities and to each MSA (not just performed among the many other daily tasks), the appointment of a coordination board, the need for each MSA to have direct contact with Customs, the identification, visibility (to the public) and access to relevant competent authorities.

- **Crucial elements for the sector-decentralised model**: the importance of formal channels and coordination procedures to ensure a coherent policy approach in different sectors.

- **Crucial elements for local-decentralised model**: the importance of formal channels and coordination procedures to ensure not only a coherent policy approach in different regions, but also coordination of investigations via a common database and tool for common decision-making.

8.4 Case study 3: Difficulties in performing market surveillance of products sold online

The objective of this case study is to identify obstacles (including legislative ones) encountered by market surveillance and, if possible, Customs authorities in controlling products sold online.

The case study makes up a **theoretical case** of a non-compliant cosmetic product made available on an online platform based in a third country. Authorities in Finland, Spain, and the Netherlands were then asked whether they would address the problem and how, for instance, they would carry out the inspection, obtain corrective action, and from which businesses.

In a second section, the case study reviews a **specific case** handled by the Finnish authorities, noting the difficulties encountered, such as the lack/inappropriateness of legal definitions, and the powers/tools needed for the inspection and to obtain corrective action.

8.4.1 Introduction

Why online sales matter in the framework of Regulation 765/2008

E-commerce[384] has grown in popularity thanks to several developments, including improvements in technology and consumer confidence, a wider range of products and services, competitive prices and a better-integrated internal market. The issue of online sales has therefore become relevant for market surveillance enforcement. Furthermore, it deserves particular consideration in light of the results of targeted surveys – 78% of participants reported that there are non-compliance issues related to online trade.

The state of the art of market surveillance enforcement of products sold online

Market surveillance of products sold online is currently fragmented and lacking coordination, resulting in a lower level of protection and legal support to consumers than that afforded to products marketed through classic distribution channels.[385]

Including online sellers and products in market surveillance is an opportunity to gain comprehensive, EU-wide insight into compliance levels of products sold via this ever-growin

384 Source: PANTEIA (2014), Good practice in market surveillance activities related to non-food consumer products sold online.
385 COM (2013) 76.

g channel. A substantial sample of online products can for instance be tested as part of all Joint Actions (JA).[386]

Several issues are linked to e-commerce,[387] and introduce new challenges for MSAs, especially in relation to cross-border online sales where different jurisdictional boundaries exist, and in markets where speed and effective action is a must but resources are limited.

8.4.2 Addressing online sales in Finland, Spain and the Netherlands

The Finnish process

The Finnish Safety and Chemicals Agency (Tukes) is in charge of market surveillance for approximately 30 product Directives, including cosmetics.[388]

Powers. Tukes does not have any special powers related to online sales. For instance, Finnish legislation does not explicitly call for MSAs to engage in 'mystery shopping', although this practice is not forbidden and, in practice, MSAs do carry out random sampling of online products and sellers like this. Similarly, MSAs are not allowed to shut down websites selling non-compliant products, although Tukes reports that it would be an effective tool together with the possibility of imposing monetary fines or criminal sanctions.[389] Possible actions against non-compliant products are recall, withdrawal, sales ban or notification letters, depending on the level of risk.

Customs. Cooperation between Tukes and Tulli (the Finnish Customs Authority) is performed following a mutually agreed, formal process, but with no specific procedures or powers for e-commerce products. Given that the bulk of products sold online are small consignments to individual e-consumers, controlling single products is not realistic nor effective. In any event, checks already take place on incoming packages (whether sold online or not) as part of regular postal and air cargo services.

Decisions on the intensity of controls depend on:

- The package size: small packages are usually considered to be less valuable, therefore controls are focused on larger ones, which also have to be declared;
- The sender's identity, e.g. known or unknown, country of origin;
- The addressee's identity: private persons or companies.

386 Joint Actions are financed by the Commission and focused on specific market surveillance topics and usually involve different Member States and authorities relevant for market surveillance. Further information available at: http://www.prosafe.org/

387 As reported in the existing literature, Member States' national programmes, the public consultation and targeted surveys.

388 Electrical products, lifts, explosives, pressure equipment, chemicals, biocides, plant protection products, cosmetics, measuring instruments, precious metals, rescue service equipment, toys, child care, machinery, PPE, construction products, packages, eco-design and energy labelling.

389 It is theoretically possible that the economic operator is brought to court, in case of serious danger. The court has the power to issue fines or even decide for a prison sentence of maximum of 6 months, but it has never happened.

Communication. Tukes enters information on non-compliant products sold via the internet on its market surveillance register, called Marek, and makes it available to the public through its official website, where market surveillance projects, reports and pictures of non-compliant products are published. It also regularly uses social media networks, such as Facebook and Twitter, to inform the public about recently banned products. Tukes and Tulli cooperate on awareness campaigns concerning online sales. Results of specific projects are often published in newspapers, while RAPEX and ICSMS are used to inform other Member States. Notably, the Finnish campaign '*There is no sheriff in this town'*,[390] aimed to raise public awareness by clarifying the 'buyer beware' principle on the risks of buying products online.

Theoretical case. MSAs find that a cosmetic product made available on an online platform is formally non-compliant. Firstly, Tukes checks the information provided on the website and orders the product to identify the economic operator and verify product compliance.

In this context, three alternative scenarios are possible:

1. Both the web-page and the economic operator are based in Finland → Tukes sends a letter informing the economic operator that the product in question is non-compliant.

   a. The economic operator answers and voluntarily complies → OK

   b. The economic operator does not answer and/or does not comply → Tukes decides on measures to be taken (e.g. sales ban)

2. Both the web-page and the economic operator are based in another EU Member State → Tukes sends a letter informing the economic operator that the product in question is non-compliant.

   a. The economic operator answers and voluntarily complies → OK

   b. The economic operator does not answer and/or does not comply → Tukes notifies the competent MSA in the EU Member State where the business is located, requesting enforcement actions.

3. The web-page is based in another EU Member State and the economic operator is based in a third country or both the web-page and the economic operator are based in a third country → Tukes sends a letter informing the economic operator that the product in question is non-compliant and mentions the European Commission's (non-legally binding) explanatory note on internet sales targeting EU consumers.

   a. The economic operator voluntarily complies → OK

   b. The economic operator does not answer and/or does not comply → Depending on the case, the Finnish MSA contacts the foreign competent MSA and/or the responsible person in the EU/EEA area who can be targeted for enforcement.

390 http://www.tukes.fi/en/Current-and-News/News/Product-safety/Supervision-by-the-authorities-and-consumer-protection-do-not-cover-the-online-stores-of-far-off-countries/

c. If the product presents a high risk in terms of consumer safety and Tukes considers that it would not be fast enough to contact the economic operator outside its jurisdiction, it warns consumers through a press release.

The Spanish process

Market surveillance of consumer products in Spain is under the responsibility of the different Federal Regions, called 'Comunidades Autonomas' (Autonomous Communities). The central Government, particularly the Ministry of Health, is in charge of coordinating their activities in this field, aimed at ensuring uniform action is taken among the different Communities.

The Agencia española de Consumo, Seguridad alimentaria y Nutrición (ECOSAN, Spanish Agency for Consumption and Food Security), operates within the Spanish Ministry of Health. This agency has a special three-person monitoring team for e-commerce. It investigates online suppliers and informs local authorities when issues arise. The Autonomous Communities organise their own responses based on information received from the central Authority.

Powers. There are no powers specifically related to online sales in Spain.

Customs. Collaboration between MSAs and Customs Authorities is regular, but it is not particularly focused on online sales. Customs Authorities act as a filter, labelling products with colours (green, yellow and red) depending on the level of risk. MSAs organise their activities and focus controls based on these indications, regardless of the sales channel.

Communication. Representatives of Communities' Authorities meet once a month in order to coordinate their action and share the main issues they are facing. The Ministry and local authorities manage campaigns via their official websites, especially during particular periods of the year such as Christmas. However, communication is not extensive and it is not usually performed via the main media.

Theoretical case. MSAs find that a cosmetic product made available on an online platform is non-compliant.

The Spanish investigation would start with online research by the Ministry of Health, looking at websites selling cosmetic products. Once they are found, the Ministry performs a formal check, controlling whether all the necessary and mandatory information is provided, such as labelling, the name of the economic operator, ingredients and materials. The follow up actions after this initial formal check of compliance can be summarised as follows:

1. Both the web-page and the economic operator are based in Spain → The Ministry contacts the Autonomous Community where the economic operator is based, urging it to comply. The subsequent action depends on the seriousness of the non-compliance and it ranges from sending a letter asking for an inspection to an obligation to withdraw the product from the market.

2. Both the web-page and the economic operator are based in another EU Member State → The Ministry asks the competent MSA in the other EU Member State for support in contacting the economic operator. In reality, this often turns out to be rather ineffective, because the economic operator does not respond.

3. The web-page is based in another EU Member State and the economic operator is based in a third country or both the web-page and the economic operator are based in a third country → The Ministry writes a letter to the economic operator and MSA of the country informing them about the issue. The rate of effective response is very low.

After a reasonable period the Ministry checks the website again.

a. The economic operator changed behaviour and complies → OK

b. The problem still persists → the Ministry raises the level of action, depending on the specific situation, adopting stronger measures.

The Dutch process

The Netherlands Food and Consumer Product Safety Authority plans its market surveillance activities on the basis of studies on consumer' behaviour, and acts more on the consumer side than on the industry side, thus investing resources in controlling e-shops but especially in educating e-shoppers. Educating consumers is less costly in the long run, and companies will be encouraged to comply – a 'positive leverage' approach.[391]

More specifically, the number of existing web-shops is huge, making it impossible for a single authority to deal with the issue. Therefore, the Food and Consumer Product Safety Authority deliberately decided not to target online platforms, but rather the consumer side. The MSA investigated Dutch e-consumers' shopping behaviour through a dedicated study. This study showed that the large majority of e-shoppers buy from web-shops located in Holland, from well-known and trustworthy economic operators, which already have physical shops. In addition, Dutch e-shoppers generally buy the same brands and the same products that they would buy in normal shops. Given that Dutch MSAs also control shops that have online pages, products sold online bought by Dutch citizens are not considered to represent an added risk in terms of product safety.

Nonetheless, Dutch e-shoppers are increasingly buying products from Chinese web-shops. They mostly buy small items, such as USB devices, chargers, textiles, cheap cosmetics, and jewellery. Dutch authorities have no power against Chinese web-shops. Therefore, the Food and Consumer Product Safety Authority decided to take various samples from the largest Chinese web-shops (such as Deal Extreme, China Buys and Lightinthebox). This led to the discovery that almost 80% of the products were unsafe and non-compliant with EU legislation: for instance, the nickel content of the jewellery was far above the thresholds allowed, while chargers and USB devices entailed a fire risk. These results were not unexpected; despite the fact that these Chinese web-shops operate on a world-wide scale, they do not necessarily target European consumers and their products are therefore not designed specifically for the EU market.

391 The Dutch enforcement action is therefore mostly proactive and based on prevention. Only 25% of activities are complaint-based - and therefore reactive. Priorities are set by looking at a combination of sources such as citizens' complaints, RAPEX notifications, international studies, previous inspection results or the number of consumers potentially impacted. Several criteria are put into the decision model and then assessed through a final validation about the product risk profile and therefore establishing priorities for upcoming inspections.

Also in this case, the Dutch approach considers **consumers as the main drivers** of the process. Therefore, the Dutch MSAs consider themselves responsible for online sellers located in the Netherlands only, since those outside of the EU are impossible to tackle and would represent a waste of resources. As a result, Dutch MSAs try to inform consumers and warn them in the most effective way, so that they are aware of possible risks related to product non-compliance. Most of these products are unbranded, and in these cases the name of the web-shop is published, together with a photo of the product. However, inspecting and testing these products is very costly in terms of money and time, so Dutch authorities are considering whether to stop these product inspections, with the exception of products presenting a serious risk.

Powers. Dutch MSAs can contact web-shops, force them to warn the public by advertising product risks, engage in 'mystery shopping', and impose fines. MSAs can also shut down websites, although it takes several months and it is considered ineffective since sellers can quickly change name and domain. For the same reason, Dutch MSAs do not frequently take actions against economic operators located outside the EU, as it takes weeks to effectively reach the economic operator and in the meantime the web-shop would continue to offer the non-compliant product.

Customs. There are no special Customs procedures related to online sales. MSAs' cooperation with Customs is very close, the information flow works well and they meet every year to discuss specific problems, though not necessarily related to online sales. Recently, Customs informed the Netherlands Food and Consumer Product Safety Authority about a structural stream of small consignments coming from Chinese web sellers that were all sent to the same economic operator's address. This sort of information triggers plans for inspections.

Communication. The main information channel is the relevant authority's website. The Netherlands Food and Consumer Product Safety Authority has registered an increase in consumer interest, as more shoppers are visiting the Authority's website, asking questions about unsafe products. Unfortunately, the number of consumers visiting the page is still relatively low (around 10,000 per month). This low number could be due to continued lack of consumer awareness about product safety issues. Studies indeed show that consumers underestimate the risk of unsafe products, assuming that there are no dangerous products on the market or that the risk to them personally is very low.

Theoretical case. MSAs find that a cosmetic product made available on an online platform is non-compliant.

Based on the Dutch approach to market surveillance of online sales, the process development can be summarised as follows:

1. Both the web-page and the economic operator are based in the Netherlands → Dutch MSAs try to inform and warn consumers in the most effective way on the risks related to product non-compliance. Moreover, when Dutch MSAs have a physical shop of reference, they can contact the seller for inspection or testing and decide on specific measures.

2. Both the web-page and the economic operator are based in another EU Member State → Dutch MSAs try to inform and warn consumers in the most effective way on the risks

related to product non-compliance. In addition, Dutch MSAs rely on other European MSAs' work, deciding whether to contact them on a case-by-case basis.

3. The web-page is based in another EU Member State and the economic operator is based in a third country or both the web-page and the economic operator are based in a third country → Dutch MSAs try to inform and warn consumers in the most effective way on the risks related to product non-compliance.

8.4.3 A concrete case: LED-lamps in Finland

In the context of Joint Action 2014 (WP8 – LED lamps/compact fluorescent lamp),[392] Tukes acquired several LED lamps and compact fluorescent lamps (CFL) from online wholesalers, which were mostly Finnish-based companies selling lighting equipment online.

The case-specific lamp was acquired from a web-shop (e-ville.com)[393] which offers electrical products for Finnish consumers. E-ville is a platform where different economic operators can sell their products, the website owner is Finnish but located in Hong Kong. The page mentioned that distributors were based in China, Hong Kong and Mäntsälä (FI), while behind the seller's name there seemed to be at least two companies, a Finnish-based and a Hong Kong-based company. The web-page indeed displays from which distributor (or company) the product is coming from, and the same product can be acquired at different prices from different distributors. The case-specific lamp was sold by a Hong Kong-based economic operator.

The LED lamp was acquired and tested by Tukes and it turned out to have many defects that could endanger users' safety, leading to it being withdrawn from the market. The Finnish MSA informed the Hong Kong seller about this, asking for a response. In addition, a second letter was sent to the seller in order to clarify the situation and to clearly state that the lamp does not comply with EU safety requirements, and thus cannot be placed on the EU market. The economic operator answered, promising to stop selling the lamp.

Tukes did not contact the competent authority in Hong Kong, due to the difficulties that they may have involved. If the economic operator did not answer, Tukes would have drafted a press release, informing the public about the non-compliant product, with a warning not to buy it and recommendation to return those already purchased to the seller.

8.4.4 Main issues and challenges

To sum up, the main issues with online sales as emerging from the above case study are:

- Unsafe products withdrawn/banned from the EU market can return on the market through a different website or under a different legal name.
- MSAs do not have a legal mandate to enforce the Regulation outside their jurisdictional boundaries and cooperation among authorities from different countries is not always fast and effective.

392 EU-funded Joint Market Surveillance Action on Consumer Products coordinated by Prosafe.
393 https://www.e-ville.com/fi/

- A lot of time is wasted if the economic operator does not reply or cooperate with the foreign authority.

- Difficulties in verifying the compliance of products sold online, because most goods are delivered to consumers directly.

- Scarce resources to check every consumer consignment entering the country, due to the volume of products sold through e-commerce channels and complex distribution chains. Controls carried out are considerably less than those deemed necessary.

- Low level of consumer awareness concerning the risks of buying products online.

8.4.5 Possible solutions

Overall, the described approaches to market surveillance of online sales are similar in the three countries considered. While MSAs are face no particular obstacles if the economic operator and the web-page are located in the relevant country, the process is more complex if they are based in another EU Member State or in a third country.

In light of the limited resources devoted to market surveillance of an impossibly large number of online shops, **mutual learning and greater emphasis on cooperation** among Member States and MSAs is strongly recommended. The use of information-sharing tools, such as RAPEX and ICSMS, needs to be increased, in terms of both the number of notifications and the number of responses. A positive signal in this direction is that, in 2014, for the first time some RAPEX notifications were related to measures taken against products sold online.

In addition, although it is true that the number of online shops and the rapidity through which they can be set up make it impossible to fully control internet sales, it is also true that there are means at hand to tackle the negative effects of online sales of non-compliant products. For instance, carry out **'mystery shopping' tests** to verify product compliance, combined with **the power to shut down websites** in cases of serious infractions, would be a cost-effective approach once the initial investment (software and skills) has been made. Another possibility could be the **designation of a responsible person/entity** (e.g. authorised representative, importer[394]) in the EU that could be held liable for non-compliant products. This could also help address the difficulties MSAs experience obtaining responses from (online) economic operators located in third countries and the limited cooperation MSAs have with authorities in those third countries. Furthermore, **in case of unresponsive economic operators**, authorities could be empowered to stop non-compliant products from entering the internal market, and ultimately destroy them, which may be more cost-efficient than lengthy procedures to trace foreign traders and/or request foreign MSAs to take enforcement measures. The case study shows that online business models evolve quickly and are increasingly complex, with many different parties and intermediaries. The ideal toolbox of the 'digital future' should allow MSAs to identify and act quickly against traders and their intermediaries in complex online supply chains.

394 More controls online overall and designation of a responsible person/importer were rated highly (49% strongly agree) in the public consultation, see interim report page 74)

The case study nonetheless also indicates that coercive enforcement action alone by the MSAs will only be a partial response. Measures are also needed to increase awareness and visibility of product warnings to end-users, including **naming and shaming**.

In this respect, if a more **structured approach** is required, particularly with respect to web-shops based in third countries, the Dutch strategy seems to be a good practice as it significantly reduces costs and is expected to increase compliance in the long run. As also reported in COM (2013) 76 final, **consumer awareness** could be increased and the **roles and responsibilities of the relevant parties** (authorities, economic operators and consumers) further defined by means of '*short, simple and clear public information statements'*.

Similarly, **consumer awareness** could be raised by increasing perception of the importance of the CE marking or by clarifying the 'buyer beware' principle for products bought online. The Finnish public-awareness campaign called '*There is no sheriff in this town'*,[395] is a good example of this.

Some interesting solutions could be based on the management of **relations with e-sellers.** This involves the possibility to punish online platforms when selling non-compliant products and the establishment of cooperation agreements with e-commerce websites in order to ensure additional control over the products offered. Providing accurate information to those wishing to sell online could represent a further path to improvement.[396]

Furthermore, one interviewee[397] underlines that **the market surveillance systems for EU regulations on feed, food and veterinary controls are particularly effective** in keeping out non-compliant products. Fees for inspection and controls are (partially or completely) paid by companies importing these goods. The Dutch Delegation has often referred to this system in discussion with the Commission and Member States, insisting that this system should be replicated for market surveillance and border controls covering non-food products as well. Obviously this system would mean additional burdens for businesses (due to fees and import controls in ports). However, a possible solution could be to introduce a list of products and countries of origin that are constantly notified in RAPEX and agree on mandatory border controls for these products (for instance, by setting a risk-based threshold e.g. 30% of all incoming shipments). Products and countries of origin can then be removed from the list if and when controls show a decline in non-compliance. As stated by the interviewee, experience within the framework for feed, food and veterinary controls shows that the authorities in the country of origin are motivated to get off this list by investing in export controls.

8.4.6 Sources

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Interview with the Finnish Safety and Chemicals Agency (Tukes)

Interview with the Dutch Food and Consumer Product Safety Authority

395 http://www.tukes.fi/en/Current-and-News/News/Product-safety/Supervision-by-the-authorities-and-consumer-protection-do-not-cover-the-online-stores-of-far-off-countries/
396 SEC (2011) 1640 final and PANTEIA (2014).
397 Netherlands Food and Consumer Product Safety Authority.

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8.5 Case study 4: Cross-border market surveillance: follow-up given to restrictive measures taken by other Member States

The objective of this case study is to assess the effectiveness of work-sharing arrangements among Member States. In particular, it focuses on two tools: the **RAPEX system** and the **safeguard clause procedure**.[398] It assesses existing issues in the work sharing among both notifying and recipient countries, the type of work carried out by MSAs, issues leading to potential disagreement among Member States, the reasons for not reacting and any other relevant aspects. In order to provide examples of these working mechanisms, a specific RAPEX case and one on a safeguard clause notification is also included.

8.5.1 Communication means among European MSAs: RAPEX system and safeguard clause

Once entering the EU, non-compliant products can freely circulate in all Member States, which makes information sharing among Member States crucial. The RAPEX system and the safeguard clause procedures are tools allowing the exchange of this information.

RAPEX[399] is an information system provided by the European Commission. Whenever Member State authorities find a non-food product posing a serious risk to the health and safety of consumers, they file a notification in the system. Each notification reports information such as the product category, brand, model, a general description, its risk level and details. Moreover, measures taken in relation to this products by the notifying country are also reported. Finally, the system displays other Member States where the product was found and that have taken measures. A list of detected dangerous products is published online – thus accessible to the wider public – by the European Commission every week.

RAPEX is a fundamental tool for the implementation of **reactive** market surveillance in most Member States. Information may also come from producers or distributors who voluntarily organise recalls of their products and want to inform the national competent MSAs. Thanks to RAPEX, data relating to dangerous products found on a national market can quickly circulate all over Europe, thus helping market surveillance efforts within the internal market.

398 The case study has few information on the safeguard clause procedure as interviewees had no experience about it.
399 http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm

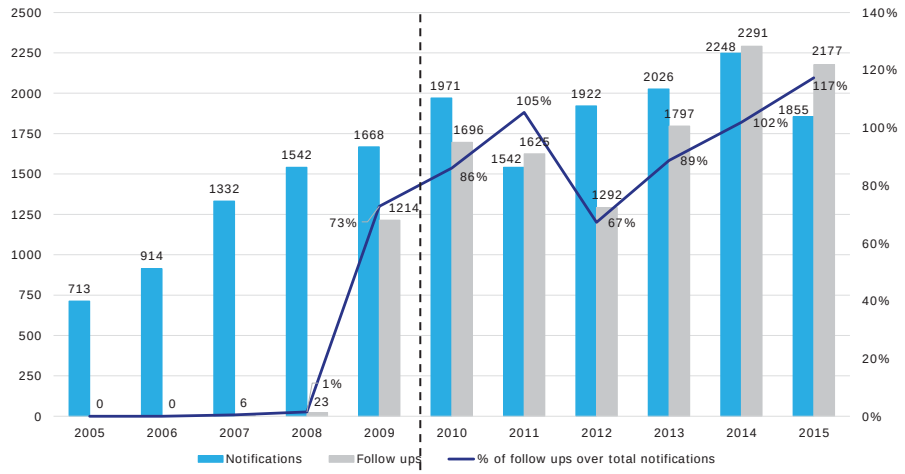
The **safeguard clause** is included in all the New Approach Directives. The safeguard clause procedure requires Member States to take measures against CE-marked products that do not comply with a specific Directive or Regulation and present a risk to the public (health and safety or other), and to inform the Commission and other Member States about these decisions and related reasons. In particular, it has to be used in non-conformity cases, in cases of incorrect application of and/or deficiency in standards. Once notified of a safeguard case, the Commission investigates and decides whether to settle it or not. The safeguard clause is a legal obligation for all Member States and it plays a role in the information exchange among Member States.

Both tools enhance the circulation of information among Member States, thus contributing to the implementation of market surveillance activities.

8.5.2 Use of RAPEX

As shown in the graph below, **the use of RAPEX has significantly increased over the years, both in terms of number of notifications and of follow-up actions**. Figure 4-49 shows that both trends are rising, with a decline only between 2011 and 2012. Overall, 3,228 RAPEX notifications (representing 18.2% of total notifications) from 2005 to 2015 had at least one follow-up reaction. The total number of follow-ups from 2005 to 2015 is 12,182 and the total number of notifications in the same period is 17,736 – the overall proportion of follow-ups to notifications is 68.7%.[400] Interestingly, **the weight of follow-ups over total notifications increased over the period** and from 2014 the number of follow-ups outweighs the number of notifications, this possibly indicating that RAPEX is growing in recognition and use as an information tool for enforcing market surveillance.

Figure 4-49 - Number of RAPEX notifications and follow-up measures per year[401]



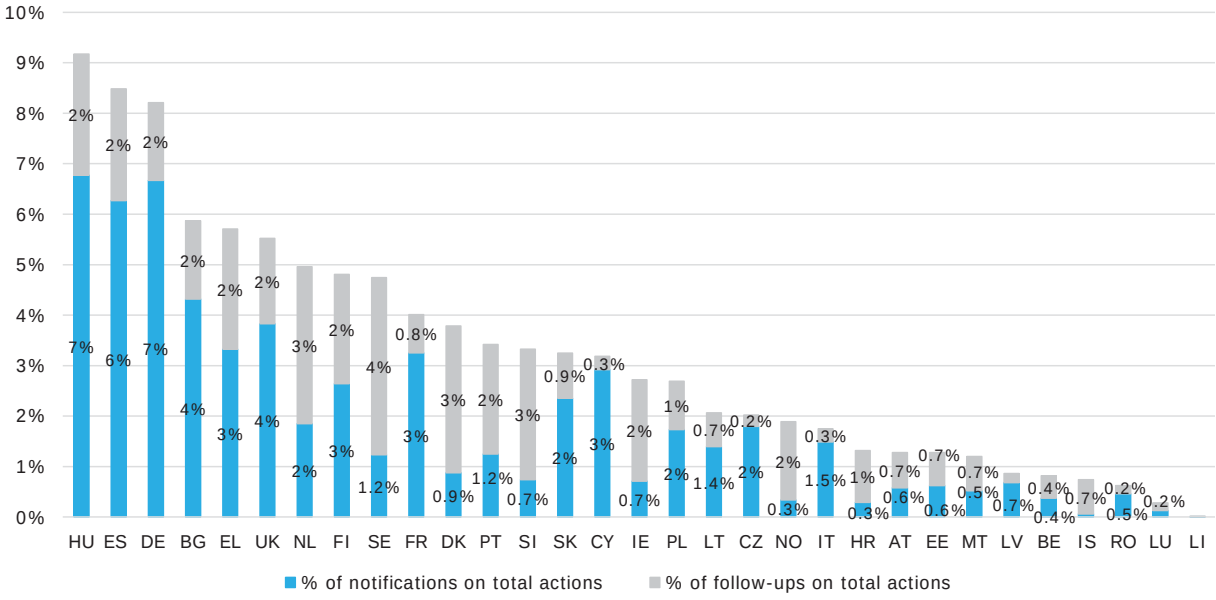
Source: Authors' elaboration on RAPEX database

The use of RAPEX across Member States differs, both as notifying and as recipient countries. As shown in Figure 4-50, overall **Hungary, Spain and Germany are the Member States**

400 The source for these data is RAPEX database.
401 2010 = entry into force of Regulation 765/2008.

reporting the most on RAPEX, while Luxembourg, Romania and Belgium are the least engaged. It is worthwhile observing the distribution of active and reactive measures across countries. **Hungary, Germany and Spain are the most active Member States**, notifying more than 1,500 products each over the last 10 years (i.e. around 33% of total notifications were filed by them). Less active Member States are Luxembourg, Croatia, Belgium and Romania, each filing less than 150 notifications. In terms of follow-up actions, **Sweden, Denmark and the Netherlands are the most reactive Member States** on RAPEX (each with more than 800 notified follow-ups over the last 10 years, representing 23.5% of total follow-ups), while Latvia, Luxembourg and Romania all reported less than 60 follow-ups in 10 years.

Figure 4-50 - Percentage of notifications and follow-ups per Member State on total actions notified on RAPEX over the period 2005 – 2015



Source: Authors' elaboration on RAPEX database

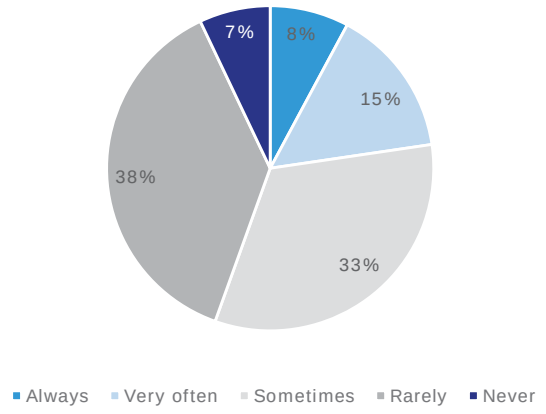
However, low notification numbers do not necessarily mean that Member States are less active against non-compliant products, since RAPEX is a communication tool and it may be that some MSAs are just not sharing all the information. **Member States' behaviour on RAPEX could help in understanding the preferred approach to market surveillance (reactive or proactive)** adopted by different Member States. For instance, it may be possible that Member States that are more active in follow-up than in notifying, such as Croatia, Ireland or Denmark, are adopting mainly a reactive approach. Whereas Member States like Cyprus, the Czech Republic or Germany seem to adopt a more proactive approach.

The answers to the targeted surveys are also useful in describing trends in the use of RAPEX. In particular, 75%[402] of MSAs say they issue a notification when they find a non-compliant

402 41 MSAs (2 AT, 2 BE, BG, 2 CY, DE, 2 DK, ES, 6 FI, 2 IT, 4 LT, LU, 2 LV, 5 NL, PL, 9 SE) and eight AdCO members (electromagnetic compatibility, explosives for civil use, gas appliances, measuring instruments, medical device, noise, pyrotechnic articles, recreational craft).

product, which means 25%[403] do not. However, as shown in the chart below, according to 38%[404] of respondents to the public consultation, MSAs '*rarely'* restrict the marketing of a product following the exchange of information about measures adopted by another MSA in the EU against the same product. This occurs '*sometimes',* according to 33%[405] of stakeholders, while a minority declare that it occurs '*very often'* (15%[406]) or '*always'* (8%[407]). While 7%[408] of respondents think that MSAs '*never'* exploit information received from other EU MSAs.

Figure 4-51 – MSAs' restrictions on the marketing of a product following measures adopted by other European MSAs



Source: public consultation

Nonetheless, stakeholders almost universally recognise the **convenience of using information on restrictive measures adopted by other MSAs to eventually adopt the same approach towards the same products supplied within another Member State's jurisdiction**. The majority of them think this would be useful for saving time and costs, for improving the focus of inspections – thus, again, increasing process efficiency – and for ensuring that restrictive measures are adopted in other jurisdictions on the same basis. That way, they can be effective in a larger part of the internal market.

8.5.3 Focus: use of RAPEX in four Member States

In ***Denmark***, **a RAPEX reaction procedure** starts with the scanning of the weekly report published on the European Commission's website. The Danish RAPEX Contact Point searches for incoming notifications and forwards them to the responsible MSA, to enforce the case. The first step is to **verify the presence** of the product on the national market. If the

403 14 MSAs (2 DE, 3 FI, 2 LT, 3 LV, 3 SE, UK).
404 Nine MSAs or Custom authorities (CY, CZ, FI, 2 NO, 2 PL, 2 SE), four public authorities (DE, ES, 2 LT), ten economic operators (BE, DE, ES, 3 FR, NL, PL, SE, UK), ten industry associations (6 BE, DE, EL, 2 UK), a Belgian trade union, 1 consumer organisation (BE), an English consumer/citizen, two others (BE, SK).
405 13 MSAs or Custom authorities (AT, CZ, 3 DE, DK, EE, ES, FI, IS, LT, NO, PL), five economic operators (DE, ES, FR, HU, NL), ten industry associations (4 BE, CH, ES, FR, NL, 2 UK), an English international organisation, two academic/law firms (DE, UK), a French 'other'.
406 Six MSAs or Custom authorities (CY, HR, NO, 3 SE), two industry associations (BE, PT), a German academic/law firm (DE), two German others.
407 Four MSAs or Custom authorities (DE, HR, IT, LT), a German public authority (DE), an English industry association.
408 A Norwegian MSA, four economic operators (ES, FR, SE, UK), three industry associations (ES, FR, IT).

economic operator indicated by the notification is Danish, the MSA assumes the product is available on the Danish market. In case the country of origin is different, the MSA starts an **online search** to detect the product and collect information about the economic operator. Once found, the MSA usually **approaches the economic operator** with a phone call, asking whether it is selling the product in Denmark. If the economic operator confirms, the MSA sends an official letter to it, explaining the issue and asking for details and information, such as the product name/brand, how many items have been sold, where it was purchased, the name of the importer on the Danish market, the name of the importer at the EU level – if different from the Danish one – and in which other Member States the product is sold. The MSA also provides a copy of the notification and a reply-form, requiring the seller to fill in and return it within a fixed time period (seven days for serious risk and two weeks in normal cases). Finally, the MSA **publishes information** about the product on its website and enters its reaction into RAPEX once a decision is made. Danish MSAs have to close market surveillance cases within 40 days.

The Danish Safety Technology Authority (the competent MSA for the specific case that will be discussed below) typically does not contact the notifying Member States or perform further tests on 'notified' products. It basically trusts the RAPEX notification and tries to solve the case by directly contacting the economic operator, if relevant.

France gives access to RAPEX not only to the National Contact Point – the Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF) – but also to other MSAs so they can check notifications relating to the sectors they are responsible for. When the notified product is manufactured, distributed, or imported into France, and therefore France is explicitly involved in a notification, the case is examined and recorded in the DGCCRF traceability system (the SORA-alert IT application). However, even if France is not directly involved, all notifications are checked daily through the CSCE (Electronic Commerce Monitoring Centre) web inquiry service, aiming to find out whether dangerous products are sold on French-language websites. After a RAPEX notification is recorded in the database, **the DGCCRF performs a risk assessment** and within 24 hours **sends a request for intervention to the MSA of the region** where the economic operator is based, asking them to investigate and take the necessary measures. The local MSA always reports back to the central MSA any information concerning the case and updates it through all phases of the process: from investigations and decisions on measures, through to final controls on whether economic operators' have taken the necessary actions. The relevant MSA takes note of the risk assessment provided by the notifying Member State and, in the event of discrepancies, carries out its own assessment.

The ***Cypriot*** Consumer Protection Service within the Ministry for Energy, Commerce, Industry and Tourism is the National Contact Point for RAPEX. Every week, it forwards the RAPEX weekly report to the other national MSAs, sending the specific notifications they are in charge of. The Consumer Protection Service is responsible for toys and GPSD and is used to translating notifications from English to Greek before forwarding them to the other national MSAs, and making public announcements about the risk and any related measures. As stated by the interviewed Cypriot MSA, Cyprus completely relies on risk assessments provided by other Member States on RAPEX and does not perform its own risk assessments, due to the

fact that it is a small country and economic resources for market surveillance are limited.[409] Once a **RAPEX notification** has been received, if the product is sold on the national market, the Cypriot MSA **immediately proceeds** with a withdrawal notice to the economic operator. Cypriot MSAs clearly **rely on other Member States' notifications**, **and test results**. Due to a lack of resources, it does not test products, even when no test report is provided. At the same time, the economic operator is asked to provide the MSA with information on the product, such as invoices, quantities sold, and number of items in stock, within 10 days. When information is received, the MSA evaluates the case and decides before entering the reaction in RAPEX. It also informs consumers about non-compliant products, asking them to return purchased items to the seller.

In ***Ireland***, the Competition and Consumer Protection Commission (CCPC) is the national contact point for RAPEX, monitoring the system on a continuous basis. The CCPC uses to follow up the notifications related to its areas of competence (i.e. toys, LVD, GPSD, Gas Burning Appliances and PPE (leisure and recreational)) with the relevant economic operators. If the notification relates to a different sector, it forwards it immediately to the relevant MSA, so that it can be processed accordingly. Once a notification relevant for CCPC is received, the MSA firstly gathers all the information available e.g. nature of the risk, details on the number of products circulating in the country, contacts of the relevant Irish economic operator. In this context, **the CCPC relies on the assessment of the notifying Member State**. The CCPC may also contact the notifying country to clarify if the products have been placed on the Irish market and to obtain the contacts details for the relevant economic operator in Ireland. In this process, **the most common issue that could arise is when the notifying country has stated that the product was placed on the Irish market, while this was not the case, or where follow-up questions submitted to the notifying country by the CCPC are not responded to or the requested information is not provided to the CCPC promptly**.

As a second step, the CCPC contacts the economic operator to ask whether the product concerned was actually placed on the Irish market. If this is the case, the MSA ensures that the national economic operator is taking all necessary measures to withdraw the product from the market and to recall it from consumers. Furthermore, it requests information on e.g. how many products they placed on the market, the contact details of any other operators they provided the product to, and details as to how they intend to recall the product. Thirdly, based on the information received, the CCPC may prepare and publish a notice giving the recall information on its own website, which may also be circulated through the CCPC social media platform. Finally, using all the relevant information obtained, the CCPC will prepare and submit the relevant reaction to the RAPEX system.

8.5.4 Focus: use of the safeguard clause in four Member States

As for **safeguard clauses**, the ***Danish*** DSTA enters the product into its internal data collection system and controls whether it is available on the national market. Three scenarios are therefore possible:[410]

409 Interviewee with the Consumer Protection Service, Ministry of Energy, Commerce, Industry and Tourism (Cyprus)

410 The four provided scenarios correspond to the four possible classification codes that DSTA adopts in order to classify safeguard clauses within its internal database.

1. **The product is not on the Danish market**: the DSTA does not need to take any actions;

2. **The product is on the Danish market:** DSTA takes the necessary follow-up actions, approaching the economic operator, providing seven or 14 days to come back with an assessment of product compliance, after which the MSA takes a decision;

3. **The product is on the Danish market and has been notified in RAPEX**: DSTA takes the necessary follow-up actions (as described under point 2);

4. **The DSTA has objections to the notification**: the DSTA provides to the EC all relevant information and documents in order to substantiate its objection.

The ***French*** DGCCRF firstly examines whether the safeguard clause notification concerns a French operator. If this is not the case, they leave it to other authorities responsible to react. If the operator is French, the DGCCRF carries out research in order to find out whether the product is present or not on the national market and assesses the product's safety and conformity levels. Procedures for safeguard clause notifications (including the case-specific notification) are similar to the one already described for RAPEX. However, safeguard clauses may lead to changes in the imposed measures, when the national MSA's opinion concerning measures to be taken diverges from the one suggested by other Member States, due to the related procedures at the European level. In those cases, the DGCCRF communicates its official reaction to the European Commission and explains its reasons, waiting for the Commission's opinion and adjusting the adopted measures in order to fully satisfy the Commission's final decision.

As for the process with **safeguard clause notifications** in ***Cyprus***, the interviewed MSA says it receives very few of them, because it is only responsible for two Directives within the scope of Regulation. Furthermore, it tends to take into consideration notifications on well-known brands and it has so far received only minor, unknown notifications relating to Chinese products that were difficult to detect on the national market. However, the procedure followed would be the same as that for RAPEX notifications.

Finally, the *Irish* CCPC have not received any safeguard alerts to date where the products concerned have been placed or made available on the Irish Market, so no information can be provided in this respect.

8.5.5 The specific case

The table below compares the main information available via RAPEX and safeguard clause notifications, in order to better present the differences and/or similarities between the two.

Table 4-32 – Comparison between a RAPEX and a safeguard clause notification

Information	*RAPEX notification*	*Information*	*Safeguard clause notification*
Year	2015	*Year*	2015
Notification number	A12/1114/15	*Notification number*	SE-15-07

Information	*RAPEX notification*	*Information*	*Safeguard clause notification*
Product	Tablet computer	*Product*	Lightning chain with LED-module
Brand	NVIDIA	*Brand*	Confidential
Name	SHIELD Tablet		
Country of origin	China	*Country of origin*	Sweden
Notifying country	Malta	*Notifying country*	Sweden
Reactions also in	Denmark, France, Ireland	*Other countries in which the equipment is placed on the market*	Belgium, Czech Republic, Denmark, Finland, France, Germany, Latvia, Norway, Russia
Risk level	Serious risk	*Reasons for measures taken*	Non-conformity with Article 2 of the Low Voltage Directive resulting from a faulty application of the applicable standard(s). Standard(s) reference: EN 60598-2-20:2010 and EN 60598-1:2008+A11:2009
Risk type	Fire		
Measures	Recall of the product from end users	*Measures*	Removal from circulation, prohibition of the placing of the equipment on the market

The NVIDIA example was chosen because it is a well-known international brand and both tablets and lighting chains are mass-consumer goods. These features make those products likely to be widespread on the market, and thus circulate in several countries.

As shown in the table above, data provided by safeguard clause notifications relate to specific Directives (Low Voltage Directive in the provided case) and contain information about non-EU countries where the product is likely to be found. It implies that Member States may be particularly encouraged to look for the product on their market and to adopt restrictive measures. A further difference between the two types of notification is the fact that, by using safeguard clauses, MSAs exchange information independently from the product risk level, while RAPEX provides accurate information on product risk. Moreover, RAPEX notifications are public, while safeguard clauses remain more confidential and may also contribute to the modification of the standards set by EC Directives.

The Danish reaction

As shown in the previous table, Denmark is among the countries reacting to the RAPEX notification and warned via the selected safeguard clause. Every time a RAPEX notification appears, the Danish Safety Technology Authority (DSTA) checks whether the case is already under scrutiny by a national authority, in order to avoid any duplication of work. In those cases, they virtually ‘re-open’ the case and insert their action in RAPEX.

With specific regard to the **safeguard clause**, the DSTA decided not to take it into account.[411] As for the **RAPEX notification**, it was already aware of the product and related risk, thanks to a notification received via a business application informing about voluntary measures against this product taken by an economic operator in the UK. So the DSTA was able to act before the publication of the RAPEX notification. Two economic operators were selling the tablet in Denmark and both were contacted by the DSTA one day before the notification appeared on RAPEX. One of the two also received the notification via the business application and voluntarily recalled the product, while the other answered that it was no longer selling the non-compliant tablet. The DSTA therefore accepted the voluntary measures and the explanations provided by the two economic operators and the case was closed. It required the economic operators to inform consumers on their website and also extended the economic operators' responsibility for product non-compliance for a period longer than the usual three months given to economic operators to take voluntary measures.

The French reaction

Contrary to Denmark, the case-specific RAPEX notification was received by the DGCCRF on the day it appeared on RAPEX (i.e. on 4 September 2015). On the same day, the DGCCRF sent a request for intervention to the MSA of the Alpes-Maritimes department, where NVIDIA's French headquarters are based. The MSA was asked to meet the economic operator to verify its legal status, check the technical documentation, establish the traceability of the product (e.g. possible re-sellers, quantities already sold and held in stock), and to inform the notifying Maltese Authority about the existing risk. Moreover, the local MSA had to ensure that the economic operator took appropriate short-term measures and informed consumers about the recall by collecting any documents used for this purpose. In the specific case, NVIDIA sent emails to its customers. On 11 September, the Alpes-Maritimes MSA informed the DGCCRF that the economic operator only had research centres within their territory, while its management was located in the Hauts-de-Seine region. Subsequently, a request for intervention was sent to the local Hauts-de-Seine MSA. On 13 October, implementation of the recall on all French territory was confirmed and a RAPEX reaction was submitted on 15 October. The local MSA in Hauts-de-Seine continued to monitor the effectiveness of the measures, reporting in November that 3,969 requests for replacement products were submitted by consumers in France. An update was provided in February 2016: by that date, the company had received 4,180 exchange requests, which represented a 53% return rate of products sold, of which 4,149 were actually replaced. In addition, they provided evidence of the destruction of 52 tablets that were still in stock. In light of this, the DGCCRF decided to close the case in February 2016.

The Irish reaction

As reported in the CCPC's website,[412] NVIDIA has announced a voluntary recall of its SHIELD™ 8-inch tablets that were sold between July 2014 and July 2015, declaring it will replace them. According to NVIDIA, a total of 89 of these tablets have been placed onto the Irish market.

411 The interviewee was not able to provide additional information.
412 http://www.consumerhelp.ie/index.jsp?p=127&n=391&a=1419

The MSAs informs that the economic operator is asking customers to visit its website for information on how to obtain a replacement device, asking consumers to stop using the recalled tablet.

8.5.6 Main issues and challenges

Several issues related to cross-border cooperation arose during the interviews. Some of them concern the **design of the RAPEX notification procedure**. When filing a notification, many Member States select the option '*ban on the marketing of the product and **any accompanying measure'*** in order to describe the measures taken. Due to its vagueness, this entry may create problems to other Member States in fully understanding the adopted measures, eventually forcing them to start a new investigation with the result of making the communication process less effective. Further information gaps may be due to the **lack of risk assessment data and test reports on RAPEX** and to **possible disagreements on risk assessments** (especially within safeguard clause notifications). In the first case, Member States may find it difficult to rely on other MSAs' decisions, leading to duplication of testing costs. In the second case, disagreements between the Commission and the notifying Member State can result in notifications not being disseminated. Moreover, a barrier for RAPEX users is based on **language –** RAPEX is only available in English.

Issues also arise when the **country of origin of the notified, non-compliant product** is not involved in the process, especially disagreements between notifying and recipient countries. For example, a product whose country of origin is Member State X is notified in RAPEX by Member State Y. If Member State Z's follow-up reaction to this notification is not in line with the measures taken by notifying Member State Y, all the other Member States may find themselves in a difficult position in choosing the best measures to adopt. Finally, according to an interviewee,[413] the **safeguard clause notification procedure is heterogeneously implemented** by Member States and its systematic application is not effective yet. In addition, the existence of two **different notification procedures** for non-compliance (i.e. RAPEX and the safeguard clause) is perceived as redundant by MSAs.[414]

8.5.7 Possible solutions

According to an interviewee there should be proportionality, both between the seriousness of non-compliance and measures adopted by a country, as well as among actions taken by different Member States. **Further details and explanations on the adopted measures** within the single notification could ease MSAs' processes in terms of speed and the proportionality of decisions.[415]

In general, the **more information posted** in a notification, the better it helps MSAs in **prioritising** follow-up actions. An interviewee[416] suggested some measures to speed up the reaction processes. Firstly, the database should be designed in order to **immediately distinguish between already opened notifications and those still to be processed**.

413 Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF).
414 Stated by all interviewees within the framework of this case study.
415 The Danish Safety Technology Authority (DSTA).
416 Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF).

Secondly, the **size of downloadable files** should be increased in order to include heavy files such as photos and colour test reports.

In addition, it may be useful to add to the RAPEX tool a function to **solicit specific Member States to react** regarding cases where an additional opinion is needed, for instance by sending an alert message personally from one Member State to the other, thus creating a sort of 'chat', or forum. As stated by two interviewees,[417] in such cases it could be useful to collect the opinion of the Member State where the good is produced. Moreover, if the supposed non-compliant economic operator is European, the Member State of origin should be aware of investigations carried out by other EU or extra-EU countries using the tool. In addition, voluntary measures taken by foreign retailers should also be notified, so relevant Member States can take adequate measures. This kind of information should be shared by other countries using RAPEX before the final decision is made.

Possible solutions to the language barrier could be to **translate** the RAPEX website into the main languages of the EU, or at least the translation into English of risk assessments attached to RAPEX notifications and a standardised description thereof.[418] Those actions would help as many users as possible to become aware of non-compliant products and to pursue investigations within their countries.

As for the presence of multiple tools for exchanging information among European MSAs, **simplifying and reducing this to one single notification procedure** may reduce administrative burden and speed up the process. In particular, it should be assessed how to improve the IT tool in order to avoid a safeguard clause notification when one has already been filed in RAPEX.

8.5.8 Sources

Interview with the Consumer Protection Service, Ministry of Energy, Commerce, Industry and Tourism (Cyprus)

Interview with the Danish Safety Technology Authority (DSTA)

Interview with the Direction Générale des Finances Publiques (France)

Interview with the Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (France)

Interview with the Swedish Board for Accreditation and Conformity Assessment (SWEDAC)

Interview with the Competition and Consumer Protection Commission (CCPC) (Ireland)

Prosafe (2013), Best practice techniques in market surveillance – available at: http://www.prosafe.org/library/knowledgebase/item/best-practices-techniques-in-market-surveillance

417 The Danish Safety Technology Authority (DSTA) and Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF).

418 Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF).

European Commission website on RAPEX: https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/main/?event=main.listNotifications

Blue Guide 2016 – available at: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=7326

8.6 Case study 5: Penalties available to Member States as incentives to comply

The objective of this case study is twofold.

Firstly, it aims at providing a **quantitative overview** of penalties (administrative and criminal, monetary and non-monetary) available to EU Member States in a specific sector among those covered by Regulation 765/2008, i.e. that of electrical appliances and equipment under the Low Voltage Directive (LVD, 2006/95/CE). For a complete overview on penalties, please also refer to Annex.

Secondly, the case study identifies four Member States where MSAs cannot impose administrative sanctions for product non-compliance without resorting to the courts. This could further hamper the enforcement powers of MSAs inasmuch as **the process for imposing sanctions is, within these models, potentially lengthy and burdensome.**

The ultimate purpose of the case study is to understand whether it is necessary to foresee some **minimum criteria within the regulatory framework** to increase the effectiveness of penalties for product non-compliance.

8.6.1 The case of the low voltage sector

The high variance across Member States in terms of sanctions is particularly evident within a single product category. The following table presents a mapping of sanctions for breaches of the LVD.

Table 4-33 – Comparison of sanctions in LVD sector across Member States[419]

MS	*Administrative penalties*	*Criminal penalties*
AT	Fines up to €25,435	Established dangers to health and fraud and falsifications of documents are the basis for criminal charges
BE	Foreseen	Foreseen
BG	Fines from €125 up to €500 for retailers, from €125 up to €7,500 for importers and manufactures	Not foreseen
CY	First non-compliance: fines up to €6,000.	First non-compliance: fines up to €20,000 and/or up

419 The table is filled on the base of multiple sources. Information mainly comes from the national transposition laws of the Low Voltage Directive 2006/95/EC. Additional sources are targeted surveys, ad-hoc requests sent to IMP-MSG representatives in each Member State and analysis of data received compared with data available in national programmes and other publicly available documents. Where information was not available within the listed sources, cells are filled with 'n.a.'.

MS	*Administrative penalties*	*Criminal penalties*
	Second non-compliance: fines up to €12,000	to two years imprisonment. Second non-compliance: fines up to €40,000 and/or up to four years imprisonment
CZ	Fines up to €1,802,776	n.a.
DE	Fines up to €100,000	n.a.
DK	Not foreseen	Foreseen
EE	Fines up to €3,200	Fines from €300 up to €16,000,000 and/or imprisonment up to three years
EL	Fines up to €1,500	n.a.
ES	Fines from €3,000 up to €601,000	Criminal fines exclude administrative fines
FI	Not foreseen	The penalty for health offence is at minimum a fine, with a maximum six months imprisonment
FR	Foreseen	Foreseen
HR	Foreseen	Fines from €652.91 to €130,582.40
HU	Foreseen	n.a.
IE	Foreseen	Fines up to €500,000 and/or imprisonment up to two years
IT	Fines from €2,000 to €62,000	Established dangers to health and fraud are the basis for criminal charges
LT	Fines for employees and individual enterprises from €50 up to €300 and between €80 and €300 for heads of legal entities. In case of repeated non-compliance: fines for employees and individual enterprises from €80 up to €600 and between €300 and €600 for heads of legal entities	n.a.
LU	Fines up to €15,000	Maximum sanction €1,000,000 and/or up to three years' imprisonment
LV	Fines up to €14,000	Not foreseen
MT	Not foreseen	Fines from €465 up to €11,646 and/or imprisonment (up to three years). If repeated offence: fines from €1,747 to €23,293 and/or imprisonment (up to four years)
NL	Fines up to €900,000	Foreseen
PL	Fines up to €24,000	Not foreseen

MS	*Administrative penalties*	*Criminal penalties*
PT	Fines from 1,500 to 44,750	Foreseen
RO	Fines from €550 up to €2,200	If non-conformities of the products lead to death or acute injuries
SE	Foreseen	Foreseen
SI	Fines from €2,000 to €40,000 for legal entities and from €200 to €4,000 for individuals	Foreseen
SK	Foreseen	n.a.
UK	Administrative fines are not foreseen	Foreseen

Sources: national laws, national reports, interviews and questionnaires sent to stakeholders

The table shows that criminal sanctions and administrative monetary sanctions are not foreseen in all Member States. Moreover, maximum fines vary significantly across countries, as well as minimum ones. For instance, fines in Lithuania go from a minimum of €14 up to a maximum of €600, while in Romania they range from €550 to €2,200, and in Bulgaria they start from a minimum of €125 up to a maximum of €7,500. Those limits are particularly low if compared to minimum fines in Slovenia (€2,000) or Spain (€3,000) and to maximum fines foreseen in Germany, Ireland and Luxembourg, which amount respectively to €100,000, €500,000 and €1,000,000. Imprisonment periods vary greatly and they range from six months in Finland, two years in Ireland, three years in Greece and Luxembourg, and four years in Cyprus and Malta.

8.6.2 The role of the courts in the sanctioning process

The main difference between administrative and criminal procedures is the role of the courts in setting criminal sanctions. They do not usually take part in the administrative process except **in some Member States** (i.e. Austria, Finland, Ireland, Malta and the UK) where the **courts are can be involved in administrative procedures as well**, though playing a different role depending on the national legislative framework.

The sanctioning process in Austria. After a preliminary investigation of suspected non-compliance, the responsible Austrian MSA contacts the economic operator, requesting information and documentation. Depending on the information provided, the MSA decides whether to close the investigation, if compliance is verified, or to impose an administrative sanction. In this case, the economic operator is given two weeks to appeal to the Administrative Court. If the sanction is not contested, the decision will be binding and enforceable. If the economic operator appeals, the case passes from the MSA to the judiciary which examines and decides whether to uphold the MSA's decision or modify it. The court is only responsible for setting the right penalty based on evidence presented, and not for verifying product compliance, which is MSA's task.

The sanctioning process in Malta. MSAs in Malta cannot impose administrative (monetary) sanctions. If a product is found to be non-compliant after an investigation, the economic operator is contacted by the MSA, which imposes a restrictive measure, such as a recall or a

withdrawal. The case is then closed if the economic operator complies. If it does not cooperate, the case is brought to court, which sets the fine and/or period of imprisonment in serious cases. Monetary sanctions in Malta can only be imposed by the court and they may vary case by case, depending on the specific sectoral law and on the seriousness of the infringement.

The sanctioning process in Finland. Finnish MSAs have the power to impose restrictive measures as foreseen by the Regulation, such as the recall, withdrawal or banning of a product from the market. They also have the option to order penalties (payments) if they impose a restrictive measure and the economic operator is not respecting it. In these cases, MSAs can directly impose payments, but only if related to a certain decision. Monetary (administrative) fines and criminal sanctions, such as imprisonment, are matters for the court. If MSAs want to impose fines on non-compliant economic operators, they have to inform the police and refer it to the court, which sets the fine following the provisions of specific sectoral laws and the criminal code.

The sanctioning process in the UK. An interviewee from the UK says that resorting to sanctions and prosecution is viewed as a '*failure of enforcement'*. Helping economic operators to understand what they did wrong and collaborating with them, setting compliance as the common goal, is considered to be more effective in the long run. When an MSA identifies a non-conformity, it generally works with the responsible economic operator and if it proactively collaborates, prosecution and fines can be avoided, unless it is in the public interest to prosecute. However, uncooperative economic operators are prosecuted through a procedure that involves the courts. Assuming the economic operator is judged to have committed an offence, the court determines a fine and considers the MSA's claim for costs, which would normally be granted.

8.6.3 Stakeholders' perception

Based on the results of the public consultation, stakeholders are divided into those stating that the current framework of market surveillance provides '*insufficient'* deterrence (52%),[420] and those thinking it is '*sufficient'* to a '*significant'* (10%)[421] or to a '*moderate'* extent (38%).[422] In particular, **the high degree of heterogeneity** in the penalty framework is indicated as generating low deterrence by some stakeholders.[423] Stakeholders indeed express a need for a **higher level of cooperation** among authorities in different Member States to resolve this

420 22 MSAs or Custom authorities (BE, CY, 6 DE, DK, 2 FI, IE, IS, LT, 3 NO, PL, 3 SE, UK), three public authorities (ES, DE, PL), three international organisations (AT, FI, UK), 21 large economic operators (AT, BE, 7 DE, 6 FR, IE, IT, 2 NL, PL, PT), eight SMEs (2 ES, FI, HU, NL, 2 PL, UK), seven micro- economic operators (BG, CZ, DE, FR, PL, 2 UK), 30 industry associations (14 BE, 2 DE, DK, EL, 2 ES, FI, 3 FR, IT, NL, 4 UK), 2 trade unions (BE, FR), four consumer organisations (3 BE, DK), one consumer/citizen from the UK, a German academic/law firm, seven others (2 BE, 2 FR, SK, TR, 1 other country).

421 Six MSAs or Custom authorities (CH, 2 HR, IS, 2 LT), an Austrian public authority, a Hungarian and a Polish micro- economic operators, a Hungarian large economic operator, a Czech and a Polish SMEs, one 'other' Czech economic operator, six industry associations (BE, CH, 2 ES, FI, FR), two others (2 DE).

422 32 MSAs or Custom authorities (AT, CY, 2 CZ, 6 DE, EE, ES, FI, 2 HR, IE, IS, IT, LT, 2 NL, 2 NO, 2 PL, 2 PT, 5 SE), eight public authorities (AT, DE, DK, IS, 2 LT, PL, RO), eight micro- economic operators (2 BG, 2 DE, HU, 2 PL, UK), six SMEs (FR, HU, 2 PL, SE, SK), five large economic operators (BG, 2 DE, NL, SE), 12 industry associations (6 BE, ES, FI, IT, PT, 2 UK), two consumer organisations (BE, UK), three academic/law firms (DE, HU, UK), an Austrian consumer/citizen, two others (AT, SE).

423 A Danish MSA, a French economic operator, two industry associations (BE, DE), a French trade union.

issue.[424] However, two interviewees[425] underline the importance of **subsidiarity** with respect to Member States' right to set their own public policy within a given European framework.

A couple of interviewees[426] believe such a fragmented framework may even distort the level playing field among EU businesses. Fair companies invest more and incur higher costs in order to comply with legislative requirements. Meanwhile, rogue economic operators avoid these kinds of costs and benefit from an unfair competitive advantage. Furthermore, an interviewee[427] suggests that MSAs prefer to target companies that are more likely to answer when they should focus on more difficult-to-reach players.

8.6.4 Conclusions

Divergences exist in the methodologies applied by MSAs in different Member States to sanction non-compliant businesses and the degree of **involvement by courts in the sanctioning process**. In some countries, the prospect of court intervention acts as a **strong deterrent**. As reported by interviewees, economic operators are used to complying and there are few cases of appeal. In other instances, involving the court in market surveillance processes means additional **administrative burden** in the overall sanctioning process. The challenge is therefore to find a balance between rapid prosecution and protecting economic operators' rights. At the same time, however, some stakeholders state it is important to **establish a set of minimum core elements[428] as well as a more detailed common methodology[429] to be shared and taken into account by all MSAs when imposing penalties**. In particular, the following distinctions need to be taken into account:

- **Formal vs substantial non-compliance**, where sanctioning the former is less burdensome than the latter, in light of the fact that in some cases of formal non-compliance (based on irregular/incomplete documentation or marking) consumer health and safety risk may be lower.

- **First vs repeated infringement**, where economic operators found to be non-compliant for the first time should be encouraged to comply in order not to incur higher sanctions in the future. It also helps in fighting 'serial' non-compliant operators. Cyprus, Denmark, Lithuania, and the Netherlands for instance are applying this distinction. An interesting suggestion also concerns the importance of giving cooperative economic operators the chance to comply. As previously stated, the lack of differentiation between 'rogue' and 'fair' businesses within sanctioning procedures affects the level playing field, in view of the higher costs fair economic operator incur in order to comply.

- **Size of the penalty vs business turnover**, where economic performance is the basis or criteria to calculate fines. Although it may seem fair to adapt fines to the size of a

424 Three MSAs or Custom authorities (2 DE, CZ), a Swedish economic operator, seven industry associations (4 BE, NL, ES, FR), three consumer organisations (2 BE, DK), a Belgian trade union.
425 Malta Standards Authority and Federal Ministry of Science, Research and Economy, Austria.
426 A large French economic operator and an EU industry association.
427 An EU industry association.
428 86% of respondents to the public consultation strongly agree and agree (33% and 53% respectively) with this statement (total number of respondents to this question = 201).
429 76% of respondents to the public consultation strongly agree and agree (31% and 45% respectively) with this statement (total number of respondents to this question = 194).

company's turnover, they should rather be related to the revenues earned as a result of the non-compliant product being on the market.[430]

- **Fixed fine vs fine determined on a case-by-case basis**, where the size of the company is a key determinant, given that bigger enterprises would have less difficulty paying fixed fines than SMEs.

Although the debate relating to the provision of common European criteria for sanctions remains open, the above-mentioned points should provide valuable insight into possible developments.

8.6.5 Sources

Interview with Department for Business, Energy and Industrial Strategy (UK)

Interview with the Federal Ministry of Science, Research and Economy, Austria

Interview with the Finnish Safety and Chemicals Agency (Tukes)

Interview with the Malta Standards Authority

Interviews with two EU industry associations

Interview with a large French economic operator

Businesseurope (2016), Strategy Paper, *Enhancing enforcement and compliance for goods*

National Programmes, Austria and Malta

8.7 Overview tables of penalties set at the national level for product non-compliance

This section is based on information collected through national reports and programmes on market surveillance. Whenever possible, it has been complemented relying on European Commission (2010), "CERTIF 2010–02, *Sanctions foreseen in the national legislation of Member States against infringements of the provisions of Regulation 765/2008/EC"*, and especially on its annex.[431] Additional information (underlined in the table) has also been provided by stakeholders' answers to the targeted surveys. Furthermore, to complement information gaps and following a specific request from the Steering Group, the IMP-MSG representative for each Member State was requested to complete the information for each sector set at the national level.

Whenever possible, the data reported distinguish between:

430 Businesseurope (2016), Strategy Paper, Enhancing enforcement and compliance for goods. Also stated by an interviewee from an EU industry association.

431 Penalties. Overview of the information provided by Member States, http://ec.europa.eu/DocsRoom/documents/6267/attachments/1/translations/en/renditions/native

- Sanctions and penalties based on Article 41 of the Regulation;[432]
- Sanctions and penalties based on Article 30(6) of the Regulation, on infringements of rules on the CE marking;[433]
- Sanctions and penalties set in specific product sectors.

432 Where it states that "*The 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. The Member States shall notify the Commission of those provisions by 1 January 2010 and shall notify it without delay of any subsequent amendment affecting them […]*".

433 Where it states that "*Without prejudice to Article 41, Member States shall ensure the correct implementation of the regime governing the CE marking and 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 […]".*

MS	**ADMINISTRATIVE PENALTIES** - Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES** - (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
AT	Fines **Medical devices**: fines up to €25,000 **Electrical appliances and equipment under LVD, eco-design and energy labelling, electrical equipment under EMC, equipment and protective systems intended for use in potentially explosive atmospheres**: fines up to €25,435	Established dangers to health and fraud and falsifications of documents are the basis for criminal charges. **Medical devices:** Established dangers to health as well as fraud and falsifications of documents form the basis of criminal charges, which are heard in a court of law. Imprisonment if a financial fine is not paid in due time.
BE	Fines (doubled in case of recidivism)	Fines up to €100,000 Imprisonment
BG	Information/publication on authorities' websites Fines ranging from €128 up to €511, from €255 up to €7,700 and €51 up to €2,555, respectively, are imposed on traders; manufacturers/importers and natural persons. There exist however sectoral exceptions, detailed below. **Medical devices, cosmetics:** fines from €500 up to €6,100. **Toys, PPE, simple pressure vessels and pressure equipment, transportable pressure equipment, machinery, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment under EMC, radio and telecom equipment under R&TTE-RED, electrical appliances and equipment under LVD, eco-design and energy labelling, recreational craft**: fines from €125 up to €500 for retailers, from €125 up to €7,500 for importers and manufactures **Aerosol dispensers, footwear labelling**: fines from €25 up to €256 **Textile labelling**: fines from €511 up to €1,534 **Lifts, cableways**: fines from €100 up to €7,500 **Electrical and electronic equipment under RoHS and WEEE and batteries:**	**CE marking:** the registration of the CE marking as a Community mark would entail the possibility of imprisonment and the setting of sanctions by the Court. Criminal penalties are not foreseen except for **chemicals**.

MS	**ADMINISTRATIVE PENALTIES** - Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES** - (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	fines from €5,112 up to €25,562 **Chemicals:** fines from €513 up to €51,282. **Fluorinated greenhouse gases and ozone depleting substances:** fines from €1,500 up to 20,000. **Detergents:** fines from €511 up to €20,452. **Paints:** fines from €250 up to €7,500. **Biocides:** fines from €5,113 up to €51,129.97 **Tyre labelling, motor vehicles and tractors:** fines from €2,550 up to €51,130 **Fertilisers:** fines from €500 up to €2,000 **Other consumer products under GPSD**: fines from €2,556 up to €12,782 **Construction products**: no administrative fine is foreseen **CE marking:** fines up to €5,000.	
CY	**Medical devices, toys, PPE, simple pressure vessels and pressure equipment, machinery, lifts, cableways, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment under EMC, electrical appliances and equipment under LVD, tyre labelling, recreational craft**: first non-compliance fines up to €6,000, second non-compliance fines up to €12,000 **Radio and telecom equipment under R&TTE-RED**: fine is €17,100 **Chemicals**: fines up to €20,000 **Eco-design**: fines up to €3,418 **Energy labelling:** fines up to €8,500, doubled if offense is repeated **Other products under GPSD**: fines up to €3,400 **Biocides**: fines up to €5,000 **Cosmetics, aerosol dispensers, transportable pressure equipment**: no administrative sanctions are foreseen. **Toys**: fines up to €12,000	**Medical devices, toys, PPE, simple pressure vessels and pressure equipment, machinery, lifts, cableways, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment under EMC, electrical appliances and equipment under LVD, tyre labelling, recreational craft**: first non-compliance fines up to €20,000 and/or up to 2 years imprisonment, second non-compliance fines up to €40,000 and/or up to 4 years imprisonment **Cosmetics**: fines up to €40,000 and/or up to 2 years imprisonment **Aerosol dispensers**: fines up to €20,000 and/or up to 2 years imprisonment **Transportable pressure equipment**: fines up to €7,000 and/or up to 2 years imprisonment **Radio and telecom equipment under R&TTE-RED**: fine is €2,562 and/or up to 6 months imprisonment **Chemicals**: fines up to €80,000 and/or up to 2 years imprisonment **Eco-design:** imprisonment up to 2 years or a fine up to €8,545, or both. In the event of a second or subsequent conviction, the said offences shall be

MS	**ADMINISTRATIVE PENALTIES** - Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES** - (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
		punished with imprisonment for a period of no more than 4 years or a fine up to €17,090 and/or both. **Other products under GPSD**: fines up to €8,500 and/or up to 2 years imprisonment **Biocides**: fines up to €20,000 and/or up to 2 years imprisonment **Toys**: fines up to €20,000
CZ	**Medical devices, toys, PPE, construction products, aerosol dispensers, simple pressure vessels and pressure equipment, transportable pressure equipment, machinery, lifts, cableways, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment under EMC, radio and telecom equipment under R&TTE-RED, electrical appliances and equipment under LVD, electrical and electronic equipment under RoHS and WEEE and batteries, recreational craft, marine equipment, non-road mobile machinery, other products under GPSD, textile and footwear labelling, crystal glass**: fines up to €1,802,776.28 **Cosmetics**: fines up to €108,166 **Chemicals, fertilisers, biocides, eco-design and energy labelling**: fines up to €180,277.63 **Motor vehicles and tractors**: fines are not foreseen Information/publication on authorities' websites **CE marking**: fines up to €2 million.	**CE marking:** the registration of the CE marking as a Community mark would entail the possibility of imprisonment and the setting of sanctions by the Court.
DE	**CE marking:** fines up to €3,000 **Measuring instruments, eco-design and energy labelling, efficiency**	**Other consumer products under GPSD:** imprisonment for up to one year or a fine.[434]

434 http://germanlawarchive.iuscomp.org/?p=777#s20

MS	**ADMINISTRATIVE PENALTIES** - Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES** - (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	requirements for hot-boilers fired with liquid or gaseous fuels, tyre labelling: fines up to €50,000 **Electrical equipment, radio and telecom equipment, transportable pressure equipment, aerosol dispensers, simple pressure vessels and pressure:** fines up to €100,000	
DK	**Medical devices, toys, appliances burning gaseous fuels, pyrotechnics, measuring instruments, measuring instruments electrical equipment under EMC, radio and telecom equipment under R&TTE-RED, electrical appliances and equipment under LVD:** administrative sanctions are not foreseen. **PPE, aerosol dispensers, simple pressure vessels and pressure equipment, transportable pressure equipment, machinery, lifts, cableways:** fines from €1,333 **CE marking:** fines if infringement is repeated. **Pyrotechnics**: fines up to €750, 000	Imprisonment is foreseen **Medical devices, toys**: criminal monetary sanctions are foreseen (no imprisonment). **Pyrotechnics**: criminal monetary sanctions and imprisonment are foreseen **Electrical equipment under EMC, radio and telecom equipment under R&TTE-RED:** criminal monetary sanctions are foreseen with no given limit (no imprisonment).
EE	Information/publication on authorities' websites **Medical devices, cosmetics, toys, PPE, construction products, aerosol dispensers, simple pressure vessels and pressure equipment, transportable pressure equipment, machinery, lifts, cableways, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment under EMC, radio and telecom equipment under R&TTE-RED, electrical appliances and equipment under LVD, eco-design and energy labelling, recreational craft, marine equipment, motor vehicles and tractors, non-road mobile machinery, fertilisers, other products under GPSD, textile and footwear labelling, crystal glass:** fines up to €3,200 **Electrical and electronic equipment under RoHS and WEEE and batteries, chemicals, biocides**: fines up to €32,000 **Tyre labelling**: fines up to €13,000	**All sectors:** fines from €300 up to €16,000,000 and/or imprisonment up to 3 years.

MS	**ADMINISTRATIVE PENALTIES** - Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES** - (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
EL	Fines up to €1,500	
ES	Fines from €3,000 up to €601,000 Oblige economic operators to inform consumers[435] Suspension of the economic operator's activity for a maximum period of five years.	
FI	Fines Oblige economic operators to inform consumers **Cosmetics, electrical and electronic equipment under RoHS and WEEE and batteries, chemicals:** fines **Recreational craft, electrical equipment, eco-design and energy labelling, equipment and protective systems, efficiency requirements for hot-boilers fired with liquid or gaseous fuels, medical devices**: MSAs have no power to impose fines, as restrictive measures already imply an economic damage. Decisions are taken case by case by a Court. **Medical devices**: fines up to €25,000	**Toys, PPE, machinery, construction products, appliances burning gaseous fuels and consumer products:** the penalty for a consumer safety offence is a fine and/or imprisonment up to 6 months. **Simple pressure vessels, equipment and protective systems intended for use in potentially explosive atmosphere, electrical equipment under EMC, electrical appliances and equipment under LVD, electrical and electronic equipment under RoHS and WEEE and batteries, chemicals, eco-design and energy labelling:** the penalty for a consumer safety offence is a fine. **Pyrotechnics, explosives for civil uses**: the penalty for a consumer safety offence is a fine and/or imprisonment. Cosmetics **Medical devices**: established dangers to health as well as fraud and falsifications of documents are the basis for criminal charges, which are decided by a court of law. Imprisonment if a financial fine is not paid in due time. The penalty for health offence is at minimum a fine and at a maximum a 6-month imprisonment.
FR	Fines **CE marking:** Fines up to €3,000 (depending on sectoral legislation), €37,500 (under	**CE marking:** imprisonment is also possible

435 http://noticias.juridicas.com/base_datos/Admin/rdleg1-2007.l1t4.html#c2

MS	**ADMINISTRATIVE PENALTIES** - Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES** - (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	the Consumer Act) or double the value of the merchandise (Customs Code).	
HR	Fines Administrative fines are foreseen for all sectors. **Pyrotechnics, explosives for civil uses**: fines from around €5,223 up to around €13,058	**Medical devices**: fines from €9,333 to €13,333 on legal and natural persons. The responsible person within the legal person is also fined from €933 to €1,333 **Cosmetics, toys, noise emission for outdoor equipment, chemicals, biocides**: monetary fines are foreseen (no imprisonment). **PPE, aerosol dispensers, simple pressure vessels, transportable pressure equipment, machinery, lifts, appliances burning gaseous fuels, electrical equipment under EMC, electrical appliances under LVD, tyre labelling, textile and footwear labelling, crystal glass:** fines from €652.91 to €130,582.40 **Construction products**: fines from €783.49 to €13,058.24 **Eco-design and energy labelling**: fines from €2,611.65 to €65,291.20 **Other products under GPSD**: fines from €6,529.12 to €32,645.60 **Equipment and protective systems intended for use in potentially explosive atmospheres**: no criminal sanctions are foreseen
HU	Fines	
IE	Fines Information/publication on authorities' websites **Fertilisers:** fines up to €3,000. **Recreational craft:** fines up to €3,000. **Medical devices**: fines up to €1,000 **CE marking**: fines up to €2,000 (in the case of explosives)	**Medical devices:** max 6-month imprisonment **Fertilisers:** max 6-month imprisonment **CE marking:** imprisonment is also possible
IT	Fines	**Recreational craft**: criminal proceedings is also possible

MS	**ADMINISTRATIVE PENALTIES** - Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES** - (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	Recreational craft: fines from €10,329 up to €154,937 **Noise emissions for outdoor equipment**: fines up to €50,000	
LT	**Dangerous products (all sectors):** fines from €144 up to €23,169. **Marking and labelling non-compliance (all sectors)**: fines for employees and individual enterprises from €30 up to €150 and between €150 and €300 for heads of legal entities. In case of repeated non-compliance: fines for employees and individual enterprises from €50 up to €300 and between €300 and €600 for heads of legal entities. **Medical devices**: fines on natural persons from €30 up to €290, fines on officers between €300 and €850. In case of repeated non-compliance: fines on natural persons from €280 up to €600, fines on officers between €820 and €1,500. **Cosmetics:** fines from €100 up to €300. In case of repeated non-compliance: fines between €280 and €600. **Chemicals:** fines from €60 up to €4,300.**C:** fines from €60 up to €4,300. **Toys, PPE, construction products, aerosol dispensers, simple pressure vessels and pressure equipment, transportable pressure equipment, machinery, lifts, cableways**: fines for employees and individual enterprises from €30 up to €140 and between €300 and €560 for heads of legal entities. In case of repeated non-compliance: fines for employees and individual enterprises from €60 up to €140 and between €550 and €1,200 for heads of legal entities. **Noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil use, appliances burning gaseous fuels eco-design and energy labelling, electrical appliances and equipment under LVD, electrical and electronic equipment under RoHS and WEEE and batteries, tyre labelling, marine equipment, motor vehicles and tractors, non-road mobile machinery, fertilisers, textile and footwear labelling, crystal glass:** fines for employees and individual enterprises from €50 up to €300 and between €80 and €300 for heads of legal entities. In case of repeated non-compliance: fines for employees and individual enterprises from €80 up to €600 and between €300 and €600 for heads of legal	**Explosives for civil uses**: criminal monetary penalties and/or imprisonment are foreseen. **Medical devices, pyrotechnics, electrical equipment under EMC, radio and telecom equipment under R&TTE-RED, recreational craft, marine equipment, motor vehicles and tractors, non-road mobile machinery, fertilisers, other products under GPSD, biocides, textile and footwear labelling crystal glass**: no criminal sanctions

MS	**ADMINISTRATIVE PENALTIES** - Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES** - (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	entities. **Electrical equipment under EMC, radio and telecom equipment under RR&TTE — RED:** fines from €750 up to €1,450. In case of repeated non-compliance: fines from €1,400 up to €3,000. Fines of up to 3% of the total annual income from activity relating to electronic communications. **Recreational craft:** fines for employees and individual enterprises from €300 up to €850 and between €600 and €1,450 for heads of legal entities. **Measuring instruments, non-automatic weighing instruments, pre-packaged products and units of measurement:** fines on natural persons from €30 up to €300. Fines on legal persons or managers of foreign company branches in the Republic of Lithuania or persons authorised thereby between €100 and €550. In case of repeated non-compliance: fines on natural persons from €300 up to €560. Fines on legal persons or managers of foreign company branches in the Republic of Lithuania or persons authorised thereby between €550 and €1500. **Biocides**: fines from €340 up to €4,300	
LU	**Medical devices, fertilisers**: fines up to €60 **Cosmetics**: no administrative fines are foreseen **Toys, PPE, construction products, aerosol dispensers, simple pressure vessels, transportable pressure equipment, machinery, lifts, cableways, equipment and protective systems in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment, radio and telecom equipment, eco-design and energy labelling, tyre labelling, textile and footwear labelling**: fines up to €15,000 **Noise emissions for outdoor equipment, electrical and electronic equipment under RoHS and WEEE and batteries, chemicals:** no administrative fine is foreseen.	**Medical devices**: fines up to €25,000 and/or imprisonment up to 1 year **Cosmetics**: no criminal sanctions foreseen **Toys, PPE, construction products, aerosol dispensers, simple pressure vessels, transportable pressure equipment, machinery, lifts, cableways, equipment and protective systems in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment, radio and telecom equipment, eco-design and energy labelling, tyre labelling, textile and footwear labelling**: maximum sanction €1,000,000 + up to 3 year imprisonment **Noise emissions for outdoor equipment:** fines up to €20,000 and/or up to 6 months imprisonment **Electrical and electronic equipment under RoHS and WEEE and batteries**: fines up to €100,000 and/or up to 6 months imprisonment **Chemicals, biocides**: fines up to €500,000 and/or up to 3 years

MS	**ADMINISTRATIVE PENALTIES** - Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES** - (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
		imprisonment **Fertilisers:** fines up to €7,500 and/or up to 6 months imprisonment
LV	Fines **CE marking**: Fines up to €4,200 for legal persons (€350 for natural persons). **Fertilisers, toys, PPE, construction products, aerosol dispensers, simple pressure vessels, transportable pressure equipment, machinery, lifts, cableways, noise emissions for outdoor equipment, appliances burning gaseous fuels, measuring and weighting instruments, electrical equipment, crystal glass, radio and telecom equipment, electrical appliances, eco-design and energy labelling, efficiency requirements for hot boilers, tyre labelling, recreational crafts, marine equipment, motor vehicles and tractors, non-road mobile machinery, textile and footwear, medical devices, cosmetics, chemical substances, biocides**: fines up to €14,000	
MT		Penalties for infringements of the Product Safety Act and/or the Pesticides Control Act only come into force following conviction by the law courts. Both laws mentioned fall under the criminal code and the penalties therein are commensurate with other criminal legal instruments, including fines, increasing in the case of subsequent indictment following the first and prison terms.
NL	Fines that may be: - *Variable*, based, for instance, on a percentage of the company's annual turnover up to €80,000. - *Fixed* for a specific infringement (around €600 for consumer products for a company with less than 50 employees up to €1,200 for larger companies). Where a fixed penalty applies, if it is a second or recurrent offence, the penalty may be doubled or tripled. **CE marking:** fines up to €1,050. **Crystal glass, cosmetics, toys, PPE, toys, machinery, appliances burning gaseous fuels, electrical appliances, eco-design, biocides, textile and footwear labelling:**	MSAs can impose fines under the criminal law, imprisonment, obligation to close down the company. **CE marking:** punishable by imprisonment not exceeding 2 years or a fine up to €74,000. **Crystal glass, cosmetics, toys, PPE, toys, machinery, appliances burning gaseous fuels, electrical appliances, eco-design, biocides, textile and footwear labelling:** imprisonment is also possible.

MS	**ADMINISTRATIVE PENALTIES** - Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES** - (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	fines up to €70,000 **Appliances burning gaseous fuels**: fines up to €810,000 or 1% yearly turnover **Motor vehicles, construction products, transportable pressure equipment, cableways, noise emissions for outdoor equipment, pyrotechnics, explosives for civil uses, electrical and electronic equipment, chemical substances, eco-design, tyre labelling, recreational craft, marine equipment, non-road mobile machinery, biocides, construction products, recreational craft:** no fixed maximum level **Measuring instruments, electrical equipment, radio and telecom equipment:** fines up to €900,000	
PL	**Medical devices, cosmetics, PPE, aerosol dispensers Machinery Cableways Noise emissions for outdoor equipment Appliances burning gaseous fuels, electrical and electronic equipment under RoHS and WEEE and batteries, chemicals, biocides, eco-design and energy labelling, motor vehicles and tractors, non-road mobile machinery, tyre labelling, crystal glass:** no administrative fine is foreseen. **Toys, construction products, simple pressure vessels and pressure equipment, transportable pressure equipment, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, measuring instruments, electrical equipment under EMC, radio and telecom equipment under R&TTE – RED, electrical appliances and equipment under LVD, recreational craft, marine equipment, fertilisers, textile and footwear, other products under GPSD:** fines up to €24,000	**Medical devices**: fines up to €270,000 and/or imprisonment up to 2 years **Toys, construction products, simple pressure vessels and pressure equipment, transportable pressure equipment, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, measuring instruments, electrical equipment under EMC, radio and telecom equipment under R&TTE – RED, electrical appliances and equipment under LVD, recreational craft, marine equipment, fertilisers, other products under GPSD:** no criminal penalties are foreseen. **Cosmetics, chemicals, biocides**: criminal monetary sanctions and/or imprisonment are foreseen **PPE, aerosol dispensers machinery cableways noise emissions for outdoor equipment appliances burning gaseous fuels, electrical and electronic equipment under RoHS and WEEE and batteries, eco-design and energy labelling, tyre labelling, motor vehicles and tractors, non-road mobile machinery, textile and footwear, crystal glass:** criminal monetary sanctions are foreseen (no imprisonment)
PT	Fines **Medical devices and cosmetics:** fines to be applied in accordance with Decree Law	Criminal penalties are foreseen for product non-compliance

MS	**ADMINISTRATIVE PENALTIES** - Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES** - (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	No 145/2009 amounts between €2,000 and €45,000. **CE marking**: Fines up to €37,890; however, major penalties are to be introduced. **Toys, PPE, Aerosol dispensers, simple pressure vessels, machinery, pyrotechnics, appliances burning gaseous fuels, electrical appliances, chemical substances, eco-design, tyre labelling, non-road mobile machinery, textile and footwear labelling, crystal glass**: fines up to €25,000.	
RO	**Medical devices, cosmetics, construction products, electrical equipment under EMC, radio and telecom equipment under R&TTE – RED, chemicals, other products under GPSD, biocides:** administrative fine is foreseen. **Toys, non-road mobile machinery:** fines from €330 up to €2,200 **PPE, aerosol dispensers, machinery, lifts, cableways, noise emissions for outdoor equipment, electrical appliances and equipment under LVD, recreational craft:** fines from €550 up to €2,200 **Transportable pressure equipment, appliances burning gaseous fuels**: fines from €1,100 up to €4,400 **Simple pressure vessels and pressure equipment:** fines from €440 up to €2,200 **Equipment and protective systems intended for use in potentially explosive atmospheres, explosives for civil uses:** fines from €550 up to €2,645 **Pyrotechnics, measuring instruments:** fines from €110 up to €2,200 **Electrical and electronic equipment under RoHS and WEEE and batteries:** Fine from €2,238 up to €111,192 and possible temporary suspension of the activity. **Eco-design and energy labelling**: fines from €2,200 up to €11,000 **Tyre labelling**: fines from €1,985 up to €4,400 **Motor vehicles and tractors**: fines from €110 up to €11,000 **Fertilisers**: fines from €1,100 up to €11,000 **Textile and footwear labelling, crystal glass:** fines from €220 up to €2,200	If the non-conformities of the products lead to death or acute injuries the Criminal Code applies. **CE marking:** there is a general provision stipulating "material, civil and contravention or criminal liability".

MS	**ADMINISTRATIVE PENALTIES** - Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES** - (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	CE marking: fine up to €1,200.	
SE	Fines are foreseen for all sectors. **CE marking:** Fines **Cosmetics**: fines up to €1,000 **Toys, other products under GPSD**: fines from €500 up to €500,000 limited to max 10% of annual sales **PPE, machinery, equipment and protective systems for use in potentially explosive atmospheres:** fines up to €100,000 + a percentage of sales revenues **Construction products**: fixed-amount fine established every year **Lifts, cableways:** fines up to €235,000	Fines and – in serious cases – even imprisonment are foreseen for **all** sectors except for: toys, PPE, eco-design and energy labelling, tyre labelling, other products under GPSD, textile and footwear labelling, crystal glass.
SI	**Medical devices**: fines from €1,000 to €150,000 for legal entities and from €300 to €7,000 for individuals **Cosmetics**: fines from €500 to €40,000 for legal entities and from €200 to €5,000 for individuals **Toys**: fines from €800 to €40,000 for legal entities and from €200 to €3,000 for individuals **PPE, construction products, aerosol dispensers, simple pressure vessels, transportable pressure equipment, machinery, lifts, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment under EMC, radio and telecom equipment under R&TTE-RED, electrical appliances and equipment under LVD, electrical and electronic equipment under RoHS and WEEE and batteries, chemicals, eco-design and energy labelling, tyre labelling, recreational craft, marine equipment, motor vehicles and tractors, non-road mobile machinery, textile and footwear labelling, crystal glass:** fines from €2,000 to €40,000 for legal entities and from €200 to €4,000 for individuals. **Cableways**: fines from €2,500 to €40,000 for legal entities and from €200 to €1,000	Payment orders, reminders and warnings of an offence committed. Fines and imprisonment are foreseen for **all** sectors. The only exception is represented by textile and footwear labelling and crystal glass, where imprisonment is not foreseen.

MS	**ADMINISTRATIVE PENALTIES** - Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES** - (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	for individuals **Fertilisers**: fines from €830 to €20,000 for legal entities and from €200 to €2,000 for individuals **Other products under GPSD**: fines from €1,000 to €40,000 for legal entities and from €100 to €2,000 for individuals **CE marking:** Monetary fines up to €15,000.	
SK	Fines **CE marking**: fines up to €167,000; these fines can be doubled if the abuse is repeated.	The registration of the CE marking as a Community mark enables criminal sanctions.
UK	Oblige economic operators to inform consumers The level of the financial penalty imposed is a matter for the Courts. Administrative fines are foreseen for **all** sectors, except from: cosmetics, toys, PPE, noise emissions for outdoor equipment, appliances burning gaseous fuels, electrical equipment under EMC, radio and telecom equipment under R&TTE-RED, electrical appliances and equipment under LVD, recreational craft. **CE marking**: the registration of the CE marking would entail civil sanctions (infringement action as set by the Court).	Fines and imprisonment are foreseen for **all** sectors. Successful prosecutions can result in monetary penalties or, in the most extreme cases, imprisonment. **CE marking**: the registration of the CE marking would entail criminal sanctions (a maximum of 10 years imprisonment and/or a fine on conviction on indictment).

8.8 Overview tables of laboratories and powers of MSAs and Customs

The following tables show the presence ("√") or the lack (blank cell) of laboratories and powers available to MSAs and Customs Authorities (CA) in each Member State. Where information was not available, cells are filled with "-". The column headings report the number of sectors as per the 2016 EC template provided to Member States for filling the national reports,[436] as reported in Table 4-1.

The tables are filled on the base of multiple sources such as the targeted surveys, ad-hoc requests sent to IMP-MSG representatives in each Member State and from the data available in national programmes and other publicly available documents.

Table 4-34 – Laboratories of national MSAs and Customs Authorities[437]

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	MSA		-	-	-	-	-	-	-	-	-		-	-	-	-	-	-		-		-	-		-		-	-	-	-	-	-	-	-
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436 Sectors: 1) Medical devices, 2) Cosmetics, 3) Toys, 4) PPE, 5) Construction products, 6) Aerosol dispensers, 7) Simple pressure vessels and pressure equipment, 8) Transportable pressure equipment, 9) Machinery, 10) Lifts, 11) Cableways, 12) Noise emissions for outdoor equipment, 13) Equipment and protective systems intended for use in potentially explosive atmospheres, 14) Pyrotechnics, 15) Explosives for civil uses, 16) Appliances burning gaseous fuels, 17) Measuring instruments, 18) Electrical equipment under EMC, 19) Radio and telecom equipment under RTTE – RED, 20) Electrical appliances and equipment under LVD, 21) Electrical and electronic equipment under RoHS and WEEE and batteries, 22) Chemicals , 23) Eco-design and energy labelling, 24) Tyre labelling, 25) Recreational craft, 26) Marine equipment, 27) Motor vehicles and tractors, 28) Non-road mobile machinery, 29) Fertilisers, 30) Other consumer products under GPSD, 31) Biocides, 32) Textile and footwear labelling, 33) Crystal glass.

437 No information was available for EL, HU, IT, PT, SK.

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
CZ	MSA		√	√	√		√					-	√		√	√			√		√		√						√	√	√			
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	CA	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
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LT	MSA		-	-	√	-	-	-	-	√	√	√	-	-				√	√	√	-	-	-	-	-		-	-	-	-	√	-	-	
	CA																																	
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LV	MSA													-	-	-	-		-											√	-			
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MT	MSA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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	CA																																	
PL	MSA		√	√												√		√	√	√		√	√								√		√	
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SI	MSA																	√																
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UK	MSA	-							-	√	√	-		√		√											-	-	-	-	-		-	-
	CA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Table 4-35 – MSAs' power of inspection: Carry out sector inquiries[438]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	√	-	√	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	-			√	√	√	√	√
CY	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√
DE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	√	-	√	-	√
DK	-	-	√	√	√	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	-	-
HR	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

438 No information was available for EL, FR, HU, IT, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
IE	√	√															√				√	√											
LT	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	-	√	√	√	√	√
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-
LV	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	√	-	-	-	√	-	-
NL	-	√	√	√	√	√	-	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	√	√	√
PL	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE	√	√	√	√	√	-	√	-	√	-	-	-	√	-	-	-	√	√	√	√	-	√	√	√	√	√	-	-	-	-	√	√	√
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	√	√	√	-	√	√	√	√
UK	-	√	√	√	√	-	√	-	√	√	-	√	√	-	-	√	√	√	√	√	√	√	√	-	√	-	-	-	-	√	√	-	-

Table 4-36 - MSAs' power of inspection: Do mystery shopping[439]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
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439 Information was not available for DE, EL, ES, FR, HR, HU, MT, PL, PT, RO, SK.

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CY	√	√	√	√	-	-	√	-	√	√	-	√	√	√	√	-	√	-	√	-	-	-	-	√	√	-	-	-	-	√	-	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	√	-	√	√	√	√	√	√
DK	-	-	-	√	-	√	√	√	√	√	√	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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IT	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-
LT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
LU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-
LV	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	-	√	-	√	√	√	√	√	√	√	√	-	√	√	-	√	√	√
MT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
NL	-	√	√	√	√	√	-	√	√	-	√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	-	-	-	√	√	√
SE	-	√	√	√	√	-	√	-	√	√	√	-	√	-	-	-	√	√	√	√	-	√	√	√	-	-	-	-	-	√	√	√	√
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	-	√	√	√	√	-	-	-	√	√
UK	-	√	√	√	√	-	√	-	√	√	-	√	√	-	-	√	√	√	√	√	√	√	√	-	√	-	-	-	-	√	√	-	-

Table 4-37 - MSAs' power of inspection: Request for information/cooperation by any possible natural or legal person[440]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	√	-	√	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√
CY	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
DE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	√	-	√	-	√
DK	√	-	√	√	√	√	√	√	√	√	√	-	√	√	-	√	√	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	√	√	√	√	-	-	-	-	-	-
HR	√	√	√	-	-	-	-	-	-	-	-	√	√	-	√	-	√	-	√	-	-	√	-	-	√	√	-	-	-	-	√	-	√
IE	√	√															√				√	√											
IT	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
LT	√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	√	√
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-

440 Information was not available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
LV	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	√	-	√	-	√	-	-
NL	-	√	√	√	√	√	-	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	√	√	√
PL	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE	√	√	√	√	√	-	√	-	√	-	-	-	√	-	-	-	√	-	√	-	-	√	√	√	√	√	-	-	-	√	√	√	√
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	√	√	√	-	√	√	√	√
UK	-	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	-	-	-	√	√	-	-

Table 4-38 - MSAs' power of inspection: Seize and detain products[441]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	√	-	√	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG		√								√							√					√				-			√		√		
CY	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	√
DE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	√	-	√	-	√

441 Information was not available for EL, FR, HU, IT, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
DK	-	-	√	√	√	√	√	√	√	√	√	-	√	√	-	√	√	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	-	-
HR	-	-	-	√	√	√	√	√	√	-	-	-	√	-	√	√	-	√	-	√	√	-	√	√	-	-	-	-	-	√	-	√	-
IE	√	√															√					√											
LT	√	-	-	√	-	-	-	-	√	-	-	-	-	-	√	√	-	√	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-
LV	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	-	√	-	√	√	√	√	√	√	√	√	-	√	√	-	√	√	√
NL	-	√	√	√	√	√	-	√	√	-	√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	-	-	-	√	√	√
PL	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE	√	√	-	-	√	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	√	√	√	√	-	-	-	-	-	√		
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	√	√	√	-	√	√	√	√
UK	-	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	-	-	-	√	√	-	-

Table 4-39 - MSAs' power of inspection: Seize documents[442]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	√	-	√	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG						√				√	√						√							√		-				√		√	√
CY	√	-	√	-	-	√	-	√	-	-	√	-	-	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
DE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	√	-	√	-	√
DK	-	-	√	√	√	√	√	√	√	√	√	-	√	-	-	√	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	-	-
HR	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	√	√	√	√	√	√
IE	√	√															√				√	√											
LT	-	-	-	√	-	-	-	-		√	√	√	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-
LV	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	√	-	-

442 No information was available for: EL, FR, HU, IT, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
NL	-	√	√	√	√	√	-	√	√	-	√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	-	-	-	√	√	√
PL	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE	√	√	-	√	√	-	√	-	√	√	√	-	√	-	-	-	√	-	-	-	-	√	√	√	√	-	-	-	-	-	√		
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	√	√	√	-	√	√	√	√
UK	-	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	-	-	-	√	√	-	-

Table 4-40 - MSAs' power of inspection: Take samples for free[443]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	√	-	√	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√	√																				√				-			√		√		
CY	√	-	√	-	-	√	-	√	-	-	√	-	-	√	√	√	√	√	√	√	-	-	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	-	-	-	√	-	√	-	√	√	√	√	√	√	√	√	-	-	-	-	-	√	√	√	√	√
DE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	√	-	√	-	√
DK	-	-	√	√	√	√	√	√	√	√	√	-	√	√	-	√	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

443 No information was available for EL, FR, HU, IT, MT, PT, RO, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	-	-	√	-	√	-	-
HR	√	√	√	√	√	√	√	√	√	-	-	-	-	-	√	√	-	√	√	√	√	√	-	√	-	√	-	-	-	√	√	√	√
IE	√	√															√				√	√											
IT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-
LT	√	√	√	√	√	√	√	√	√	-	-	-	√	√	-	√	√	√	√	√	√	√	√	√	√	-	-	√	-	√	√	√	√
LU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-
LV	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	-	√	-	√	√	√	√	√	√	√	√	-	√	√	-	√	√	√
NL	-	-	-	-	√	-	-	√	-	-	√	√	-	√	√	-	√	√	√	-	√	√	-	√	√	√	√	-	-	-	√	-	-
PL	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE	√	√	√	√	√	-	√	-	√	√	√	-	√	-	-	-	√	√	√	√	-	√	-	-	√	√	-	-	-	√	√	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	√	√	√	-	√	√	-	√
UK	-	-	-	-	-	-	-	-	-	√	-			-	√	-	√	-		-	√	√	-	-	-	-	-	-	-	-	√	-	-

Table 4-41 - MSAs' power of inspection: Make use of test reports by MSAs in other EU countries[444]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	-	-	-	-	-	√	√	√	√	√	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-				√	√		
CY	√	√	√	-	-	√	-	√	-	-	√	-	-	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	-	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
DE	√	-	√	√	√	√	√	√	√	√	-	√	√	√	√	√	-	-	-	√	-	√	√	-	√	-	-	-	√	-	√	-	-
DK	-	-	√	√	√	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
FI	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	-	-	√	-	√	-	-
HR	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	√	-	-	-	-	-	√	√	-	-	-	-	-	-	-
IE	√	√															√																
LT	-	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	√	-	√	-	√	√	√	√
LU	-	-	√	√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-
LV	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	-	√	-	√	√	√	√	√	√	√	√	√	√	√	-	√	√	√
MT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

444 Information was not available for EL, ES, FR, HU, IT, PT, RO, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
NL	-	√	√	√	-	√	-	-	√	-	-	-	-	-	-	√	√	√	√	√	-	-	√	-	-	-	-	-	-	-	-	√	√
PL	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SE	√	√	-	√	√	-	√	-	√	-	-	-	√	-	-	-	√	-	-	-	-	√	√	√	√	√	-	-	-	-	√	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	-	-	-	√	√	-	-

Table 4-42 - MSAs' power of sanction: Destroy products[445]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	-	-	-	√	√	-	-	√	√	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√	√	√	√	√		√	√	√	√		√	√	√	√	√	√	√	√	√	√	√	√		√	-			√	√	√		
CY	√	√	√	√	-		√		√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ			√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√				√		√	√
DE	√		√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	-	√	-	-	√	√	√	-	-	-	√	-	-	-	√
DK		-		√		√	√	√	√	√	√	-	√	√	-	√	√				-	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-		√	√	-	-	-	-	-	-	-	-	-	-	√	-

445 No information was available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
FI	-	√	√	√		-	√		√	-	-	√	√			√	-	√	-	√	√	√	√	-	√	-	-	-	-	√	√	-	-
HR	√	√	√	√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	-	√	√	√	√	√			√	√	√	√	√	√	√
IE	√	√																				√											
IT	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-
LT		√	√	√	√	√	√	√				√	√	√	√	√				√	√	√	√	√			√	√	√	√	√	√	√
LU		-																			√								√				-
LV			√	√	√	√	√	√	√	√	√	√					√		√	√	√		√	√	√	√	√	√				√	√
NL	-	-	√	√	√	√	-	-	√		√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	√	-		√	√	√
PL		√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√			√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE		√	√	√	√		√		√	√	√		√	-	-	-	√					-			√		√		-		-		
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√
UK	-	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√		√	-	-	-	-	-	√	-	-

Table 4-43 - MSAs' power of sanction: Impose administrative economic sanctions (without resorting to national courts)[446]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√		√	-	-	-	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√		√	√	√	√	√
CY	√		√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
DE	-		-	-		√	√	√	-	-		√	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-
DK		-										-			-						-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-				-	-	-	-	-	-	-	-	-	-	-	-	-				-	-	-	-	-	-	-	-	-	-		-
FI		√			√	-		√		-	-			√	√		-		-		√	√		-	√	-	-	-	-		√	-	-
HR		√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√		√	√	√	-	√			-	-	-	√	√	√	√
IE	√																				√												
IT	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-
LT	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	-

446 No information was available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
LV	√	√	√	√	√	√	√	√	√	√	√	√					√		√	√	√	√	√	√	√	√	√	√			√	√	√
NL	-	-	√	√	√	√	-	-	√		√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	√	-		√	√	√
PL		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	-	√	-	√	√	√	√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE		√	√	√	√		√		√	√	√		√	-	-	-	√				√	-	√	√	√				-	√	-	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-				√	√	√	-	√	√	-		√	√	√	√	√				√	√	√			-	-	-	-	-	√	-	-

Table 4-44 - MSAs' power of sanction: Impose compensation for consumers/users of non-compliant products[447]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		-		-	-		-		-	-	-	-	-	-	-	-
BE	-	-	√	√		√	-	-	-	√	√	-	-	√	√	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG										√																-							
CY					-			√													-		-			-	-	-	-			-	-
CZ																												√					
DE	√		-	-		-	-	-	√	-		√	-	-	-	-			-	√	-	-			√	-	-	-		-	-	-	

447 No information was available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
DK		-										-			-						-	-	-	-	-	-	-	-	-	-	-	-
EE																																	
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-		√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI						-	√			-	-		√		√		-	√	-	√				-		-	-	-	-			-	-
HR		√	√	-	-	-	-	-	-	-	-	√				-	-	-	-	-	-	√	-	-			-	-	-	-	√	-	√
IE	√																																
IT	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
LT									√	√	√						√																√
LU		-																				-											-
LV																																	
NL	-	-			-		-	-			-	-	-	-	-		-	-	-		-	-		-	-	-	-	-	-				
PL			√		√		√			√	-	√	√	√	√	√	√	√	√	√							-		-	√			
RO																																	
SE		-	-	-										-	-	-	-	√	√	√		-							-	√	-	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-							-			-												√			-	-	-	-	-		-	-

Table 4-45 - MSAs' power of sanction: Impose provisional measures pending investigations[448]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√		√	-	-	-	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	-	√		√	√	√	√	√
CY	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√
DE	√		√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	-	√	-	-	√	√	√	-	-	-	√	-	-	-	√
DK		-										-		√	-		√				-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-		√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI	√	√	√	√	√	-	√	√	√	-	-	√	√	√	√	√	-	√	-	√	√	√	√	-	√	-	-	-	-	√	√	-	-
HR	√	√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	-	√			-	-	-	√	√	√	√
IE	√	√															√				√												
IT	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-
LT	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√		√	√	√	√	√	√	√	√
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√		√	√	√	-

448 No information was available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
LV	√	√	√	√	√	√	√	√	√	√	√	√					√		√	√	√	√	√	√	√	√	√	√			√	√	√
NL	-	-			-		-	-			-	-	-	-	-		-	-	-		-	-		-	-	-	-	-	-				
PL	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√			√
RO																																	
SE	√	√	√	√	√		√		√			√	√	-	-	-	√	√	√	√		-					√	√	-	√	-	√	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-				√		√	-			-			√	√		√				√	√	√			-	-	-	-	-	√	-	-

Table 4-46 - MSAs' power of sanction: Publish decisions on restrictive measures[449]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		-		-	-		-		-	-	-	-	-	-	-	-
BE	-	-	√	√		√	-	-	-	√	√	-	-	√	√	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√		√	-	√			√		√	√
CY	√		√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√		√	√		√		√	√	√	√
DE	√		√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	-	√	-	-	√	√	√	-	-	-	√	-	-	-	√
DK		-	√	√	√	√	√	√	√	√	√	-	√	√	-	√				√	-	-	-	-	-	-	-	-	-	-	-	-	-

449 No information was available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
EE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
FI	√	√	√	√	√	-	√	√	√	-	-	√	√	√	√	√	-	√	-	√	√	√	√	-		-	-	-	-	√	√	-	-
HR	√	√	√	√	√	√	√	√	√	√	√	√				√	√	√	√	√	√	√	√	√			√	√	√	√	√	√	√
IE	√	√																			√												
IT	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-
LT	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√			√	√	√	√	√	√	√
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√		√	-
LV			√	√	√	√	√	√	√	√	√	√					√		√	√	√		√	√	√	√	√	√				√	√
NL	-	-	√	√	√	√	-	-	√		√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	√	-		√	√	√
PL	√		√	√	√	√	√		√	√	√	√	√	√	√	√	√	√		√					√	√	-	√	-	√			√
RO																			√														
SE	√	√	√	√	√		√		√	√	√	√	√	-	-	-	√	√	√	√		-			√	√	√	√	-	√	-	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-							-	√	√	-	√	√		√	√		√	√	√			√		√	-	-	-	-	-		-	-

Table 4-47 - MSAs' power of sanction: Recover from economic operators costs borne to test products found to be non-compliant[450]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	-	-	-	√	√	-	-	√	√	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√		√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√		√		√	-			√	√			√
CY		-	√	√	-		√		√	√	√	√	√	√	√	√	√	√	√	√	-		-	√	√	-	-	-	-	√		-	-
CZ	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	√	√		√		√	√
DE	√		√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	-	√	-	-	√	√	√	-	-	-		-	-	-	√
DK		-	√	√	√	√	√	√	√	√	√	-	√	√	-	√					-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-				-	-	-	-	-	-	-	-	-	-	-	-	-				-	-	-	-	-	-	-	-	-	-		-
FI	√	√	√	√	√	-	√	√	√	-	-	√	√	√	√	√	-	√	-	√	√	√	√	-	√	-	-	-	-	√	√	-	-
HR	-	√	√	√	√	√	√	√	√	√	-	√	√			√	√	√	-	√	√	√	-	√			-	-	-	√	√	√	√
IE	√	√																				√											
IT	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-
LT	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√			√	√	√	√	√	√	√
LU		-	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√			√	√	√	√	√	√		√		√	-

450 No information was available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
LV	√	√	√	√	√	√	√	√	√	√	√	√					√		√	√	√	√	√	√	√	√	√	√			√	√	√
NL	-	-			√		-	-			√	√	-	√	√		-	-	-		√	√		√	√	√	√	√	-				
PL	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	√	√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE		-	√	√	-		√		√	√	√		√	-	-	-	√	√	√	√		-			√	√			-	√	-	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-						√	-	√	√	-		√	√							√		√			-	-	-	-	-		-	-

Table 4-48 - MSAs' power of sanction: Sanction economic operators that do not cooperate[451]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	-	-	-	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√		√	√	√	√	√
CY	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
DE	√		√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	-	√	-	-	√	√	√	-	-	-	√	-	-	-	√
DK	√	-	√		√							-		√	-	√	√	√	√		-	-	-	-	-	-	-	-	-	-	-	-	-

451 No information was available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
EE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-		√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI	√					-				-	-						-		-					-	√	-	-	-	-			-	-
HR	-	√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	-	√			-	-	-	√	√	√	√
IE	√	√															√				√												
IT	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-
LT	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	√	√	√		√	√			√	√	√	√	√	√	√
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	-
LV	√	√	√	√	√	√	√	√	√	√	√	√					√		√	√	√	√	√	√	√	√	√	√			√	√	√
NL	-	-	√	√	√	√	-	-	√		√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	√	-		√	√	√
PL	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√			√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE	√	√	√	√	√		√		√	√	√	√	√	-	-	-	√	√	√	√		-	√	√	√	√	√	√	-	√	-	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√		√	-	-	-	-	-	√	-	-

Table 4-49 - MSAs' power of sanction: Shut-down websites[452]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		-		-	-		-		-	-	-	-	-	-	-	-
BE	-	-			√		-	-	-			-	-			-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG										√																-							
CY	√				-																-		-			-	-	-	-			-	-
CZ																																	
DE			-	-		-	-	-	-	-		-	-						-	-	-	-				-	-	-		-	-	-	
DK		-										-		-	-						-	-	-	-	-	-	-	-	-	-	-	-	-
EE	-	√	√																					-	-	-	-	-	√	√	-	√	√
ES	-	-				-	-	-	-	-	-	-	-	-	-	-	-	-				-	-	-	-	-	-	-	-	-	-		-
FI	-					-				-	-						-		-					-		-	-	-	-			-	-
HR		-	-	-	-	-	-	-	-	-	-	-				-	-	-	-	-	-	-	-	-			-	-	-	-	-	-	-
IE	√																																
IT	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
LT																																	
LU		-																															-

452 No information was available for EL, FR, HU, MT, PT, RO, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
LV			√	√	√	√	√	√	√	√	√	√					√		√	√	√		√	√	√	√	√	√				√	√
NL	-	-			-		-	-			-	-	-	-	-		-	-	-		-	-		-	-	-	-	-	-				
PL																											-		-				
SE		-												-	-	-	-					-			-				-	-	-	-	-
SI																																	
UK	-	√	√	√			√	-	√	√	-	√	√			√		√	√	√					√	-	-	-	-	-		-	-

Table 4-50 - MSAs' power of sanction: Take off or require to take off illegal content from a website[453]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BE	-	-			√		-	-	-			-	-			-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG			√	√	√		√	√	√			√	√	√	√	√	√	√	√	√	√		√		√	-							
CY	√				-											√		√		√	-		-			-	-	-	-		√	-	-
CZ		√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√				√	√		√	√	√		√	√
DE			-	-		-	-	-	-	-		-	-						-	√	-	-				-	-	-	-		-	-	-	-
DK	√	-										-		√	-		√	√	√		-	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	√	√

453 No information was available for EL, FR, HU, MT, PT, RO, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
ES	-	-				-	-	-	-	-	-	-	-	-	-	-	-	-				-	-	-	-	-	-	-	-	-	-		-
FI	-	√	√	√	√	-	√	√	√	-	-	√	√	√	√	√	-	√	-	√	√	√	√	-	-	-	-	-	-	√	√	-	-
HR	-	√	√	-	-	-	-	-	-	-	-	-				-	-	-	√	-	-	√	-	-			-	-	-	-	√	-	√
IE	√																																
IT	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
LT	√								√	√	√			√	√		√	√	√														√
LU		-	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√		√	√	√	√	√	√	√		√	√	√	-
LV			√	√	√	√	√	√	√	√	√	√					√		√	√	√		√	√	√	√	√	√				√	√
NL	-	-	√	√	√	√	-	-	√		√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	√	-		√	√	√
PL	√	√																									-		-				
SE	√	√	√											-	-	-	-	√	√	√		-	√	√	-				-	-	-	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-	√	√	√	√	√	√	-	√	√	-	√	√			√	√	√	√	√	√	√	√		√	-	-	-	-	-	√	-	-

8.9 Mapping of national reports

As already mentioned, we structured the mapping of national market surveillance reports following the EC template provided to Member States, which is reported in the table below. This is a non-exhaustive list of the sectors included in the scope of the Regulation.

Table 4-51 - Reference list of product sectors

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 emissions 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	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 R&TTE	Directive 1999/5/EC - Directive 2014/53/EU

Product sectors	*Relevant legislation*
– RED	
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. Chemical (Detergents, paints, persistent organic pollutants, fluorinated greenhouse gases, ozone depleting substances, etc.)	Regulation (EC) 648/2004, Directive 2004/42/EC, Regulation (EC) 850/2004
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. Recreational craft	Directive 1994/25/EC - Directive 2013/53/EU
26. Marine equipment	Directive 96/98/EC -Directive 2014/90/EU
27. Motor vehicles and tyres	Directive 2002/24/EC, Directive 2007/46/EC, Regulation (EC) 1222/2009
28. Non-road mobile machinery	Directive 97/68/EC
29. Fertilisers	Regulation (EC) 2003/2003
30. Other consumer products under GPSD (optional)	Directive 2001/95/EC

We organised the data collection by using an excel file where each sheet corresponded to one of the 30 product sectors specified in the EC template. Each sheet has then been divided to collect:

1) **Information relating to the resources available to MSAs** over the period 2010-2013 for each Member State, and namely:

- Budget available to MSAs in nominal terms (€);
- Budget available to MSAs in relative terms (% of total national budget);
- Staff available to MSAs (FTE units);
- Number of inspectors available to MSAs (FTE units).

2) **Information relating to the market surveillance activities** performed over the period 2010-2013 in each Member State, and namely:

- Number of product related accidents / users' complaints;

- Number of substantiated complaints by industry concerning unfair competition;
- Number of inspections (total number);
- Number of reactive inspections;
- Number of self-initiated inspections;
- Number of inspections prompted by Customs;
- Number of inspections based on:
  - Tests performed in laboratories;
  - Physical checks of products;
- Number of inspections resulting in:
  - Finding of non-compliance;
  - Corrective actions taken by economic operators ("voluntary measures");
  - Restrictive measures taken by MSA;
  - Application of sanctions/penalties;
- Number of inspections where other Member States were invited to collaborate.

However, in light of all the limitations reported, the available information is so scattered and rare that these data are not comparable across countries or across sectors.

The table below presents in detail the sectoral coverage provided by the national reports. An "N" indicates sectors excluded from a national report. DE and LT are not included as they did not follow the EC template when providing information on market surveillance activities.

Table 4-52 - List of sectors covered by each national report

MS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
AT													N								N			N				N	N	
BE	N	N						N			N			N	N		N								N	N				
BG		N																						N		N				
CY		N										N					N				N	N		N	N	N		N	N	N
CZ																										N	N	N		
DK															N									N						N
EE						N						N											N	N				N		
EL	N	N										N	N													N	N	N		
ES	N	N	N	N	N	N		N			N	N	N	N	N	N	N	N	N		N	N	N	N	N	N		N	N	N
FI																												N		
FR																								N				N		
HR	N					N	N	N		N	N	N	N	N	N	N		N			N		N	N	N	N	N	N		
HU						N					N														N					
IE					N	N					N	N						N	N						N	N	N	N		
IT					N	N	N	N		N	N		N			N		N			N	N		N	N		N	N	N	
LU	N	N			N							N		N	N						N	N		N	N	N	N	N	N	

LV																													
MT																							N				N		N
NL								N			N	N											N		N		N		N
PL																							N			N	N		N
PT								N		N												N	N	N			N		
RO	N	N																											
SE																													
SI																							N						N
SK						N	N	N	N	N		N	N					N	N		N			N		N		N		N
UK											N						N					N		N	N	N			N	

Data on market surveillance activities implemented for each sector are not always available in the national reports. This makes unreliable any comparisons between countries and sectors over the period 2010-2013. The table below shows examples of the extent of gaps in data availability by providing the number of Member States reporting data on some indicators of market surveillance activities.

Table 4-53 - Number of Member States reporting data on accidents, sanctions and restrictive measures

	Number of Member States reporting data on:		
Product sectors	*Accidents*	*Application of sanctions/ penalties*	*Restrictive measures*
Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	16	12	14
Cosmetics	12	12	14
Toys	15	18	20
Personal protective equipment	13	16	16
Construction products	14	15	1
Aerosol dispensers	10	9	11
Simple pressure vessels and pressure equipment	10	11	12
Transportable pressure equipment	7	11	13
Machinery	15	15	0
Lifts	8	9	7
Cableways	7	9	7
Noise emissions for outdoor equipment	7	10	12
Equipment and protective systems intended for use in potentially explosive atmospheres	9	9	10
Pyrotechnics	13	15	16
Explosives for civil uses	11	12	14
Appliances burning gaseous fuels	12	15	16
Measuring instruments, non-automatic weighing instruments, pre-packaged products and units of measurement	12	17	15
Electrical equipment under EMC	7	13	14

Radio and telecom equipment under R&TTE RED	14	17	18
Electrical appliances and equipment under LVD	16	17	19
Electrical and electronic equipment under RoHS and WEEE and batteries	8	10	12
Chemical substances under REACH and Classification and Labelling Regulations and other chemicals (detergents, paints, persistent organic pollutants, fluorinated greenhouse gases, ozone depleting substances, etc.)	0	14	15
Eco-design and energy labelling; efficiency requirements for hot boilers fired with liquid or gaseous fuels	11	17	19
Tyre labelling	0	3	3
Recreational craft	6	11	9
Marine equipment	8	9	9
Motor vehicles and tractors	3	3	4
Non-road mobile machinery	2	4	4
Fertilisers	11	14	12
Other consumer products under GPSD (optional)	13	12	15

8.10 Mapping of national programmes

As already mentioned, we followed the EC template for the mapping of national market surveillance programmes. More in detail, we organised the data collection process by using an excel file, in which columns reported information corresponding to the sections of the EC template and rows related to Member States. This allowed us a cross-country comparison of market surveillance implementation. An example of the final output is provided at the end of this section.

The first part of the national programmes provides information on the **organisation and structure** of market surveillance at national level, and namely on:

- **National MSAs**, their competences/responsibilities (either sector-specific or horizontal) and the available resources in terms of budgets, staff, and technical means.
- **Coordination and cooperation mechanisms between MSAs**: evidence of permanent ad-hoc bodies for coordinating MSAs, with details on the bodies' composition, members, decision-making mechanisms, working practices, responsibilities and core tasks; mechanisms in place to ensure cooperation among MSAs such as bilateral agreements, for a, joint actions and procedures for information sharing.

- **Cooperation between national MSAs and Customs**: identification of the existing mechanisms (e.g. regular dialogue, joint actions, communication on an ad-hoc basis); other existing cooperation mechanisms such as working groups, ad-hoc permanent bodies and bilateral agreements;

- **RAPEX**: information on the authorities responsible for managing the system; details on how and for which product sectors MSAs use the RAPEX notification system.

- **ICSMS**: information on the authorities responsible for managing the system; details on how and for which product sectors MSAs use the ICSMS notification system.

- **General description of market surveillance activities and relevant procedures**: approach (reactive vs proactive) and criteria at the basis of these approaches (e.g. risk assessment, users' complaints, notifications from other authorities or Customs, press releases, specific strategies); information on the forms of surveillance (e.g. documentary checks, inspections, laboratory testing); evidence of procedures for dealing with complaints, for monitoring accidents, for warning users of dangerous products; description of any monetary, administrative and criminal penalties available to national MSAs; mechanisms for ensuring the involvement of businesses and consumers in activities related to market surveillance.

- **General framework of cooperation with other Member States and non-Member States**: description of any international partnerships for market surveillance that MSAs engage in with other EU Member States or third countries;

- **Evaluation of market surveillance actions and reporting**: description of the evaluation and monitoring of market surveillance by MSAs at the national level, including timing, objectives and criteria of the evaluation.

- **Horizontal activities planned for the relevant period**: description of any changes in the national market surveillance structure; identification of EU projects for market surveillance; description of any update of the risk assessment methodology for market surveillance.

The second section of the EC template for national programmes aims to provide information about the market surveillance activities carried out in the specific product areas covered by the Regulation. More in detail, Member States are asked to report on the relevant MSAs for the sector, on their specific procedures, activities, and strategies, and on their reporting practices.

Finally, we analysed the sectoral programmes only when information about the general market surveillance frame was not available, to draw a general overview of its implementation at national level.

8.11 Evaluation grids

The study methodology is based on the so-called "evaluation grids".

The evaluation grids present all the elements of our methodology, and namely:

- The evaluation questions;
- The judgement criteria used to specify the focus of the evaluation questions;
- The analytical approach indicating the type of analysis performed in order to answer the evaluation questions, based on the judgement criteria;
- The indicators used to evaluate the achieved results as well as to signal potential shortfalls;
- The sources of information, including both primary sources (i.e. stakeholders) that directly provide data and information on the specific issue, and secondary sources that are based on documents, publications, reports or tools that analyse or comment on existing data or information.

Moreover, they include specific reference to the questions (Q) of the targeted surveys (TS),[454] the interviews (I) and the public consultation (PC)[455] that fed the answers to the evaluation questions.

The evaluation grids are presented below.

454 "TS1" stands for the targeted surveys designed for Public Authorities (i.e. MS coordinating authorities, MSAs and Customs). "TS2" stands for the targeted surveys designed for economic operators, industry associations, consumer and user associations.

455 When referring to the public consultation, we refer to the Public consultation launched by the Commission under the initiative "Internal Market for Goods – Enforcement and Compliance".

Criterion	*Effectiveness*			
Evaluation questions	EQ1. How effective was the measure as a mechanism and means to achieve a high level of protection of public interests, such as health and safety in general, health and safety at workplace, the protection of consumers, protection of the environment and security? What have been the quantitative and qualitative effects of the measure on its objectives? EQ2. How effective was the measure as a mechanism and means to achieve a level playing field among businesses trading in goods subject to EU harmonisation legislation? What have been the quantitative and qualitative effects of the measure on its objectives? EQ3. Are the results in line with what foreseen in the impact assessment for the Regulation, notably as to the specific objectives of (i) enhanced cooperation among Member States/within Member States, (ii) uniform and sufficiently rigorous level of market surveillance, (iii) border controls of imported products? EQ4. Are there specific forms of the implementation of the Regulation at Member State level that render certain aspects of the Regulation more or less effective than others , and – if there are – what lessons can be drawn from this? EQ5. To what extent the different implementation (i.e. discrepancies in the implementation) of the initiative in Member States impacted the effectiveness of the measures on the objective?			
Understanding the questions	Questions under this criterion are focused on the following aspects: - Evaluating how far the provisions under the scope of the evaluation and namely those under Ch. III (market surveillance and controls) and under Ch. V (financing) contributed to achieve the **overarching objectives** of the Regulation (Q1 and Q2) - Identifying whether the Regulation is performing in line with expectations (as defined in its IA) especially as regards **cross-border controls** (Q3) - Identifying relevant aspects in the **national implementation** of the Regulation that impact its effectiveness (Q4 and Q5)			
Focus of the question	*Judgement criteria*	*Analytical approach*	*Indicators and descriptors*	*Sources*
Q1. a) Effectiveness towards achieving the objective of protection of public interests b) Quantitative and qualitative effects on this objective	Increased protection of public interests	a) Desk and field research to provide an analysis on: • Trends in accidents; • Emerging safety, health and environmental risks; • Scale and perception of stakeholders of non-compliant non-food products circulating in the EU. b) Correspondence matrix between the Regulation, the main issues/risks in the market of non-food products and the results of the Regulation in preventing/solving those issues.	• Trends in the number of accidents related to non-food products before and after the implementation of the Regulation as reported by stakeholders and quantitatively/qualitatively assessed in the literature; • Number of non-food products covered by Regulation (EC) No 765/2008 recalled/withdrawn from the market or subject to corrective measures due to safety issues; • Number of and trends in RAPEX notifications related to non-food products covered by Regulation (EC) No 765/2008; • Stakeholders' perception of the extent of non-compliant products existing in the internal market.	Primary: • PC: section B1: Q1, Q2, Q3; section B2: Q4 • TS1: Q47, 48, 60-63, 65, 66; TS2: Q18, 19, 24-27, 42, 43. • I: Q7, Q9, Q17. Secondary: • RAPEX database; • EU IDB; • National market surveillance reports and programmes; • IA for Regulation (EC) No 765/2008.
Q2.	Increased level	a) Desk and field research to provide	• Trends in the EU non-food product market;	Primary:

Criterion	*Effectiveness*			
a)Effectiveness towards achieving the objective of a level playing field among businesses b)Quantitative and qualitative effects on this objective	playing field among businesses	an analysis of non-food product market trends, with specific focus on disproportionate obstacles to the free movement due to the way market surveillance is carried out and the relevance of unfair competition of non-compliant goods in the area of non-food products covered by Regulation (EC) No 765/2008. b) Correspondence matrix between the Regulation, the main obstacles or threats to compliant businesses in the market of non-food products and the results of the Regulation in preventing/ solving those issues.	• Trends in competitiveness of EU businesses as reported by stakeholders during interviews and in targeted consultations; • Qualitative evidence of the effects of the Regulation on competitiveness unbalances between EU and Extra-EU; • Competitiveness indicators: comparison before and after 2010; • Perception of economic operators on the creation of a level playing field by means of the Regulation.	• PC: section B1: Q4, Q5; section B2: Q4; section B4: Q6, Q7 ; section B5: Q5, Q6, Q7, Q8; • TS1: Q47, 48, 64, 65, 66; TS2: Q18-23, 28, 29, 42, 43; • I: Q7, Q10-12, Q14, Q15. Secondary: • Eurostat database on international trade; • IA for Regulation (EC) No 765/2008.
Q3. Comparison between expected and actual results as for (i) enhanced cooperation among/within MS, (ii) uniform and sufficiently rigorous level of market surveillance, (iii) border controls of imported products	• Enhanced cooperation among/within Member States • Uniform and sufficiently rigorous level of market surveillance • Increased border controls of imported products	a) Desk and field research to provide an analysis of trends in product safety and other public interest, with specific focus on: • Existing cooperation mechanisms among/ within MS, possibly in a comparison with those existing before the Regulation was implemented; • Differences in national strategies of market surveillance; • Scale of imported non-compliant non-food products circulating in the EU. • Mapping of national approaches to sanctions and powers granted to authorities (e.g. procedures) b) Correspondence matrix between the Regulation, the IA and the current situation.	• Number of AdCO groups before/ after the implementation of the Regulation; • Number of meetings of AdCO groups before/after the implementation of the Regulation; • Number of and trends in measures taken against non-compliant products (at the EU and MS level); • Number of authorities; • Type and level of sanctions at MS level – if possible, information disaggregated by sector will be extracted based on the answers to the targeted surveys; • Perception of involved stakeholders of the uniformity and rigorousness of market surveillance and border controls.	Primary: • PC: section B1: Q14, Q15, Q16, Q17, Q18; section B4: Q6, Q7; section B5: Q8 • TS1: Q17-31, 34, 39-42, 49-55. TS2: Q9-17, 30, 31, 48, 49. • I: Q2-5, Q8, Q10-12, Q14, Q16-20. Secondary: • RAPEX database; • National market surveillance reports and programmes; • IA for Regulation (EC) No 765/2008.

Criterion	*Effectiveness*			
Q4. a) How MS have implemented specific aspects of the Regulation b) Lessons learned	Effectiveness of different implementation mechanisms set at Member State level impacting on certain aspects of the Regulation	Desk and field research to provide an analysis of the implementation of the Regulation, with specific focus on: • Distribution of surveillance competences; • Resources and tasks; • National procedures and powers for inspections; • National procedures for sanctions; • National arrangements and practices for the controls of imports from third countries; • Practices of cross-border cooperation. Issues related to failures in the correct implementation of the Regulation. Identification of national good practices in the implementation of the Regulation.	• Tools for coordination among national authorities; • Authorities product specialisation vs horizontal cross-sectoral competencies; • Resources allocated; • Clear distinction between market surveillance tasks/budget and other attributions of a given authority; • Light vs heavy-handed procedures to impose sanctions on businesses; • Possible additional powers granted by national legislation; • Active use by specific authorities of tools for exchanging information with other MS; • Mapping of criteria for selection of sectors as market surveillance priorities; • Perception of MS on the usefulness of market surveillance reports and programmes.	Primary: • PC: section B1: Q7, Q8, Q9, Q10; section B4: Q4, Q5; • TS1: Q17, 18, 19, 32, 33, 41, 42, 49-55. Ts2: Q16, 17, 30, 31, 48, 49; • I: Q6, Q8, Q13, Q16. Secondary: • National market surveillance reports and programmes; • IA for Regulation (EC) No 765/2008 ; • Evaluation reports of sectoral legislation.
Q5. Extent to which differences in the implementation of the Regulation at national level have an impact on its effective functioning	MS differences in the Regulation's implementation induce different levels of product safety and of other public interest at national level	• Conclusions of Q1, Q2 and Q4, to understand whether and to what extent national differences in the implementation of the Regulation have an impact on its effectiveness. • Analysis of the correlation between national differences in the implementation and the effectiveness of the Regulation at the national level.	Same indicators as Q1, Q2, Q4	Same sources as Q1, Q2, Q3, Q4

Criterion	*Efficiency*
Evaluation questions	EQ6. What are the regulatory (including administrative) costs for the different stakeholders (businesses, consumers/users, national authorities, Commission)? EQ7. What are the main benefits for stakeholders and civil society that derive from the Regulation? EQ8. To what extent have the market surveillance provisions been cost effective? EQ9. Are there any significant differences in costs (or benefits) between Member States? If so, what is causing them?
Understanding the questions	Questions under this criterion are focused on the following aspects: - **Identification and quantification** of the costs and benefits - Assessment of the **proportionality** of costs and benefits - Identification of the reasons for **differences** among countries

Focus of the questions	*Judgement criteria*	*Analytical approach*	*Indicators and descriptors*	*Sources*
Q6. Identification and quantification of regulatory (including administrative) costs for stakeholders	MS authorities incur several costs related to the enforcement of the Regulation, especially for market surveillance activities, and other activities such as administrative cooperation with other MS. The market surveillance measures implemented by MSA create administrative	For the **cost of the enforcement** of the Regulation the following approach will be followed**:** • Definition of activities required to implement and enforce the Regulation; • Estimation of frequency of activities - f (e.g. 1=once a year); • Estimation of the cost of activities; • Estimation of the business-as-usual (BAU) factor; • Sum up and extrapolate costs at EU level.	Enforcement Costs for MSAs and Customs: • Budget allocated to market surveillance (including costs of the enforcement activities, costs for sharing information among authorities) • Difference in the enforcement costs by MS • Difference in the enforcement costs by sectors Costs for economic operators for: • Preparing the documentation and information requested by MSAs in implementing surveillance measures as	Primary: • TS1: Q43, 44, 50, 51, 56, 57 ; TS2: Q39; • I: Q21, Q22 Secondary: • Enforcement indicators; • Enterprise Europe Network;

Criterion	*Effectiveness*			
	costs for economic operators.	For the **administrative costs** for economic operators the following approach will be followed: • Definition of activities required to comply with the administrative costs; • Estimation of frequency of activities - f (e.g. 1=once a year); • Estimation of the cost of the activities; • Estimation of the business-as-usual (BAU) factor; • Sum up and extrapolate costs at EU level. • For the **administrative costs** for MS: estimation of the costs to draft national market surveillance reports and programmes.	required from art. 19 of Reg. 765/2008	• National market surveillance reports.
Q7. Identification and quantification of benefits for stakeholders	**The Regulation creates the following benefits:** • Increased level of protection of safety or other public interest; • Increased clarity and certainty; • Increased effectiveness and efficiency of market surveillance; • Reduction of unfair competition in non-food markets	**Qualitative measurement** of the benefits of the EU Regulation based on stakeholder consultation. Particular aspects that will be investigated are if**:** • The costs of the measures taken by MSAs to prohibit or restrict products being made available on the market, to withdraw them from the market or to recall them, are proportionate to the expected benefits; • The Regulation provides the framework to ensure a level playing field and a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security.	• Trends of internal market trade and exports • Number of notifications on products covered by Regulation (EC) No 765/2008 sent through RAPEX per type (i.e. for information, serious risks and other risk levels) • Number of measures taken against non-compliant products per category of product • Number of measures taken against non-compliant products per type of risk • Perceived level of protection of public interests • Level of satisfaction of economic operators on the procedures put in place (e.g. possibility to be consulted in case of adoption of restrictive measures by MS as per Art. 21 of Regulation (EC) No 765/2008) • Level of satisfaction of economic operators	Primary: • TS1: Q72; TS2: Q55. • I: Q26, Q30 Secondary: • RAPEX; • Eurostat international trade database; • National market surveillance reports.

Criterion	*Effectiveness*			
			on the benefits in terms of fair competition/creation of a level playing field	
Q8. Cost effectiveness of the market surveillance provisions	The implementation of a market surveillance mechanism at European level increases the cost effectiveness of the Regulation	**Analysis of the practical implementation of the Regulation,** in terms of: • Resources used (inputs); • Actions and measures taken (outputs).	• Total budget allocated to law enforcement • Budget allocated in proportion to the number of retailers on the national market and their turnover • Number and budget for inspectors • Number of inspections • Number of products tested • Number of products withdrawn from the market • Number of products recalled from consumers • Number of decisions to reject products at the border • Number of notifications per MS • Number and type of measures adopted at MS level	Primary: • PC: section B1: Q7, Q8, Q9, Q10, Q11, Q12, Q13, Q18, Q19; section B3: Q2; • TS1: Q45, 46; • I: Q21, Q24, Q25; Secondary: • RAPEX; • National market surveillance reports and programmes.
Q9. a) identification of differences in costs/ benefits between Member States b) related causes	Cost and benefits from the implementation differ from MS	The estimation of costs and benefits will take into consideration differences among MS in order to identify possible best practices	• Quantification of differences at MS level of indicators computed for Q6, Q7 and Q8	Primary: • TS1: Q58, 59, 67; TS2: Q36, 40 • I: Q23. Secondary: • See Q6, Q7 and Q8.

Criterion	*Relevance*
Evaluation questions	EQ10. To what extent are market surveillance provisions of the Regulation still relevant in the light for instance of increasing online trade, the increase in imports from third countries, shortening product life, increasing budgetary constraints at national level, etc.? EQ11. To what extent do the effects of the market surveillance provisions satisfy (or not) stakeholders' needs? How much does the degree of satisfaction differ according to the different stakeholder groups? EQ12. Is the concept of *lex specialis* still a suitable interface between the market surveillance provisions in the Regulation and those in other (notably sector) legislation? EQ13. Is there an issue on the scope (i.e. all EU product harmonisation legislation) of the measure or some of its provisions?
Understanding the questions	Questions under this criterion are focused on the following aspects: - Whether market surveillance provisions of the Regulation are relevant and aligned with **market dynamics** (Q10, Q12, Q13) - Whether market surveillance provisions of the Regulation satisfy **stakeholders' needs** (Q11, Q12, Q13)

Focus of the questions	*Judgement criteria*	*Analytical approach*	*Indicators and descriptors*	*Sources*
Q10. Relevance vis-à-vis online trade, the increase in imports from third countries, shortening product life, increasing budgetary constraints at national level, etc.	The Market surveillance provisions of the Regulation are aligned with current market dynamics	a) Desk and field research with a specific focus on • Main changes and developments in manufacturing, marketing and distribution of non-food products in the EU • Main trends in international trade of non-food products directed towards the EU • Emerging risks at EU and global level; • Main trends in budgetary constraints at national level	• EU market of non-food products in terms of volumes and values; • Number of health and safety issues related to market developments not addressed by market surveillance provisions of the Regulation; • Correspondence between emerging market and safety issues with results from IA for the Product Safety and Market Surveillance Package including proposals for a revision of the Regulation; • Sector-specific cases and practices	Primary: • PC: section B4: Q1, Q3; section B5: Q1, Q2, Q3, Q4; • TS1: Q35-38, 69, 70; TS2: Q32-35, 45, 46 • I: Q1, Q7, Q28. Secondary: • National market surveillance reports and programmes; • EU IDB; • Results of the market analysis;

Criterion	*Effectiveness*			
		b)Correspondence matrix between Regulation (EC) No 765/2008 and the main market developments occurred	that are not fully covered by market surveillance provisions of the Regulation.	• IA for the Product Safety and Market Surveillance Package (SWD(2013) 33).
Q11. a) Satisfaction of stakeholders' needs b) Differences in the degree of satisfaction among stakeholder groups	Stakeholder groups are satisfied with the effects of market surveillance provisions, presenting different degree of satisfaction according to their belonging to different groups	Desk and field research with a specific focus on • Main trends in market surveillance measures of non-food products (release, recall or withdrawal of products, cost incurred by economic operators) • Emerging risks at EU and global level • Trends in stakeholder information and engagement with regard to market surveillance of non-food products	• Trends in market surveillance measures taken in the EU in different sectors and addressing different stakeholders • Current and emerging problems regarding health, safety and other public interest related to marketing of non-food products • Qualitative perception of different stakeholders, including national MSAs, border control authorities, SMEs, main economic operators and selected categories of consumers (sample), on market surveillance of non-food products	Primary: • PC: section B4: Q1, Q2; • TS1: Q8, 9, 68; TS2: Q44. • I: Q1, Q27, Q29, Q30. Secondary: • RAPEX; • EU IDB; • National market surveillance reports and programmes; • DG GROW report on the application of the Regulation; • IA for the Product Safety and Market Surveillance Package (SWD(2013) 33).
Q12. Relevance of the concept of lex specialis	The concept of *lex specialis* functions as a suitable interface between market surveillance provisions included in the Regulation and in other sector-specific legislation	a)Desk and field research with a specific focus on • Overview of sector-specific legislations including market surveillance provisions vis-à-vis the whole domain where the Regulation applies • Trends in the implementation at the national level of market surveillance provisions included in the Regulation and in sector-specific legislations • Risk analysis of market surveillance	• Number of sector-specific legislations including market surveillance provisions • Trends in the implementation of market surveillance provisions in different sectors linked to Regulation and other sector-specific legislations • Perception of stakeholders on possible risks deriving from the concept of lex specialis in the framework for market surveillance	Primary: • TS1: Q6, 7, 14; • I: Q32, Q33. Secondary: • Sector-specific legislations including market surveillance provisions; • National market surveillance reports and programmes; • DG GROW report on the application of the Regulation;

Criterion	*Effectiveness*			
		provisions included in the Regulation and in other sector-specific legislation • Cluster analysis of sectors/ domains where market surveillance provisions are defined by sector-specific legislation b)Correspondence matrix between market surveillance provisions included in sector-specific legislations and those included in the Regulation in terms of protection of health, safety and other public interest		• IA for the Product Safety and Market Surveillance Package (SWD(2013) 33); • IA accompanying legislative proposals listed in section 5 of ToR.
Q13. Presence of issues on the scope of the measure or some of its provisions	The scope of market surveillance provisions of the Regulation (i.e. all EU product harmonisation legislation) is still relevant and does not present particular issues	Desk and field research with a specific focus on potential misalignments between market surveillance provisions included in the Regulation and their implementation	Stakeholders' perception on the need to modify the Regulation's scope in light of emerging issues in terms of internal market and public interest	Primary: • TS1: Q4, 5, 70, 71; TS2: Q37, 38, 46, 47 • I: Q1, Q31. • Secondary: • RAPEX; • National market surveillance reports and programmes; • DG GROW report on the application of the Regulation; • IA for the Product Safety and Market Surveillance Package (SWD(2013) 33).

Criterion	*Coherence*			
Evaluation questions	*EQ14. To what extent are the market surveillance provisions above still coherent with other Union legislation on market surveillance on non-food products?* *EQ15. To what extent are the market surveillance provisions coherent internally?* *EQ16. To what extent are these provisions coherent with wider EU policy?*			
Understanding the questions	*Questions under this criterion are focused on the following aspects:* - *Whether market surveillance provisions in the Regulation are coherent with other Union legislation on market surveillance on non-food products and internally with the Regulation itself (Q14 and Q15)* - *Whether market surveillance provisions in the Regulation are coherent with the EU policy framework (Q16)*			
Focus of the questions	**Judgement criteria**	**Analytical approach**	**Indicators and descriptors**	**Sources**
Q14. Coherence with other Union legislation	Market surveillance provisions of the Regulation are coherent with other Union legislation on market surveillance on non-food products	Desk and field research on other Union legislation on market surveillance of non-food products in order to identify potential overlapping / contradictions with the Regulation	Number of provisions of the Regulation not coherent with other pieces of Union legislation or where overlapping or contradictions are recorded, extent of incoherence and related consequences	Primary: • TS1: Q11, 12, 15, 16; TS2: 51, 52, 54 • I: Q34. Secondary: • Directive 2001/95/EC on General Product Safety • Market surveillance provisions of sector-specific legislations covered by Regulation 765/2008; • IA for the Product Safety and Market Surveillance Package (SWD(2013) 33).
Q15. Internal coherence	Market surveillance provisions of the Regulation are coherent with	Desk and field research on market surveillance provisions on non-food products included in the Regulation	Number of provisions of the Regulation not coherent with other provisions included in the same legislation or where	Primary: • TS1: Q13, 15, 16; TS2: Q53.

Criterion	*Coherence*			
Evaluation questions	*EQ14. To what extent are the market surveillance provisions above still coherent with other Union legislation on market surveillance on non-food products?* *EQ15. To what extent are the market surveillance provisions coherent internally?* *EQ16. To what extent are these provisions coherent with wider EU policy?*			
Understanding the questions	*Questions under this criterion are focused on the following aspects:* - *Whether market surveillance provisions in the Regulation are coherent with other Union legislation on market surveillance on non-food products and internally with the Regulation itself (Q14 and Q15)* - *Whether market surveillance provisions in the Regulation are coherent with the EU policy framework (Q16)*			
Focus of the questions	**Judgement criteria**	**Analytical approach**	**Indicators and descriptors**	**Sources**
	themselves and the scope of the legislation		overlapping or contradictions are recorded, extent of incoherence and related consequences	• I: Q35. Secondary: • Market surveillance provisions of Regulation (EC) No 765/2008; • IA for the Product Safety and Market Surveillance Package (SWD(2013) 33).
Q16. Coherence with wider EU policy	Market surveillance provisions of the Regulation are coherent with EU policies (e.g. in the field of market surveillance, protection of public interests, internal market and	Desk and field research on EU policy documents (e.g. in the field of market surveillance, protection of public interests, internal market and controls of products on the internal market) in order to identify potential overlapping / contradictions with market surveillance	Number of market surveillance provisions of the Regulation not coherent with other EU policy documents (e.g. in the field of market surveillance, protection of public interests, internal market and controls of products on the internal market), extent of incoherence and related	Primary: • TS1: Q11, 12, 15, 16. TS2: Q51, 52, 54. • I: Q36. Secondary: • COM(2013) 76 final – multiannual action plan on market surveillance; • SEC(2011) 1640 final – Bringing e-commerce to

Criterion	*Coherence*			
Evaluation questions	*EQ14. To what extent are the market surveillance provisions above still coherent with other Union legislation on market surveillance on non-food products?* *EQ15. To what extent are the market surveillance provisions coherent internally?* *EQ16. To what extent are these provisions coherent with wider EU policy?*			
Understanding the questions	*Questions under this criterion are focused on the following aspects:* - *Whether market surveillance provisions in the Regulation are coherent with other Union legislation on market surveillance on non-food products and internally with the Regulation itself (Q14 and Q15)* - *Whether market surveillance provisions in the Regulation are coherent with the EU policy framework (Q16)*			
Focus of the questions	**Judgement criteria**	**Analytical approach**	**Indicators and descriptors**	**Sources**
	controls of products on the internal market)	provisions of the Regulation	consequences	consumers; • IA for the Product Safety and Market Surveillance Package (SWD(2013) 33).
Criterion	*EU added value*			
Evaluation questions	*EQ17. What is the additional value resulting from the market surveillance provisions at EU level, compared to what could be achieved by Member States at national and/or regional levels?* *EQ18. To what extent do these provisions support and usefully supplement market surveillance policies pursued by the Member States? Do the provisions allow some sort of 'control' by the EU on the way national authorities carry out market surveillance?*			
Understanding the questions	*Assessing to what extent the results of the EU action are additional to the value that would have resulted from action at Member State level.*			

Criterion	*Coherence*			
Evaluation questions	*EQ14. To what extent are the market surveillance provisions above still coherent with other Union legislation on market surveillance on non-food products?* *EQ15. To what extent are the market surveillance provisions coherent internally?* *EQ16. To what extent are these provisions coherent with wider EU policy?*			
Understanding the questions	*Questions under this criterion are focused on the following aspects:* - *Whether market surveillance provisions in the Regulation are coherent with other Union legislation on market surveillance on non-food products and internally with the Regulation itself (Q14 and Q15)* - *Whether market surveillance provisions in the Regulation are coherent with the EU policy framework (Q16)*			
Focus of the questions	**Judgement criteria**	**Analytical approach**	**Indicators and descriptors**	**Sources**
Focus of the question	*Judgement criteria*	*Analytical approach*	*Indicators and descriptors*	*Sources*
Q17. Added value as compared to national/regional measures	• Simplification of the circulation of non-food products across MS. • Improved safety and other public interests due to harmonisation of market surveillance practice and setting of minimum standards.	Desk and field research aimed at: • Analysis of internal market trade of non-food products; • Analysis of convergence between Member States legislative framework concerning market surveillance; • Stakeholders' perception of the uniformity of market surveillance across the EU; • Analysis of data on accidents due to non-compliant food-products.	• Stakeholders' perception on the benefits resulting from a common Regulation.	Primary: • TS1: Q72; TS2: Q55 • I: Q37, Q38. Secondary: • RAPEX database; • EU IDB; • DG GROW report on cross-border cooperation; • Results of the market analysis; • IA for Regulation (EC) No

Criterion	*Coherence*			
Evaluation questions	*EQ14. To what extent are the market surveillance provisions above still coherent with other Union legislation on market surveillance on non-food products?* *EQ15. To what extent are the market surveillance provisions coherent internally?* *EQ16. To what extent are these provisions coherent with wider EU policy?*			
Understanding the questions	*Questions under this criterion are focused on the following aspects:* - *Whether market surveillance provisions in the Regulation are coherent with other Union legislation on market surveillance on non-food products and internally with the Regulation itself (Q14 and Q15)* - *Whether market surveillance provisions in the Regulation are coherent with the EU policy framework (Q16)*			
Focus of the questions	**Judgement criteria**	**Analytical approach**	**Indicators and descriptors**	**Sources**
				765/2008.
Q18. a) Contribution of the Regulation to national policies b) Contribution of the Regulation to the EU control on Member States	• Increased market surveillance effectiveness and efficiency at MS level; • Increased level of safety and other public interest at the EU level.	Desk and field research aimed at: • Analysis of convergence between Member States legislative framework concerning market surveillance; • Stakeholders' perception of the uniformity of market surveillance across the EU; • Analysis of the amendments introduced in the national legislation for compliance with the Regulation.	• Increased cooperation among authorities involved in market surveillance at national level; • Number of positive achievements of the Regulation for the different stakeholder groups; • Increased intra-EU trade and competitiveness; • Stakeholders' perception on the supportive role of Regulation 765/2008 to national policies.	Primary: • TS1: Q73, 74, 75; TS2: Q56, 57. • I: Q39, Q40. Secondary: • Eurostat international trade database; • National market surveillance reports and programmes; • IA for Regulation (EC) No 765/2008.

8.12 Targeted survey questionnaires

The survey was circulated via the EY eSurvey tool. The questionnaires were also provided in French, Italian, German and Romanian. "MS" indicates the Member State authority in charge of coordinating market surveillance activities at the national level. "CA" tands for "Custom Authority".

8.12.1 Questionnaire for Public Authorities

N	Question	MS	MSA	CA
About you				
1.	**Authority name**	X	X	X
2.	**Please qualify the role of your Authority with respect to Regulation (EC) No 765/2008**	X	X	X
	a. Implementing authority (focused on coordination and implementation of the Regulation)			
	b. Market surveillance authority (focused on the enforcement of the Regulation)			
	c. Both a and b			
	d. Custom Authority			
3.	Localisation of the Authority you work for	X	X	X
4.	Please select your relevant sectors *(reference list of sectors in scope of the Regulation, multiple choice)*	X	X	X
About the content of Regulation (EC) No 765/2008				
5.	Are the following definitions clear, appropriate, complete and up-to-date?[456] *(a pop-up appears for each definition)*	X	X	X

456 *Clear*: the definitions are easy to understand or interpret; *Appropriate*: the definitions are suitable for the situations when they are used; *Complete*: the definitions cover all relevant aspects; *Up-to-date*: the definitions incorporate the latest developments and trends.

N	Question	MS	MSA	CA

Definition	Clear			Appropriate			Complete and up to date		
	Yes	No	I do not know	Yes	No	I do not know	Yes	No	I do not know
Making available on the market									
Placing on the market									
Manufacturer									
Authorised representative									
Importer									
Distributor									
Recall									
Withdrawal									
Product									

6.	Please add here any comments relating the existing definitions, or on concept/ definitions that according to you are missing in Regulation (EC) 765/2008.	X	X	X
7.	Does the concept of *lex specialis*[457] cause any problem of implementation? (*yes/no/I do not know)*	X	X	

457 In accordance with the principle of *lex specialis*, the Regulation should apply only as far as there are no specific provisions with the same objective, nature or effect in other existing or future rules of the EU harmonisation legislation.

N	Question	MS	MSA	CA
8.	Please specify	X	X	
9.	Do you deem the provisions of Article 18(5)[458] on market surveillance programmes as useful? (yes/no/I do not know)	X	X	
10.	If not, what should be changed? If yes, why?	X	X	
11.	Is there a need for any additional guidance on any areas of the Regulation? *(y/n)*	X	X	X
12	Could you please highlight any inconsistencies (if any) between the Regulation and any other pieces of EU legislation (e.g. with the General Product Safety Directive,[459] with sector-specific product legislation)?	X	X	X
13	Could you please highlight any contradictions (if any) between the provisions of the Regulation?	X	X	X
14.	Can you indicate any misalignments between the market surveillance provisions included in the Regulation and their implementation in different non-food product sectors?	X	X	
15.	Are there conflicts of jurisdictions of authorities? *(y/n)*	X	X	X
16.	Please explain	X	X	X
About the implementation of Regulation (EC) No 765/2008				
17.	Do MSAs in your Member State have/does your authority have the following powers	X	X	
	□ To carry out sector inquiries *(y/n)*			
	□ Take samples for free *(y/n)*			

458 According to Article 18(5) of Regulation (EC) No 765/2008: "*Member States shall establish, implement and periodically update their market surveillance programmes. Member States shall 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, by way of electronic communication and, where appropriate, by other means.*"

459 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0095&from=EN

N	Question	MS	MSA	CA
	□ Recover from economic operators costs borne to test products found to be non-compliant *(y/n)*			
	□ Do mystery shopping *(y/n)*			
	□ Seize and detain products *(y/n)*			
	□ Destroy products *(y/n)*			
	□ Recover from economic operators costs borne to store or destroy products *(y/n)*			
	□ Seize documents *(y/n)*			
	□ Impose provisional measures pending investigations *(y/n)*			
	□ Sanction economic operators that do not cooperate *(y/n)*			
	□ Request information/cooperation by any possible natural or legal person when this is necessary to take corrective action *(y/n)*			
	□ Take off or require to take off illegal content from a websites *(y/n)*			
	□ Shut-down websites *(y/n)*			
	□ Impose administrative economic sanctions (without resorting to national courts) *(y/n)*			
	□ Publish decisions on restrictive measures *(y/n)*			
	□ Impose compensation for consumers/users of non-compliant products *(y/n)*			
18.	Is there any need to grant MSAs more powers to enter businesses' premises? *(y/n)*		X	
19.	Please specify		X	
20.	Do you usually perceive to have sufficient market knowledge (i.e. on products made available and their suppliers) to target checks to be carried out?		X	X

N	Question	MS	MSA	CA
21.	Do MSAs and Customs in your Member State have in-house laboratories for testing?		X	
	□ No, only Customs have in-house laboratories for testing			
	□ Yes, both MSAs and Customs have in-house laboratories for testing			
	□ Neither MSAs nor Customs have in-house laboratories for testing			
	□ I do not know			
22.	Do MSAs and Customs in your Member State make use of test reports by MSAs in other EU countries? *(y/n/I do not know)*		X	X
23.	If not, why?		X	X
24.	Does Regulation (EC) No 765/2008 attribute adequate powers to Custom Authorities? *(y/n)*			X
25.	If not, what should be changed?			X
26.	Are the guarantees provided sufficient to cover possible costs linked to market surveillance checks? *(yes/no/ "no guarantees exist", + "I do not know")*			X
27.	Do authorities in your Member State have/does your authority have the following powers:			X
	□ Request business to provide information and exhibit documents on products presented for release for free circulation (y/n)			
	□ Recover from economic operators costs borne to test products found to be non-compliant *(y/n)*			
	□ Destroy products *(y/n)*			
	□ Recover from economic operators costs borne to store or destroy products *(y/n)*			

N	Question	MS	MSA	CA
Focus on powers of control				
28.	In terms of uniformity[460] and rigorousness of controls by Market Surveillance/ Authorities in charge with EU external border controls, are you aware of any discrepancies **across EU Member States**? *(y/n)*	X	X	X
29.	Could you please provide some examples?	X	X	X
30.	In terms of uniformity and rigorousness of controls of Market Surveillance/ Authorities in charge with EU external border controls, are you aware of any discrepancies **across sectors in your Member State**? (y/n)	X	X	X
31.	Please specify	X	X	X
32.	If any, are they:	X	X	X

	To a large extent	To a small extent	Not at all	I do not know
Hindering the free circulation of goods				
Influencing market behaviour (e.g. decision of companies to enter the EU market via certain Member States – both non-EU and EU products)				
Reducing the safety of products or their degree of non-compliance				
Influencing the regulatory/administrative costs for Member State/Market Surveillance/Custom Authority across Member States? (please answer this question according to the category you belong to)				

460 *Uniformity*: all products and all economic operators are equally targeted by controls across all EU Member States. *Rigorousness*: The types of controls and the criteria for imposing sanctions are equal across the EU Member States.

N	Question	MS	MSA	CA
33.	What are the criteria Market Surveillance/Customs Authorities in your Member State use to select a particular sector as a priority for controls?		X	X
34.	Could you briefly describe the criteria your Market Surveillance/Customs Authorities apply to determine the "*adequate scale*"[461] of product controls?		X	X
35.	Do you consider the procedures for the control of products entering the EU market as described in articles 27 to 29 of the Regulation as:			X
	□ Clear? *(y/n/I do not know)*			
	□ Easy to apply? *(y/n/I do not know)*			
	□ Still relevant to the need of Authorities in charge of external border control? *(y/n/I do not know)*			
36.	Are there issues with/obstacles to checks of products imported into the EU carried out by Authorities in charge with EU external border controls? *(y/n/I do not know)*		X	X
37.	Are there issues with/obstacles to performing market surveillance or controls of imported products in any sector in particular?		X	X
38.	Are there issues /obstacles related to the increasing importance of online trade? *(y/n/I do not know)*		X	X
39.	Could you please provide some examples?		X	X
Focus on powers of sanction				
40.	How did your Member State (for MS) /your authority (for MSAs) implement article 41[462] of Regulation (EC) No 765/2008?	X	X	

461 According to Article 19(1) of the Regulation, "Market surveillance authorities shall 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." Article 27 (1) of the Regulation refers to the same principle for Authorities in charge of border controls.

462 According to Article 41 of the Regulation, "*The 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. The Member States shall notify the Commission of those provisions by 1 January 2010 and shall notify it without delay of any subsequent amendment affecting them*".

N	Question	MS	MSA	CA
41.	Are you aware of any discrepancies across EU Member States **in the level of sanctions** for non-compliant products? *(y/n)*	X	X	
42.	Could you please provide some examples?	X	X	
43.	In your Member State and in your sector, what is the highest possible economic sanction applicable in case of serious infringements of product requirements that can be applied by MSAs without resorting to courts?	X	X	
	□ Total value (€): _____			
	□ As percentage of turnover: _____			
	□ Other: _____			
	□ I do not know			
44.	In addition to economic fines, could you specify the maximum sanction MSAs are entitled to ask for by law in your sector in your Member State?	X	X	
45.	To what extent is the procedure to impose economic sanctions burdensome?		X	
	□ To a large extent			
	□ To a small extent			
	□ To no extent			
	□ I do not know			
46.	Can you please specify in what respect?		X	
47.	Do you see any scope for efficiency gains, in the following stages of the investigative and sanctioning process?		X	
	□ Targeting of enforcement action *(y/n/I do not know)*			

N	Question	MS	MSA	CA
	□ Inspection *(y/n/I do not know)*			
	□ Dialogue with businesses to obtain cooperative corrective action *(y/n/I do not know)*			
	□ Adoption of the enforcement decision *(y/n/I do not know)*			
	□ Appeal against the enforcement decision/litigation *(y/n/I do not know)*			
	□ Other (please specify) *(y/n/I do not know)*			
48.	Could you please provide evidence for your previous answer?		X	
49.	Do you see any scope for efficiency gains, in the following stages of the process for control of imported products?			X
	□ Targeting of controls (y/n/ *I do not know*)			
	□ Inspection of products and suspension of release for free circulation *(y/n/ I do not know)*			
	□ Transmission of information to competent Market Surveillance Authority *(y/n/ I do not know)*			
	□ Reception of information from competent Market Surveillance Authority *(y/n/ I do not know)*			
	□ Authorisation of release for free circulation following corrective measures *(y/n/ I do not know)*			
	□ Refusal of release for free circulation *(y/n/ I do not know)*			
	□ Other (please specify) *(y/n)*			
50.	Could you specify what could be improved there?			X
51.	Which type of restrictive measure[463] had been the most frequent in your Member State and in your sector over the period 2010-2015?		X	X

463 A “restrictive measure” prohibits or restrict a product's being made available on the market, withdraws it from the market or recalls.

N	Question	MS	MSA	CA
	□ Product withdrawal			
	□ Product recall			
	□ I do not know			
	□ Other, please specify			
52.	Which sector had been the most affected by restrictive measures due to product non-compliance over the period 2010-2015?		X	X
Communication and collaboration activities				
53.	Do you usually cooperate with other MSAs/Customs in other Member States? (y/n)		X	X
54.	Is your communication and collaboration with other Member State Authorities in other Member States useful? Could it be improved and, if so, how?	X	X	X
55.	In case of a non-compliant product, do you usually notify to MSAs in other Member States the restrictive measures you impose (if any)? (y/n)		X	
56.	Have you ever used the ICSMS[464] system until now? (y/n)	X	X	
57.	What are the challenges and difficulties (if any) in the use of ICSMS?	X	X	
58.	Does your Market Surveillance Authority (or do Market Surveillance Authorities in your Member State) participate in AdCO[465] activities? (y/n)	X	X	
59.	How do you consider participation in AdCO work? *(multiple choice)*		X	
	□ Essential to coordinate action			

464 ICSMS is the internet-supported information and communication system for the pan-European market surveillance. https://webgate.ec.europa.eu/icsms/

465 European cooperation on market surveillance takes place through informal groups of Market Surveillance Authorities, called Administrative Cooperation Groups (AdCOs). The members of these groups are appointed by Member States and represent national authorities competent for market surveillance in a given sector.

N	Question	MS	MSA	CA
	□ Useful to keep an eye on what Market Surveillance Authority in other Member States do and/or to learn from each other			
	□ Of little practical relevance for my authority work / not a priority			
	□ Other (please specify)			
Costs related to Regulation (EC) No 765/2008				
60.	What is the average annual salary (€) of an employee to perform general market surveillance activities (e.g. inspection, testing, product withdrawal, investigation)?		X	X
61.	Could you please provide an estimate (€) of the annual cost for economic operators related to the application of the Regulation (e.g. preparing documents and information requested by MSAs/ Authorities in charge with EU external border controls in implementing surveillance measures) on top of compliance costs to ensure and demonstrate conformity to EU legislation applicable to your products in your sector/ country?		X	X
62.	Are you aware of any differences in costs for enforcing the Regulation across Member States? *(y/n)*	X	X	X
63.	Please specify	X	X	X
Impact of Regulation (EC) No 765/2008				
64.	According to you experience, in the last 5 years overall product non-compliance in your sector has:		X	X
	□ Substantially diminished			
	□ Diminished			
	□ Remained equal			
	□ Increased			
	□ Substantially increased			

N	Question	MS	MSA	CA
	□ I do not know			
65.	**Which sector** had been heavily affected by product non-compliance **in your country** over the period 2010-2015?		X	X
66.	**Which country** has been heavily affected by product non-compliance **in your sector** over the period 2010-2015?		X	X
67.	Could you explain why?		X	X
68.	Do you think that checks of products imported into the EU carried out by Authorities in charge with EU external border controls are sufficient to deter rogue traders in your sector in your Member State?		X	X
	□ Yes, definitely			
	□ Yes, somehow			
	□ No			
	□ I do not know			
69.	To what extent do you agree or disagree with the following statements? *The regulation effectively provides the right framework to support*:	X	X	X

	Strongly agree	**Somewhat agree**	**Neither agree nor disagree**	**Somewhat disagree**	**Strongly disagree**	**I do not know**
Health and Safety in General						
Health and Safety at the Workplace						
Protection of consumers						
Protection of the environment						

N	Question	MS	MSA	CA
	Free movement of products			
	Level playing field for all EU businesses			
	Other public interests (please specify)			
70.	Could you please provide evidence for your previous answers?	X	X	X
71.	Are you aware of any best practices[466] in market surveillance and controls of imported products in place in EU Member States or in major trading partners (i.e.: Iceland, Norway, Liechtenstein, Turkey, Switzerland, USA, China, Korea, and Japan)?	X	X	X
Relevance of the Regulation for current needs				
72.	In general, does the Regulation currently meet your needs? *(y/n)*	X	X	X
73.	To what extent do you think the Regulation currently addresses specific issues deriving from: *(to no extent, to some extent, to a large extent, I do not know)*	X	X	X
	□ Online trade/Delivery via small postal consignments or express couriers			
	□ Increasing imports from third countries			
	□ Shortening product life impacting the ability of authorities to track non-complaint product and ensure corrective action			
	□ Increasing budgetary constraints			
74.	In addition to those reported in the previous question, could you please indicate additional issues affecting non-compliance with EU harmonisation legislation for the marketing of non-food products (e.g. related to health, safety and other public interest) that the Regulation is not properly addressing?	X	X	X

466 A "best practice" is a commercial or professional procedure recognised as being more effective or efficient as compared with other procedures having the same objective.

N	Question	MS	MSA	CA
75.	The Regulation applies to a number of products: do you find the current scope of application of the Regulation clear? *(y/n/I do not know*)	X	X	X
76.	Could you indicate if there is any additional products that the Regulation should cover or any products that should be excluded from the Regulation's scope?	X	X	X
Added value of the Regulation				
77.	Could you please highlight the benefits linked to having a European legislation on harmonising market surveillance and control of imported products instead of 28 national legislations?	X	X	X
78.	Is the framework provided by the Regulation useful to define your national market surveillance and control of imported products policies?	X	X	X
	□ Yes, to a large extent			
	□ Yes, to a small extent			
	□ To no extent			
	□ I do not know			
Concluding remarks				
79.	Is there any other issue you would like to bring to the European Commission's attention?	X	X	X

8.12.2 Questionnaire for economic operators and civil society

N	Question	EO	CS
About you			
1.	**Legal entity name**	X	X
2.	Please select who you are:	X	X

N	Question	EO	CS
	□ Company		
	□ Industry association		
	□ Consumer association		
3.	Type of economic operator you are or represent	X	
	□ Product Importers / Distributors		
	□ Product Manufacturers / Authorised Representative		
	□ Online intermediaries		
	□ Other		
4.	Please select the size of the firm you are or represent	X	
	□ Less than 10 employees		
	□ from 10 to 49 employees		
	□ from 50 to 249 employees		
	□ more than 249 employees		
5.	Localisation of the establishment you work in *(closed list of EU28 Member States + EEA countries+ Switzerland +Turkey + 'Other third country')*	X	X
6.	Geographical coverage of your association *(multiple choice: list of EU28 Member States + EEA countries + Switzerland + Turkey + 'Other third country' + EU level + International (beyond EU level)*	X	X
7.	Please select your relevant sectors (*multiple choice: list of sectors covered by Regulation (EC) No 765/2008 + possibility of selecting "Other", multiple choices possible)*	X	X

N	Question	EO	CS
Focus on controls			
8.	In terms of uniformity[467] and rigorousness of controls by Market Surveillance Authorities/ Authorities in charge with EU external border controls, are you aware of any discrepancies **across EU Member States**? *(y/n)*	X	X
9.	Could you please provide some examples?	X	X
10.	In terms of uniformity and rigorousness of controls of Market Surveillance Authorities/ Authorities in charge with EU external border controls, are you aware of any discrepancies **across sectors** (e.g. lifts/machinery, electrical equipment under EMC/electrical appliances and equipment under LVD) in your Member State? *(y/n)*	X	X
11.	Could you please provide some examples?	X	X
12.	If any, are they:	X	X

467 *Uniformity*: all products and all economic operators are equally targeted by controls across the EU Member States. *Rigorousness*: The types of controls and the criteria for imposing sanctions are equal across the EU Member States.

N	Question	EO	CS

	To a large extent	To a small extent	Not at all	I do not know
Hindering the free circulation of goods				
Influencing market behaviour (e.g. decision of companies to enter the EU market via certain Member States – both non-EU and EU products)				
Reducing the safety of products				
Influencing the regulatory/administrative costs of businesses across Member States (e.g. preparing documents and information requested by Market Surveillance Authorities/ Authorities in charge with EU external border controls in implementing surveillance measures)? (only for economic operators and industry associations)				

Focus on sanctions			
13.	Are you aware of any discrepancies across EU Member States **in the level of sanctions** for non-compliant products?	X	X
14.	Could you please provide some examples for instance of having being subject to different sanctions for the same problem?	X	
15.	Could you please provide some examples?		X
16.	In your Member State and in your sector, what is the highest possible economic sanction applicable in case of serious infringements of product requirements[468] that can be applied by market surveillance authority without resorting to courts?	X	
	□ Total value (€): _____		

468 The EU technical harmonisation directives specify essential requirements to which products must conform. These requirements are designed to ensure a high level of product safety.

N	Question	EO	CS
	□ As percentage of turnover: _____		
	□ Other: _____		
	□ I do not know		
17.	In addition to economic fines, could you specify the maximum sanction Market Surveillance Authorities are entitled to ask for by law in your sector in your Member State?	X	
Focus on restrictive measures			
18.	**Which sector** had been heavily affected by restrictive measures due to product non-compliance over the period 2010-2015?		X
19.	**Which type of restrictive measure**[469] had been the most frequent in your Member State and in your sector over the period 2010-2015? *(single choice: list of restrictive measures + "I do not know")*		X
	□ Product withdrawal		
	□ Product recall		
	□ I do not know		
	□ Other, please specify		
20.	Have you ever been subject to any of the following restrictive measures? *(list of restrictive measures + "I have never been subject to a restrictive measure")*	X	
	□ I have never been subject to a restrictive measure		
	□ Product withdrawal		

469 A "restrictive measure" prohibits or restrict a product's being made available on the market, withdraws it from the market or recalls.

N	Question	EO	CS
	□ Product recall		
	□ I do not know		
	□ Other, please specify		
21.	If yes, did you have been given the opportunity to be heard within an appropriate period of not less than 10 days (as per art. 21 of Regulation 765/2008)?[470] *(y/n/n.a.)*	X	
22.	Have you found this consultation process appropriate?[471]	X	
	□ Yes, to a large extent		
	□ Yes, to a medium extent		
	□ Yes, to a low extent		
	□ No		
	□ Not applicable		
23.	Could you please provide evidence for your previous answer?	X	
Focus on the impact of Regulation (EC) No 765/2008			
24.	**Which country** had been the most affected by product non-compliance in your sector over the period 2010-2015? *(list of Member States + EEA countries+ Switzerland +Turkey + "I do not know")*		X

470 According to Article 21(3) of the Regulation, prior to the adoption of restrictive measures, "*the economic operator concerned shall be given the opportunity to be heard within an appropriate period of not less than 10 days, unless such consultation is not possible because of the urgency of the measure to be taken, as justified by health or safety requirements or other grounds relating to the public interests covered by the relevant Community harmonisation legislation. If action has been taken without the operator's being heard, the operator shall be given the opportunity to be heard as soon as possible and the action taken shall be reviewed promptly thereafter*".

471 Appropriateness: the process has not been too time-consuming nor too difficult to understand (i.e. transparent) and your level of involvement and the information shared has been satisfactory.

N	Question	EO	CS
25.	Could you explain why?		X
26.	According to you experience, in the last 5 years overall product non-compliance in your sector has:	X	X
	□ Substantially diminished		
	□ Diminished		
	□ Remained equal		
	□ Increased		
	□ Substantially increased		
	□ I do not know		
27.	Do you think that market surveillance activities are sufficient to deter rogue traders in your sector in your Member State?	X	X
	□ Yes, definitely		
	□ Yes, somehow		
	□ No		
	□ I do not know		
28.	**Which sector** had been the most affected by product non-compliance over the period 2010-2015? *(list of sectors + "I do not know")*		X
29.	Do you think that checks of products imported into the EU carried out by Authorities in charge with EU external border controls are sufficient to deter rogue traders in your sector in your Member State?	X	X
	□ Yes, definitely		
	□ Yes, somehow		

N	Question	EO	CS
	□ No		
	□ I do not know		
30.	Is there any need to grant Market Surveillance Authorities more powers to enter businesses' premises? *(y/n/I do not know)*	X	
31.	Please specify	X	
32	Is there any need to grant Market Surveillance Authorities any other additional powers to effectively detect non-compliance and obtain corrective action *(y/n/I do not know)*	X	X
33.	Please specify	X	X
34.	Is there any need to grant Authorities in charge with EU external border controls any additional powers to effectively detect non-compliant products? *(y/n/I do not know)*	X	X
35.	Please specify	X	X
36.	Are you aware of any issue with/obstacles to checks of products imported into the EU carried out by Authorities in charge with EU external border controls? *(y/n)*	X	X
37.	Are you aware of any issue with/obstacles to market surveillance in any sector in particular? *(list of sectors + "No, there are not issues")*	X	X
38.	Are there issues for your activity related to the increasing importance of online trade? *(y/n/I do not know)*	X	X
39.	Please explain	X	X
40.	Are you aware of any best practices[472] in market surveillance and controls of imported products in place in EU Member States or in major trading partners (i.e.: Iceland, Norway, Liechtenstein, Turkey, Switzerland, USA, China, Korea, and Japan)?	X	X
About the content of Regulation (EC) No 765/2008			

472 Appropriateness: the process has not been too time-consuming nor too difficult to understand (i.e. transparent) and your level of involvement and the information shared has been satisfactory.

N	Question	EO	CS
41.	Are the following definitions clear, appropriate, complete and up-to-date?[473] *(a pop-up will appear displaying each definition)*	X	

Definition	Clear			Appropriate			Complete and up to date		
	Yes	No	I do not know	Yes	No	I do not know	Yes	No	I do not know
Making available on the market									
Placing on the market									
Manufacturer									
Authorised representative									
Importer									
Distributor									
Recall									
Withdrawal									
Product									

42.	Please add here any comments relating the existing definitions, or on concept/ definitions that according to you are missing in Regulation (EC) 765/2008.	X	

473 *Clear*: the definitions are easy to understand or interpret; *Appropriate*: the definitions are suitable for the situations when they are used; *Complete*: the definitions cover all relevant aspects; *Up-to-date*: the definitions incorporate the latest developments and trends.

N	Question	EO	CS
43.	Could you please provide an estimate (€) of the annual cost for economic operators related to the application of the Regulation (e.g. preparing documents and information requested by Market Surveillance Authorities/ Authorities in charge with EU external border controls in implementing surveillance measures) on top of compliance costs to ensure and demonstrate conformity to EU legislation applicable to your products in your sector/ country?	X	
44.	To what extent do you agree or disagree with the following statements? *The Regulation effectively provides the right framework to support*:	X	X

	Strongly agree	**Somewhat agree**	**Neither agree nor disagree**	**Somewhat disagree**	**Strongly disagree**	**I do not know**
Health and Safety in General						
Health and Safety at the Workplace						
Protection of consumers						
Protection of the environment						
Free movement of products						
Level playing field for all EU businesses						
Other public interests (please specify)						

45.	Could you please provide evidence for your previous answers?	X	X
46.	In general, does the Regulation currently meet your needs in terms of (e.g.) harmonisation of market surveillance practices? *(y/n)*	X	X
47.	To what extent do you think the Regulation currently addresses specific issues deriving from: *(to no extent, to some extent, to a large extent)*	X	X

N	Question	EO	CS
	□ Online trade/Delivery via small parcel consignments or express couriers		
	□ Increasing imports from third countries		
	□ Shortening product life impacting the ability of authorities to track non-complaint product and ensure corrective action		
48.	In addition to those reported in the previous question, could you please indicate additional issues affecting non-compliance with EU harmonisation legislation for the marketing of non-food products (e.g. related to health, safety and other public interest) that the Regulation is not properly addressing?	X	X
49.	The Regulation applies to a number of products: do you find the current scope of application of the Regulation clear? (*y/n/I do not know*)	X	X
50.	Have you ever used the section of ICSMS[474] system publicly accessible? (y/n)	X	X
51.	Do you find the information in the publicly accessible part of the ICSMS system relevant? (y/n) Please explain	X	X
52.	Is there a need for any additional guidance on any areas of the Regulation? *(y/n)*	X	X
53.	Could you please highlight any inconsistencies (if any) between the Regulation and any other pieces of EU legislation (e.g. with the General Product Safety Directive,[475] sector-specific product legislation)?	X	X
54.	Could you please highlight any contradictions (if any) between the provisions of the Regulation?	X	X
Added value of Regulation (EC) No 765/2008			
55.	Could you please highlight the benefits linked to having a European legislation harmonising market surveillance and controls of imported products instead of 28 national legislations?	X	X

474 ICSMS is the internet-supported information and communication system for the pan-European market surveillance. https://webgate.ec.europa.eu/icsms/

475 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0095&from=EN

N	Question	EO	CS
Concluding Remarks			
56.	Is there any other issue you would like to bring to the European Commission’s attention?	X	X

8.13 Interview grids

The following table presents the list of questions used in semi-structured interviews (i.e. those interviews not related to the data collection for case studies or for the CBA).

These interviews served to further investigate, clarify or triangulate data collected through the desk research, targeted surveys and public consultation. Given they were based on open discussion, these questions should be consider as non-exhaustive.

N	*Question*
Effectiveness	
1.	Are there any implementation issues and open points that need to be addressed at national/EU level?
2.	Are you aware of any discrepancies between EU Member States in the level of market surveillance in terms of uniformity and rigorousness of controls?
3.	Are you aware of any discrepancies between EU Member States in the level of sanctions?
4.	Are you aware of any discrepancies between sectors in your Member State in terms of uniformity and rigorousness of controls of MSAs? If yes, could you explain why?
5.	If any, are these discrepancies impacting the safety of products or the level playing field for businesses?
6.	Is there a need for any additional guidance on any areas of the Regulation?
7.	According to your experience, what is the main reason for product non-compliance in the Single Market?
8.	Do you have experience/knowledge of instances where an MSA lacks/lacked sufficient financial/human/ technical resources to carry out specific tasks in your sector?
9.	According to your experience, has the Regulation impacted on product non-compliance over the last 5 years? Could you explain why and how?
10.	Are MSAs in your Member State usually granted resources targeted to specific sectors/objectives?
11.	Overall, do you perceive that the introduction of the Regulation ensured the establishment of a level playing field among businesses? Why?
12.	Could you estimate which proportion of non-compliant products is eventually targeted with sanctions or restrictive measures by MSAs? Can you identify any trends before/after 2010?
13.	Do you perceive sanctions/penalties as effective and proportionate deterrence mechanisms to prevent product non-compliance in your Member State and rogue traders?
14.	Are you aware of any best practices in market surveillance in place in other EU Member States or in major trading partners (i.e.: Iceland, Norway, Liechtenstein, Turkey, Switzerland, USA, China, Korea, and Japan) in terms of national organisation of market surveillance, of particularly effective/efficient mechanisms to perform checks and controls, to ensure communication among MSAs and Customs?

N	*Question*
Efficiency	
15.	Did the Regulation introduce any type of costs on consumers/end-users (e.g. derived from Art. 19 stating that the MSAs may require economic operators to make documentation and information regarding the products available, to present test reports or certificates attesting conformity)?
16.	Do you think these costs affect disproportionately a particular category of stakeholders?
17.	Are you aware of any differences in costs for implementing the Regulation across Member States?
18.	Are the measures taken by MSAs proportionate to their objectives?
19.	Is the regulation able to provide the framework to ensure a higher level of protection of public interests?
20.	Do you think the level of compliance with the Regulation is increased/decreased? How the level of fair competition has been affected?
Relevance	
21.	In general, do you think that the Regulation meets the needs of stakeholders (e.g. in terms of scope)?
22.	To what extent do you think the Regulation currently meets new safety issues deriving from online trade, increasing imports from third countries, shortening product life, increasing budgetary constraints?
23.	Since the entry into force of Regulation (EC) No 765/2008, what have been the main emerging issues regarding health, safety and competitiveness related to marketing of non-food products?
24.	How does non-compliance affect consumers and other end-users? How does it affect competitiveness?
25.	Does the concept of *lex specialis* cause any problems of implementation or any risks in the framework for market surveillance?
26.	Are there any misalignments between the market surveillance provisions included in the Regulation and their implementation in different non-food product sectors?
Coherence	
27.	Are there overlapping or contradictions between the Regulation and any other pieces of EU legislation (e.g. GPSD and sectoral provisions on market surveillance)?
28.	Are there contradictions between the provisions of the Regulation?
Added value	
29.	What is additional value resulting from Regulation (EC) No 765/2008, as compared to what could be achieved through single Member State action?
30.	Do you think that the introduction of common market surveillance requirements strengthened the protection of public interest through the reduction of non-compliant products on the EU Single Market?
31.	To what extent do the Regulation provisions support and usefully supplement market surveillance

N	*Question*
	policies pursued by the Member States?
32.	Do the provisions allow some sort of 'control' by the EU on the way national authorities carry out market surveillance?
Concluding remarks	
33.	Is there any other issue you would like to bring to the European Commission’s attention?

8.14 Correspondence tables and data for the market analysis

As stressed, there is not full correspondence between the EC template and NACE/PRODCOM classifications, due to the different nature of issues under analysis (i.e. legislation vs statistical classifications). Therefore, in order to obtain reliable sources of data for the analysis at product and sector level, some hypotheses have been made, and results shall be interpreted having this caveat in mind.

The following tables present the assumed correspondence between the EC list of harmonised sectors and the sectors included in the market analysis at both sectoral and product level.

Correspondence between the EC list of harmonised sectors and economic sectors included in the market analysis (sectoral level)

Harmonised sectors	NACE	Description
1. Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	21	Manufacture of basic pharmaceutical products and pharmaceutical preparations
	26	Manufacture of computer, electronic and optical products
	32	Other manufacturing
2. Cosmetics	20	Manufacture of chemicals and chemical products
3. Toys	32	Other manufacturing
4. Personal protective equipment	14	Manufacture of wearing apparel
	15	Manufacture of leather and related products
	32	Other manufacturing
5. Construction products	23	Manufacture of other non-metallic mineral products
6. Aerosol dispensers	20	Manufacture of chemicals and chemical products
	25	Manufacture of fabricated metal products, except machinery and equipment

Harmonised sectors	NACE	Description
	28	Manufacture of machinery and equipment not elsewhere classified (n.e.c.)
	32	Other manufacturing
7. Simple pressure vessels and pressure equipment	22	Manufacture of rubber and plastic products
	24	Manufacture of basic metals
	25	Manufacture of fabricated metal products, except machinery and equipment
	23	Manufacture of other non-metallic mineral products
	28	Manufacture of machinery and equipment n.e.c.
8. Transportable pressure equipment	22	Manufacture of rubber and plastic products
	25	Manufacture of fabricated metal products, except machinery and equipment
	28	Manufacture of machinery and equipment n.e.c.
9. Machinery	27	Manufacture of electrical equipment
	28	Manufacture of machinery and equipment n.e.c.
	30	Manufacture of other transport equipment
10. Lifts	28	Manufacture of machinery and equipment n.e.c.
11. Cableways	28	Manufacture of machinery and equipment n.e.c.
12. Noise emissions for outdoor equipment	28	Manufacture of machinery and equipment n.e.c.
13. Equipment and protective systems intended for use in	26	Manufacture of computer, electronic and optical products

Harmonised sectors	NACE	Description
potentially explosive atmospheres	26	Manufacture of computer, electronic and optical products
	32	Other manufacturing
	25	Manufacture of fabricated metal products, except machinery and equipment
14. Pyrotechnics	20	Manufacture of chemicals and chemical products
15. Explosives for civil uses	20	Manufacture of chemicals and chemical products
16. Appliances burning gaseous fuels	28	Manufacture of machinery and equipment n.e.c.
17. Measuring instruments, non- automatic weighing instruments, pre-packaged products and units of measurement	26	Manufacture of computer, electronic and optical products
	28	Manufacture of machinery and equipment n.e.c.
18. Electrical equipment under EMC	27	Manufacture of electrical equipment
19. Radio and telecom equipment under RTTE - RED	26	Manufacture of computer, electronic and optical products
20. Electrical appliances and equipment under LVD	27	Manufacture of electrical equipment
	28	Manufacture of machinery and equipment n.e.c.
21. Electrical and electronic equipment under RoHS and WEEE and batteries	26	Manufacture of computer, electronic and optical products
	27	Manufacture of electrical equipment
	28	Manufacture of machinery and equipment n.e.c.
	32	Other manufacturing

Harmonised sectors	NACE	Description
	32	Other manufacturing
22. Chemical substances under REACH and Classification and Labelling Regulations (22A) and other chemicals (22B: Other chemicals: detergents, paints, persistent organic pollutants, fluorinated greenhouse gases, ozone depleting substances, etc.)	20	Manufacture of chemicals and chemical products
	25	Manufacture of fabricated metal products, except machinery and equipment
	26	Manufacture of computer, electronic and optical products
	27	Manufacture of electrical equipment
	36	Water collection, treatment and supply
	38	Waste collection, treatment and disposal activities; materials recovery
	45	Wholesale and retail trade and repair of motor vehicles and motorcycles
	71	Architectural and engineering activities; technical testing and analysis
	72	Scientific research and development
23. Eco-design and energy labelling; efficiency requirements for hot-boilers fired with liquid or gaseous fuels	25	Manufacture of fabricated metal products, except machinery and equipment
24. Tyre labelling	22	Manufacture of rubber and plastic products
25. Recreational craft	30	Manufacture of other transport equipment
26. Marine equipment	13	Manufacture of textiles
	25	Manufacture of fabricated metal products, except machinery and equipment
	26	Manufacture of computer, electronic and optical products

Harmonised sectors	NACE	Description
	27	Manufacture of electrical equipment
	28	Manufacture of machinery and equipment n.e.c.
	29	Manufacture of motor vehicles, trailers and semi-trailers
	30	Manufacture of other transport equipment
27. Motor vehicles and tractors 28. Non-road mobile machinery	28	Manufacture of machinery and equipment n.e.c.
	29	Manufacture of motor vehicles, trailers and semi-trailers
29. Fertilisers	20	Manufacture of chemicals and chemical products
30. Other consumer products under the GPSD	n.a.	n.a.
31. Biocides	20	Manufacture of chemicals and chemical products
32. Textile and footwear labelling	14	Manufacture of wearing apparel
	15	Manufacture of leather and related products
33. Crystal glass	23	Manufacture of other non-metallic mineral products

Correspondence between the EC list of harmonised sectors and manufacturing products included in the market analysis (product level)[476]

Harmonised sectors	NACE	Description
1. Medical devices (including in vitro diagnostic medical	21.2	Manufacture of pharmaceutical preparations

476 We included all PRODCOM codes under the level 4 (four-digit code) NACE hierarchy included in the table.

Harmonised sectors	NACE	Description
devices and active implantable medical devices)	26.6	Manufacture of irradiation, electrometrical and electrotherapeutic equipment
	32.5	Manufacture of medical and dental instruments and supplies
2. Cosmetics	20.42	Manufacture of perfumes and toilet preparations
3. Toys	32.4	Manufacture of games and toys
4. Personal protective equipment	14.12	Manufacture of workwear
	15.2	Manufacture of footwear
	32.99	Other manufacturing n.e.c.
5. Construction products	23.32	Manufacture of bricks, tiles and construction products, in baked clay
	23.51	Manufacture of cement
	23.52	Manufacture of lime and plaster
	23.61	Manufacture of concrete products for construction purposes
	23.62	Manufacture of plaster products for construction purposes
	23.63	Manufacture of ready-mixed concrete
	23.64	Manufacture of mortars
	23.65	Manufacture of fibre cement
	25.11	Manufacture of metal structures and parts of structures
6. Aerosol dispensers	20.3	Manufacture of paints, varnishes and similar coatings, printing ink and mastics

Harmonised sectors	NACE	Description
	20.41	Manufacture of soap and detergents, cleaning and polishing preparations
	20.42	Manufacture of perfumes and toilet preparations
	25.29	Manufacture of other tanks, reservoirs and containers of metal
	28.13	Manufacture of other pumps and compressors
	28.29	Manufacture of other general-purpose machinery n.e.c.
	32.99	Other manufacturing n.e.c.
7. Simple pressure vessels and pressure equipment	22.21	Manufacture of plastic plates, sheets, tubes and profiles
	24.2	Manufacture of tubes, pipes, hollow profiles and related fittings, of steel
	24.51	Casting of iron
	25.21	Manufacture of central heating radiators and boilers
	25.29	Manufacture of other tanks, reservoirs and containers of metal
	25.3	Manufacture of steam generators, except central heating hot water boilers
	23.32	Manufacture of bricks, tiles and construction products, in baked clay
	28.11	Manufacture of engines and turbines, except aircraft, vehicle and cycle engines
	28.12	Manufacture of fluid power equipment
	28.13	Manufacture of other pumps and compressors
	28.14	Manufacture of other taps and valves

Harmonised sectors	NACE	Description
	28.15	Manufacture of bearings, gears, gearing and driving elements
	28.25	Manufacture of non-domestic cooling and ventilation equipment
	28.29	Manufacture of other general-purpose machinery n.e.c.
8. Transportable pressure equipment	22.23	Manufacture of builders' ware of plastic
	25.21	Manufacture of central heating radiators and boilers
	25.29	Manufacture of other tanks, reservoirs and containers of metal
	25.91	Manufacture of steel drums and similar containers
	28.14	Manufacture of other taps and valves
9. Machinery	27.11	Manufacture of electric motors, generators and transformers
	28.11	Manufacture of engines and turbines, except aircraft, vehicle and cycle engines
	28.12	Manufacture of fluid power equipment
	28.13	Manufacture of other pumps and compressors
	28.22	Manufacture of lifting and handling equipment
	28.25	Manufacture of non-domestic cooling and ventilation equipment
	28.29	Manufacture of other general-purpose machinery n.e.c.
	28.41	Manufacture of metal forming machinery
	28.49	Manufacture of other machine tools

Harmonised sectors	NACE	Description
	28.92	Manufacture of machinery for mining, quarrying and construction
	28.99	Manufacture of other special-purpose machinery n.e.c.
	30.11	Building of ships and floating structures
	30.2	Manufacture of railway locomotives and rolling stock
10. Lifts	28.22	Manufacture of lifting and handling equipment
11. Cableways	28.22	Manufacture of lifting and handling equipment
12. Noise emissions for outdoor equipment	28.11	Manufacture of engines and turbines, except aircraft, vehicle and cycle engines
	28.12	Manufacture of fluid power equipment
	28.13	Manufacture of other pumps and compressors
	28.22	Manufacture of lifting and handling equipment
	28.25	Manufacture of non-domestic cooling and ventilation equipment
	28.29	Manufacture of other general-purpose machinery n.e.c.
	28.3	Manufacture of agricultural and forestry machinery
	28.41	Manufacture of metal forming machinery
	28.49	Manufacture of other machine tools
	28.91	Manufacture of machinery for metallurgy
	28.92	Manufacture of machinery for mining, quarrying and construction

Harmonised sectors	NACE	Description
	28.93	Manufacture of machinery for food, beverage and tobacco processing
	28.94	Manufacture of machinery for textile, apparel and leather production
	28.95	Manufacture of machinery for paper and paperboard production
	28.96	Manufacture of plastics and rubber machinery
	28.99	Manufacture of other special-purpose machinery n.e.c.
13. Equipment and protective systems intended for use in potentially explosive atmospheres	26.3	Manufacture of communication equipment
	26.51	Manufacture of instruments and appliances for measuring, testing and navigation
	32.99	Other manufacturing n.e.c.
14. Pyrotechnics	20.51	Manufacture of explosives
15. Explosives for civil uses	20.51	Manufacture of explosives
16. Appliances burning gaseous fuels	28.21	Manufacture of ovens, furnaces and furnace burners
17. Measuring instruments, non- automatic weighing instruments, pre-packaged products and units of measurement	26.51	Manufacture of instruments and appliances for measuring, testing and navigation
	28.29	Manufacture of other general-purpose machinery n.e.c.
18. Electrical equipment under EMC	27.12	Manufacture of electricity distribution and control apparatus
19. Radio and telecom equipment under RTTE - RED	26.3	Manufacture of communication equipment
20. Electrical appliances and equipment under LVD	27.4	Manufacture of electric lighting equipment
	27.51	Manufacture of electric domestic appliances

Harmonised sectors	NACE	Description
	27.9	Manufacture of other electrical equipment
	28.24	Manufacture of power-driven hand tools
21. Electrical and electronic equipment under RoHS and WEEE and batteries	26.11	Manufacture of electronic components
	26.12	Manufacture of loaded electronic boards
	26.2	Manufacture of computers and peripheral equipment
	26.4	Manufacture of consumer electronics
	26.51	Manufacture of instruments and appliances for measuring, testing and navigation
	26.6	Manufacture of irradiation, electromedical and electrotherapeutic equipment
	27.4	Manufacture of electric lighting equipment
	27.51	Manufacture of electric domestic appliances
	27.9	Manufacture of other electrical equipment
	28.23	Manufacture of office machinery and equipment (except computers and peripheral equipment)
	28.29	Manufacture of other general-purpose machinery n.e.c.
	32.3	Manufacture of sports goods
	32.4	Manufacture of games and toys
	32.5	Manufacture of medical and dental instruments and supplies
22. Chemical substances under REACH and Classification	20.13	Manufacture of other inorganic basic chemicals

Harmonised sectors	NACE	Description
and Labelling Regulations (22A) and other chemicals (22B: detergents, paints, persistent organic pollutants, fluorinated greenhouse gases, ozone depleting substances, etc.)	20.14	Manufacture of other organic basic chemicals
	20.41	Manufacture of soap and detergents, cleaning and polishing preparations
	25.61	Treatment and coating of metals
	25.62	Machining
	25.91	Manufacture of steel drums and similar containers
	25.92	Manufacture of light metal packaging
	25.93	Manufacture of wire products, chain and springs
	25.94	Manufacture of fasteners and screw machine products
	25.99	Manufacture of other fabricated metal products n.e.c.
	26.11	Manufacture of electronic components
	26.12	Manufacture of loaded electronic boards
	27.2	Manufacture of batteries and accumulators
	27.31	Manufacture of fibre optic cables
	27.32	Manufacture of other electronic and electric wires and cables
	27.33	Manufacture of wiring devices
	27.4	Manufacture of electric lighting equipment
	36	Water collection, treatment and supply

Harmonised sectors	NACE	Description
	38.21	Treatment and disposal of non-hazardous waste
	38.22	Treatment and disposal of hazardous waste
	38.31	Dismantling of wrecks
	38.32	Recovery of sorted materials
	45.2	Maintenance and repair of motor vehicles
	71.2	Technical testing and analysis
	72.11	Research and experimental development on biotechnology
	72.19	Other research and experimental development on natural sciences and engineering
	72.2	Research and experimental development on social sciences and humanities
	72.2	Research and experimental development on social sciences and humanities
23. Eco-design and energy labelling; efficiency requirements for hot-boilers fired with liquid or gaseous fuels	25.21	Manufacture of central heating radiators and boilers
	25.3	Manufacture of steam generators, except central heating hot water boilers
24. Tyre labelling	22.11	Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres
25. Recreational craft	30.12	Building of pleasure and sporting boats
26. Marine equipment	13.92	Manufacture of made-up textile articles, except apparel
	25.99	Manufacture of other fabricated metal products n.e.c.
	26.51	Manufacture of instruments and appliances for measuring, testing and navigation

Harmonised sectors	NACE	Description
	27.4	Manufacture of electric lighting equipment
	28.11	Manufacture of engines and turbines, except aircraft, vehicle and cycle engines
	29.1	Manufacture of motor vehicles
	30.11	Building of ships and floating structures
	30.12	Building of pleasure and sporting boats
27. Motor vehicles and tractors	28.3	Manufacture of agricultural and forestry machinery
28. Non-road mobile machinery	28.3	Manufacture of agricultural and forestry machinery
	28.92	Manufacture of machinery for mining, quarrying and construction
	28.92	Manufacture of machinery for mining, quarrying and construction
	29.1	Manufacture of motor vehicles
29. Fertilisers	20.15	Manufacture of fertilisers and nitrogen compounds
30. Other consumer products under GPSD	n.a.	n.a.
31. Biocides	20.2	Manufacture of pesticides and other agrochemical products
32. Textile and footwear labelling	14.12	Manufacture of workwear
	14.13	Manufacture of other outerwear
	14.14	Manufacture of underwear
	14.19	Manufacture of other wearing apparel and accessories

Harmonised sectors	NACE	Description
	14.31	Manufacture of knitted and crocheted hosiery
	14.39	Manufacture of other knitted and crocheted apparel
	15.2	Manufacture of footwear
33. Crystal glass	23.13	Manufacture of hollow glass

Number of active enterprises in harmonised sectors by MS (NACE Digit-3)

MS	2012	2013	2014
AT	9,217	9,600	9,794
BE	13,363	12,757	13,691
BG	15,022	15,058	15,093
CY	2,097	2,078	1,959
CZ	73,402	70,183	69,813
DE	103,922	104,765	108,282
DK	8,138	7,866	7,854
EE	2,573	2,841	2,949
EL	27,132	22,979	23,604
ES	78,929	75,908	74,079
FI	11,323	:	10,878

MS	2012	2013	2014
FR	68,041	71,010	:
HR	9,947	9,594	9,275
HU	23,911	22,742	22,568
IE	1,870	:	:
IT	202,747	195,102	190,216
LT	5,443	5,983	6,687
LU	389	396	380
LV	3,718	3,944	4,136
MT	:	:	:
NL	25,533	28,423	28,646
PL	81,362	80,548	84,522
PT	33,670	:	31,558
RO	21,052	21,350	22,033
SE	27,560	26,969	25,942
SI	8,493	8,527	8,565
SK	36,318	34,679	35,232
UK	63,358	63,731	67,330

MS	2012	2013	2014
Total	1,801,221	1,704,093	1,625,106

Source: Authors' elaboration on SBS (2016)

Value of intra EU imports of harmonised products at MS level, €bn

MS	2008	2009	2010	2011	2012	2013	2014
AT	44	37	42	46	46	47	48
BE	102	89	98	102	103	99	100
BG	7	5	5	6	7	7	8
CY	2	2	2	2	1	1	1
CZ	37	30	37	41	42	43	47
DE	218	185	217	242	240	240	250
DK	26	20	21	23	25	25	26
EE	4	2	3	5	5	5	5
ES	77	60	64	67	63	64	69
FI	18	14	15	17	17	17	17
FR	147	126	142	154	154	154	155
HE	18	16	14	13	12	12	12
HR	6	5	4	4	5	5	6

MS	2008	2009	2010	2011	2012	2013	2014
HU	24	18	22	25	26	27	29
IE	17	13	13	14	14	16	17
IT	96	80	99	104	98	99	100
LT	6	4	5	6	7	7	8
LU	5	5	5	6	6	6	6
LV	4	2	3	4	4	4	4
MT	1	1	1	1	1	1	1
NL	73	61	69	77	81	78	79
PO	53	41	50	55	55	57	61
PT	22	19	20	20	19	19	20
RO	21	15	18	21	21	22	23
SE	35	27	34	40	39	38	39
SI	8	7	7	8	8	8	8
SK	17	14	17	20	21	22	23
UK	101	85	97	104	113	115	118
Total	**1,189**	**983**	**1,123**	**1,229**	**1,235**	**1,239**	**1,281**

Source: EU trade since 1998 by SITC, EUROSTAT (2016)

8.15 Information sources

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PART 3/3

COMMISSION STAFF WORKING DOCUMENT

REFIT EVALUATION

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) 466 final} - {SWD(2017) 467 final} -
{SWD(2017) 468 final} - {SWD(2017) 470 final}

ANNEX 5: UNION HARMONISATION LEGISLATION AND OVERVIEW OF APPLICABLE EU MARKET SURVEILLANCE PROVISIONS

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 and repealing Council Directive 89/106/EEC;

(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. OVERVIEW OF EU MARKET SURVEILLANCE PROVISIONS APPLICABLE TO HARMONISED PRODUCTS

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**
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		

MARKET SURVEILLANCE PROVISIONS IN EU LEGISLATION		
MARKET SURVEILLANCE MEASURES AND STRUCTURES	**REGULATION (EC) No 765/2008**	**SECTOR LEGISLATION**
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**

ANNEX 6: 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 systems has helped to raise awareness of high-risk products. 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[1]. 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[2].

For example, the impact assessment[3] 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%[4]. In other areas (e.g. Gas Appliances, Personal protective equipment) the existing studies indicate non-compliance levels of no more than 5-10%[5] and there are also cases – such as explosives – where, according to the relevant

1 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

2 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

3 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

4 Evaluation of the Ecodesign Directive (2009/125/EC) - Final Report

5 Impact assessment study on the review of the Gas Appliances Directive 2009/142/EC

evaluation study[6], 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 the internal market since there could be variations for economic operators in their

6 Evaluation on dg enterprise and industry legislation – Cosmetics and Explosives Directives

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**[7], 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 converge 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 the value added of each database".

7 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.

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 6-1: A systems-based and horizontal approach to market surveillance and regulatory enforcement[8]

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 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

8 Source: Systeemtoezicht en Horizontaal Toezicht, conceptleidraad voor de Rijksinspecties, Begrippen en randvoorwaarden, December 2012 http://www.inspectieloket.nl/vernieuwing_toezicht/programma_systeemtoezicht/

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 7: 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').[9] 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[10].

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.

9 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.

10 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[11] and in the Report on the implementation of Regulation (EC) No 765/2008[12].

- 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.

2.1 Belgium

General market surveillance activities

General organisation: Belgium refers to the information on the general organisation of market

11 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

12 COM(2013)77.

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 7-1: 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[13] (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[14] 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.

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[15] (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

13 The budget also covers inspections of industrial equipment during use, as well as quality control of liquid fuels.
14 Correspondingly, the share of KZP's resources dedicated to market surveillance went down from 62% to 40%.
15 Directive 94/62/EC.

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 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[16] (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[17], 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

16 The figure excludes the wages of personnel not directly involved in markets surveillance.

17 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.

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.

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[18]. On the other hand, the report does not provide for a more general assessment of the effectiveness or efficiency of these sector specific activities.

18 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.

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[19]). 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.

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

19 The proportion of staff who are inspectors may be slightly greater, since some authorities have not classified their staff in more detail.

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[20] 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[21] implemented under each area.

Table 7-2: 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
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 requirements22. By contrast, the proportion of those products that presents a serious risk is only 0.7 % (1032 cases).

20 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).

21 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).

22 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

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 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[23], either by carrying out checks

23 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;

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. [24] 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.[25] 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 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[26].

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.

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.

24 Budget including both tests carried out by State laboratory and tests subcontracted to private laboratories.

25 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.

26 The percentage mentioned here are very rough and purely indicative estimates.

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 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[27] - 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.

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[28]that carry out documentary checks, and more than 900 inspectors[29]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

27 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.

28 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.

29 This figure includes 500 FTEs from Guardia di Finanza, 275 from Chambers of Commerce, 100 Carabinieri NAS.

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[30].

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.

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.

30 However pyrotechnics and civil explosives also come under the responsibility of the police.

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[31] 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.

31 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).

– 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).

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[32]) 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

32 According to the Lithuanian study that the scope of the Product Safety Law in respect of foodstuff is unclear.

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, 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[33]. 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.[34] The responsibilities of ILNAS and ITM cover about two-thirds of the sectors mentioned in the reference list.

33 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

34 On 1 August 2014 the responsibility for market surveillance authority in these areas were transferred to ILNAS

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 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[35], 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

35 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).

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 EU product legislation. Verispect mentions a budget of 0.2 million EUR market surveillance of measuring 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 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[36] (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

36 This concerns around 100 district administration authorities across the nine federal provinces.

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.

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[37].

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[38] each with their own sector(s) of responsibility. The report further

37 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).

38 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).

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 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[39] 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.

39 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.

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.

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[40], is the market surveillance authority for most non-food consumer products.[41]

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[42] (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[43] 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[44].

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

40 The Ministry's responsibility also encompasses the Main Mining Office, which carries out the state surveillance of the explosives market.

41 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.

42 Together with 36 regional public health authorities.

43 16 inspectors from regional labour inspectorates and 2 employees of the National Inspectorate.

44 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.

activities, such as official inspections of foodstuffs.

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[45] (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 RAPEX.

45 Including checks for hot-water boilers efficiency requirements.

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 section 7.

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[46]. The objective is to shed a brighter light on some aspects of market surveillance activities in practice.

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,

46 Naturally differences between countries can partly be attributed to different levels/styles of enforcement activities and partly to diverging interpretations of the indicators.

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[47], 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[48] 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[49]:

- 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[50]; 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 (7-11 million inhabitants): Belgium reports 1 270[51] inspections per year on average; Greece reports 28 inspections[52], 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

47 Also includes those concerning non-harmonised consumer goods.

48 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.

49 The number of inhabitants is taken here as a very simple (although admittedly very rough) estimate of national market sizes.

50 The figure does not include checks carried out by customs that in France are market surveillance authorities.

51 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.

52 The Greek report notes these were carried out "at virtually zero cost".

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[53]; 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[54] 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).

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[55] for the period 2010-2013 were proactive inspections. However the situation changes from country to country (see Table 7-3 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%),

53 Not limited to toys.

54 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.

55 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.

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%)[56] – recorded a high number of reactions to Rapex notifications – and Ireland (0%).

Table 7-3: 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
NL	n.a.
AT	n.a.
PL	83
PT	50
RO	99
SI	77

56 As regards Belgium the share is calculated on the figures provided for 2013 only.

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% [57], 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 7-4: Share of inspections prompted by customs (percentages)

BE	n.a.
BG	26
CZ	n.a.
DK	10
DE	n.a.
EE	n.a.
IE	100
EL	0
ES	n.a.

57 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.

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[58]. 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

58 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.

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.

4.5 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.[59]

Table 7-5 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 7-5: Follow up to inspections: percentage of cases of non-compliance where measures and/or penalties were applied

BE	n.a.
BG	37
CZ	37
DK	68
DE	n.a.
EE	100
IE	100

59 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.

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.

4.6 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.

4.7 On budget and staff

Only 10 Member States indicated budget[60] 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;
- 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.

60 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.

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).

4.8 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 7-6: 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 7-7: 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				

		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**
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

		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**
SL	2.06	16.50	8.00	1921.5[61]	931.47	1,756.50[62]	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
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				

61 Figures include also all beauty care services inspections.
62 Figures include also inspections in kindergartens.

		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

		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**
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

		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**
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

		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**
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

		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**
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

		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**
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

		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**
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

		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**
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 7-8: 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

		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**
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										

		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**
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										

		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**
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		

		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**
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										

		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**
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

		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**
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										

		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**
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

		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**
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										

		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**
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								

		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**
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

		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**
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		

		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**
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 7-9: 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 7-10: 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

Sectors	Number of Member States providing penalties information	Average number of penalties applied per Member State and per year (simple average)
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.

7

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]

[....]

9

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	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	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	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	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	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
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
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

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
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
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

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
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

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
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[63]	4	3	5	5
2.	Number of substantiated complaints by industry concerning unfair competition	1	1		
3.	Number of inspections (total number)[64]	138	133	91	90
3.1	number of reactive inspections[65]	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[66]	133	81	81	81
5	Number of inspections resulting in:				
5.1	finding of non-compliance	30	20	44	24

63 Data available from the Environmental Protection Agency only.
64 The table covers the number of products and not the number of inspections. The number is based on an average.
65 A significant proportion took place as the result of complaints from consumers, possibly as the result of accidents.
66 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
5.2	corrective actions taken by economic operators ("voluntary measures")	8	16	13	11
5.3	restrictive measures taken by market surveillance authorities[67]	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 purely because it has a warning symbol indicating that it is 'not suitable for children aged 0-3'.

67 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.

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[68]	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[69]	49	57	47	15
Number of products presenting a serious risk	10	13	13	17

Measures applied[70]	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[71]	21	10	6	7
Number of products recalled from consumers[72]	2	19	Data not available	Data not available
Number of voluntary measures taken by economic operators[73]	6	8	6	7

68 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.

69 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%.

70 For the Consumer Protection Board, only the number of memos is available.

71 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.

72 The data from 2010–2011 consist of data of the Consumer Protection Board. The Health Board has no data available.

73 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[74]

		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				

74 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.	Number of inspections (total number)		1	3	9
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		[75]	
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")	[76]			
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. 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

75 Representative items from customs consignments were visually and physically checked.
76 The Agency achieved voluntary corrective actions (where necessary) in majority of cases.

covered by the EU Directives, enforcement of product safety legislation, 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 (€)[77]	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)[78]	7	7	8	8
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)[79]	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.

77 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.

78 Number of authorised officers in Product Safety Unit with additional authorised Officers available to assist on specific projects if required.

79 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[80]	10	6	6	4
5.4	application of sanctions/penalties[81]	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

80 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).

81 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 (€)[82]				
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)[83]				
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

82 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).

83 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 (€)[84]	2000000	1620000	1300000	1320000

84 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[85]

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
5.3	restrictive measures taken by market surveillance authorities				60

85 Data only between 1 July 2013 – 31 December 2013

		2010	2011	2012	2013
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:				
4.1	tests performed in laboratories		415		
4.2	physical checks of products				
5	Number of inspections resulting in:				

		2010	2011	2012	2013
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
5.3	restrictive measures taken by market surveillance authorities	1	7	18	22

		2010	2011	2012	2013
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[86]	95	113	129	243
4	Number of inspections based on: [87]				
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")[88]	486	1082	1047	1016
5.3	restrictive measures taken by market surveillance authorities[89]	77	80	70	45
5.4	application of sanctions/penalties[90]	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

86 The number of opinions issued at the request of the customs authorities is given.
87 Estimate data. In case of some authorities the number of products is given.
88 The number of operations is given.
89 The number of measures applied is given.
90 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[91] 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.

91 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 [92]	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.

The meetings were organized by the Regional Chamber of Craft; we introduced legislation on the safety of toys.

92 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.

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 (€)[93]	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)[94]	135	133	134	129
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)[95]	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.

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.

93 Overall authority budget.
94 Number of employees instead of full-time equivalent units.
95 Total number of inspectors instead of full-time equivalent units.

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
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

		2010	2011	2012	2013
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)
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	
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	

		2010	2011	2012	2013
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 8: BACKGROUND INFORMATION ON COOPERATION AMONG MEMBER STATES AND RESOURCES AVAILABLE FOR CONTROLS OF PRODUCTS

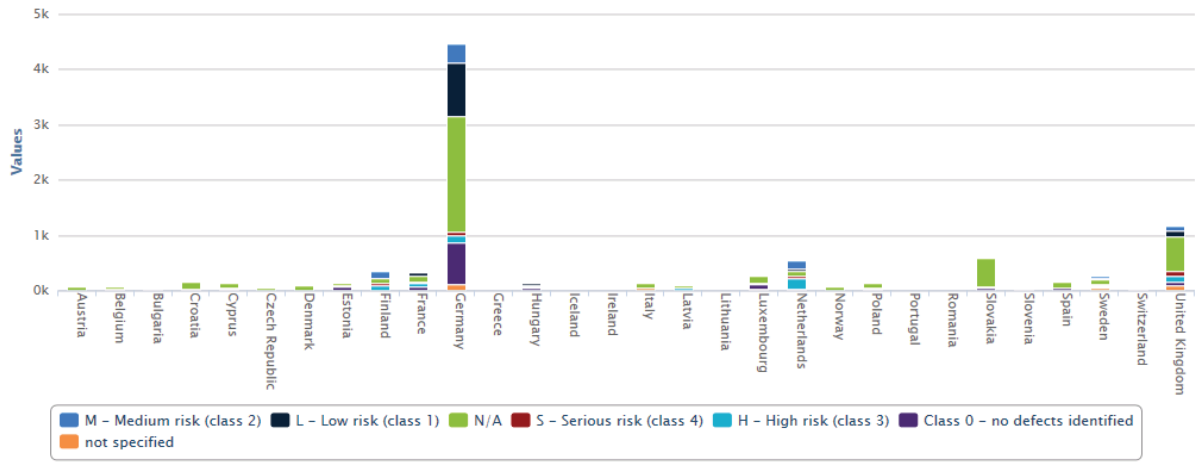
1. COORDINATION OF ENFORCEMENT OF PRODUCT LEGISLATION WITHIN THE EU (BASELINE)

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.

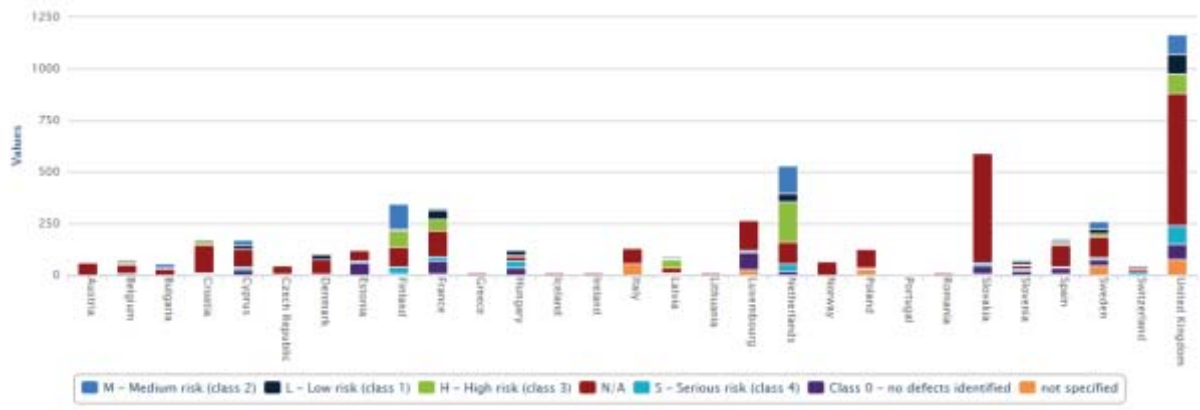
1.1 ICSMS

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 to converge ICSMS and RAPEX (see below) into a single platform.

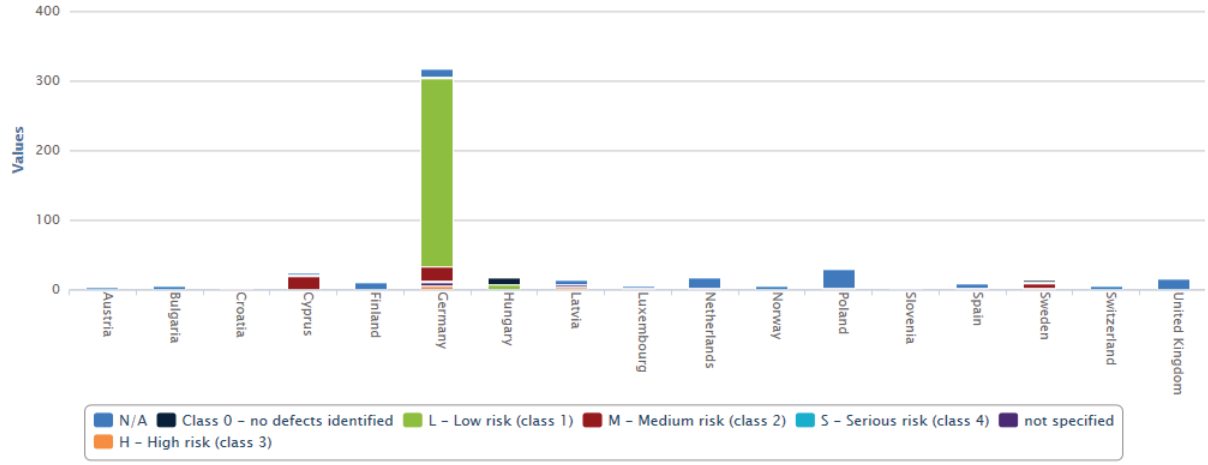
However, Member States use the system to different degrees, as shown in the diagrams below which show the numbers of product information input to the ICSMS system during 2016. Clearly the system is not used very well by many market surveillance authorities and some are not using the system at all. Even 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.



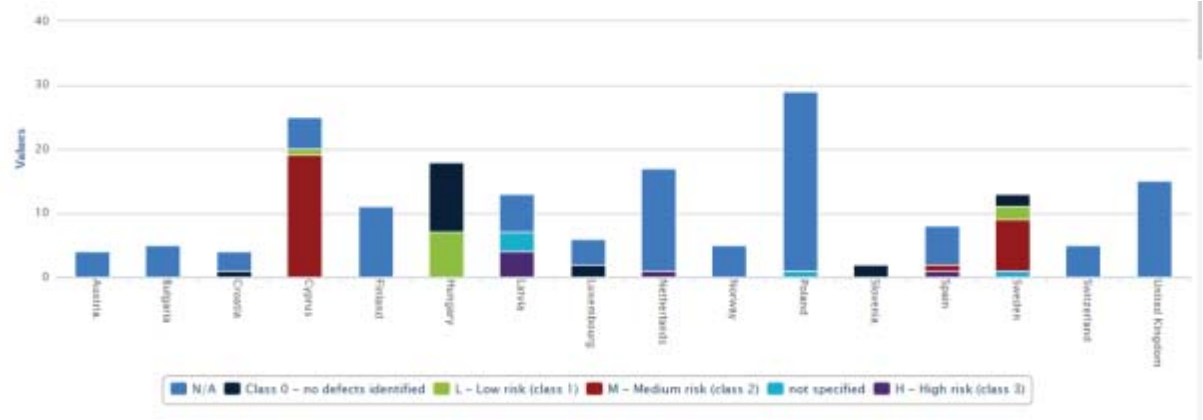
Use of ICSMS by all EU/EEA Member States in 2016 (2 with no entries)



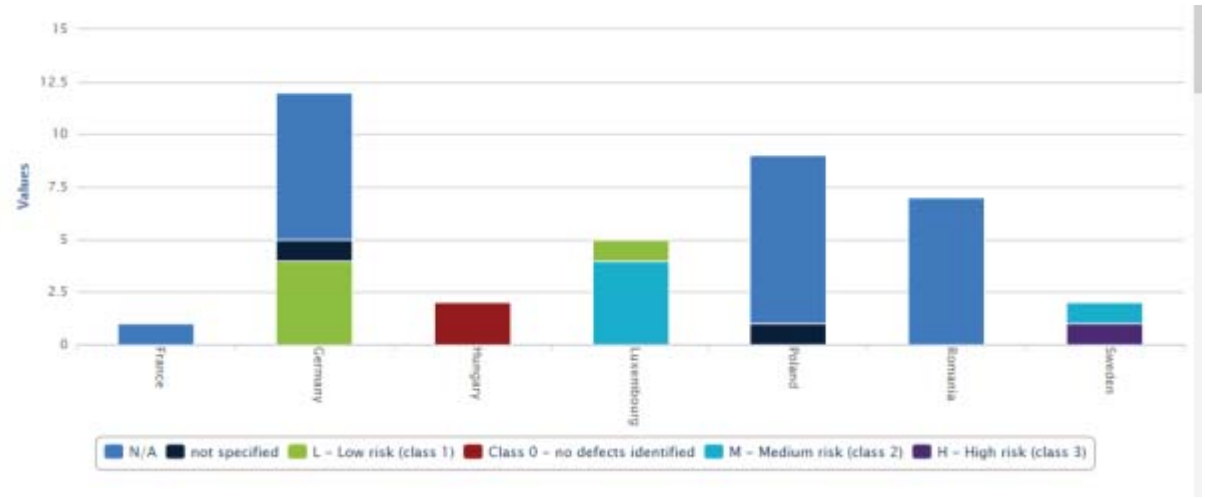
Use of ICSMS by EU/EEA Member States excluding Germany in 2016



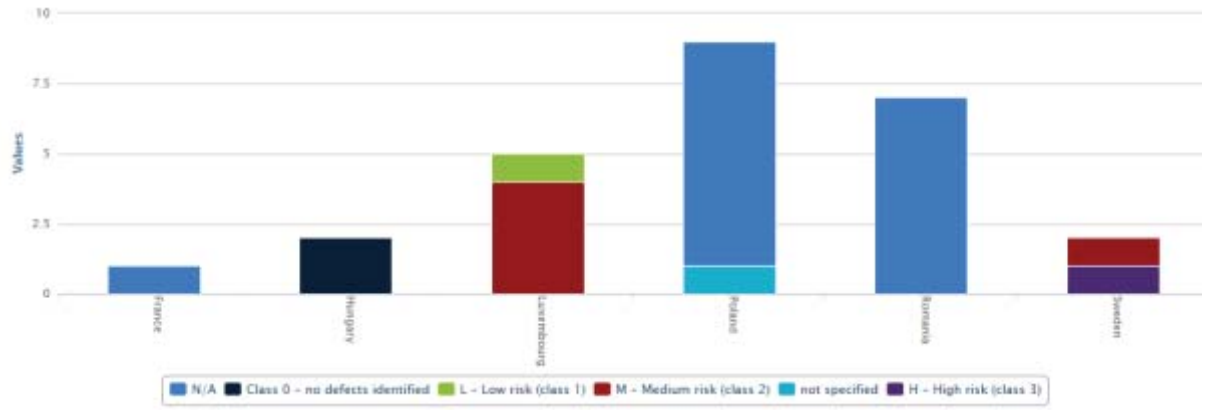
Use of ICSMS for EMC 2004 by all EU/EEA Member States in 2016 (15 with no entries)



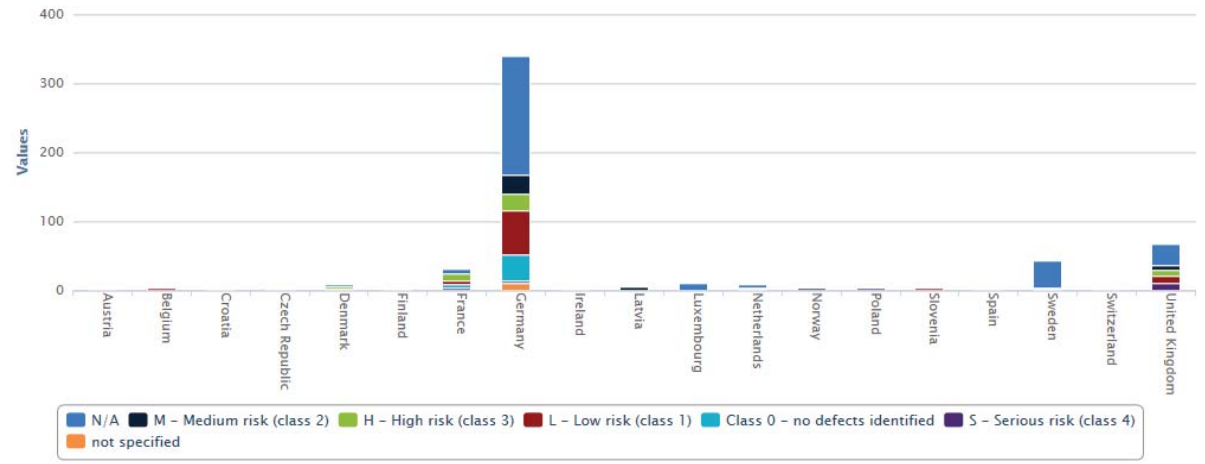
Use of ICSMS for EMC 2004 by EU/EEA Member States excluding Germany in 2016



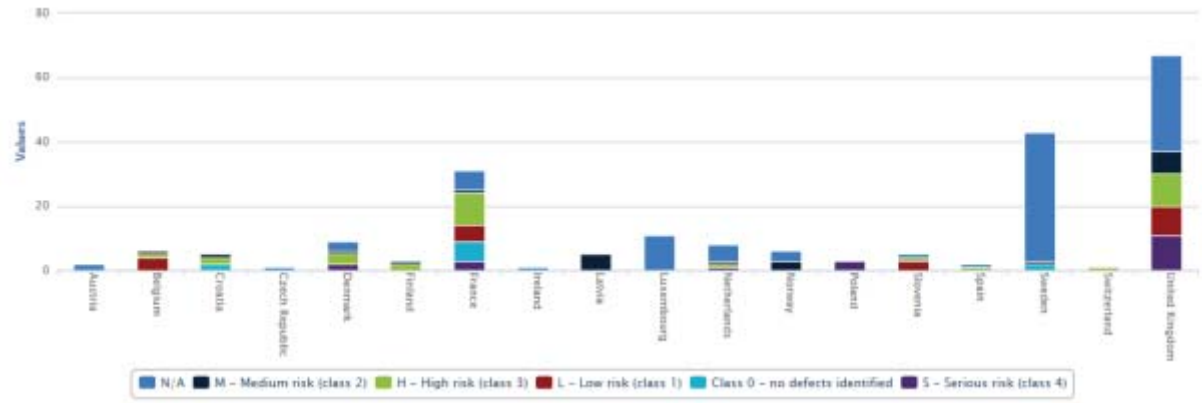
Use of ICSMS for EMC 2014 by all EU/EEA Member States in 2016 (25 with no entries)



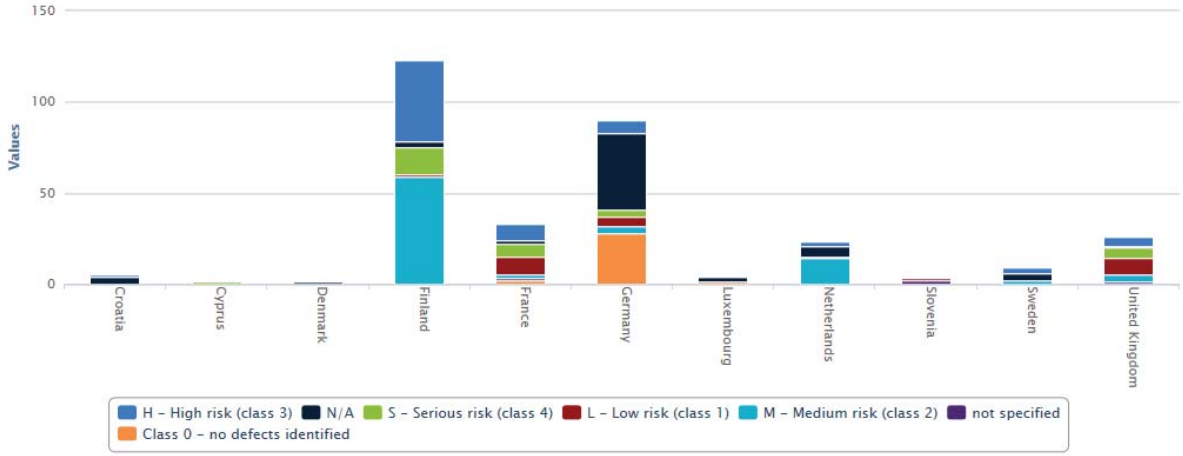
Use of ICSMS for EMC 2014 by EU/EEA Member States excluding Germany in 2016



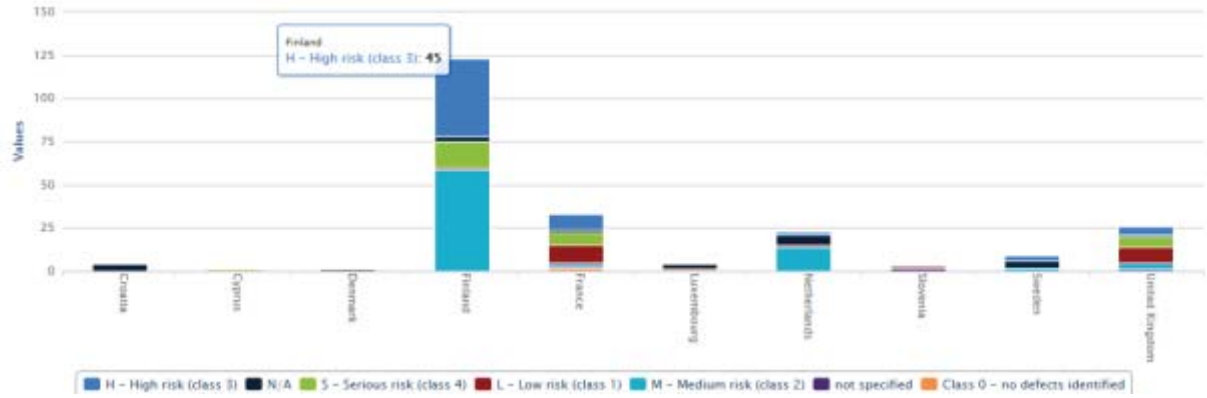
Use of ICSMS for Machinery by all EU/EEA Member States in 2016 (13 with no entries)



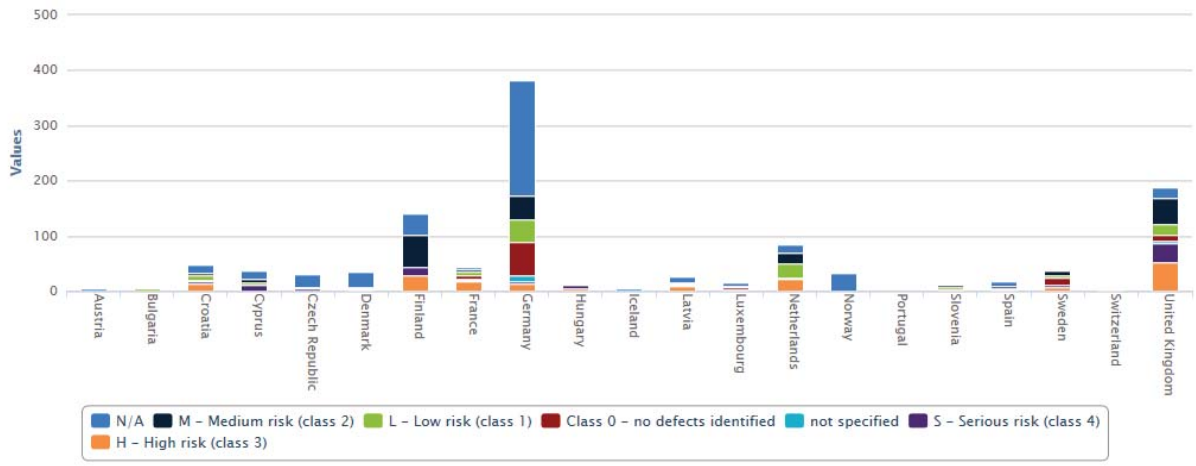
Use of ICSMS for Machinery by EU/EEA Member States excluding Germany in 2016



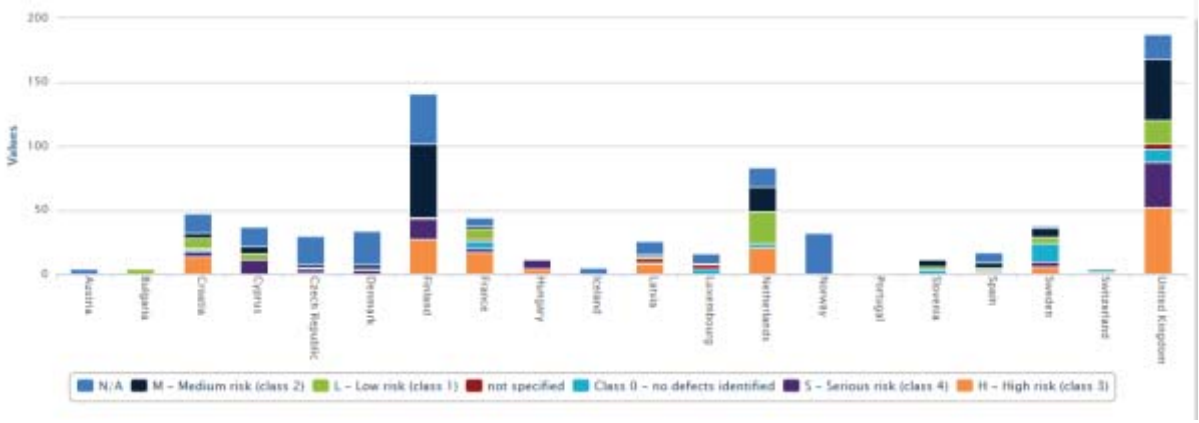
Use of ICSMS for LVD 2014 by all EU/EEA Member States in 2016 (21 with no entries)



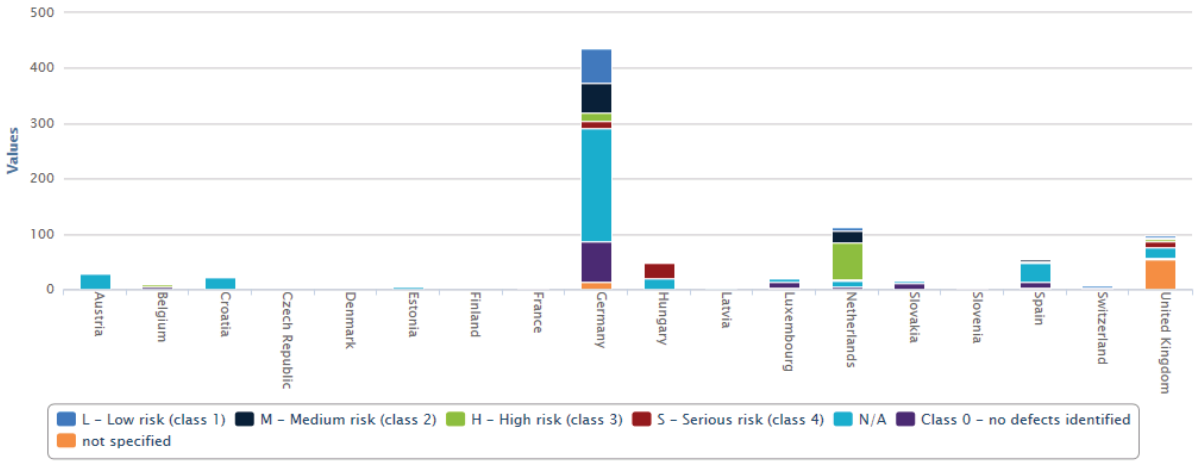
Use of ICSMS for LVD 2014 by EU/EEA Member States excluding Germany in 2016



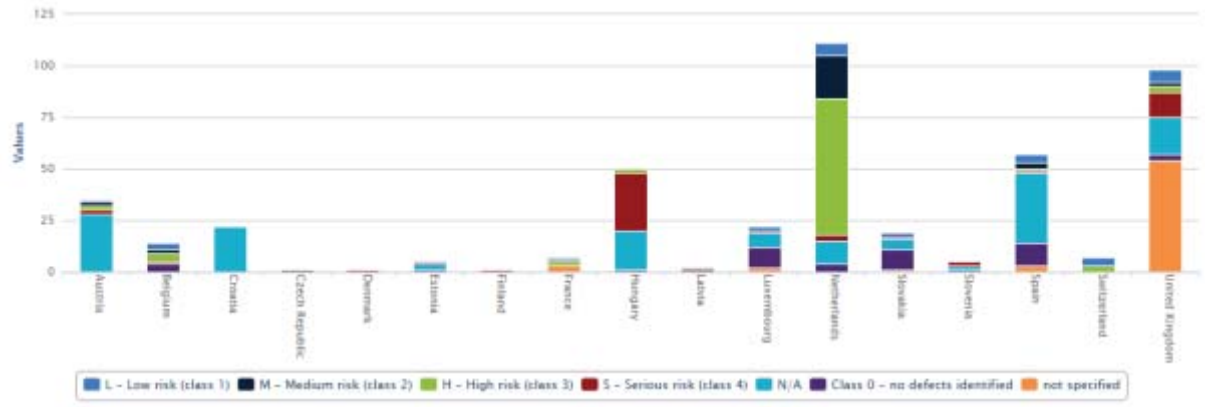
Use of ICSMS for LVD 2006 by all EU/EEA Member States in 2016 (11 with no entries)



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

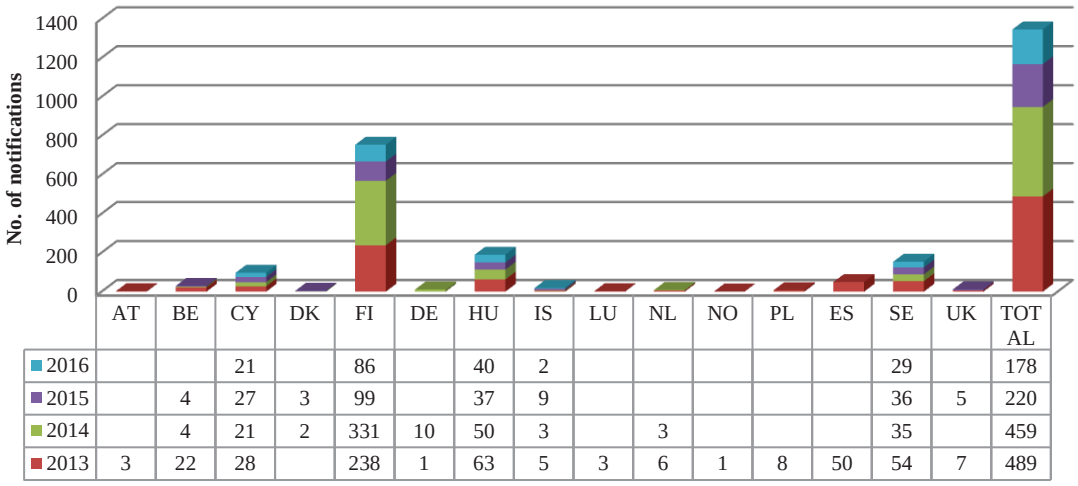
EU product legislation set out an obligation for Member States' competent authorities to communicate to the other Member States restrictive measures taken against non-compliant products. Furthermore, receiving Member States then have an obligation to 'follow up' on those notifications, i.e. adopt in 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[96]. Recent guidance discussed at expert's working group level clarifies principles for cooperation based on the existing legal framework[97]. 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.

96 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.

97 Guidance on cross-border cooperation among EU market surveillance authorities (http://ec.europa.eu/DocsRoom/documents/17108/attachments/1/translations).

Figure 8-1: 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[98]. Since 2004, more than 20 000 measures taken against dangerous products have been raised in the Rapid Alert System.[99] 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 8-1: Notifications and reactions in RAPEX Rapid Alert System in 2015[100]

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%

98 Articles 20 and 22 of Regulation (EC) No 765/2008.

99 Source: RAPEX statistics and reports: http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/reports/index_en.htm

100 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.

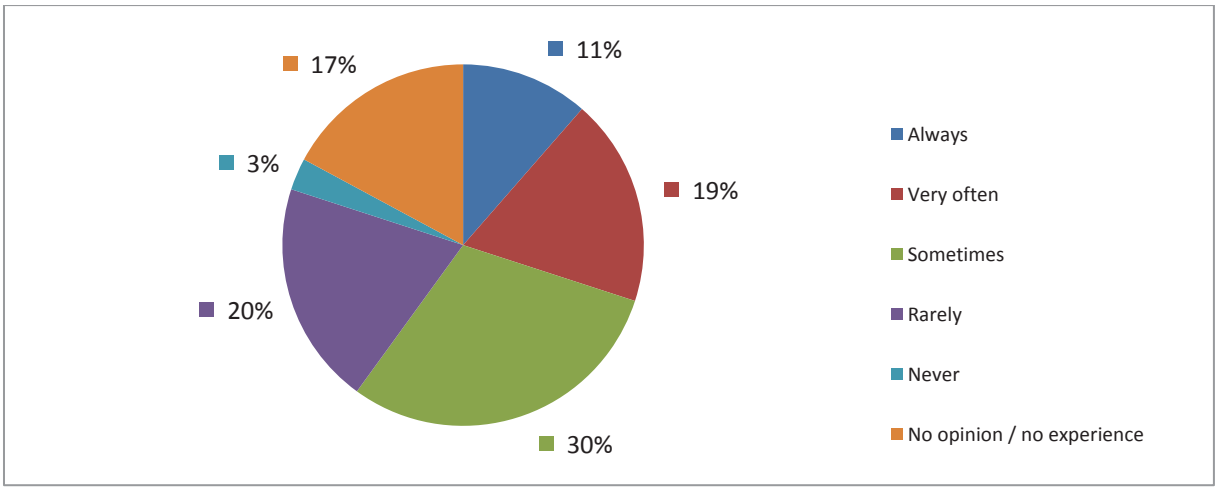
Country	Notifications		Reactions	
	Number	Percentage	Number	Percentage
Croatia	7	0.34%	138	5.03%
Cyprus	117	5.62%	17	0.62%
Czech Republic	109	5.24%	18	0.66%
Denmark	27	1.30%	209	7.61%
Estonia	21	1.01%	32	1.17%
Finland	52	2.50%	179	6.52%
France	135	6.48%	105	3.83%
Germany	208	9.99%	85	3.10%
Greece	14	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%

Country	Notifications		Reactions	
	Number	Percentage	Number	Percentage
Spain	239	11.48%	319	11.62%
Sweden	78	3.75%	181	6.59%
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 8-2).

Figure 8-2: 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[101] 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

101 Article 24 of Regulation (EC) No 765/2008.

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[97].

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[102] 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[103], 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)[104]. It concerns a number of sectors.[105] 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.[106]

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

102 The figure of 200 requests was mentioned during a meeting with national authorities.
103 See figures in Annex 7 Section 5.
104 https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups_en
105 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.
106 http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2798

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 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 8-2. 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 8-2: 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 8-3: Joint actions organised within AdCos and number of Member States (MS) participating[107]

AdCo[105]	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)	
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[108]	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)

107 Most joint actions are indicated under the year during which they were launched, although projects lasted two or more years.

108 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.

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[109]. In particular, the following calls for proposals were made since 2013:

- 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"[110].

- 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

109 Chapter V of Regulation (EC) No 765/2008.
110 http://www.prosafe.org/about-us/contentall-comcontent-views/what-is-prosafe

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.[111]

Furthermore, joint actions are regularly financed by the Commission under the Consumer Programme[112]. 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.

Table 8-4: Joint actions financed under the Consumer Programme

	Member States + EFTA countries	Authorities	Product categories		Budget (in M€)	Grant (70%) (in M€)	Work-days
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	2.14	1.48	3169

111 http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=28611&no=1
112 http://ec.europa.eu/consumers/eu_consumer_policy/financial-programme/index_en.htm

				Cosmetics Childcare Articles- Highchairs, Cords and Drawstrings, Ladders, CO and smoke detectors)			
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[113] – 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.

– EEPLIANT[114]– 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.

113 http://www.ecopliant.eu/wp-content/uploads/2012/10/Final-Publishable-Report.pdf
114 http://www.eepliant.eu

– MsTyr15[115] 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.*

*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.*

115 http://www.mstyr15.eu/index.php/en /

*[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.**

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. 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.

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.

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:

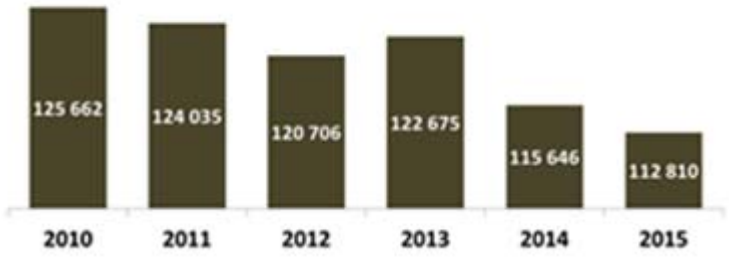
Benefit	AEOC	AEOS
Easier admittance to customs simplifications	X	
Fewer physical and document-based controls • related to security & safety • related to other customs legislation	 X	 X
Prior notification in case of selection for physical control (related to safety and security)		X
Prior notification 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
Mutual Recognition with third countries		X

5. Customs resources

Customs face a significant challenge to manage increasing volumes of goods and tasks while facing a downward trend in resources[116]. The total number of personnel working in Customs

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

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[117] 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:[118]
  - Decreased during 2010-2013 (from €133.4 mil. to €123.8 mil.),
  - 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%[119] 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;

117 Source: Final report of the Ex-post evaluation of the application of market surveillance provisions of regulation (EC) No 765/2008.
118 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.
119 The figures refer to 10 countries that provided reliable data, precisely: Denmark, Estonia, Spain, Finland, Italy, Latvia, Malta, Poland, Sweden and Slovakia.

- 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).

3.2 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 8-5: 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)[120]
SECTOR 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	8[121]	1,391,889 €	34.14 €
SECTOR 2 - Cosmetics	8[122]	4,993,718 €	43.21 €
SECTOR 3 - Toys	8[123]	1,917,787 €	17.48 €
SECTOR 4 - Personal Protective Equipment	7[124]	270,913€	2.53 €
SECTOR 5 - Construction Products	8[125]	425,273 €	3.39 €

120 Population on 1 January 2015 as provided by Eurostat
121 Denmark, Ireland, Cyprus, Latvia, Portugal, Slovenia, Finland and Sweden.
122 Denmark, France, Hungary, Portugal, Slovenia, Slovak Republic, Finland and Sweden
123 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.
124 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.
125 Bulgaria, Denmark, France, Cyprus, Hungary, Romania, Finland and Sweden.

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)[120]
SECTOR 6 - Aerosol dispensers	4[126]	9,635 €	0.50 €
SECTOR 7 - Simple pressure vessels and Pressure Equipment	6[127]	355,540 €	3.39 €
SECTOR 8 - Transportable pressure equipment	6[128]	274,912 €	2.86 €
SECTOR 9 - Machinery	7[129]	564,028 €	5.27 €
SECTOR 10 - Lifts	4[130]	425,111 €	15.08 €
SECTOR 11 - Cableways	2[131]	741,722 €	57.67 €
SECTOR 12 - Noise emissions for outdoor equipment	4[132]	169,647 €	1.94 €
SECTOR 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	6[133]	210,451 €	2.04 €
SECTOR 14 - Pyrotechnics	5[134]	336,074 €	3.90 €
SECTOR 15 - Explosives for civil uses	4[135]	196,517€	2.44 €
SECTOR 16 - Appliances burning gaseous fuels	8[136]	186,410 €	1.70 €

126 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.

127 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.

128 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.

129 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.

130 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.

131 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.

132 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.

133 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.

134 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.

135 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.

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)[120]
SECTOR 17 - Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	9[137]	316,777€	2.74 €
SECTOR 18 - Electrical equipment under EMC	11[138]	1,213,247 €	5.51 €
SECTOR 19 - Radio and telecom equipment under RTTE	11[139]	1.630.901 €	7.37 €
SECTOR 20 - Electrical appliances and equipment under LVD	10[140]	663,663 €	5.74 €
SECTOR 21 - Electrical and electronic equipment under RoHS, WEEE and batteries	5[141]	191,120 €	5.83 €
SECTOR 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)	7[142]	145,000 €	1.50 €
SECTOR 23 - Ecodesign and Energy labelling	8[143]	215,344 €	1.99 €
SECTOR 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	4[144]	120,924 € €	2.65 €
SECTOR 25 - Recreational craft	4[145]	284,264 €	2.86 €
SECTOR 26 - Marine Equipment	2[146]	75,854 €	2.97 €

136 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.

137 Bulgaria, Denmark, France, Hungary, the Netherlands, 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.

138 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.

139 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.

140 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.

141 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.

142 Denmark, Ireland, France, Latvia, Hungary, Slovenia and Finland.

143 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.

144 Belgium, Ireland, Hungary and Romania.

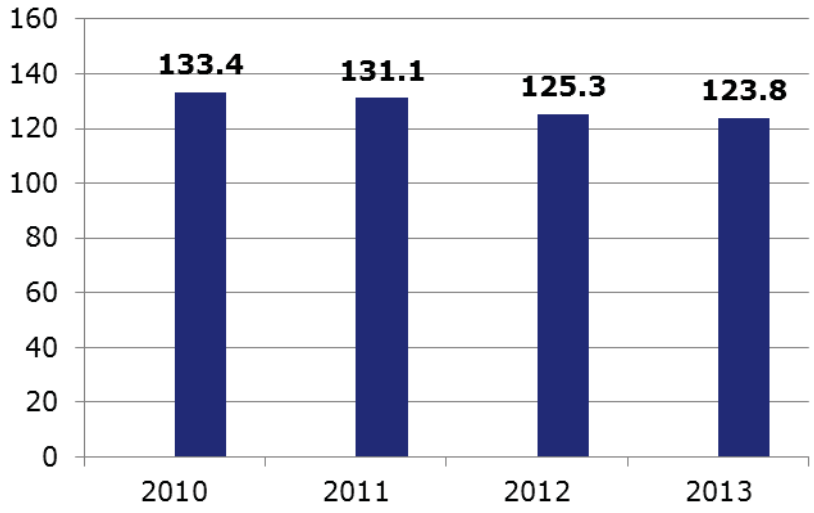
145 Bulgaria, France, Romania and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

146 Denmark and Romania.

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)[120]
SECTOR 27 - Motor vehicles and tyres	6[147]	456,843 €	4.30 €
SECTOR 28 - Non-road mobile machinery	2[148]	14,324 €	0.73 €
SECTOR 29 - Fertilisers	9[149]	135,641 € €	1.06 €
SECTOR 30 - Other consumer products under GPSD	5[150]	1,514,284 €	15.26 €

Source: national reports

Figure 8-3: Total budget available to MSAs in nominal terms during 2010-2013, € millions [151]



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

147 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.

148 Hungary and Sweden.

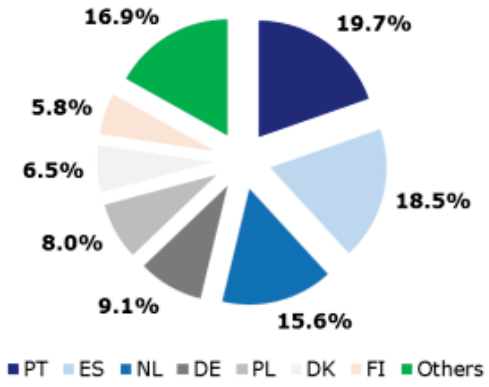
149 Czech Republic, Denmark, France, Latvia, Hungary, Romania, Slovenia, Slovak Republic and Finland. Belgium provided also figures but this has not been taken into account, since the FASFC submitted its total annual budget which covered integrated inspection services covering the whole of the food chain.

150 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.

151 The data correspond to 19 out of 28 EU Member States (please see the explanation in the paragraph above the figure)

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.

Figure 8-4: Contribution of each MS to the total budget available in nominal terms to MSA at EU level over 2010-2013[152]

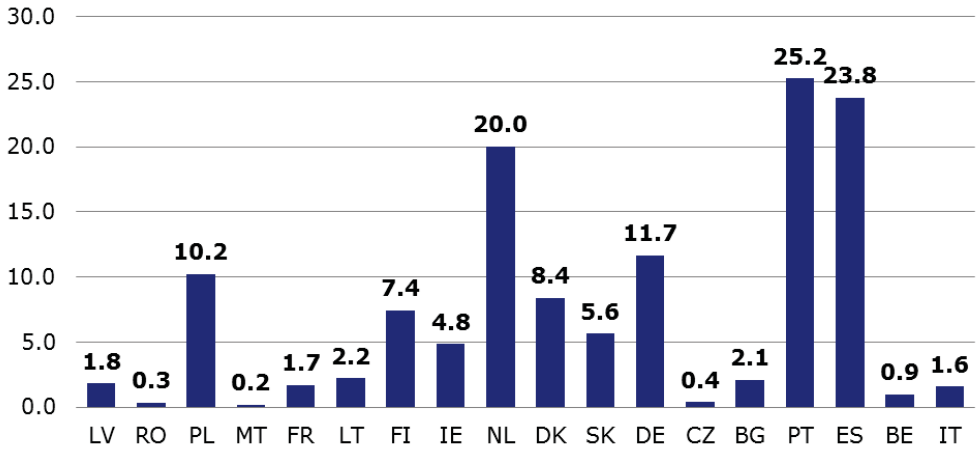


Source: National reports

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 8-5: Annual budget available to MSA in nominal terms, average 2010-2013, € millions



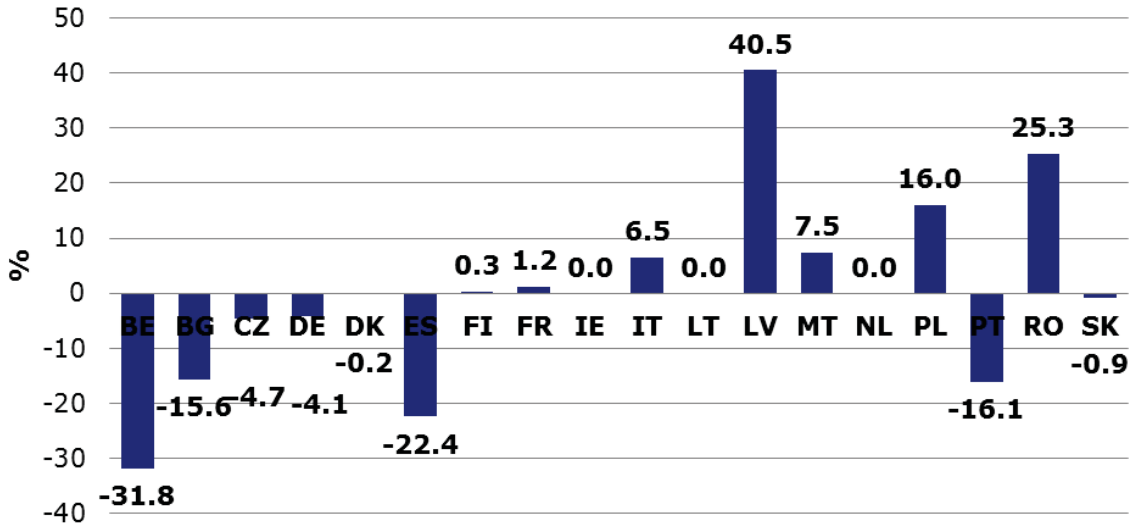
Source: National reports

152 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[153] and decreased in seven Member States.[154] 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 8-6: 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

153 FI, FR, IT, LT, LV, MT, PL, RO.
154 BE, BG, CZ, DE, ES, PT, SK.

for the first indicators, Hungarian authorities have not reported data for 2010, therefore the country was not included in the analysis.

3.3 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 8-6: 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)[155]
SECTOR 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	12[156]	58.60	0.46
SECTOR 2 - Cosmetics	11[157]	255.55	1.33
Sector 3 - Toys	9[158]	32.28	0.26
Sector 4 - Personal Protective Equipment	8[159]	12.38	0.10
SECTOR 5 - Construction Products	11[160]	17.94	0.11
SECTOR 6 - Aerosol dispensers	6[161]	21.82	0.53
SECTOR 7 - Simple pressure vessels and Pressure Equipment	8[162]	23.40	0.18

155 Population on 1 January 2015 as provided by Eurostat
156 Czech Republic, Denmark, Ireland, Italy, Cyprus, Latvia, Hungary, Portugal, Slovenia, Slovak Republic, Finland and Sweden.
157 Czech Republic, Denmark, Ireland, France, Italy, Hungary, Portugal, Slovenia, Slovak Republic, Finland and Sweden.
158 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.
159 Belgium, Bulgaria, Denmark, Greece, France, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.
160 Belgium, Bulgaria, Czech Republic, Denmark, Greece, France, Cyprus, Hungary, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.
161 Belgium, Bulgaria, Denmark, Greece, Cyprus and Finland. Bulgaria has submitted the total number of employees.
162 Belgium, Bulgaria, Denmark, Greece, France, 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)[155]
SECTOR 8 - Transportable pressure equipment	8[163]	23.27	0.21
Sector 9 - Machinery	8[164]	71.67	0.41
SECTOR 10 - Lifts	5[165]	22.51	0.58
SECTOR 11 - Cableways	6[166]	18.41	0.42
SECTOR 12 - Noise emissions for outdoor equipment	6[167]	13.54	0.14
SECTOR 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	7[168]	12.41	0.12
SECTOR 14 - Pyrotechnics	9[169]	10.30	0.06
SECTOR 15 - Explosives for civil uses	8[170]	9.62	0.08
SECTOR 16 - Appliances burning gaseous fuels	9[171]	9.82	0.08
Sector 17 - Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	10[172]	9.91	0.07
SECTOR 18 - Electrical equipment under EMC	11[173]	17.45	0.08

163 Bulgaria, Denmark, Greece, France, Cyprus, Hungary, Slovenia and Finland. Bulgaria has submitted the total number of employees.
164 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.
165 Bulgaria, Denmark, Greece, Hungary and Finland. Bulgaria has submitted the total number of employees.
166 Bulgaria, Denmark, Portugal, Slovak Republic, Finland and Sweden. Bulgaria has submitted the total number of employees.
167 Bulgaria, Denmark, Italy, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.
168 Bulgaria, Denmark, France, Cyprus, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.
169 Bulgaria, Czech Republic, Denmark, Ireland, Greece, France, Italy, Cyprus and Finland. Bulgaria has submitted the total number of employees.
170 Bulgaria, Czech Republic, Ireland, Greece, France, Cyprus, Hungary and Finland. Bulgaria has submitted the total number of employees.
171 Belgium, Bulgaria, Denmark, Greece, France, Cyprus, Luxembourg, Hungary and Finland. Bulgaria has submitted the total number of employees.
172 Bulgaria, Denmark, France, Hungary, the Netherlands, Austria, Slovenia, Slovak Republic, Finland and Sweden. Bulgaria has submitted the total number of employees.
173 Belgium, Bulgaria, Denmark, Germany, Greece, France, Cyprus, Hungary, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.

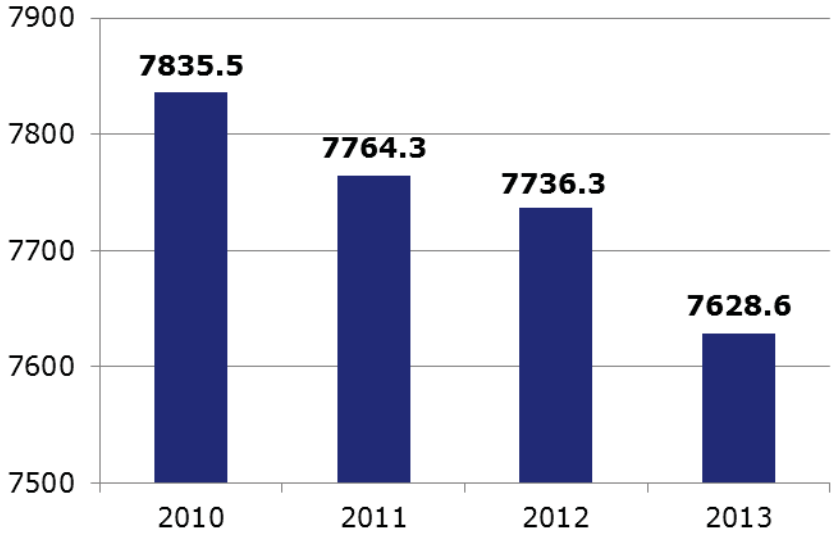
Sectors	Number of Member States providing staff information	Average amount of staff available per Member State and per year(simple average)	Average amount of staff available per 1000000 inhabitants (population on 1 January 2015)[155]
SECTOR 19 - Radio and telecom equipment under RTTE	11[174]	18.49	0.08
Sector 20 - Electrical appliances and equipment under LVD	10[175]	16.64	0.13
SECTOR 21 - Electrical and electronic equipment under RoHS, WEEE and batteries	6[176]	13.54	0.31
SECTOR 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)	9[177]	64.44	0.55
SECTOR 23 - Ecodesign and Energy labelling	10[178]	14.53	0.11
SECTOR 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	6[179]	9.18	0.15
SECTOR 25 - Recreational craft	7[180]	12.35	0.12
SECTOR 26 - Marine Equipment	5[181]	1.58	0.01
SECTOR 27 - Motor vehicles and tyres	10[182]	17.43	0.12
SECTOR 28 - Non-road mobile machinery	3[183]	0.43	0.02
SECTOR 29 - Fertilisers	12[184]	9.19	0.06

174 Belgium, Bulgaria, Denmark, Germany, Estonia, France, Cyprus, Portugal, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.
175 Belgium, Bulgaria, Denmark, Greece, France, Cyprus, Latvia, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.
176 Bulgaria, Denmark, Ireland, Greece, Hungary and Finland. Bulgaria has submitted the total number of employees.
177 Czech Republic, Denmark, Ireland, Greece, France, Latvia, Hungary, Slovenia and Finland.
178 Belgium, Bulgaria, Czech Republic, Ireland, Greece, France, Cyprus, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.
179 Belgium, Ireland, Greece, Hungary, Romania and Finland.
180 Bulgaria, Denmark, Greece, France, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.
181 Denmark, France, Italy, Romania and Finland.
182 Belgium, Bulgaria, Denmark, France, Cyprus, Portugal, Romania, Slovenia, Finland and Sweden. Bulgaria has submitted the total number of employees.
183 Denmark, Hungary and Sweden.
184 Belgium, Czech Republic, Denmark, Ireland, Greece, France, Latvia, Hungary, Romania, Slovenia, Slovak Republic and Finland.

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)[155]
SECTOR 30 - Other consumer products under GPSD	5[185]	46.94	0.47

185 Bulgaria, France, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

Figure 8-7: Total staffs available to MSAs (FTE units) during 2010-2013 at EU level[186]



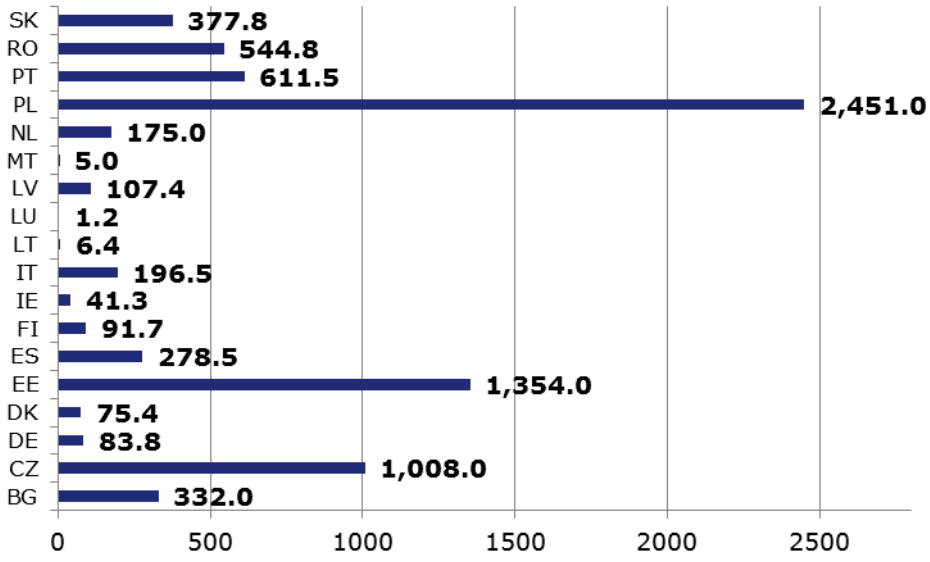
Source: National reports

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.

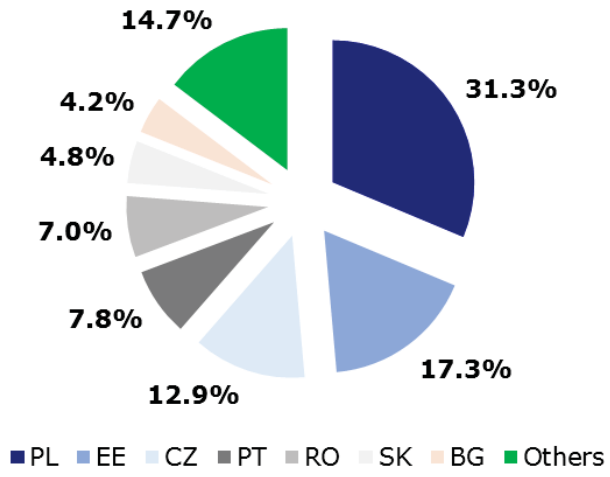
186 The analysis includes the following countries: Bulgaria, Czech Republic, Deutschland, Denmark, Estonia, Spain, Finland, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Poland, Portugal, Romania, Sweden, Slovakia; the other EU Member States have not provided complete and reliable data in their national reports

Figure 8-8: Total staff available to MSAs at country level (average 2010 – 2013), FTEs



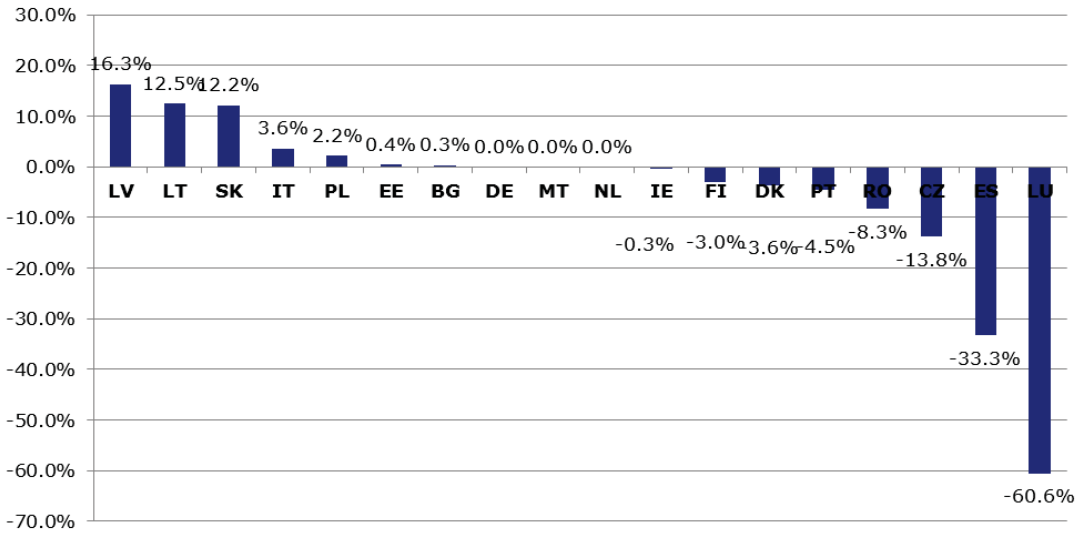
Source: National reports

Figure 8-9: Total staff available to MSAs (FTE units) per country over 2010-2013



Source: National reports

Figure 8-10: 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:

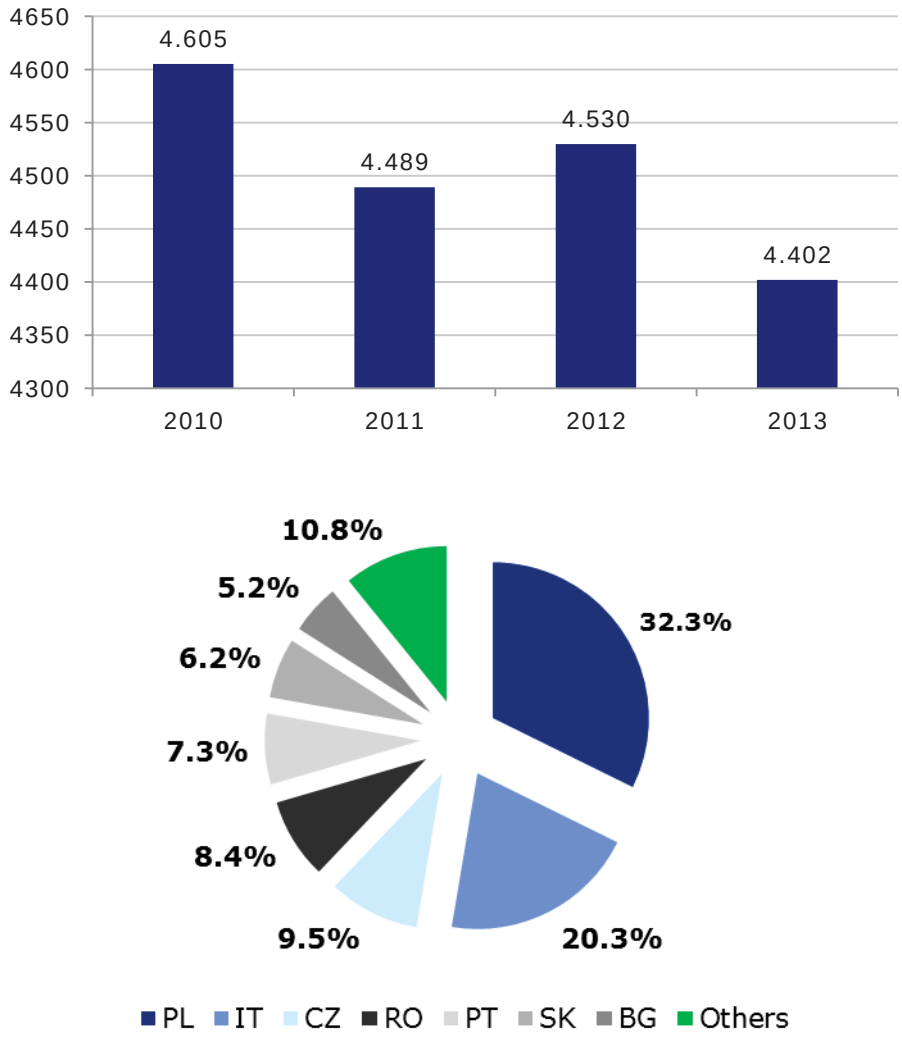
- More than half of the Member States considered (11) displayed a relatively stable trend in the number of staff resources available to MSA (FTE units) with a variation of less than 5% of the value registered in 2010;

- 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 8-11: 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



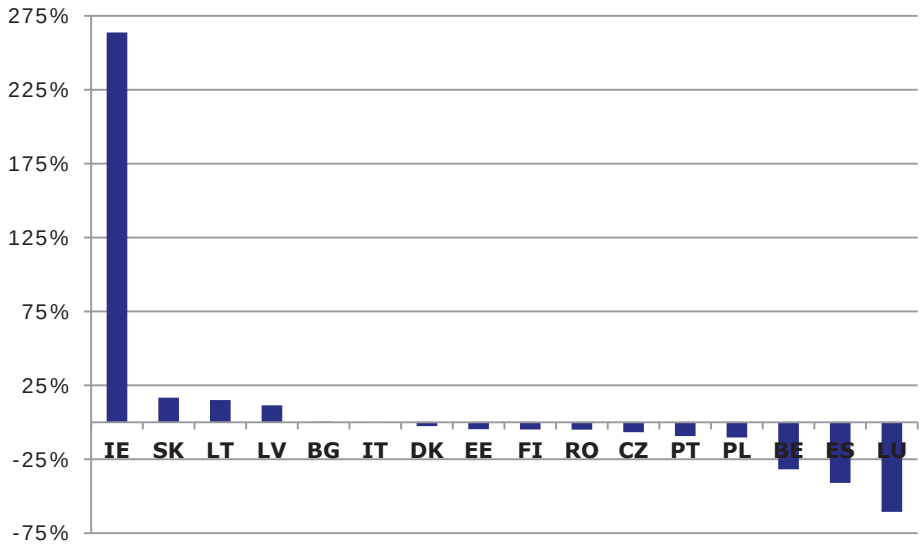
Source: National reports

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 8-12: 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 8-7: Indicative estimate of costs of inspections in Member States

Country	Average number of annual inspections (A)	Average Annual Budget available for (B)	Average costs per inspection (B)/(A)	Average annual number of Inspectors (C)	Average costs per inspector (B)/(C)
AT	1966	n/a	n/a	n/a	n/a
BE	n/a	946903	n/a	9.375	101003
BG	121	2114559	17475.7	232.25	9104.668
CY	20.75	n/a	n/a	n/a	n/a
CZ	1382.25	384594.1	278.2377	426.25	902.2734
DE	n/a	11675000	n/a	n/a	n/a
DK	107.5	8386750	78016.28	32.5	258053.8
EE	1277.75	n/a	n/a	42.25	n/a
EL	n/a	n/a	n/a	n/a	n/a
ES	n/a	23785801	n/a	183.25	129799.7
FI	395.5	7417861	18755.65	64.85	114384.9
FR	1589.5	1680000	1056.936	n/a	n/a
HR	103.75	n/a	n/a	n/a	n/a
HU	12391.25	n/a	n/a	n/a	n/a
IE	48.25	4825000	100000	70.2025	68729.75
IT	1416.5	1561372	1102.274	917	1702.695
LT	n/a	74875	n/a	5.4375	13770.11
LU	n/a	n/a	n/a	1.15	n/a
LV	437.75	1818645	4154.528	78.125	23278.65
MT	83.75	163592.3	1953.34	n/a	n/a
NL	n/a	20000000	n/a	n/a	n/a
PL	236.75	10229088	43206.29	1455.5	7027.886
PT	3182	25229517	7928.824	330.375	76366.3
RO	n/a	320108.1	n/a	377.25	848.5305
SE	155.25	12370917	79683.85	n/a	n/a
SK	n/a	5634232	n/a	280.75	20068.5
min	**20.75**	**74875**	**278.2377**	**1.15**	**848.5305**
max	**12391.25**	**25229517**	**100000**	**1455.5**	**258053.8**
average	**1465.618**	**7295727**	**29467.66**	**281.6572**	**58931.49**

Source: draft Evaluation study

3.4 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 8-8: 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	

Country	Staff dedicated to REACH enforcement	Budget allocated to REACH enforcement
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	
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 8-9: 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	

Country	Staff dedicated to CLP enforcement	Budget allocated to CLP enforcement
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 9: JRC REPORT ON MARKET SURVEILLANCE OF NON-FOOD PRODUCTS BASED ON A SMALL-SCALE SURVEY CARRIED OUT IN FEBRUARY 2017

1. INTRODUCTION

This report presents the result of a survey on Market Surveillance (MS) conducted by the Joint research Centre (European Commission), on behalf the Single Market Policy, Mutual Recognition and Surveillance Unit, in DG GROW.

A short questionnaire – in the Annex of this report – was sent via e-mail to a subset of ADCO (Administrative Cooperation Groups) members. These had volunteered to provide their view on the current status of Market Surveillance activity in EU and on future possible developments. Out of the 13 members contacted, 10 replied to the survey (a 77% response rate). However, 2 respondents – based in the same Country – submitted the very same reply, across all questions. We decided to include only one of these two replies as, given the small size of the sample, this would have biased the results.

The questionnaire includes 6 sections: 1) on market surveillance, in general; 2) on cooperation, in general; 3) on internal cooperation; 4) on EU cooperation; 5) on national cooperation and 6) on personal information. We will present the results by following the various sections of the questionnaire.

1.1 On market Surveillance, in general

In question 1 we asked the respondents' view on 13 statements related to Market Surveillance. Respondents could choose between the following options:

a) Strongly agree;

b) Agree;

c) Disagree;

d) Strongly disagree;

e) Not to express any view ("don't know (DK)").

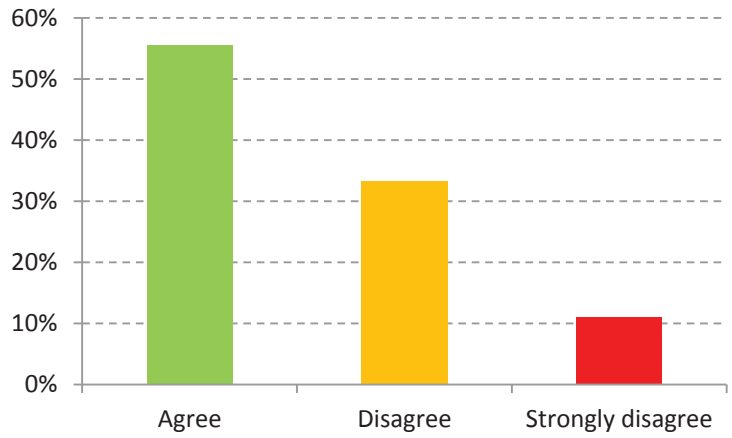


Figure 9-1: "Product harmonisation legislation is overly complex"

We observed divergent views on whether "product harmonisation legislation is overly complex", with roughly half of respondents agreeing this is the case, and the other half of them either disagreeing or strongly disagreeing (see Fig. 9-1). It would be interesting, in the future, to find out the motivations underpinning such different views, for example, whether this is due to specific sectors or to other reasons.

The second statement tackles the reverse side of the coin of complex legislation. Whether or not we agree that product harmonisation legislation is complex, it is relevant to find out whether the resources allocated to effectively perform MS are sufficient. Almost 80% of respondents expressed the view that MS is under-budgeted in their own Country, or in their sector of activity (Fig. 9-2).

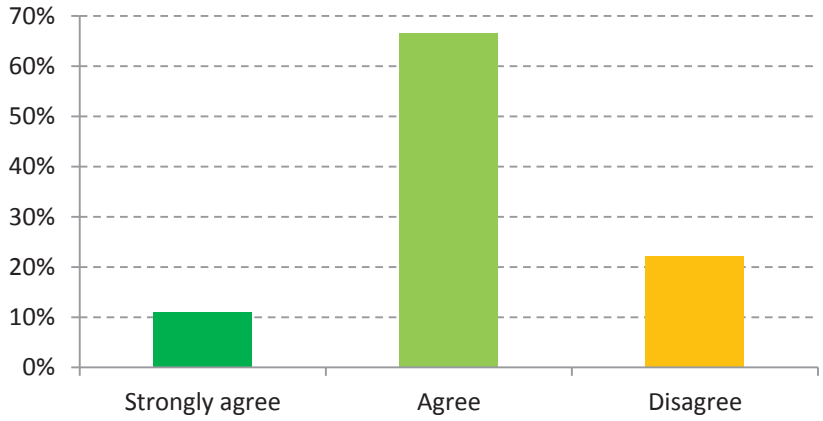


Figure 9-2: "MS is under-budgeted in my own Country, in my sector of activity"

From a behavioural perspective, in order to explore all possible explanations of a specific behaviour, it is often interesting to find out about what others are doing or about our perceptions of what others do. Indeed, we do not live in a social vacuum but we are rather influenced by others. This is particularly the case with respect to an activity with is performed and financed by each EU MSs, but that is functional to the pursuit of a public good. For example, in the iterative Public Good Game - used to study the tension between the individual incentive to free ride in collective activities of this type, and the social benefit generated by the sum of individual investments – the investment of a specific member decreases when (s)he observes free-riding behaviour from others. In the absence of corrective measures, this often leads to a *race to the bottom*. In our case, 2/3 of respondents shared the view that MS is under-budgeted across the EU, in their sector of activity (Fig. 9-3). In the future, it would be worth finding out whether there is any causal relationship between the perceptions described in Fig. 9-3 and each individual EU Country's willingness to invest in MS.

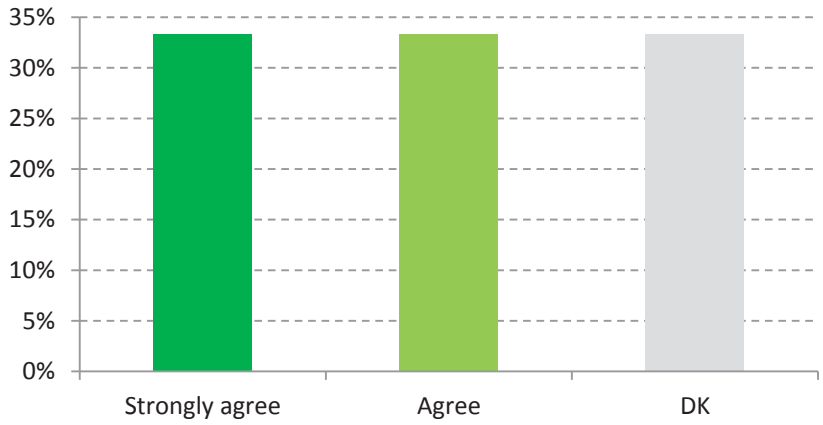


Figure 9-3: "MS is under-budgeted across the EU, in my sector of activity"

Within-Country coordination between the various office of MS Authorities doesn't seem to be too much of an issue, though there seems to be room for improvement in specific Countries. 30% of respondents agreed with the following statement: "There is poor within-Country coordination between the various local offices of MS Authorities" (Fig. 9-4).

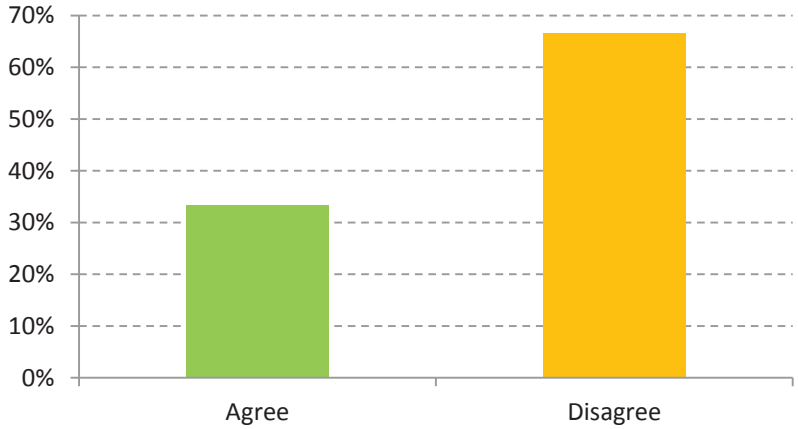


Figure 9-4: "There is poor within-Country coordination between the various local offices of MS Authorities"

The respondents' view of the quality of within-Country coordination with Customs roughly reflects the situation within MS Authorities, with 1/3 of respondents agreeing that there is a margin of improvement (Fig. 9-5).

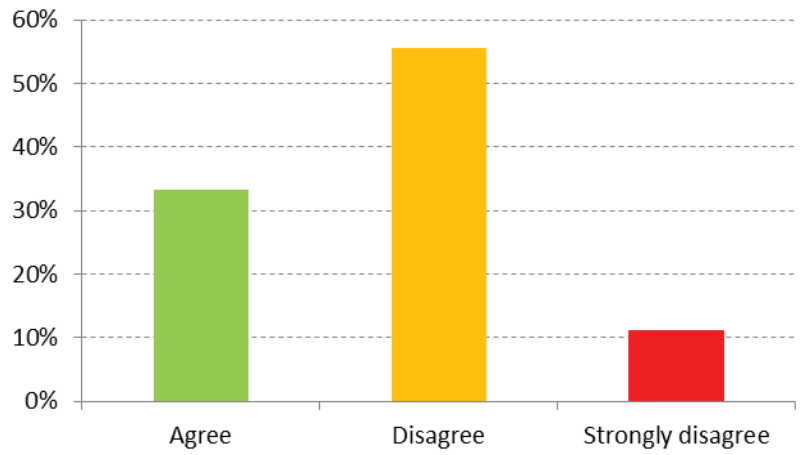


Figure 9-5: "There is poor within-Country coordination with Customs"

Interestingly, respondents seemed to be slightly less happy about the quality of cross-border coordination of national MS Authorities. 40% of them agreed with the following statement: "There is poor cross-border coordination of national MS Authorities" (Fig. 9-6).

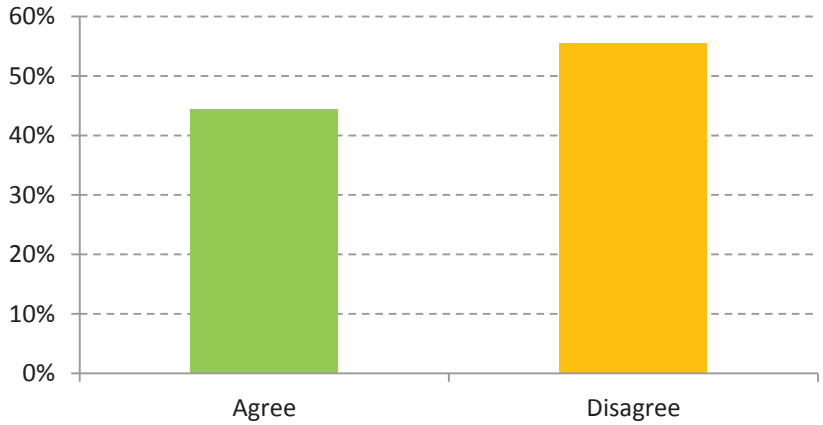


Figure 9-6: "There is poor cross-border coordination of national MS Authorities"

When it comes to solutions or possible remedies, it is fairly clear that MS cannot rely on consumers' awareness. Indeed, there is a common view that consumers are not aware about EU product harmonisation legislation (Fig. 9-7).

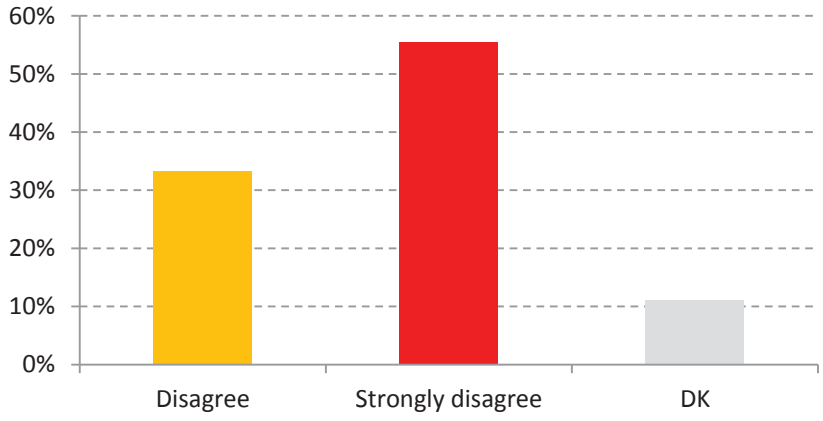


Figure 9-7: "There is great consumers' awareness about EU product harmonisation legislation"

As to firms' awareness of EU product harmonisation legislation, respondents' perception seems to be different, depending on whether this relates to EU or non-EU firms (Figures 9-8 and 9-9, respectively). In particular, while 30% of respondents think that EU firms have great awareness of EU product harmonisation legislation, none of the respondents believe this is the case for non-EU firms.

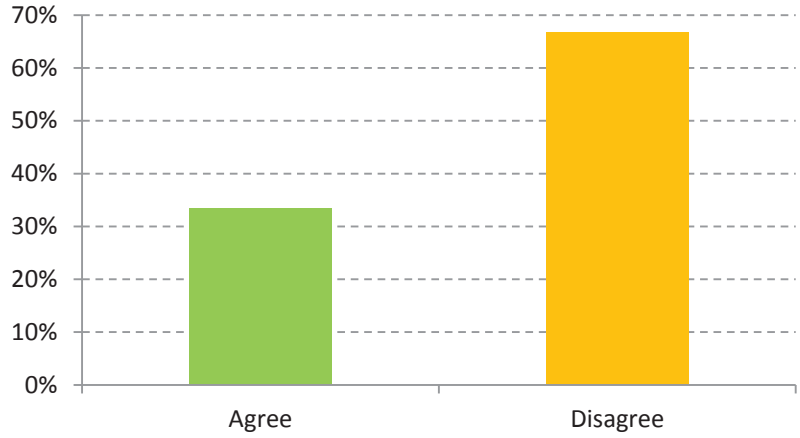


Figure 9-8: "EU firms have great awareness of EU product harmonisation legislation"

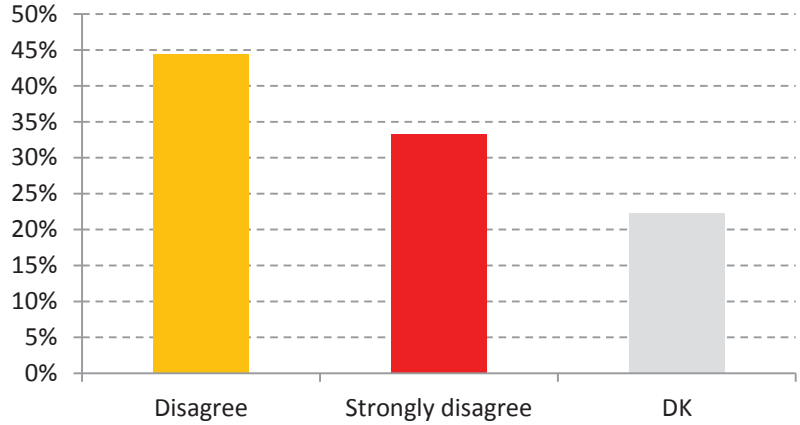


Figure 9-9: "Non-EU firms have great awareness of EU product harmonisation legislation"

Cooperation with the private sector to identify non-compliant products seems to be a relatively under-explored area (Fig. 9-10).

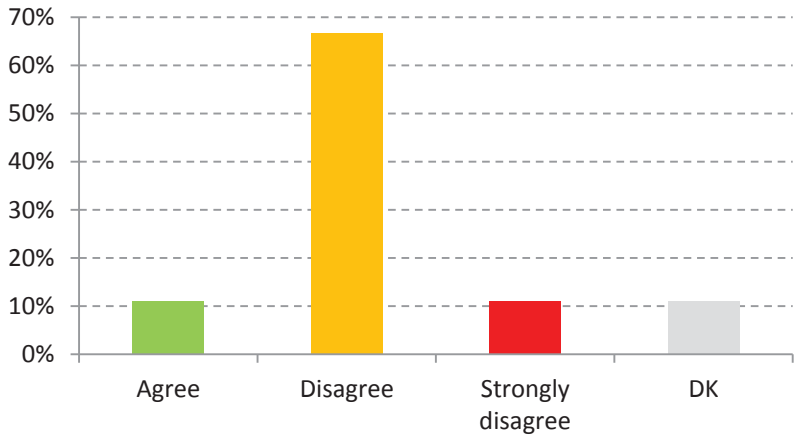


Figure 9-10: "There is great cooperation with the private sector to identify non-compliant products (e.g, with actors in the online supply chain)"

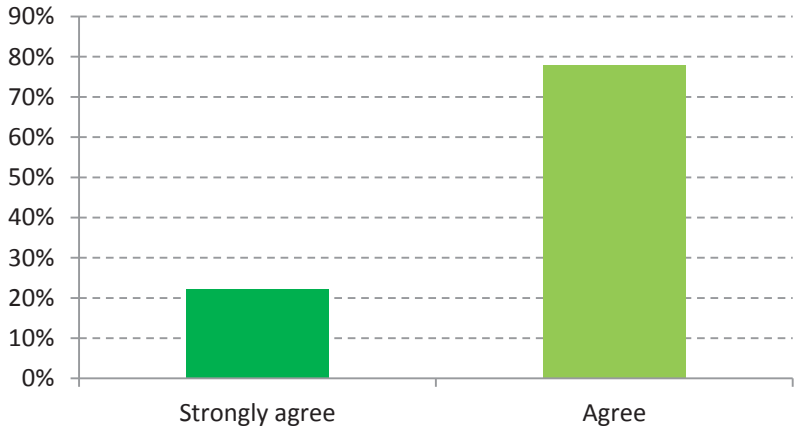


Figure 9-11: "Over the last 10 years, there has been an improvement of MS activity in EU"

We also observed a marked divergence of opinions as to whether product compliance should be encouraged by using the carrot instead of the stick (Fig. 9-12), that is by timely advice and information to operators (only 1/3 of the respondents were of this opinion) instead of by imposing fines and penalties for non-compliance (55% believed that the latter are more effective).

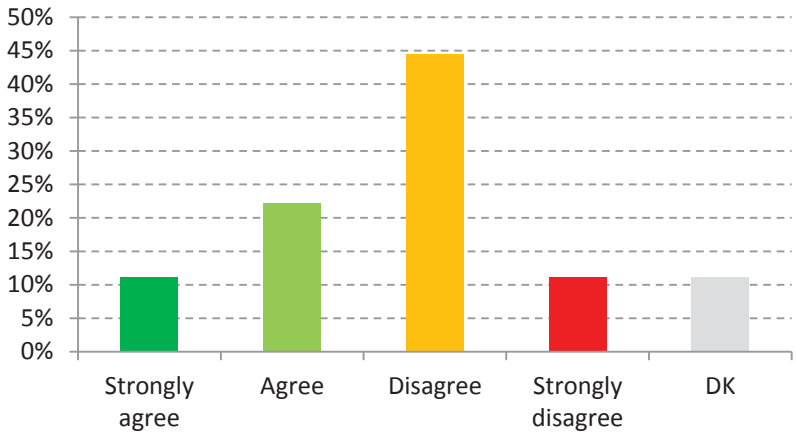


Figure 9-12: "Penalties and fines for non-compliance are less effective than timely advice and information to operators"

We also wondered whether using incentives for consumers contributing to MS Activity could in time become a complementary approach, but only 10% agreed whereas 45% disagreed and the remaining 45% said they "didn't know" (Fig. 9-13).

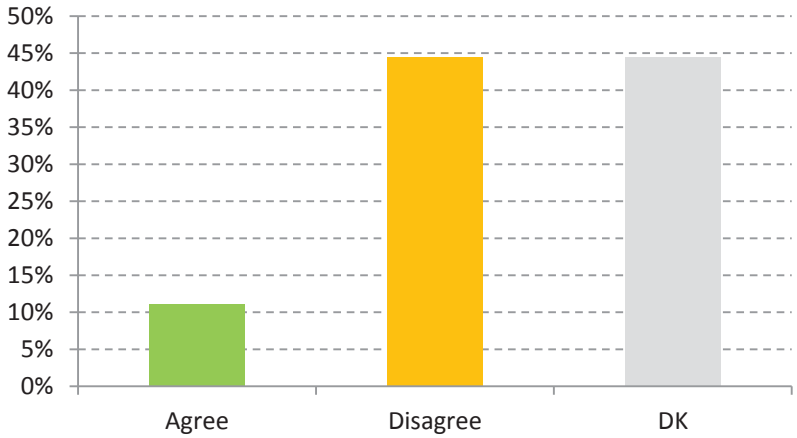


Figure 9-13: "Consumers filing an appropriate complaint related to product-related harmonisation should be properly compensated, for having contributed to MS Activity"

Finally, we asked whether the respondents identified any other specific factors that are relevant to pursue an effective MS Activity, and we collected interesting insights:

"On e-Commerce: *The import of products directly to the end user and the new concept of involving "fulfilment houses" with (at the moment) no responsibilities is a large problem. The competitive disadvantage for both European manufacturer and importers are obvious. Furthermore the European end-users are receiving and using non-compliant products for which – in most of the cases – no responsible party in the EU exists. A responsible party for each product located within EU (like for Medical devices) or the introduction of a registration system for all products could be a solution. A registration system would make it easier for customs to determine if a product can enter the market or not without involving*

national MSA. In a nutshell, there seems to be a lack of effective measures and tools to prevent a flow of dangerous products sold online."

"The availability of specialist resources to carry out testing, or lack of in-house laboratories. This is particularly the case for eco-design and energy labelling, the testing of which is often costly."

"Reinforcement of cooperation via AdCo Groups, despite some AdCO members are not entitled to take decisions."

"Accessibility and cost of standards for the MSA and economic operators, especially if the MSA covers several Directives."

"A better definition of the role of Customs, in order to better address the many imports of non-compliant products."

- *"*in many cases, the time spent for a MS procedure is longer than the *life cycle of the product. This means that a product is no longer on the market when the sales ban is pronounced;*
- *it is simple for a manufacturer to shorten a sales ban: by changing the identification of the product, the MS authority is obliged to start a new procedure;*
- *a sales ban in one country is not automatically valid for all countries;*
- *legal procedures too time-consuming and resource-intensive*
- *no control if a product banned from the market of an EU country may come back through other channels to another national market;*
- *even if there is the idea of a common internal market, it seems that market surveillance is still focussed on national market;*
- *different national prosecution legislation."*

The replies to our questions and the comments provided constitute invaluable insights for any discussion as to the approaches and priorities of any future MS Activity.

1.2 Cooperation activity

In the general section on cooperation activity, we asked a series of question that were designed to convey respondents' relative appreciation of the potential benefits coming from various types of cooperation activity.

In question 3 we asked "In your view, what specific type of market surveillance cooperation brings most value for money". Interestingly, no respondent mentioned national cooperation, while almost 80% mentioned EU Cooperation, and the remaining 20% opted for International Cooperation (Fig. 9-14).

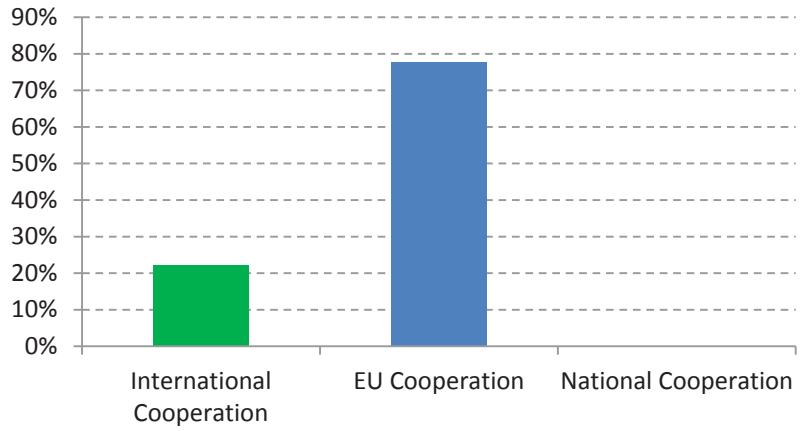


Figure 9-14: "In your view, what specific type of market surveillance cooperation brings most value for money"

A number of reasons were put forward to justify the preference for international and EU cooperation:

"With the globalisation and Internet, there are no border any more for products, this means that in future, there will be a change, people will buy more and more from internet and less from "normal" shops. Most of the products will be delivered from outside EU and the resources needed for their check at the EU border will be disproportionate. Therefore if an international cooperation would be possible to stop the products at the source, it will be more effective and efficient. Furthermore, as soon as a manufacturer has placed a product on a specific market (e.g. outside EU), this product is not anymore under its control. An EU importer may buy a batch of this product and placed it on the EU market even if the intention of the manufacturer was not to place it on the EU market."

"*Free movement of goods allows to place products anywhere within the European Economic Area, so the cooperation among EU MSAs is crucial to stop rough traders effectively. Networks created within ADCO groups as well as EU RAPEX or ICSMS systems help to communicate rapidly and to ensure consumers safety. Cooperation with big producers' countries is important as well but education and awareness campaigns addressed to European economic operators and a simplification of EU product harmonisation legislation seem to be more effective.* "

*"*It gives most value if the market surveillance authority can take non-complaint product out of the marked in EU and not only out of national markets."

"International cooperation with MSA/Government outside EU might reduce the number of non-compliant products being made available on the EU market."

With questions 5-7, we further explored the same issue. The replies to these questions could be used in the future to strike to most appropriate balance between various types of cooperation activities, avoiding overinvesting or underinvesting in any of them. We asked respondents to provide an estimate of the budget percentage allocated to

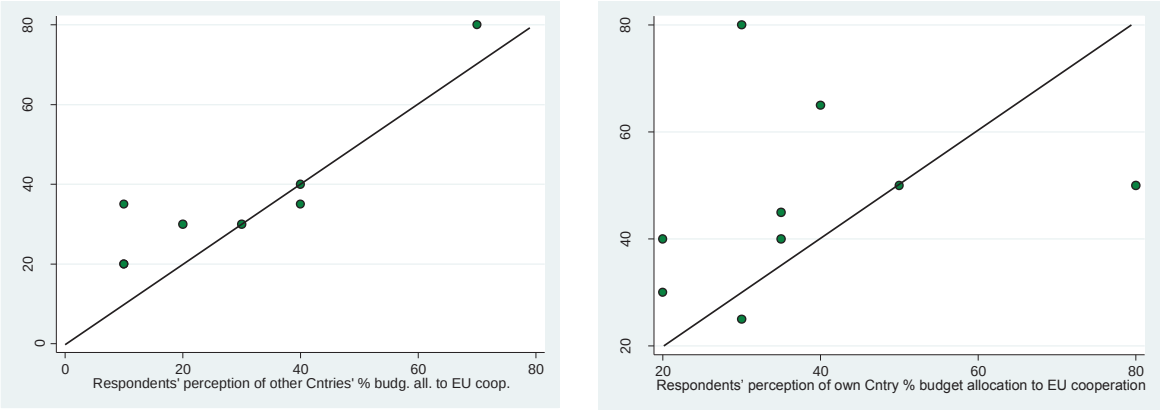
- International cooperation
- EU cooperation and

- national cooperation

both by their own Country and by other Countries. We also asked what budget percentage they would themselves allocate to each cooperation level, were they free to choose.

The results show first of all that respondents understood the objective of the question – which was a follow-up of question 3 (see Fig. 9-14) – and its relevance, as they all provided estimates.

On international cooperation, whereas the average perceived budget allocation by the home Country is 3.3%, the respondents' average ideal budget allocation is 18%, which provides a quantification of the extent to which international cooperation should represent more of a priority.



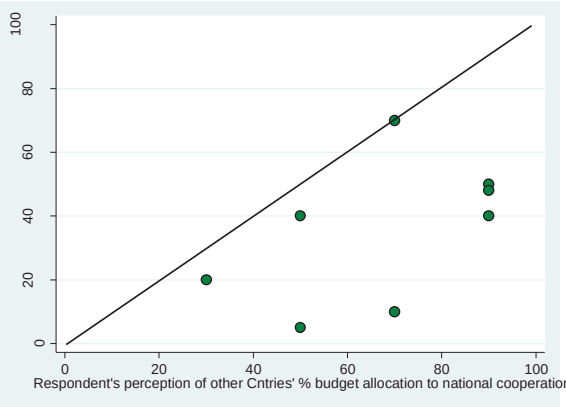
Figures 9-15a and 9-15b: Respondents' perception of and preference for budget allocated to EU cooperation

On EU cooperation, two results are worth noticing:

- respondents tend to perceive their home Country as more engaged (at least from a budgetary point of view) in EU cooperation (Fig. 15a). Indeed, if all respondents perceived other Countries to invest as much as their home Country in EU cooperation, all observations would fall on the 45° line (whereas in our case, all but one fall above the 45° line). From a behavioural point of view, perceiving others as less engaged could discourage one's own engagement. Therefore this could be object of a specific intervention;

- respondents ideal budget allocation on EU cooperation tends to be larger than the perceived budget allocation of one's own Country. When this is not the case, it is to the benefit of international cooperation, rather than to national cooperation (Fig. 15b).

Finally, on national cooperation, the opposite applies. Respondents' ideal budget allocation to national cooperation is below the perceived budget allocation of both their own Country (Fig. 9-16a) and of other Countries (Fig. 9-16b). Again, these results clarify the respondents' view as to what type of cooperation activity should be seen as a priority.



Figures 9-16a and 9-16b: Respondents' perception of and preference for budget allocated to national cooperation

1.3 International cooperation activity

In question 8 we asked the respondents' view on 7 statements related to International Cooperation Activity. Respondents could choose between the following options:

a) Strongly agree;

b) Agree;

c) Disagree;

d) Strongly disagree;

e) Not to express any view ("don't know (DK)").

From a behavioural perspective, an analysis of the target population is a fundamental prerequisite to be able to design effective interventions. Indeed, considering the private sector as a homogeneous population of firms, regardless of their size, their sector, their international exposure or their Country, would prevent any possibility of targeting and tailoring specific interventions.

Respondents see differences between various types of companies, multinationals, EU SMEs and non-EU SMEs. Only 10% of respondents perceived that multinationals tend to be non-compliant, while 20% of them said the same about EU SMEs, and a striking 80% thought that non-EU SMEs tend to be non-compliant (Figures 9-17 to 9-19). This result, coupled with the view that more attention should be paid at international (beyond EU) cooperation, should suggest specific lines of actions which have probably been under-explored so far.

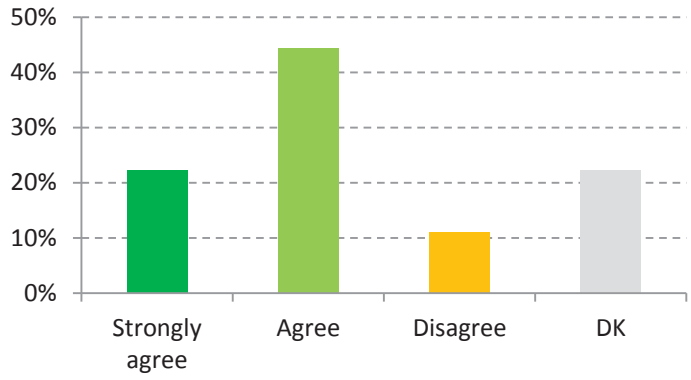


Figure 9-17: "Multinationals tend to be compliant with EU product harmonisation legislation"

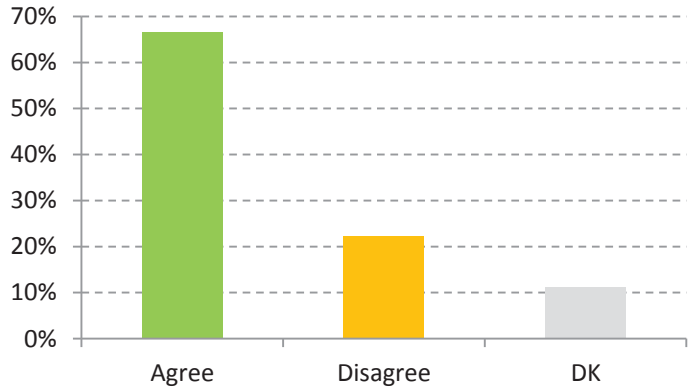


Figure 9-18: "EU SMEs tend to be compliant with EU product harmonisation legislation"

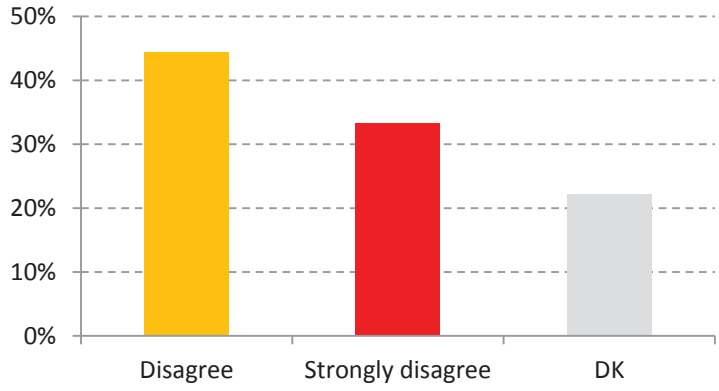


Figure 9-19: "Non-EU SMEs tend to be compliant with EU product harmonisation legislation"

As it happened to the data presented in Figure 9-15, respondents tended to show some level of "overconfidence" projected to their own country. To the question "Do national customs perform thorough controls of incoming goods", they in fact responded differently depending

on whether this referred to their own Country (Fig. 9-20) or to other Countries (Fig. 9-21). While 45% agreed that national Customs of their own Country perform through controls of incoming goods, only 45% disagreed that this also applies to national Customs of foreign EU Countries.

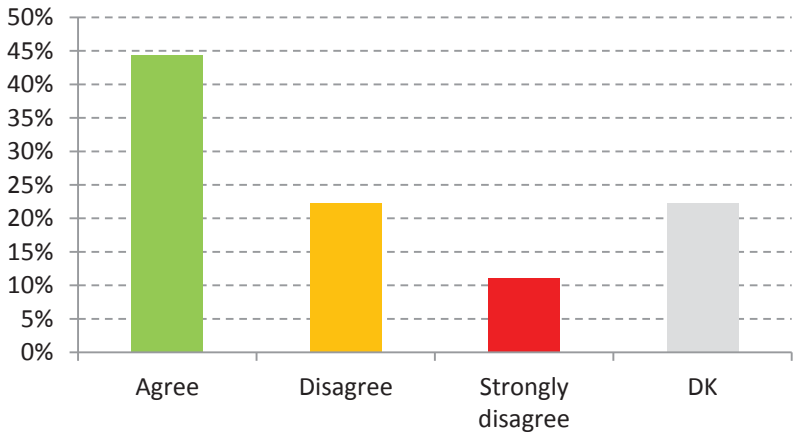


Figure 9-20: "National Customs of my Country perform thorough controls of incoming goods"

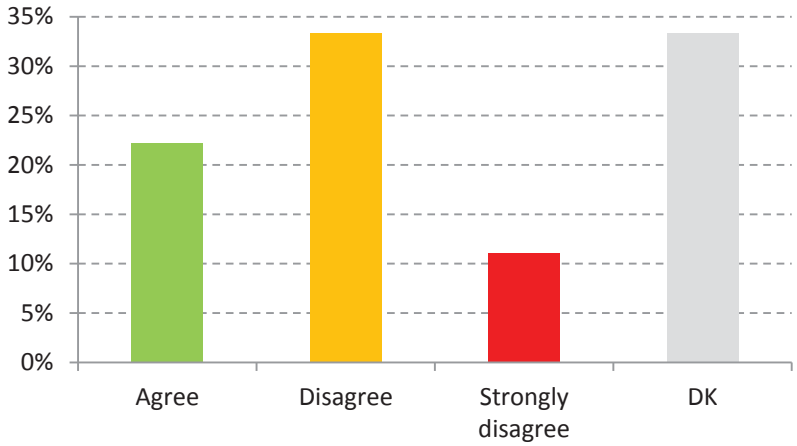


Figure 9-21: "National Customs of other EU Countries perform thorough controls of incoming goods"

The scale of the challenge for MS Authorities should not be undermined, however. Although all respondents agreed that "Over the last 10 years, there has been an improvement of MS activity in EU" (see Fig. 9-11 above), more that half of them believe that "Over the last 10 years, the proportion of non-EU non-compliant products that entered the EU market has decreased" (Fig. 9-22).

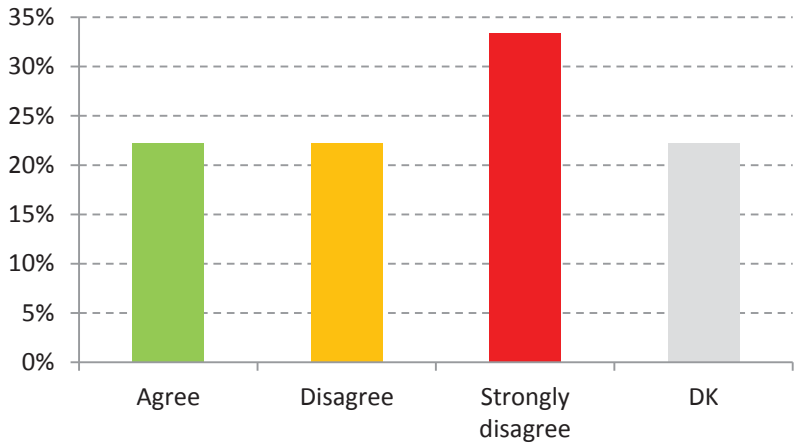


Figure 9-22: "Over the last 10 years, the proportion of non-EU non-compliant products that entered the EU market has decreased"

Interestingly, 2/3 of respondents agree that "Cooperation with sectoral SMEs associations of non-EU Countries could provide up-front advice and information and limit enforcement costs" (Fig. 9-23), a finding that resonates well with the view that international surveillance cooperation brings good value for money (see Fig. 9-14 above).

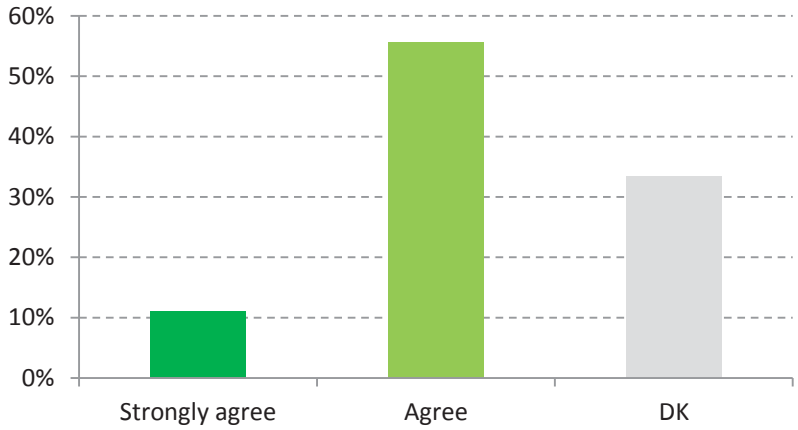


Figure 9-23: "Cooperation with sectoral SMEs associations of non-EU Countries could provide up-front advice and information and limit enforcement costs"

Finally, we asked whether the respondents identified any other specific factors that may improve the effectiveness of International cooperation on Market Surveillance activity for goods or services, we collected interesting insights:

"*Improving the communication, control, cooperation, performance and enforcement among Custom authorities in the EU member states, for example early notifications for incoming risky goods*."

"*European standards should be obligatory to eliminate uncertainty of law and be changed only due to technology progress.*"

"*Stop non-compliant products at the border. Improve cooperation between MSAs and Customs."*

"- to give a certain responsibility to the consumer who is buying products from outside EU, looking only at the price (in this case the consumer is responsible to support unfair competition);

- to find an effective way on how to perform market surveillance on products sold via Internet;

- to concentrate the information on non-compliant products on one single homepage (e.g. public part of ICSMS) instead to have this information on many homepages;

- to concentrate the information on the rules on one single point (today the information is located on various homepages between commission an Member States);

- to give consumers the tools to search for and filter out non-compliant products."

"More joint actions funded by the EU, organized and carried out by MSAs in ADCOs"

"A number of products manufactured in a non-EU country do not fulfil the requirements of the applicable European legislation. Importers (if available because of the new "fulfilment houses" challenge) are only partly able to verify if a product complies with the requirements or not, as they are often just salesmen."

Some of these insights identify the underlying causes challenging the effectiveness of MS activity, whereas others rather focus on possible remedies. In this perspective, these indicate possible lines of work that could further pursued by ADCOs.

1.4 Within-EU cooperation activity

With reference to the work and discussions taking place within the Administrative Co-operation Working Group (ADCO), in question 10 we asked "what does prevent or hamper you from implementing the necessary changes within your national context?" Respondents could select up to 3 options and could rank them from 1, the most important, to 3, the third-most important.

The three main reasons hampering the implementation of the necessary changes within each respective national context seems to be (see Table 9-1):

1. The complexity of the respondent's administration, and the fact that the common line agreed within the ADCO does not trickle down to all levels;

2. The low recognition and value attributed by the respondent's respective administration to his/her role of "connector" between his/her MSA and foreign MSAs;

3. The fact that "only half of EU countries regularly attend ADCO's meetings".

Number of replies per rank	**1**	**2**	**3**
My management does not show interest for the views expressed by the ADCO		2	
My colleagues do not show interest for the views expressed by the ADCO	1		3
My role of "connector" between my MSA and foreign MSA is not properly recognised and	2	2	

valued by my administration			
Our administration is complex, and the common line agreed within the ADCO does not trickle down to all levels	4	2	
There is a general perception that foreign MSAs don't take any concrete action			3
Only half of EU countries regularly attend ADCO's meetings	2	1	
My management does not show interest for the views expressed by the ADCO		2	

Table 9-1: "What does prevent or hamper you from implementing the necessary changes within your national context? (Up to 3 possible options, ranked from 1 (top one) to 3 (bottom one)"

As to the reasons why each respondent's management and/or colleagues do not easily endorse the common line agreed within the ADCO, on certain matters, all respondents agreed that this is *not* because the line agreed within the ADCO brings more costs than benefits. This is a key result as it is a clear acknowledgement of the benefits of following the line agreed with the ADCO (see Fig 9-24). However ¼ of replies stressed that the line agreed within the ADCO is often not clear, another ¼ complained that only half of EU MSs regularly attend ADCO's meetings, and about 1/6 of replies stated that there is a general perception that foreign MSAs would not endorse the line agreed within the ADCO and that such perception, as a result, discouraged others to endorse it.

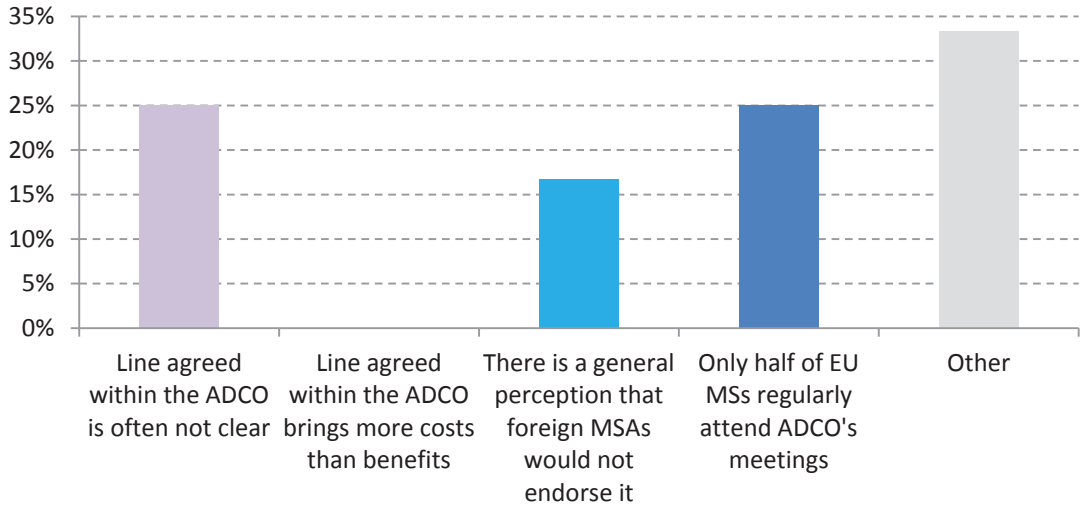


Figure 9-24: "What could be the reasons why your management and/or colleagues do not easily endorse the common line agreed within the ADCO, on certain matters? (Multiple replies possible)"

One third of respondents opted for "Other" reasons, and suggested that:

"*In general there is easy endorsement of a common line agreed, within the ADCO (ECHA FORUM), once the common line is robust and well founded/argumented, in relation to the relevant EU aquis. Also clear positions by COM or EU Agencies (like ECHA) are helpful for having good national endorsement*."

"- The decisions taken by ADCO are not legally binding

- National prosecution legislation is instead binding though it differs by Country.

- Less than half of MSA attending ADCO are concretely active, the rest attends on a rather listening mode."

"Sometimes implementing the common line agreed within the ADCO requires us to commit significant resource outside our core function."

"*In some cases, my administration cannot implement ADCO agreements as these are not compatible with the national transposition of the relevant Directive.*"

From the previous result it does not come as a surprise that most respondents state that they do not find it easy to involve their own MSA in joint actions proposed in ADCO meetings (Fig. 9-25). Indeed, some argue that this is due to the specific governance structure of their own Country, to their involvement in other type of joint actions or simply to funding issues. On the other hand, some of those replying that it is easy, point out that "*the number of participants to joint actions is very important for the acceptance of the results of those actions.*"

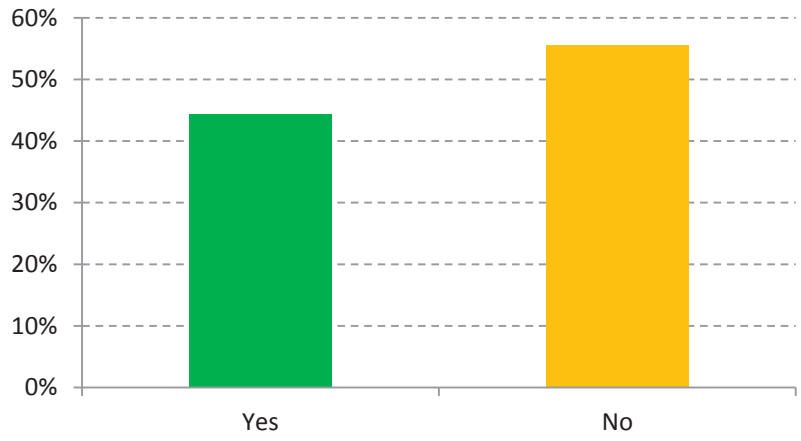


Figure 9-25: "Do you find easy to involve your MSA in joint actions proposed in ADCO meetings?"

1.5 National cooperation activity

In question 13 we asked the respondents' view on 8 statements related to national cooperation activity. Respondents could choose between the following options:

a) Strongly agree;

b) Agree;

c) Disagree;

d) Strongly disagree;

e) Not to express any view ("don't know (DK)").

The landscape of Market Surveillance seems to be less complex and problematic. 2/3 of respondents say that their respective Country has a single Authority responsible on their specific sector, ¾ of respondents declare that cooperation within the local offices of their respective Authority is effective and only 10% thinks that "within my Authority, there are overlapping responsibilities that generate confusion and waste of resources" (Figures 9-26 to 9-28).

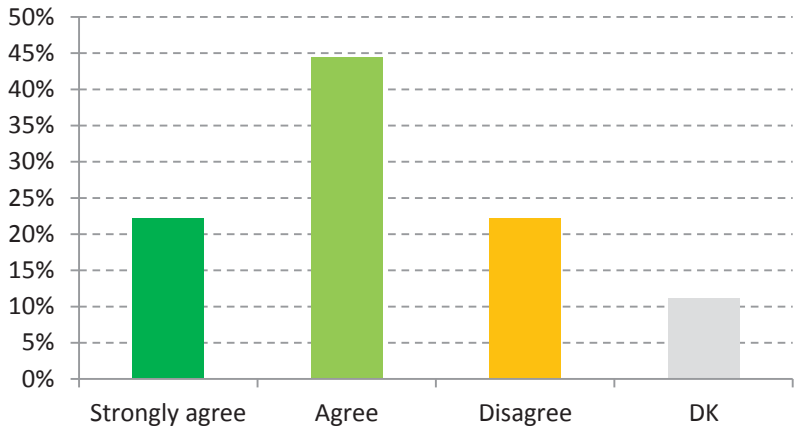


Figure 9-26: "We have a single Authority responsible on my sector"

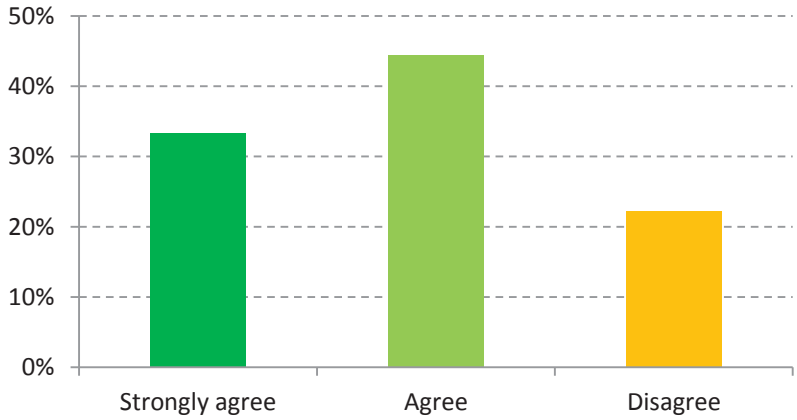


Figure 9-27: "Cooperation within the local offices of our Authority is effective"

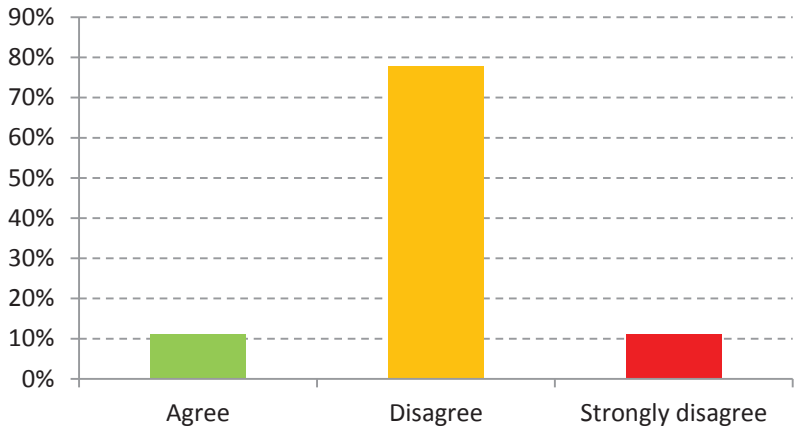


Figure 9-28: "Within my Authority, there are overlapping responsibilities that generate confusion and waste of resources"

Notwithstanding, ¾ of respondents believe that collaboration with national Customs could be further developed and deepened, perhaps in view of avoiding overlapping responsibilities, witnessed by 30% of respondents (respectively Fig. 29 and Fig. 30).

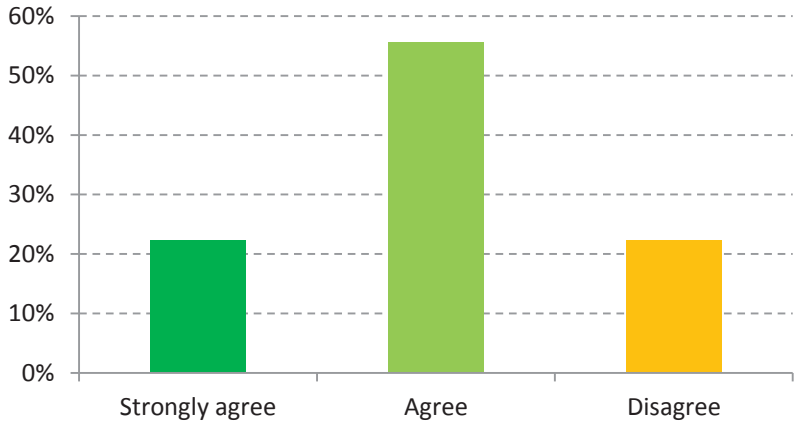


Figure 9-29: "Collaboration with Customs could be further developed and deepened"

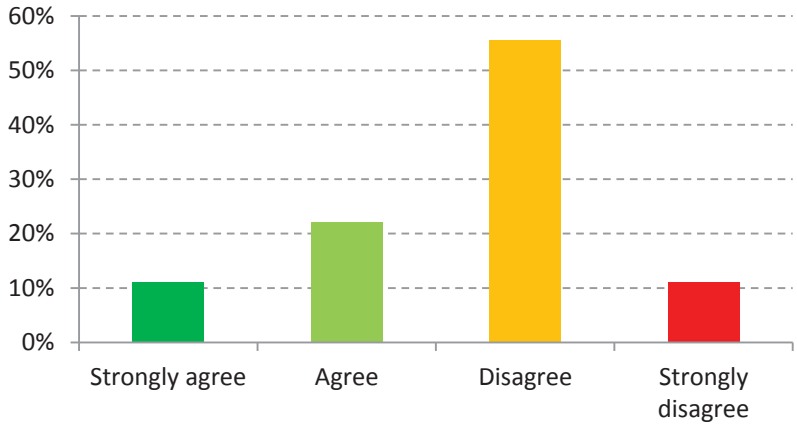


Figure 9-30: "Between national relevant bodies, there are overlapping responsibilities that generate confusion and waste of resources"

On the possible remedies to improve national cooperation activity, almost half of the respondents believe that "Incentives for effective MS Activity could be better designed (e.g., the overall national budget for MS Activity should better reflect the results obtained by each office)" (Fig. 9-31).

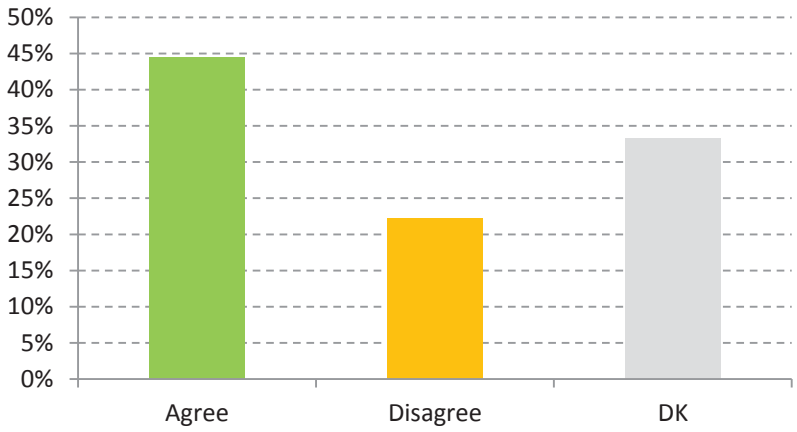


Figure 9-31: "Incentives for effective MS Activity could be better designed (e.g., the overall national budget for MS Activity should better reflect the results obtained by each office)"

In this section we also enquired about the potential usefulness of consumer awareness campaigns. Surprisingly, as respondents had previously stated that consumers are not aware about EU product harmonisation legislation (Fig. 9-7), in this case respondents argue that consumer awareness campaigns bring concrete results (Fig. 9-32). In the future, it would be necessary to clarify whether they think that future awareness campaigns are necessary because of consumers' currently low level of awareness of EU product harmonisation legislation.

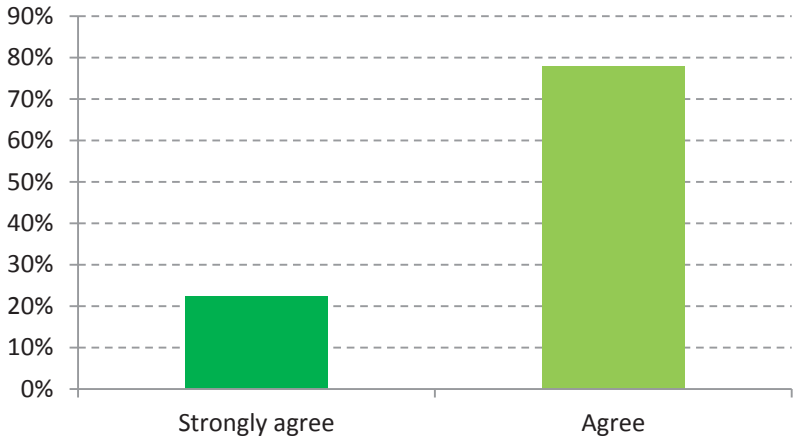


Figure 9-32: "Consumer awareness campaigns are good value for money (i.e., they bring concrete results)"

Finally, in line with a more preventive approach observed in other sections of the survey, 2/3 of respondents agreed that "more collaboration with business sectoral associations should be developed" (Fig. 9-33).

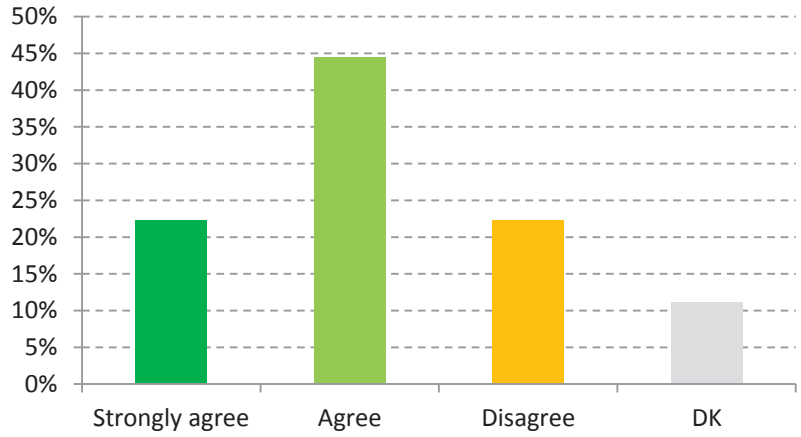


Figure 9-33: "More collaboration with business sectoral associations should be developed"

Finally, we asked whether the respondents identified any other specific factors that may improve the effectiveness of national cooperation on Market Surveillance activity, and we collected insightful comments:

"*Clear joint actions planning of the inspections."*

"*More frequent and perhaps real-time communication and consultation on tough cases.****"***

"*It might be useful (necessary) to agree on a common working language (e.g. English) and colleagues enforcing EU-harmonisation legislation should be familiar with that language. Capacity-building actions could be considered as we should make sure that officers should be competent in the relevant sector."*

"*- Common national prosecution rules;*

- No "safeguard clause" anymore: the decision taken by a national market surveillance authority is automatically valid for the whole EU internal market (economic operators have the possibility to appeal from a decision at national level);

- Better coordination and exchange of information between MSA to avoid double checks;

*- Benchmarking between MSA on how to assess the requirements.****"***

"*- Better cooperation between colleagues participating in meetings with the European Commission and the people who do the market surveillance.*

*- Better cooperation between the people who do the national market surveillance in the harmonized area.****"***

"- Most of the products entering the EU market are not only covered by one European Directive. Customs sometimes do not know which national MSA to involve. This should be improved.

- More clear rules for products imported from non EU would make it easier for customs to determine if a product can enter the EU market (e.g., mandatory DoC accompanying the product; the identification of one responsible party for placing a product on the EU market and at least one contact party within the EU; the obligation of a user manual in the language of the customs country)."

2. ANNEX: QUESTIONNAIRE

SECTION 1 / 6: ON MARKET SURVEILLANCE, IN GENERAL

Question 1

Please express your view on the following statements related to Market Surveillance (MS):

	Strongly agree	**Agree**	**Disagree**	**Strongly disagree**	**I don't know**
1. Product harmonisation legislation is overly complex					
2. MS is under-budgeted in my own Country, in my sector of activity					
3. MS is under-budgeted across the EU, in my sector of activity					
4. There is poor within-Country coordination between the various local offices of MS Authorities					
5. There is poor within-Country coordination with customs					
6. There is poor cross-border coordination of national MS Authorities					
7. There is great consumers' awareness about EU product harmonisation legislation					
8. EU firms have great awareness of EU product harmonisation legislation					
9. Non-EU firms have great awareness of EU product harmonisation legislation					
10. There is great cooperation with the private sector to identify non-compliant products (e.g, with actors in the online supply chain)					
11. Over the last 10 years, there has been an improvement of MS activity in EU					

12. Penalties and fines for non compliance are less effective than timely advice and information to operators					
13. Consumers filing an appropriate complaint related to product-related harmonisation should be properly compensated, for having contributed to MS Activity					

Question 2

Please indicate and comment on other specific factors that, in your view, may hinder an effective Market Surveillance activity:

SECTION 2 / 6: COOPERATION ACTIVITY

Question 3

In your view, what specific type of market surveillance cooperation brings most value for money?

☐ International cooperation (outside EU)

☐ EU cooperation

☐ National cooperation

Question 4

Please briefly explain why:

Question 5

Speaking of cooperation, how do you believe your Market Surveillance Authority roughly allocate the available budget across the following cooperation activities, on average, in percentage terms? (Please make sure the total adds up to 100)

Description of the Activity	**Percentage**
International cooperation (outside EU)	
EU cooperation	
National cooperation	
	100

Question 6

How do you believe foreign Market Surveillance Authorities roughly allocate their available budget across the following cooperation activities, on average, in percentage terms? (Please make sure the total adds up to 100)

Description of the Activity	**Percentage**
International cooperation (outside EU)	
EU cooperation	
National cooperation	
	100

Question 7

Imagine you could freely decide how to allocate your Authority's budget across the following cooperation activities. How would you allocate it in percentage terms? (Please make sure the total adds up to 100)

Description of the Activity	**Percentage**
International cooperation (outside EU)	
EU cooperation	
National cooperation	
	100

SECTION 3 / 6: INTERNATIONAL COOPERATION ACTIVITY

Question 8

Please express your view on the following statements related to international cooperation related to Market Surveillance (MS) activity:

	Strongly agree	**Agree**	**Disagree**	**Strongly disagree**	**I don't know**
1. Multinationals tend to be compliant with EU product harmonisation legislation					
2. EU SMEs tend to be compliant with EU product harmonisation legislation					
3. Non-EU SMEs tend to be compliant with EU product harmonisation legislation					
4. National customs of my Country perform thorough controls of incoming goods					
5. National customs of other EU Countries perform thorough controls of incoming goods					
6. Over the last 10 years, the proportion of non-EU non-compliant products that entered the EU market has decreased					
7. Cooperation with sectoral SMEs associations of non-EU Countries could provide up-front advice and information and limit enforcement costs					

Question 9

Please indicate and comment on other specific factors that, in your view, may improve the effectiveness of cooperation on Market Surveillance activity for non-EU goods or services:

SECTION 4 / 6: WITHIN-EU COOPERATION ACTIVITY

Question 10

With reference to the work and discussions taking place within the Administrative Co-operation Working Group (ADCO), what does prevent or hamper you from implementing the necessary changes within your national context? (Up to 3 options can be selected please order them from 1, the most important, to 3, the third-most important)

☐ My management does not show interest for the views expressed by the ADCO

☐ My colleagues do not show interest for the views expressed by the ADCO

☐ My role of "connector" between my MSA and foreign MSA is not properly recognised and valued by my administration

☐ Our administration is complex, and the common line agreed within the ADCO does not trickle down at all levels

☐ There is a general perception that foreign MSAs don't take any concrete action

☐ Only half of EU countries regularly attend ADCO's meetings

Question 11

What could be the reasons why your management and/or colleagues do not easily endorse the common line agreed within the ADCO, on certain matters? (multiple replies are possible)

☐ The common line agreed within the ADCO is often not clear

☐ The common line agreed within the ADCO brings more costs than benefits

☐ There is a general perception that foreign MSAs would not endorse it

☐ Only half of EU countries regularly attend ADCO's meetings

☐ Other

If "other", please briefly explain why:

Question 12

Do you find it easy to involve your MSA in joint actions proposed in ADCO meetings?

☐ Yes

☐ No

Please briefly explain why:

SECTION 5 / 6: NATIONAL COOPERATION ACTIVITY

Question 13

Please express your view on the following statements related to the cooperation activity carried out with other offices of your Authority, or with other relevant national bodies of your Country:

	Strongly agree	**Agree**	**Disagree**	**Strongly disagree**	**I don't know**
1. We have a single Authority responsible on my sector					
2. Cooperation within the local offices of our Authority is effective					
3. Within my Authority, there are overlapping responsibilities that generate confusion and waste of resources					
4. Collaboration with Customs could be further developed and deepened					
5. Between national relevant bodies, there are overlapping responsibilities that generate confusion and waste of resources					
6. Incentives for effective MS Activity could be better designed (e.g., the overall national budget for MS Activity should better reflect the results obtained by each office)					
7. Consumer awareness campaigns are good value for money (i.e., they bring concrete results)					

8. More collaboration with business sectoral associations should be developed					

Question 14

Please indicate and comment on other specific factors that, in your view, may improve the effectiveness of national cooperation on Market Surveillance activity:

SECTION 6 / 6: Contact details

Please include your contact details here below, and tick the appropriate box should you agree to be contacted by telephone, in the week of 27th February, to follow up on your replies to this survey:

Country:

Organisation Name:

Type of organisation:

- **MSA with national vs. local competences (delete accordingly)**
- **Product specialised vs. cross-sectoral portfolio (delete accordingly)**

Sectoral activity, if any (e.g., chemicals, transport):

Contact Person:

Position:

E-mail address:

Telephone number:

Yes, I accept to be contacted by telephone for a follow-up interview

No, I am not available to be contacted by telephone for a follow-up interview