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PROPOSAL

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date of receipt:	20 December 2017
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council

Delegations will find attached document SWD(2017) 466 final PART 4/4.

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PART 4/4

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

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

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

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ANNEX 14: BACKGROUND INFORMATION ON OBJECTIVE 4 – PROMOTING COMPLIANCE

1. COMPLIANCE AND MIXES OF REGULATORY STRATEGIES[1]

Compliance-oriented regulation is often aimed at providing incentives and encouragement for voluntary compliance and nurturing the ability of enterprises to secure compliance through self-regulation, internal management systems, and market mechanisms where possible, rather than automatically using punishment for violations of the rules in the first instance. When organisations do fail to comply, a compliance-oriented regulatory approach will attempt to *restore* compliance rather than revert immediately to a purely punishment-oriented approach.

Restorative justice must always be backed up by the possibility of more punitive sanctions. This gives regulators the option of responding to non-compliant enterprises that demonstrate bad faith in the restorative justice process with more punitive sanctions. It is also important that enterprises know that "softer" enforcement strategies such as restorative justice will be followed by harsher strategies such as fines and license suspensions, if non-compliance persists. Indeed the evidence shows that persuasive and compliance-oriented enforcement methods are more likely to work where they are backed up by the possibility of more severe methods. The central principle here is that a regulator should have available a range of enforcement mechanisms in order to be responsive to the particular type of non-compliance it faces in any individual situation. A regulator can start with persuasive or restorative strategies and then move to more punitive strategies if voluntary compliance fails. If the application of punitive sanctions succeeds in bringing about compliance then the regulator can respond by reverting to a trusting demeanour, rather than building resistance by being overly punitive. If the initial round of punitive sanctions does not bring about compliance, then the regulator can respond by invoking harsher sanctions. The wider the range of strategies (from restorative to punitive) available to the regulator, the more successful this type of responsive, "tit-for-tat" enforcement is likely to be.

This principle has been demonstrated in the idea of a pyramid of enforcement strategies (see below). The pyramid is a schematic representation of the idea that instead of using the most drastic regulatory strategies first, regulators should trade on the goodwill of those they are regulating. Regulators should encourage those regulated to comply voluntarily, using more drastic regulatory measures only when that fails and reverting to a trusting demeanour when these strategies achieve their goal: "Compliance is optimised by regulation that is contingent, co-operative, tough and forgiving." In this model prioritising restorative, compliance-oriented means of regulation in time ensures that co-operative, voluntary measures are used more frequently without compromising the possibility of using harsher measures where necessary. In the pyramid illustrated, license suspension and revocation are at the top of the pyramid because they represent the complete closing down of a business, as compared with a criminal financial penalty or the jailing of a particular executive. Each regulatory regime would, however, design its own pyramid of sanctions. For example corporate probation (where a company is put on "probation" until it is adequately in compliance) might be included, or criminal penalties might be considered harsher than license revocation. This concept does not suggest that the direct use of punitive sanctions as part of a tit-for-tat enforcement strategy should be excluded.

1 OECD\ (2000), pp. 41-42 and 73-76.

Source: Ayres, I. & Braithwaite, J. (1992), *Responsive Regulation: Transcending the Deregulation Debate*, Oxford University Press, New York, p. 35.

Summary of scholarly literature on regulatory compliance

[…] The developments in research on deterrence and compliance have led to a more holistic, pragmatic, and outcome-oriented approach to regulatory research: many contemporary regulation scholars are *pragmatic* in the sense that they use empirical evidence about what is likely to work, rather than being guided purely by ideological positions about what form of regulation is most desirable. Scholarly interest has turned towards research that evaluates alternatives to traditional "command-and-control strategies" that relied on a simple theory of deterrence. In particular this research takes a more *holistic* approach towards regulation and examines the effectiveness of mixes of regulatory strategies that will utilise the complexity and variety of motivations underlying compliance. This type of research is also extending beyond looking at regulatory enforcement strategies to the impacts on compliance of total regulatory design. The result is a more *outcome-oriented* approach to the study of regulatory compliance. The emphasis is on the substantive policy objectives of the regulation, and whether the regulatory policy instruments chosen are capable of accomplishing those objectives, not on compliance with rules that may or may not be effective at achieving the desired result.

The most influential theory of the optimal mix of regulatory strategies is Ayres and Braithwaite's (1992) pyramid of enforcement strategies. In their book, *Responsive Regulation*, Ayres and Braithwaite demonstrate why this pyramid of regulatory strategies is an effective and efficient approach to accomplishing compliance with policy objectives on the basis of empirical psychological and sociological evidence, as well as economic and political modelling and game theory. The pyramid is a schematic representation of the idea that instead of using their most drastic regulatory strategies first, regulators should trade on the goodwill of those they are regulating, encouraging them to comply voluntarily, using more drastic regulatory measures only when that fails and reverting to a trusting demeanour when these strategies achieve their goal: "Compliance is optimised by regulation that is contingently co-operative, tough and forgiving" (Ayres & Braithwaite, 1992, p. 51). In this model prioritising restorative, compliance-oriented means of regulation in time ensures that co-operative, voluntary measures are used more frequently without compromising the possibility of using harsher measures where necessary. […]

An impressive array of research supports Ayres and Braithwaite's basic premise that it is more effective to maximise self-regulatory possibilities for business by using less coercive, more dialogic methods of regulation first and more coercive measures only when less coercive means fail. Braithwaite's own research programme with various co-authors has demonstrated and evaluated the relevance of the pyramid as an explanatory heuristic in a variety of substantive regulatory arenas including coal mine safety, pharmaceutical safety, and nursing home regulation (*e.g.* Braithwaite, 1984, 1985; Grabosky & Braithwaite, 1986; Braithwaite & Makkai, 1991, 1994). A number of other researchers have also found the pyramid useful as a descriptive tool to explain where regulation is successful at accomplishing compliance, and as a normative theory for how compliance could be improved: for example Rees (1988, 1994) on occupational health and safety regulation and nuclear power industry self-regulation, Gunningham (1994) on environmental regulation, Parker (1997, 1999*a*, 1999*b*) on regulation of the legal profession, competition and consumer protection law, and anti-discrimination law, Hopkins (1995; see generally 1994, p. 432) on occupational health and safety, and Haines (1997) on safety in the construction industry.

Other researchers have discovered complementary explanations of the interdependence of co-operative and punitive regulation in accomplishing compliance. Burby and Paterson (1993); see also Honneland (1998), for example, compare co-operative enforcement with sanction-oriented enforcement for improving compliance with North Carolina state environmental regulation. In their study compliance-oriented regulatory design in the form of performance standards were more effectively enforced by co-operative strategies that were in turn backed up by potential application of deterrent sanctions than by the application of deterrent sanctions alone.

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2. COMPLIANCE ASSISTANCE ORGANISED AT EUROPEAN LEVEL[2]

2.1. Product Contact Points under Regulation (EC) 764/2008

The Regulation[3] aims to guarantee the free movement of goods in the internal market, in the absence of harmonised rules. It lays down procedures to be followed by Member States when denying market access to a product lawfully marketed in a Member State. Another goal is to increase awareness of the mutual recognition principle, which allows for products lawfully marketed in another Member State to be sold in other Member States, despite the fact that this product complies with different national technical rules, ensuring legal certainty for national authorities and businesses and improving administrative cooperation between national authorities.

As the application of the mutual recognition principle is not automatic, certain national technical regulations may prevail. Economic operators may wish to know about the applicable national rules before entering a market. The Regulation contains the obligation for Member States to establish national Product Contact Points ("PCPs"). These provide, upon request, information on the national technical rules applicable to a specific product, the contact details of the competent authorities in charge of supervising the implementation of the technical rules in question and remedies available in case of dispute between the economic operator and the competent authority. The scope of the PCPs is limited to the non-harmonised sector[4]. They therefore qualify as "assistance services".

The Regulation contains a limited number of quality criteria, mostly voluntary. The only "hard" criterion is that PCPs should reply to requests within 15 working days of receiving them. According to a recital, PCPs should be adequately equipped and resourced, and are encouraged to make the information available online and in other Community languages. The provision of information in the scope of the Regulation should be free of charge. For additional information PCPs may charge proportionate fees. The list of PCPs can be found on

2 For further detailed info, please consult SWD(2017)213 final = Evaluation of existing (regulatory and non-regulatory) framework of relevance to the Single Digital Gateway

3 Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC

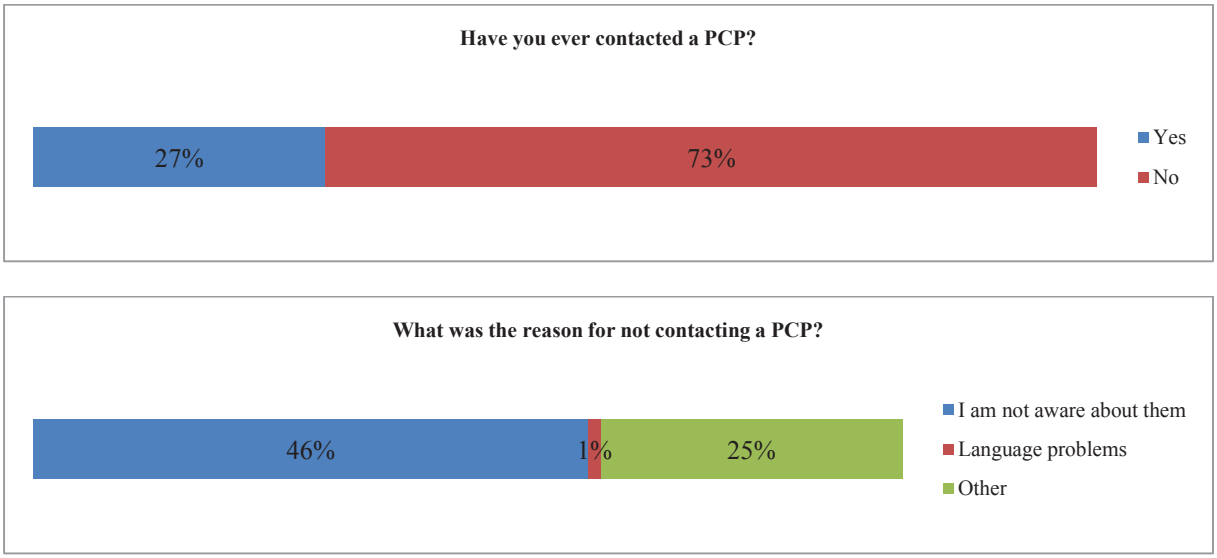
4 As opposed to the (EU) harmonised sector, for which the PCPs are not responsible.

https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/contacts-list/.

PCPs have been established in all EU Member States. Their list was initially published in the OJ[5] and is regularly updated and available online on the Commission's website[6]. The Regulation left the set-up of PCPs to the discretion of Member States, thus, their organisation and function vary significantly. Most Member States have a single PCP, responsible for all inquiries related to non-harmonised products. In a few Member States[7], the PCP is split between a general one and a construction products specific one. Other Member States[8] have PCPs in 6-7 different ministries. In almost all Member States, the PCP (or the co-ordinator, where there are several PCPs) is located within the ministry responsible for industry/business and the internal market, often as part of a group or team dealing with internal market policy. Only in Slovenia the PCP is located in an independent institute (the Slovenian Institute for Standardisation). A few PCPs handle queries (or part of queries) themselves. In Malta, the PCP is responsible for all communication with companies. However, this setup is unique to Malta (and difficult, if not impossible, to handle in a larger Member State), and in most cases queries from economic operators are passed on to the responsible ministry, department or directorate or, occasionally, the relevant local authority. In Italy, there is an appointed PCP, however, economic operators must contact the relevant ministry in charge of their product and receive their answer from this authority – without the PCP being involved. The way replies are being provided to economic operators also varies from one Member State to another. Very often, the responsible authority replies directly to the company making the query. Thus, the PCP has little insight on the outcome of the queries. Sometimes, national authorities provide answers to companies via the PCP.

It should be noted that most of the businesses replying to the 2016 public consultation declared that they have never contacted a PCP in order to obtain information about the applicable national rules and the mutual recognition principle, mostly because they are not aware about them.

Figure 14-1: Public consultation on mutual recognition - 2016



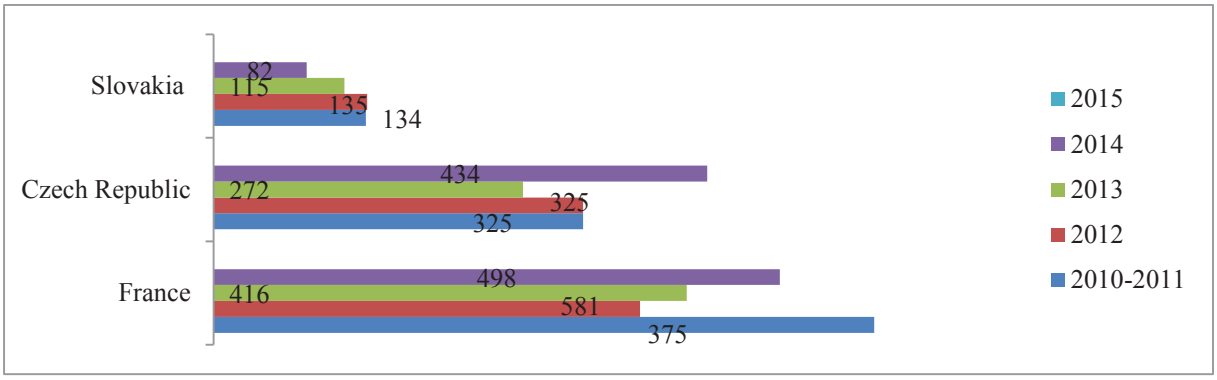
5 OJ C 185 of 7.08.2009, p. 6-12
6 https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/contacts-list_en
7 Estonia, Latvia and Poland
8 Romania, Portugal and the Netherlands

In the period between 2009 and 2015, the Product Contact Points received **8024** questions from economic operators.

2010-2011[9]	2012	2013	2014	2015
1402	1439	1826	1793	1564

The PCPs that were most contacted are France and the Czech Republic, followed by Slovakia.

Figure 14-2: Most contacted PCPs



However, the number of questions indicated above is only indicative and does not constitute an accurate picture of all questions received or treated by the PCPs. This is because not all Member States are indicating in their annual reports the number of questions received and treated by the PCPs. In 2010-2011, 2012 and 2014, 17 Member States indicated the number of questions received by the PCPs. 19 Member States supplied this information in 2013 and 16 Member States supplied this information in 2015. Also, with regard to the number of questions received, it is not certain that the number indicated covers questions related to mutual recognition only. Some Member States are reporting those questions related to mutual recognition only, while others are reporting all questions received, even when outside the remit of the PCPs. A few Member States[10] conducted national survey on the usefulness of the PCPs, and the results show that economic operators are globally satisfied with the services provided by the network, which are considered as useful.

The evaluation of mutual recognition in the area of goods indicates that, in general, the main issues underlined by economic operators in relation to PCPs are the long delays for receiving an answer, the quality of the answer or even the absence of it. These issues are also highlighted by the Member States in their annual reports. Some Member States indicated that the 15 days deadline set out by the Regulation is difficult to meet, although most of the time respected. According to the information submitted in the annual reports, these delays are caused by the wide range of products (or aspects of) falling under the scope of mutual recognition as well as the increasing number of applicable national rules, which makes it difficult to easily identify the responsible persons having the necessary expertise. The decentralisation of certain Member States administration and the fact that most often the necessary competences are distributed between different ministries add to these difficulties. Very often, the PCPs have to send the inquiry to the local responsible officer. Last but not least, language issues, especially when technical language is involved, add further delays and contributes to the sometimes low quality of the answers provided. Some good practices were

9 The reporting in annual since 2012
10 See annual reports from SE 2015, DE and FR 2013

also highlighted by Member States in their annual reports as regards the functioning of PCPs. Slovakia for example indicated that an expert network was put in place to support the work of the PCP. Furthermore, the PCP is located in the same department dealing with Directive (EU) 2015/1534, thus aware of all national regulations notified to the Commission and subject to the application of the mutual recognition principle.

Overall, the PCPs network is considered by Member States in their annual reports as a useful tool, having the potential to help economic operators in obtaining information about the applicable national rules and the mutual recognition principle. Member States consider however that it needs to be further strengthened. In their annual reports, they call on enhancing administrative cooperation, and integrating the PCPs into a wider network, in order for them to gain in expertise and to reply more efficiently to the inquiries they received. This view is also shared by businesses, as 58% of the respondents indicated in the 2016 public consultation that PCPs are a useful tool, despite the fact that only 7% of them considered their experience with PCPs as satisfactory.

National authorities incurred costs related to implementing their obligation to establish PCP (putting them in place and having them functioning on an annual basis). Most of the time, the PCP has been integrated in an already existing department dealing with internal market issues. Based on the annual reports[11], one person in average is fulfilling the task of PCP. This is the case for example in France, Sweden, Ireland, Greece, the Netherlands, Bulgaria and Poland. In cases where the function of PCP is available in several ministries, such as in Romania or Portugal, several persons (5-8) have PCP related tasks among their portfolio. Estimates of labour costs for PCPs can be made by taking into account the costs of Full Time Equivalents (FTEs) necessary to perform the required tasks every year. As detailed information on the salary costs of administrative staff employed PCP are not available, an estimate has be made based on the Eurostat data (period 2010-2011) on the gross annual salaries for employees in national public administrations, as shown in the table below:

Table 14-1: Gross annual salaries for employees in the public administration Eurostat

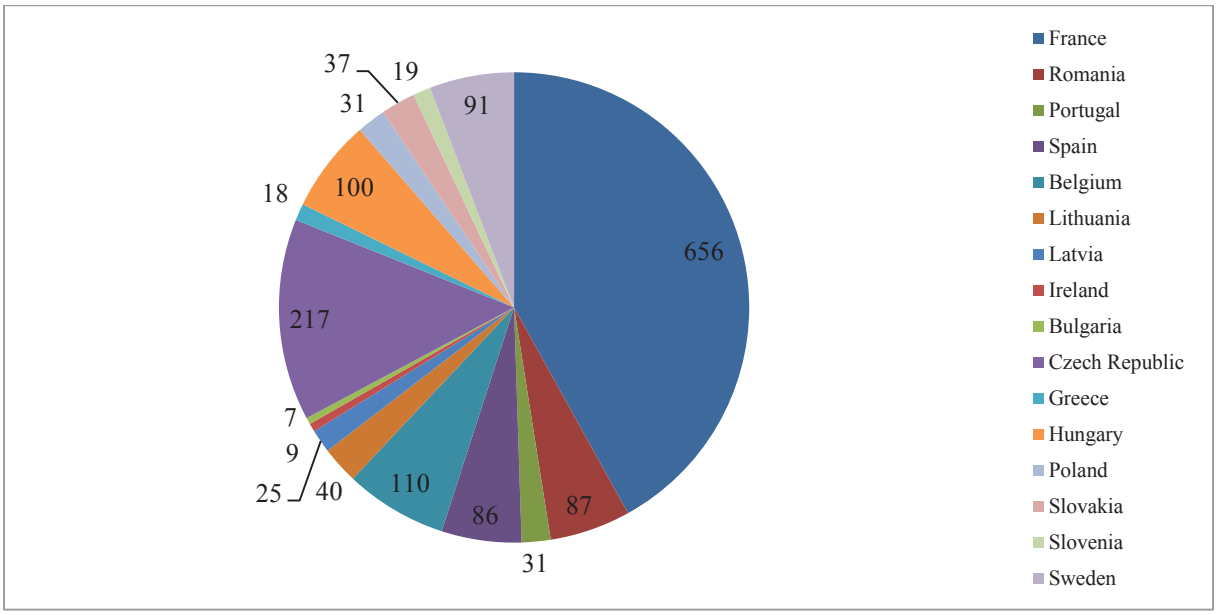
GEO/TIME	N of staff	2010	2011
Belgium	1	40124	40921
Czech Republic	5[12]	12786	12850
Denmark	2	*Information not available*	
Germany	2	*Information not available*	
Estonia	1	11541	11944
Ireland	1	*Information not available*	
Greece	2	*Information not available*	
Spain	0.5	29541	29069
France	1	*Information not available*	
Netherlands	1	46988	47450
Portugal	8	*Information not available*	
Romania	8	7675	7417
Slovakia	0.5	11648	11060
Sweden	1	38954	41963

PCPs reply to inquiries from economic operators within the limits set out by the Regulation, and the necessity, very often, to communicate in English. Most Member States (25)[13] have online portals providing information on the role of PCPs and mutual recognition. 18 Member

11 See annex 7
12 For all issues related to internal market information, so we can assume that one person fulfils the tasks of PCP
13 See "Screening Report on Member States Product Contact Points and Product Contact Points for Construction", Ecorys, 2016

States provide this information (sometimes partially) in English. The availability of online information generates costs related to creating the website and keeping it up-to-date; however, these are easily counterbalanced by the potential reduction of the number of "basic" inquiries PCPs would have to deal with in the absence of such online information. The number of inquiries received by PCPs varies from one Member State to another. Some Member States (France, Czech Republic, Belgium, Hungary and Sweden) registered a high number of requests, while other very little. For example, in 2015, out of the 22 annual reports received, **16 only indicate the number of inquiries received**. The number of questions received amounted to **1645**. The most active Member States are France, Czech Republic and Belgium, followed closely by Hungary and Sweden.

Figure 14-3: PCPs activity 2015



The fact that some PCPs receive a higher number of inquiries can be explained by the fact that these are big attractive and / or more difficult markets, or that promotion of PCPs has been more efficient. The low numbers registered in certain Member States can be also explained by the fact that requests are not properly registered and monitored, or reported to the Commission. For example, some Member States are indicating in their annual reports an increase of the number of inquiries received by the PCPs, while the actual number of these inquiries was never communicated.[14]

2.2. Product Contact Points for Construction under Regulation 305/2011

The aim of the Construction Products Regulation[15] (CPR) is to facilitate the free movement of construction products.

Member States had to set up Product Contact Points for Construction ("PCPCs") that should provide information on technical rules for construction products, contact details of authorities and information on remedies at the request of the economic operator. They cover the

14 For a full overview of the number of inquiries received by the PCPs see annex 7
15 Regulation 305/2011

harmonised and non-harmonised sector. They qualify as "assistance services" for the purposes of the Single Digital Gateway, as they offer a personalised service. A website with information is voluntary.

The quality provisions for the PCPCs have been modelled on those applying to the PCPs under the Mutual Recognition Regulation (MRR) that was adopted three years earlier. For example, the 15 working-day deadline also applies to requests made to the PCPCs. However, many of the voluntary quality recommendations of the MRR have been weakened or dropped. The only quality criterion that the CPR contains and the MRR doesn't is that information shall be provided using "transparent and easily understandable terms".

No information is available on whether PCPCs are recording the enquiries (and replies sent) in a database.

2.3. Your Europe

The "Your Europe" (YE) portal has been created under the IDABC initiative[16] and was first launched in 2005. The 2013 Commission Communication on an "Action Plan for boosting Your Europe in cooperation with the Member States" was positively welcomed by both the EP and the Council.

The portal is part of the inter-institutional "Europa" website[17] and contains practical and user-friendly information, in 23 languages, for citizens and businesses on rights and opportunities in the Single Market. The portal is divided into a Citizens section and a Business section.

As it is essential for people to find out about EU rights and how to exercise them in a particular country, Your Europe is a joint project of the Commission and the Member States. Visitors find EU level information provided by the Commission as well as the respective national information and implementation provided by the Member States through an Editorial Board, if not already collected through other expert groups/networks. Your Europe is divided up into topical sections that present EU-level content (EU rights) and national content, including through links to Member States' pages.

Your Europe also links to relevant assistance and problem-solving services (Your Europe Advice, Europe Direct, SOLVIT, EEC-Net, Enterprise Europe Network, etc.), other EU portals (e.g. e-justice, Euraxess, EURES), Commission websites, national contact and enforcement bodies, relevant forms and to relevant EU law and a few e-procedures (European Professional Card, Online Dispute Resolution).

As part of the Europa platform of the Commission, Your Europe respects the corporate "Information Providers Guide"[18], i.e. the Europa-specific quality standards on content (definition, drafting, SEO, …) and design (structure, layout, usability, accessibility, …). Your Europe is a multilingual portal covering currently 23 languages[19] for the EU-level content. Information is provided in plain language, avoiding legal and administrative jargon. The portal is adapted for use through mobile devices and complies with corporate standards for web accessibility.

16 Decision 2004/387/EC of the European Parliament and of the Council of 21 April 2004 on interoperable delivery of pan-European eGovernment services to public administrations, businesses and citizens (IDABC).
17 http://europa.eu/youreurope
18 http://ec.europa.eu/ipg/index_en.htm
19 All official EU languages but Irish, the business sections also covers Norwegian.

2.4. Your Europe Advice

"Your Europe Advice" (YEA)[20] is a Europe-wide service funded and supported by the Commission that offers citizens and businesses tailored information and advice on their EU rights (mainly internal market rights), free of charge and in all 24 EU languages. The service is outsourced to an external contractor that manages a network of about 65 legal experts with EU law background and expertise and experience in national law and administration in all Member States. YEA is mentioned in the Your Europe Action Plan of 2013. The objective of YEA is to provide a fast, high-quality, personalised legal advice service to citizens and businesses free of charge.

YEA is intended to be an extension of the practical information provided on the Your Europe portal. The Your Europe portal offers a link to YEA whenever citizens need personalised and specialised advice. In their replies YEA advice experts also signpost to other information and advice services, including, but not limited to, the Scadplus website, EURES, ECC Net and other EU and national level information services. YEA has a mandate to respond to enquiries submitted by EU or EEA citizens or their family members who are entitled to benefit from EU rights.

Citizens and businesses receive comprehensive advice within one week and are directed or "signposted", when appropriate, to the authority or other body (local, national or European) best placed to solve their problem. The contract with the contractor specifies the speed of replies to enquiries (within 72 hours), and how the deadlines are calculated. Deadline compliance is monitored by the contractor and the Commission. A large number of quality criteria apply to the replies. Some refer to substance, such as relevance, accuracy, completeness, legal reference and sign-posting, where possible. Others refer to style, e.g. the requirement for the replies to be polite, personalized and tailor-made; in clear, simple, non-technical and non-legalistic terms and easily understandable for "normal" citizens without legal knowledge. The legal experts must also live up to quality criteria as regards their qualification, experience and communication skills.

Apart from its core activity – provision of legal advice to citizens – the service has a number of other functions. Among these is the provision of feedback about the cases and the problems experienced by EU citizens in the various Member States through quarterly feedback reports to the Commission. Enquiries are analysed and regular reports are sent to the Commission. These reports provide an up-to-date picture of where obstacles to exercising EU rights persist. The YEA database with more than 200 000 real life cases constitutes a wealth of information which can be exploited by Commission services for policy shaping or impact assessments.

2.5. Enterprise Europe Network (EEN)

The Enterprise Europe Network was launched in February 2008 by the European Commission. It is co-financed under COSME (Competitiveness of Small and Medium-sized Enterprises) — an EU funding programme designed to encourage the competitiveness of European enterprises. According to the EEN call for proposals the Network is established "to contribute to the objectives of the COSME programme by facilitating access to European and international markets for European SMEs and by providing growth-oriented integrated business and innovation support services that help strengthen the competitiveness and sustainability of European Enterprises." The Enterprise Europe Network is the world's largest

20 http://europa.eu/youreurope/advice/about_en.htm

support network for small and medium sized businesses (SMEs) with international ambitions. It has 3,000 experts across 600 member organisations in more than 60 countries. Member organisations include chambers of commerce and industry, technology centres, and research institutes. The Commission Executive Agency for Small and Medium-Sized Enterprises (EASME) implements the Network for the Commission.

The Network helps SMEs innovate and grow internationally. It provides international business expertise with local knowledge in three areas: partnership services[21], innovation support and advisory services. Only the latter are of relevance to the Single Digital Gateway. Advisory services include practical and customised advice on doing business in another country and national legal requirements applying to the marketing of goods and the provision of services, advice on intellectual property and information and advice on EU law and standards and the Internal Market more generally. SMEs can contact domestic EEN partners, which get in touch with relevant EEN partners in the target country and receive information and advice from them.

The EEN also signposts to other suitable providers of SME-oriented services. This is called the "no wrong door" principle.

The performance of the network is monitored through "Key Performance Indicators". Performance is defined as growth in turnover and employment of SMEs. More specific guidelines apply to advisory services, as specified in the EEN's "Achievement Guidelines on Advisory Services Outcomes" of June 2015. As a starting-point, the network partner should agree an "advisory plan" with the client. This plan should be a short and clear document defining the actions to address the gaps and needs, identify other service providers where relevant, and schedule the actions. All provided services need to be documented in the Customer Relations Management or internal documentation. This could cover emails exchange and documentation forwarded to the client, client confirmation on the advisory plan implementation, etc.

All achievements must be reported on in the achievement report, to be submitted to EASME's Achievements Database in the Network IT Platform. The achievements report has to contain a short section on the advice given and the advisory plan, how the plan was implemented and what initial and longer-term impacts on the client are expected. The documentation of outputs is to be kept at the premises of the Network partners and should be available to EASME or auditors upon request. Quality checks are performed regularly to verify the quality and eligibility of registered achievement reports. The Network will assess the impact of the implemented advisory plan through the impact assessment procedure of the Network. The EASME Project Adviser in charge of partner reporting can perform in-depth evaluations of achievements and can put achievement reports on hold or reject them.

Enterprise Europe Network partners make use of the SME Feedback database to record problems or cases faced by SMEs in the internal market Some broad headings are provided[22] to facilitate the analysis, and businesses are asked to quantify the loss of time and loss of income (additional costs) caused by the problem. Businesses can also provide details on how the problem could be solved. European Commission officials can check the database.

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21 The Network manages Europe’s largest database of business cooperation opportunities.

22 Lack of detail in the text of the European legislation/programme, national requirements in a cross border activity avoid correct functioning of the Internal Market, severe difficulties to find European information needed to carry out the activity, the wording of the European legislation/programme or the procedure negatively affects in particular SMEs, and wrong interpretation at national level of a European text, other.

2.6. Evaluation

An evaluation of these instruments was performed in the context of the creation of the 'Single Digital Gateway'[23]. The focuses on a number of elements that are particularly important for businesses and citizens with respect to their rights and obligations concerning the Single Market: information, assistance and problem-solving services, online procedures, quality criteria for such services, (online) findability and visibility of services, as well as one element that is important for the Commission as guardian of the Single Market, namely the collection of case feedback to inform policy making. It does not consider other elements or functionalities of the instruments. The evaluation aims at analysing how these services are performing together, and to what extent they are reaching the objectives to deliver to businesses and citizens the information, assistance and procedures they need in relation with their EU rights and obligations. In turn, this contributes to a better functioning Single Market, increased cross-border activities, more competition, jobs and growth.

Centralised helpdesk service at EU level, building on Your Europe Advice service

To assist business with compliance information, the option of a centralised *helpdesk service* was considered. This option would however be less effective for SMEs, in particular if no regular awareness campaigns were to be launched, but which would also raise costs. The relative distance from the target audience would entail that its efficiency could be quite questionable, especially in combination with the Single Digital Gateway.

Besides the Single Digital Gateway, the extension of the 'Your Europe Advice' (YEA) service would involve annual costs of about EUR 1.8 million for all areas. Adding regular awareness raising would total such an option to EUR 2 million/year. The direct and indirect costs of YEA per reply correspond to other comparable possibilities citizens have to get the same level of advice (e.g. ask a lawyer; send a question to the European Commission or a national administration). The estimated cost of the Europe Direct Call Centres is EUR 88.26 per hour. However, these hourly cost would increase when specific technical and legal expertise with respect to EU product legislation would have to be hired. The experts in YEA would have to have a good grasp of the technicalities of EU product legislation and the cover all EU languages, especially when the target audience might ask fairly technical questions. At the same time, they would have to be familiar with the national transpositions and implementations of Union harmonisation legislation and developments in national product markets. It may be very challenging to find available experts who would meet these criteria and who together would be able to cover product legislation in all Member States at a reasonable cost. This option was therefore not further examine in this impact assessment.

3. COMPLIANCE SCHEMES

3.1. Abbreviations

AR	Awareness Raising
AdCo	Administrative Cooperation Groups

23 SWD(2017)213 final - Evaluation of existing (regulatory and non-regulatory) framework of relevance to the Single Digital Gateway

BSI	The British Standards Institution
CA	Compliance Assistance
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CS	Compliance Schemes
EC	European Commission
EEA	European Economic Area
EU	European Union
IMP-MSG	Internal Market for Products - Market Surveillance Group
MS	Market Surveillance
MSAs	Market Surveillance Authorities
NCP	National Contact Point for Market Surveillance
SME	Small and Medium Sized Enterprises
TA	Trade Association

3.2. Definitions

Awareness raising	Campaigns designed to heighten the widespread awareness of economic operators to the requirements of the legislation that governs the product sectors in which they operate and to direct them to sources of information and practical assistance.
Compliance assistance	Assistance provided by public authorities to support economic operators by helping them understand and comply with the rules. They are aimed at economic operators who want to comply but lack the competence or resources; most often SME's.
Compliance schemes	Schemes developed by Member States establishing criteria which,

	when fully followed by an economic operator, would provide a reinforced presumption that the economic operator is following all applicable rules regarding the safety and compliance of the products intended to be placed on the market in the EU. The "earned recognition" would be taken into consideration by MSAs when setting enforcement priorities and carrying out risk assessment to determine inspection frequency or scope.
Earned recognition	Recognised and approved activities and procedures undertaken by economic operators to ensure compliance with EU legislation that are taken into consideration by MSA as part of their risk-based inspection programmes.
Practices	Awareness campaigns, compliance assistance initiatives or compliance schemes

3.3. Introduction

Market surveillance authorities in EEA countries have the duty to check compliance with EU directives and regulations. They must deal with rogue operators but also with economic operators who are willing and able to comply with the rules and those willing to comply, but unknowingly breaking the rules because they lack sufficient knowledge. There are increasing pressures on the Market Surveillance Authorities to rethink their approach to how they seek to enforce EU legislation with both large national and international economic operators and small and medium enterprises (SMEs). Increasingly, the modernising regulation agenda is likely to drive agencies towards modernising their approach to enforcement practices.

MSAs in twenty Member States provided information concerning the compliance practices that they use; three provided quite limited information and eight did not provide details of any practices at all. This limited and disappointing response allowed the study to identify and analyse 56 specific compliance practices across all product categories. The analysis produced a total of 27 compliance practices that had some particular merit and these were further reduced to produce 14 "best practice" schemes based upon the information received.

The breakdown of the 14 compliance practices identified as "best practice" is as follows:

- Awareness raising: 4 "best practices" examples;
- Compliance assistance: 6 "best practices" examples;
- Compliance schemes: 4 "best practices" examples.

The compliance practices are not rated in any order of importance or preference as they all have strengths and weaknesses that are important if their usage is being considered in a

specific set of circumstances and in relation to specific product sectors. Issues such as cost, resources and opportunity costs need to be considered.

Whilst it is not possible to be definitive about the total number, scope, quality, cost or usage of the practices that are in operation across all MSA in Member States, the picture that has emerged is that Awareness Raising and Compliance Assistance are much more common than Compliance Schemes but that many Member States may not use any such schemes at all.

The usage of the identified compliance practices appears to be evenly spread across most of the Member States. The result also indicates that the usage of compliance practices does not appear to be related to the length of time that a country has been a member of the European Union and shows that no Member State reported a significantly greater number of compliance practices than the rest. Equally there is no evidence that suggests that specific Member States have adopted a policy stance upon the usage of compliance practices that has determined that MSAs should engage in their operation.

There is a degree of uniformity in that some product sectors feature prominently in all three categories of compliance practices. As the number of practices identified is small and some product categories cover a wide range of products, it is very difficult to be precise about which product sectors attract compliance practices. However, the split of compliance practices appears to relate slightly more towards consumer products rather than professional products. Mass produced products such as toys, electrical products, pre-packaged items and personal protective equipment, as well as machinery that covers both types of products, all featured strongly in the practices identified whilst large pieces of specialised equipment such as non-road machinery did not feature at all. It is surprising that practices aimed at the manufacturers and importers of products covered by the General Product Safety Directive (2001/95/EC) did not feature more highly, in view of the relative lack of harmonised standards for such products.

The practices employed by MSAs do not always sit exactly within the EU chosen definitions as they often have features that cross these boundaries. Many Compliance Assistance protocols have the flexibility to extend into Awareness Raising when there is a change in legislation or a major example of non-compliance is discovered. They can also have elements of a Compliance Scheme if economic operators use the compliance advice provided and then can provide evidence of systems or activities that would reduce their risk assessment scores for inspection frequency or scope based upon their improved likelihood of compliance through an earned recognition protocol.

It was very difficult to assign a specific cost to the compliance practices when they are embedded in the normal market surveillance protocols of the MSA and not budgeted separately. Very few practices were developed with key performance indicators and performance measurement procedures in place. This in turn made it very difficult to determine the effectiveness or cost efficiency of the practices.

The report concludes with a number of recommendations that that should serve as a toolkit for improving compliance practices and to encourage a greater use of them by MSAs.

3.4. Results

The initial collation of information from the survey sought to establish the full range of product sectors covered by Awareness Raising, Compliance Assistance practices and

Compliance Schemes. Initially each practice was counted as a separate practice under every product sector that it covered. However, as many of the practices reported by MSAs covered a range of product sectors, this recording format appeared to indicate a much larger number of separate practices in operation than is the case. Based upon the further information received from MSAs and additional research by members of the study team, practices that cover a range of product sectors were defined as single compliance practices if they operated under a common set of principles by the same MSAs irrespective of how many product groups are covered.

Based upon this accounting procedure, the results of the survey can be summarised as follows:

- 56 specific compliance practices across all product categories have been identified;
- 13 specific practices[24] were classified as Awareness Raising Campaigns;
- 22 specific practices were classified as Compliance Assistance;
- 9 practices were classified as Compliance Schemes;
- 7 practices were classified as joint Awareness Raising Campaigns and Compliance Assistance;
- 2 practices were classified as joint Compliance Assistance and Compliance Schemes;
- 3 practices were classified as covering aspects of all three practices. [AR/CA/CS]; and
- The practices have been in operation for between 1 and 15 years.

This initial information was then analysed and based upon how well it met the study criteria, further enquiries were made by the experts of the Study Team and a larger data file was created based upon the information gained to answer the questions posed in the "questionnaire".

This detailed analysis took account of the selection criteria as set out in the terms of reference for Task 1 and Task 2 and looked for evidence of their effectiveness as specified.

Details of each Member States response; the categories of practices operated by MSA's in those Member States, classification of the practice, the product sectors involved in each practice are provided in Table 14-2.

Further analysis of the survey results was undertaken to determine which product sectors featured most heavily across all three types of compliance practice and in each separate practice category. This information is given in Tables 14-3 & 14-4 and the product sectors are identified by the numbering as set out in the reference document contained in Annex.

24 Irrespective of the number of product groups covered – similarly for all practices

Table 14-2: Information of practices provided by MSAs in Member States25

COUNTRY	AR	CA	CS	Details
Austria	×	×	✔	1. Compliance scheme **[CS]** – Products: (30)[26] *Very limited information obtained*
Belgium	×	✔	✔	1. Yearly inspection campaign [**CA/CS**] - Products - (1, 2, 21, 22, 24, 25, 30) 2. Self-checking guides for fertilizers to be used by economic operators [**CA**] - Products: (30)
Bulgaria	✔	✔	×	1. Awareness Raising [**AR**] – Products: (22B) 2. Compliance Assistance [**CA**] – Products: (22B)
Croatia	✔	×	×	1. Awareness Raising [**AR**] – Products: (2,3,22 & 32)
Cyprus	✔	✔	✔	1. Ensuring the Safety of Toys [**AR & CA**]– Products: (3) 2. Market Surveillance of Medical Devices [**AR/CA/CS**] – Products: (1) 3. Labour Inspection Awareness Campaigns and Compliance Assistance Initiatives [**AR &CA**] - Products:(4, 7, 9, 10, 12, 13) 4. Import control protocol [**CS**] – Products: (14 & 15)
Czech Republic	-	-	-	No information of practices received

25 As this table is based upon voluntary responses from Member States an **X** in any column should not be interpreted that relevant practices are not in operation.
26 () Product category as set out in Annex

COUNTRY	AR	CA	CS	Details
Denmark	✔	×	×	1. Good Communication – a catalogue of best practice [**AR**] – (*All* = All product sectors*)
Estonia	✔	✔	✔	1. Pyrotechnic Awareness Campaigns [**AR**] – (14) 2. EEE Awareness Campaigns [**AR**] - Products: (18,20,21,23) 3. EEE Compliance Assistance [**CA]** - Products: (18,20,21,23) 4. EEE Compliance Scheme [**CS**] - Products: (18,20,21,23) 5. Metrology Awareness Campaigns [**AR**] – (17) 6. Metrology Compliance Assistance [**CA**] – (17) 7. Metrology Compliance Scheme [**CS**] – (17)
Finland	×	✔	×	1. EEE Compliance Assistance [**CA**] – Products:(13, 18, 20, 21, 23) 2. Lifts Safety Campaign[27] [**AR**] – Products: (10) 3. Toy safety Campaign[28] [**AR**] – Products: (3)
France	✔	✔	✔	1. Initial market release of products [**CS**] - Products: (3, 4, 5, 9, 13, 14, 17) 2. Awareness campaigns – [**AR**] - Products: (3, 4, 5, 9, 13, 14, 17)

27 Aimed at lift owners and lift users
28 Aimed at children

COUNTRY	AR	CA	CS	Details
				3. Compliance Assistance – [**CA**] - Products: (3, 4, 5, 9, 13, 14, 17) Compliance Scheme – [**CS**] - Products: (3, 4, 5, 9, 13, 14, 17)
Germany	-	-	-	General information provided but no details of specific practices
Greece	✔	✔	✔	1. Control of Chemicals other than REACH – [**AR/CA/CS**] Products: (22B) – *very limited information obtained*
Hungary	-	-	-	No information of practices received
Iceland	×	×	×	Practices not used in product sectors 5, 13, 18, 20, 21, 23 and no information received for the rest
Ireland	✔	✔	✔	1. MS protocol [**CA**] – Product: (14) 2. Training scheme [**CA**] – Product: (23) 3. MS protocols [**AR/CA**] – Products: (4, 9, 10, 17, 18, 22)
Italy	-	-	-	No information of practices received
Latvia	✔	✔	×	1. Medical Devices advice [**CA**] - Products: (1) 2. Cosmetics advice [**CA**] – Products: (2) 3. Chemical Substances advice [**CA**] –Products: (22 A/B) 4. Biocides advice [**CA**] – Product: (32)

COUNTRY	AR	CA	CS	Details
				5. Be smart–build safe campaign [**AR/CA**]–Products (5) 6. Consultation protocol [**CA**] – (*All**)
Liechtenstein	-	-	-	No information of practices received
Lithuania	✔	✔	✔	1. Legal metrology supervision [**AR/CA**]– Products: (17) 2. Pyrotechnics supervision [**CA/CS**] – Products: (14)
Luxembourg	✔	✔	✔	1. Accredited quality management system [**AR/CA/CS**] Covers MS of 25 of the 33 product categories including (3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 15, 17, 18, 19, 20, 22A 23, 25, 31, 32, 33)
Malta	-	-	-	No information of practices received
Netherlands	✔	✔	✔	1. MS protocols [**CS**] – Products: (*All**) 2. MS scheme [**CA**] – Products: (18, 19) 3. MS scheme [**AR**] – Products: (17, 18, 19)
Norway	✔	×	×	1. MS protocols [**AR**] – Product: (5)
Poland	✔	×	×	1. MS awareness campaign [**AR**] – Product: (5) *Very limited information obtained*
Portugal	✔	✔	×	1. Regulatory & Scientific Advice Office [**AR/CA**] – (1, 2)

COUNTRY	AR	CA	CS	Details
Romania	-	-	-	No information of practices received
Slovakia	×	✔	×	1. MS Information activities [**CA**] – Product: (2)
Slovenia	×	✔	✔	1. MS protocols [**CS**] – Products: (17)
Spain	×	✔	×	1. MS protocols [**CA**] – Products: (3, 4, 5, 20, 21, 22, 31, 33)
Sweden	✔	✔	×	1. MS protocols [**AR/CA**] – Products: (4, 7, 9, 13) 2. Sectoral agreements [**CA**] – Products: (*All**) 3. MSP proactive activities [**AR**] – Products: (*All**) 4. Information brochure [**CA**] – Products: (4) 5. Educational package [**CA**] – Products: (3)
UK	✔	✔	✔	1. Primary Authority [**CS**] – Products: (*All**) 2. Home Authority [**CA**] – Products: (*All**) 3. MS activity [**AR**] – Products: (5) 4. Regulatory information [**CA**]: Product (15, 22A, 32) 5. Trader Advice [**CA**] – (*All**)

Table 14-3: Number of Practices in operation by product sector29

NUMBER OF PRACTICES IN EACH CATEGORY OF COMPLIANCE PRACTICE AND IN TOTAL FOR EACH PRODUCT SECTOR																		
Product sectors	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**
AR[30]	2	2	5	5	4	1	3	1	5	4	1	1	4	3	1	0	6	4	2
CA[31]	4	4	4	7	6	1	3	1	5	3	1	1	5	4	2	0	5	5	2
CS[32]	2	1	3	3	3	1	1	1	4	1	1	0	3	5	2	0	5	2	1
Totals	**8**	**7**	**12**	**15**	**13**	**3**	**7**	**3**	**14**	**8**	**3**	**2**	**12**	**12**	**5**	**0**	**16**	**11**	**5**

Product sectors	**20**	**21**	**22**	**22A**	**22B**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**Total**	**ALL[33]**
AR	2	0	2	1	2	2	0	1	0	0	0	0	0	1	2	1	0	**68**	2
CA	4	3	4	2	2	4	1	2	0	0	0	0	2	2	3	2	0	**94**	2
CS	2	1	1	1	1	2	1	2	0	0	0	0	2	1	1	1	0	**55**	2
Totals	**8**	**4**	**7**	**4**	**5**	**8**	**2**	**5**	**0**	**0**	**0**	**0**	**4**	**4**	**6**	**4**	**0**	**217**	**6**

Table 14-4: Practices in order of usage by product sector

29 Annex Reference List of Product Sectors as per the project ToR
30 AR = Awareness raising
31 CA = Compliance assistance
32 CS = Compliance scheme
33 ALL = Practices that cover all product sectors

THE PRACTICES FOR EACH CATEGORY OF COMPLIANCE PRACTICE AND IN TOTAL FOR EACH PRODUCT SECTOR SHOWN IN ORDER OF USAGE BY MARKET SURVEILLANCE AUTHORITIES																			
Product sectors	**17**	**4**	**9**	**5**	**13**	**14**	**3**	**18**	**1**	**20**	**23**	**10**	**7**	**2**	**22**	**32**	**15**	**19**	**25**
AR	6	5	5	4	4	3	5	4	2	2	2	4	3	2	2	2	1	2	1
CA	5	7	5	6	5	4	4	5	4	4	4	3	3	4	4	3	2	2	2
CS	5	3	4	3	3	5	3	2	2	2	2	1	1	1	1	1	2	1	2
Totals	**16**	**15**	**14**	**13**	**12**	**12**	**12**	**11**	**8**	**8**	**8**	**8**	**7**	**7**	**7**	**6**	**5**	**5**	**5**

Product sectors	**22B**	**21**	**22A**	**30**	**31**	**33**	**6**	**8**	**11**	**12**	**24**	**16**	**26**	**27**	**28**	**29**	**34**		
AR	2	0	1	0	1	1	1	1	1	1	0	0	0	0	0	0	0		
CA	2	3	2	2	2	2	1	1	1	1	1	0	0	0	0	0	0		
CS	1	1	1	2	1	1	1	1	1	0	1	0	0	0	0	0	0		
Totals	**5**	**4**	**4**	**4**	**4**	**4**	**3**	**3**	**3**	**2**	**2**	**0**	**0**	**0**	**0**	**0**	**0**		

3.5. Conclusions of the Survey

The Study was charged to ascertain whether MSAs typically or exceptionally use compliance schemes, provide compliance assistance or resort to awareness raising when enforcing the relevant legislation.

As the response to the survey was voluntary and as replies were only received from a minority of MSAs in each Member States, the results of the survey cannot necessarily be taken as an absolute statement of the current usage of compliance practices by MSAs across the European Union. In addition, MSAs did not provide answers to all the questions posed by the study.

Whilst it is not possible to be definitive about the total number, scope, quality, cost or usage of the practices that are in operation across all MSA in Member States, it is very clear that many MSA's did not feel compelled to confirm or deny that they operate such practices as an intrinsic feature of their market surveillance procedures. The picture that has emerged from the survey results is that Awareness Raising and Compliance Assistance are more common than Compliance Schemes but that many Member States may not use any such schemes at all.

This view is supported by the responses of Member States as reported in 2014 in meetings with the Commission, amongst others due to considerations of costs and administrative burden:

> *The majority of the delegates at a meeting of the Expert Group on the Internal Market - Market Surveillance Group on 19 May 2014 informed the European Commission that **they do not run such schemes**. But they do perform horizontal checks at manufacturer and importer level. The current practice takes into account good compliance records, and quality systems in place to define the economic operator's risk profile and decide if he will be checked. However, market surveillance authorities were generally opposed to formalising this current practice and to restricting their options for checking all businesses and products.*[34]
>
> *They were concerned that such practices could be seen as providing an ex-ante approval of products. Questions were also raised regarding the possibility for the economic operator to take advantage of the compliance scheme and use it as publicity.* [35]
>
> *The national market surveillance authorities of the EEA EFTA States **did not, for the time being, see a value added by introducing such schemes**, mainly due to the administrative burdens demanded by operating them. And **were not aware of any relevant schemes** at national level in the EEA EFTA States.*[36]

Having contacted over 500 separate MSAs that are responsible for 34 product sectors in each Member State and only being provided with detailed information on 56 practices, the conclusion that can be drawn from the study is that many MSA's have not greatly changed their position since May 2014.

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34 Summary of the Minutes of the Meeting of The Expert Group on the Internal Market for Products – Market Surveillance Group Monday 19 May 2014

35 Ibid

36 European Economic Area Standing Committee of the EFTA States, Ref: 14-131336, Rev.1 18 July 2014 Subcommittee I On The Free Movement Of Goods EEA EFTA - Compliance Schemes Operated By MSAS

If it is accepted that Member States and their MSAs would normally respond positively to a request for information from a Directorate General and would be keen to detail successful market surveillance initiatives, then a reasonable conclusion is that compliance practices are not being widely used across all product sectors by many MSAs. However, another possibility that is supported by some of the responses to the questionnaire is that the operation of such practices is now so firmly embedded within the general market surveillance protocol that they are no longer perceived as a separate or independent practice. This explanation would apply more specifically to Compliance Assistance and to a lesser degree, Awareness Raising.

The usage of this relatively small number of identified compliance practices appears to be evenly spread across most of the Member States, even if the countries that did not respond are not considered to have adopted any compliance practice. The result indicates that the usage of compliance practices does not appear to be related to the length of time that a country has been a member of the European Union while also showing that no Member State reported a significantly greater number of compliance practices than the rest. There also appeared to no discernible difference in the usage of compliance practices between large and small countries. Equally there is no evidence that suggests that specific Member States have adopted a policy stance upon the usage of compliance practices that has determined that MSAs should engage in their operation. Usage of compliance practices could be considered to be more dependent upon the policies and strategies of individual MSAs and quite independent of the member country.

From the information provided to the Study Team through the survey it was found that:

- Almost half of all the practices identified were applicable to a range of product sectors:
    - 52% of practices related to a single product sector [29 practices];
    - 34% of practices related to a range of product sectors – these included between 2 & 25 separate product sectors [19 practices];
    - 14% of practices were applicable across all product sectors [8 practices];
- The product sectors where these practices were mostly in operation are:
    - Measuring instruments, non-automatic weighing machines, pre-packaged products and units of measurement;
    - Personal protective equipment;
    - Machinery;
    - Construction products;
    - Equipment and protective systems intended for use in potentially explosive atmospheres;
    - Pyrotechnics;
    - Toys; and

- Electrical products (EMC & LVD),

- The product sectors where specific practices do not appear to be in use:
  - Appliances burning gaseous fuels;
  - Recreational craft;
  - Marine equipment;
  - Motor vehicles and tractors;
  - Non-road mobile machinery; and
  - Crystal glass.

- The product sectors where awareness raising features most often:
  - Measuring instruments, non-automatic weighing machines, pre-packaged products and units of measurement;
  - Personal protective equipment;
  - Machinery;
  - Construction products;
  - Toys;
  - Lifts:
  - Explosives for civil use; and
  - Electrical Equipment under EMC

- The product sectors where compliance assistance features most often:
  - Personal protective equipment;
  - Construction products;
  - Machinery;
  - ATEX[37]
  - Measuring instruments, non-automatic weighing machines, pre-packaged products and units of measurement; and
  - Electrical Equipment under EMC

- The product sectors where compliance schemes feature most often:

37 ATEX = Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres.

- Pyrotechnics;
- Measuring instruments, non-automatic weighing machines, pre-packaged products and units of measurement; and
- Personal protective equipment.

There is a degree of uniformity in that some product sectors feature prominently in all three categories of compliance practices. The split of compliance practices appears to relate slightly more towards consumer products rather than professional products except that ATEX equipment, a non-consumer product category features quite prominently, whilst crystal glass, a consumer product, does not feature at all; and of those product sectors that do feature prominently, a number contain both consumer and professional products (e.g. machinery and construction products). Mass produced products such as toys, electrical products, pre-packaged items, and personal protective equipment all featured strongly in the practices identified whilst large pieces of specialised equipment such as non-road machinery did not feature at all. It is accepted that compliance practices may not be as relevant in every product group, if, for instance, products are subject to type approval and obligatory surveillance by a third party through the relevant conformity assessment procedure, e.g. the automotive industry or gas appliances.

Whilst the study focused primarily on EU harmonised product legislation, in view of the relative lack of harmonised standards for products covered by the General Product Safety Directive (2001/95/EC), it is surprising that practices aimed at the manufacturers and importers of such products did not feature more highly.

The practices employed by MSAs do not always sit exactly within the EU chosen definitions as they often have features that cross these boundaries. Many Compliance Assistance protocols have the flexibility to extend into Awareness Raising when there is a change in legislation or a major example of non-compliance is discovered. They can also have elements of a Compliance Scheme if economic operators use the compliance advice provided and then can provide evidence of systems or activities that would reduce their risk assessment scores for inspection frequency or scope based upon their improved likelihood of compliance through an earned recognition protocol. It is often very difficult to assign a specific cost to the compliance practices when they are embedded in the normal market surveillance protocols of the MSA and not budgeted separately.

3.6. Feedback from businesses and trade associations

The study team sought to conduct interviews with twenty large scale economic operators and industry associations that have made use of compliance practices or have members operating within the relevant product sectors to gain their opinions upon the use and benefits of these practices. The choice of business stakeholders also sought to provide a balanced representation of businesses' typology (large business vs SMEs; manufacturers, importers and distributors) and geographical origin within the EEA.

This task was originally part of Task 1.1 but at the Kick-off meeting it was agreed that this task would provide better information if it was conducted after the “10 best practice” schemes, had been identified. This change of timeframe allowed the study team to obtain specific industry feedback upon the types of practices identified and the comments received

have been incorporated in the development of the recommendations that form part of this report.

It proved difficult to arrange interviews with some trade associations due to the appropriate personal not being available or the association requiring time to consult is membership or to draft a formal response. It was particularly difficult to gain a comprehensive response from economic operators regarding compliance schemes as so few member countries appear to have adopted such practices. However, it was possible to discuss compliance practices in general with nine trade associations and with three economic operators. To compensate for the lack of response from trade associations, the study team have researched public statements made by trade associations on the topic of compliance and MSA support and specific cases studies.

Feedback from trade associations and economic operators included:

Positive comments:

1 Trade associations are generally in favour of compliance initiatives.

2 They favour the concept of recognition in cases where all legal requirements were being complied with – earned recognition or recognition as an 'approved' economic operator, leading to less pressure directed at such economic operators.

3 They support a risk based approach as this would allow more pressure to be directed towards those who did not comply.

4 They support practices that have a single point of contact for approach.

Less positive comments included:

1 Many Trade Associations are not aware of examples of compliance practices, suggesting that not many schemes are in use.

2 They indicate that there is only low level of activity happening with any of these schemes.

3 They feel that more awareness raising should be initiated by market surveillance authorities to encourage greater compliance and to publicise those practices in operation.

4 Too many MSAs are only reactive in their approach to compliance assistance.

5 There needs to be greater harmonisation between MSA's on such matters as risk assessment which is currently too subjective.

6 Although no specific pitfalls were highlighted, concern was raised that in regards to non-harmonised product groups, a single compliance scheme might not be appropriate for all compliant products.

7 Concern was also expressed as to whether the MSAs would have the resources and expertise to keep up to date with regular legislation amendments and an extensive product range.

8 A view was expressed that in respect of Regulation 1223/2009 there would be no added benefit to having regulators develop compliance schemes as it would require resources to develop, maintain and update both from the regulatory authorities involved and from the trade association in consulting over their content. Such a procedure would delay informing manufacturers regarding changes and updates to the Regulation or its practical interpretation.

Issues raised:

1. Trade Associations feel that they should have input to MS testing programmes through national market surveillance programmes and EU MS programmes (WELMEC) so that suggestions from industry can be included in these programmes.

2. Awareness campaigns could include an annual conference open to both regulators and industry which is organised by the regulator and/or the trade association.

3. The incentive of earned recognition could encourage more trade associations to develop Codes of Practices for their members but this is not always possible due to the current state of the regulatory market.

4. There can be a disincentive to engage with MSAs because cheap imports from countries such as China which do not comply with legal requirements are not being controlled as little or no enforcement now takes place due to cutbacks.

5. They are concerned about a lack of budget to undertake enforcement and the difficulties with controlling the online marketplace.

6. Inconsistencies with enforcement, some MSA's being tougher than others.

7. Little or no account is taken of the history of the business and the risk posed and the extra steps the legitimate industry takes to get things right such as extra sampling and the wish for this to be recognised and distinguished from the industry 'bad guys'.

8. Inconsistencies between MSA's on failure rates and results of failures from Notified bodies which raises issues on such matters as adequacy of controls imposed by member states on Notified bodies.

9. For boilers, third party compliance verification has been helpful as an additional tool for compliance assessment in the interest of authorities, consumers and industry.

Trade Associations and economic operators providing feedback:

- Association of European Heating (EHI)
- European Fireworks Association
- Toy Industries of Europe (TIE)
- UK Weighing Federation
- Agricultural Engineers Association

- Cosmetics, Toiletries and Perfumery Association (CTPA)
- British Constructional Steelwork Association Ltd (BCSA)
- British Safety Industry Federation (BSIF)
- British Candlemakers Federation
- IKEA (UK and Ireland)
- Wm Morrison Supermarkets PLC (UK)
- SIA "Pipelife Latvia" (Latvia)

Specific comments:

Latvian business

- The modern approach to market surveillance is much better. A fast response to requests for information and the help provided by the MSA is appreciated by businesses.
- Training seminars are helpful in reducing misunderstandings but they need to be widely publicised in order to reach as many economic operators as possible

Previously published Market Surveillance Best Practice Case Studies

"The European Partnership for Energy and the Environment (EPEE), the voice of the manufacturers of heating and cooling equipment in Europe, is committed to improving market surveillance implementation, which is often fragmented and insufficiently resourced throughout the EU Member States. Without proper enforcement, legislation will not reach its full potential and the market will be further distorted at the expense of the environment, consumers and industry. Sharing knowledge on projects and policies is key for better market surveillance in Europe. Within this context, this guide offers some best practices from national market surveillance authorities of EU Member States on how to navigate current challenges and obstacles. EPEE has focused particularly on the EU Eco-design legislation."[38]

- **Finnish Safety and Chemicals Agency (TUKES)**, Finland's market surveillance authority, has provided several insights for other Member States on how to deal with market surveillance. Since 1992, TUKES has been active on safety related legislation. From their experiences, the following best practices have been identified.
  - **A holistic, integrated approach to market surveillance**

    TUKES provides information on eco design through its telephone hotline and FAQ page and online forum. The agency reports a further need to communicate basic eco design information with small and medium sized enterprises (SMEs) that are among the first to be impacted by EU eco design legislation.
  - **Regional Initiatives on market surveillance:**

38 Market Surveillance Best Practice Case Studies – The European Partnership for Energy and the Environment (EPEE)

Finland is a member of the Nordic Forum, a regionally-focused platform for sharing information and providing assistance on market surveillance among Denmark, Finland, Iceland, Sweden and Norway. The Nordic Forum meets three to four times each year to discuss these issues.

- **Greater EU market surveillance cooperation on non-safety issues for products:** TUKES has prioritised the creation of an EU-wide database dedicated to market surveillance on non-safety related issues, on which Member States do not have an organized system or initiative to share information within the EU.

Previously published views of Industry[39]

- In the UK the National Audit Office (NAO), the Better Regulation Executive (BRE) and the Better Regulation Delivery Office (BRDO), both from the Department for Business, Innovation and Skills (BIS) and Department for Environment, Food and Rural Affairs (Defra) commissioned a survey to determine businesses' views on the extent of the burden of regulation, both in general and in specific regulatory areas. The survey, conducted by Jigsaw Research in February and March 2014, comprised 2,500 20-minute telephone interviews with senior business decision-makers.

  - Some key findings:

    - 91% of businesses use some form of external support when complying with the one specific law type that they were asked questions about. This support includes using websites (54%), seeking help from advisors/agents (51%), trade associations/business organisations (46%), friends/peers (43%) and inspectors (38%).

    - Medium and large sized companies (50+ employees) are more likely to seek external support from websites and advisors. Micro and small companies (less than 50 employees) are more likely to seek external support from friends and peers.

    - 46% make use of trade associations or business organisations and 43% talk to friends, family, other contacts or peers.

    - Around two-fifths (38%) use inspectors from the local council or regulatory bodies to help their business in complying.

    - Half (50%) use external agents because of a lack of clarity in the legal requirement for regulatory compliance, and two-fifths (40%) do so because of insufficient advice from regulators.

    - Sole employee businesses are least likely to seek more/specialist knowledge (possibly due to a lack of perceived need) and small to medium companies more so (possibly due to fewer internal specialists when compared with large businesses).

    - Small businesses are more likely to use a number of sources to help with compliance for one specific law type. 62% use government websites

39 Business Perceptions Survey 2014

(compared with 54% of all businesses) while 62% use external advisers/agents (compared with 51% of all businesses).

- ❖ Just under a half of businesses (49%) agree that 'good regulatory advice helps make confident investment decisions'.

- ❖ Approaching six in ten (59%) agree that finding information about which regulations apply is a burden and just over half (53%) feel this applies to finding guidance and advice explaining what you have to do to comply.

Previously published comments of Trade Associations

- ➢ "The European machinery industry, represented by CECE, CECIMO, CEMA, FEM and EUROMAP, warmly welcomes the proposal for a Regulation on market surveillance from the Commission, as it reflects many of the suggestions that our industry has made during the past months. - "Trade Associations should be taken on board to cooperate with the Authorities of the Member States to set up technical procedures for the inspection of the machines".

- ➢ "Improving information from authorities to businesses: Dissemination of information to the various stakeholders is a key part of effective market surveillance. Ensure that the existing system contains the information on results of market surveillance that is relevant for businesses."

  -The Association of Swedish Engineering Industry (Teknikföretagen) and the Swedish Trade Federation (Svensk Handel) - Stockholm, September 2009.

Orgalime answer to the Commission questionnaire on "Internal Market for Goods – Enforcement and Compliance"

Question B2.4. What is your opinion on the following approaches by national authorities to reduce the level of non-compliant products on the market?

1. National authorities should focus exclusively on enforcement and leave it entirely up to the businesses to ensure compliance by developing their own approaches. → **not effective**

2. In addition to enforcement national authorities should also provide information on product requirements. → **effective**

3. In addition to enforcement national authorities should also provide support to businesses through guidance on how to interpret product requirements**.** → **effective**

4. In addition to enforcement national authorities should also allow businesses to enter into agreements with authorities to receive binding advice from them on how to interpret product requirements in specific situations. → **not effective**

We would like to emphasize that information should be made available first and foremost at local level, in a tailored manner for each sector. While such information needs to be updated and co- ordinated centrally, a single multilingual portal is not the best way to ensure greater awareness of SMEs. We should also promote the role of national trade associations.

Comments about UK Primary Authority

- **Large International business: "**The Company signed up to the Primary Authority scheme in the UK, there being no similar scheme in Ireland. They find this scheme works for them well and are positive about the outcomes it provides for the company, but the expense of it is constantly reviewed and questioned as to whether it is still value for money, especially where regulators are fully stretched on other priorities, but this appears to be the only potential pitfall".

- **Large UK business:** "Primary authority has provided us with sound advice from a regulatory perspective but more so on a practical level to improve safety standards for our circa 8500 staff and circa 430,000 members."

- **UK trade association with 160 members:**

    - "Primary Authority partnerships are built on trust, and have resulted in a much better understanding and working relationship between MSAs and industry".

    - "Because the MSA has confidence that members of the trade association [TA] are compliant, they can focus their resources more effectively on areas of market surveillance where non-compliance is more likely to be found".

    - "The co-ordinated primary authority partnership serves as a conduit for shared intelligence about non-compliant businesses and this is very helpful to MSA in targeting their resources effectively".

Comments from a primary authority evaluation in 2013 re business benefits:

- A reduction in the amount of time businesses spend on regulatory activities;

- Improvements in relationships with regulators;

- Improved intelligence about regulatory matters;

- Improvements in the consistency of regulatory advice and guidance;

- Access to advice, both Primary Authority Advice and other non- statutory advice;

- Support for staff development;

- Advice on planned or future developments;

- Support for addressing "incoming" regulatory issues from enforcing authorities;

- Advice on standardising policies, procedures, systems and documentation.

Overall summary of view of industry

Trade Associations represent the economic operators who seek to comply with the law and therefore are generally supportive of compliance practices. They are concerned about ease of access to guidance, accuracy and consistency of advice and demands upon their resources. However, they are also seeking protection for unfair competition from the easy availability of non-compliant products or activities. They are often keen to work closely with the

enforcement authorities so that the experience, views and needs of their members are considered in the planning and development stages of compliance practices. Trade associations are often a major source of advice and guidance for their members and would not see any advantage if the MSAs merely duplicated their efforts.

The feedback received from the trade associations consulted when added to the previously published comments from industry and the results of research publically available gives a clear indication that compliance practices are welcomed and supported by economic operators if they are well designed, appropriately resourced, backed by relevant expertise and are efficient and effective. However, these is a concern that the development and operation of compliance practices might divert resources from delivering a scale of inspection that provides compliant economic operators with the protection and assurance of a "level playing field" and rewards the investment of resources into compliance systems and best practices.

As consistent market surveillance practices universally applied across all EU member countries still appear to be some way off, part of an ideal solution could provide a mechanism for economic operators to seek advice from a single point of contact on an EU wide basis that is recognised, acknowledged and respected by all other EU MSA's in a consistent manner. Perhaps it can never be achieved, or is a long-term aspiration. There would also need to be some form of dispute resolution process between MSA's but either way, this sort of approach utilising a single point of contact appears to be favoured by industry.

3.7. Further analysis of identified compliance practices

The study team reviewed the 56 compliance practices that had been detailed through the survey, applied the benchmark criteria and sought to identify specific elements essential for their success that included:

a. cost-efficient compared with more classical styles of enforcement;

b. more suitable for a range of market/product sectors; and

c. easily replicated in other Member States.

Visits were made to interview the Market Surveillance Authorities operating the compliance practices that appeared to meet some of the benchmark criteria and offered elements of good practices and transferability. It was not always possible to arrange interviews with all the MSAs that we wished to interview due to a lack of availability of personnel from the MSA. When interview were not possible, further details were obtained through exchanges of e-mails.

In total interviews were conducted with MSAs in 13 member countries. The countries visited were:

- Belgium
- Croatia
- Cyprus
- Denmark
- Eire
- Finland
- France
- Latvia
- Luxembourg
- Netherlands
- Slovenia
- Sweden
- United Kingdom

❖ Detailed information was obtained by e-mail from Portugal and Spain.

This consultation produced a total of 27 compliance practices that had particular merit and these were further reduced to produce 14 "best practice" schemes. The 13 compliance practices that did not make the final 14 are detailed in Section 27 of this report. The breakdown of the 27 compliance practices into 14 identified as "best practice" is as follows:

- Awareness raising: a total of 10 practices including 4 "best practices" examples;
- Compliance assistance: a total of 12 practices including 6 "best practices" examples;
- Compliance schemes: a total of 5 practices including 4 "best practices" examples.

The compliance practices are not listed in any order of importance or preference as they all have strengths and weaknesses that are important if their usage is being considered in a specific set of circumstances and in relation to specific product sectors. Issues such as cost, resources and opportunity costs need to be considered. The list is followed by a detailed analysis of each practice.

3.8. The List of "Best Practice" Schemes

COMPLIANCE SCHEMES

- **UNITED KINGDOM - BEIS: Primary Authority/CTSI: Home Authority [CS1]**
- **FRANCE - DGCCRF: Market Surveillance protocol - Supply chain supervision [CS2]**

- **NETHERLAND - NVWA: Market Surveillance – Regulatory protocols [CS3**
- **LUXEMBURG - ILNAS - SURVEILLANCE DU MARCHÉ: MS Quality Management System [CS4]**

COMPLIANCE ASSISTANCE

- **PORTUGAL - INFARMED I.P: Regulatory and Scientific Advice Office & Guide [CA1]**
- **NETHERLANDS - AGENTSCHAPTELECOM: Market Surveillance Protocols [CA2]**
- **CYPRUS - CCPS: Ensuring the Safety of Toys [CA3]**
- **SWEDEN - SWEDISH CONSUMER AGENCY: PPE Compliance brochure [CA4]**
- **SPAIN - SOIVRE INSPECTION SERVICE: Market Surveillance protocol [CA5]**
- **SWEDEN - SWEDISH CONSUMER AGENCY: Web based information [CA6]**

AWARENESS RAISING

- **CYPRUS - LABOUR INSPECTION: Market Surveillance protocols [AR1]**
- **LATVIA - CRPC: BE SMART – Build Safe Campaign [AR2]**
- **DENMARK - DANISH MS COMMITTEE - Good Communication [AR3]**
- **IRELAND - DEPARTMENT OF JOBS, ENTERPRISE AND INNOVATION - Market Surveillance protocols [AR4]**

3.9. Good Practice

GOOD PRACTICE FOR GENERAL AWARENESS RAISING – *[See section 27]*

- **FINLAND – PIKI'S ROOM**

OTHER EXAMPLES OF GOOD PRACTICE – *[SEE SECTION 26]*

- **BUSINESS AWARENESS RAISING INITIATIVES**
- **PROOF OF AGE SCHEMES**
- **FOOD HYGIENE RATING SCHEME**
- **BUSINESS COMPANION**
- **COMPLIANCE ADVICE CENTRES**

3.10. Compliance Schemes

TITLE: *CS1 -* **Market Surveillance protocol - Primary & Home Authority**

OPERATOR: **DEPARTMENT FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY**

COUNTRY: **United Kingdom**

DETAILS: Primary Authority [PA][40] is a statutory scheme, established in the UK by the Regulatory Enforcement and Sanctions Act 2008, that came into operation in 2009 and allows economic operators to be involved in their own regulation. The scheme enables them to form a statutory partnership with one MSA, which then provides them with robust and reliable assured advice and requires all other local regulators to consider this advice when carrying out inspections or addressing non-compliance.

Through Primary Authority, Economic Operators and MSAs can develop better working relationships that are based on trust. One of the main purposes is to ensure that consistent advice on compliance can be given to and received by businesses across whole trading sectors and can provided through trade associations in conjunction with the PA MSA.

Economic operators receiving and following assured advice from their primary authority can be confident that they are compliant.

An inspection plan for all sites operated by an economic operator can be produced by its primary authority to improve the effectiveness of visits by local regulators, avoid repeated checks, and enable better sharing of information. Other inspection bodies must follow the requirements of the plan, unless the primary authority is notified in advance and has agreed to an alternative course of action.

COMMENT: A scheme designed to provide economic operators with a single point of contact and consistency of advice when they are responsible to multiple MSAs all enforcing within the same product sectors. A unique element is the financial arrangement between the MSA and the economic operator that allows the MSA to recover the costs of providing guidance. This will probably require legislative approval in Member Countries before it could be replicated. This scheme is run along aside a non-regulatory, free scheme called "Home Authority" operated by the MSAs themselves based upon a model developed by the professional association for Market Surveillance Inspectors. (CTSI)[41]

ASSESSMENT:

1. **Effectiveness**

   - Design: To ensure that local enforcement is consistent at a national level and sufficiently flexible to address local circumstances. It allows an eligible Economic Operator to form a legally recognised partnership with a single local MSA in relation to regulatory compliance. This MSA is then known as its 'primary authority' (PA).

40 https://www.gov.uk/government/publications/primary-authority-overview
41 Chartered Trading Standards Institute

- Evidence of results: Numbers of EO agreeing PA partnerships has increased from 6 joining in 2009 to 9,370 in 2016. As of 12th October, there are 15,733 EOs involved in 16,849 PA agreements with 180 MSAs. Very few PA partnerships have been discontinued since the commencement of the scheme.

  An Independent Review of Primary Authority in 2013 concluded that EOs were deriving a wide range of benefits from Primary Authority including a reduction in the amount of time EOs spent on regulatory activities. The large number of EOs involved and countless thousands of pieces of advice issued are a very positive indicator as there has only been two challenges to Primary Authority Advice resulting in formal determinations.

- Costs: The resourcing of each partnership is a matter for the EO & MSA concerned. The design and launch cost were covered by the Ministry. The total budget is not known because the operational costs are shared between several sources.

- Duration: 7 years

- Coverage: **National** - through local MSAs across all product sectors

- Meets product harmonisation principles: Easier for EOs to be compliant, by removing uncertainties and eliminating the possibility of MSAs providing inconsistent or conflicting advice. The availability of a single point of contact at a PA to deal with a major issue such as a product recall has many benefits for the EO, including a consistent approach, shared knowledge and expertise.

2. **Cost-efficiency:** EO's can tailor the terms of their PA agreement to meet their own needs and cost benefits. The partnership agreements provide MSAs with the ability to fund their advice provision. Co-ordinated planning between MSAs with a designated lead MSA can reduce both scope and frequency of inspection and sampling and avoid duplication.

3. **Specific elements:**

   - Eligible economic operators can be local, regional or national.

   - Statutory scheme to provide robust and reliable assured advice to Economic Operators;

   - Terms and conditions set in Primary Authority Handbook[42] [159 pages]

   - Voluntary engagement with MSAs by individual EO's who can decide what level of support they require;

   - Resourcing of partnerships is a matter for the parties concerned

   - Advice given by PA must be respected by all other MSA's who may have an overlapping interest in the EO.

42 www.gov.uk/government/publications/primary-authority-handbook

- A PA can recover its costs from the EO - but charging is not mandatory[43]

4. **Ease of replication:** May conflict with legislation or anti-corruption initiatives that prohibit government departments and their staff from receiving recompense for advice and assistance provided during their official duties. Would need legislation in most/all member countries.

   This type of practice may work best in member countries that operate market surveillance at both national and regional or local level through independent MSAs and municipal bodies as the practice aims to provided consistency of advice and enforcement whilst avoiding uncertainty and duplication. It would also require an identified need of the national and regional EOs and an indication of their willingness to meet the PA costs.

5. **Earned recognition/impact upon inspection:** An inspection plan for an EO can be produced by its PA to improve the effectiveness of visits by local regulators, avoid repeated checks, and enable better sharing of information. All other MSA's must follow the requirements of a PA plan, unless the PA is notified in advance and has agreed to an alternative course of action. The 2013 review of PA conclude that it had a positive impact upon enforcement activity.

TITLE: ***CS2 -*** **Market Surveillance protocol - Supply chain supervision –**

"Contrôle de la première mise sur le marché" [CPMM]

OPERATOR: **DIRECTION GÉNÉRALE DE LA CONCURRENCE, DE LA CONSOMMATION ET DE LA RÉPRESSION DES FRAUDES (DGCCRF)[44]**

COUNTRY: **France**

DETAILS: MS Inspection of the main operators placing products on the French market to assess their ability to respect all applicable product legislation and identify those with efficient internal checking procedures. The practice was devised as a cost-efficient and time-efficient inspection method for the operators responsible for most of the products being placed on the market, before they are dispatched in the retail shops. The targeted operators are subjected to initial CPMM inspection and regular follow-up inspections. Specific indicators determine the frequency of inspections and risk-rating system of EOs is included in the scheme, with inspection frequency being reduced if the risk level of the EO is reduced. EOs with a good CPMM control history and known to have appropriate procedures in place are more readily left in full control of recall operations when these situations arise. CPMM can be translated into 'Initial market release control' and covers both food and non-food products when covered by sector-specific regulations e.g.: products with the CE marking (LVD, Toys, REACH). The sector-specific regulation can also be a national regulation: e.g.: in France, some GPSD products are also covered by national regulations: bicycles, child-care articles or leather products.

43 See **Annex E** for a full explanation of cost recovery
44 www.economie.gouv.fr/dgccrf

Key elements designed to make CPMM effective and efficient:

- Ensure proper coverage of economic operators
- Objective risk rating system
- Qualified inspectors
- Result assessment?
- What is the acceptable cost?

COMMENT: A market surveillance approach focused upon the head of the supply chain to prevent non-compliant products from entering the market. The procedures adopted present economic operators with the ability to reduce their inspection frequency if they can demonstrate that they have systems and procedures in place to ensure complaint products.

The CPMM controls are only one constituent of the market surveillance activity, along with control programs targeting specific products and reactive controls following safety alerts and consumer complaints.

ASSESSMENT:

1. **Effectiveness**

   - Design: To ensure the compliance of regulated products by a focus upon the head of the supply chain achieved through risk-based inspection of the main EO's placing product on the market to assess their ability to comply with all applicable product legislation. Practice aimed at EOs placing regulated products on the market with a yearly turn-over > 2 million euros.

   - Evidence of results: The effect is claimed to be similar to market surveillance, but targeting the operators placing on the market ensures better coverage (multiplier effect).

   - Costs: Budget comes from the main yearly MSA operation budget and was never individualized. But human resources for the CPMM scheme to function at national level is estimated around 18 FTE.

   - Duration: 10 years in current form.

   - Coverage: **National** - All product sectors if regulated (3,4,5,9,13,14,17) and covering EU and national regulations.

   - Meets product harmonisation principles: provides a risk-based approach to market surveillance that encourages EO to set up effective compliance measures.

2. **Cost-efficiency**: The practice was devised as a cost-efficient and time-efficient inspection method to cover the operators responsible for most of the products being placed on the market, before they are dispatched to the retail shops. Controls upstream in the distribution chain are the most cost efficient and ensure the widest coverage.

3. **Specific elements**:

1. There is a national list of economic operators subject to the CPMM control scheme, but the eligibility assessment of an operator is made at the regional level (following harmonized national criteria).

2. Economic operators included in CPMM include those:

- place a product on the national market (manufacturers, importers … but also introducers)
- Dealing in products that have to comply with sector-specific regulations (European + National)
- Companies of significant importance
    i. Size: revenues around 2 million euros (approx.); or
    ii. Product distribution: nationwide

- The *Code de la consummation* provides a legal basis for the controls and procedures are set in several internal control policy documents covering programming, preparing, realizing, follow-up and training.

3. Each company has an ID file that details:

- If the company is subject to the CPMM scheme
- When the last inspection took place & next CPMM control is scheduled
- The lastest risk rating

- A detailed risk-based inspection policy provides a strong incentive for companies to take steps to prevent non-compliant products from entering the market.

4. CPMM offers the opportunity of a wide-spectrum inspection covering an assessment of the company's capacity to comply with applicable law; an assessment of the company's capacity to handle a crisis situation; and its product checks;

- The EO risk-approach of the CPMM does not go into too many details when it comes to product categories of the operator (An EO dealing with both low-risk products and high-risk products will mainly be considered as dealing with high-risk products)
- The CPMM scheme ensures that all operators in the target group are inspected with an appropriate frequency.
- The scheme was expanded from producers to importers and/or distributors placing a product on the market
- CPMM is a mandatory inspection: operators cannot choose to be part or not scheme.

- There is no contract between operators and the MSA.
- It is not an audit nor a consultancy service: no fee is paid.

4. **Ease of replication**: The practice can be transferred if MSAs have the power to conduct preventive inspections during which inspectors can have access to all company premises, documents and information relating to product compliance.

5. **Earned recognition/impact upon inspection**: Inspection frequency is reduced as the risk profile of an EO diminishes. However, EOs do not "engage with the scheme" as it is up to DGCCRF to decide whether an operator should be included in this control scheme. Companies with a good CPMM control history and known to have appropriate procedures in place are more readily left in full control of recall operations if these situations arise.

TITLE: ***CS3 -*** **Market Surveillance protocols**

OPERATOR: **NEDERLANDSE VOEDING AND WAREN AUTORITEIT [NVWA]**

NETHERLANDS FOOD AND CONSUMER PRODUCT SAFETY AUTHORITY[45]

COUNTRY: Netherlands

DETAILS: A Market Surveillance system based upon documented procedures, risk assessment, process audits and planned sampling. This process allows the MSA to group economic operators into defined categories that have specific inspection criteria. The reasoning behind this practice is that it will encourage economic operators to improve their in-house quality procedures and raise their category rating. The revision of the General Product Safety Directive in 2001 was the trigger for the adoption of a more system approach market surveillance.

"Operators that make a demonstrable effort to improve compliance are eligible for reduced surveillance. Under certain circumstances agreements can be concluded with such businesses laying down a regime of reduced supervision and constant effort to improve compliance on the part of the operator. The market surveillance authority and the company see each other as partners with respect to assurance of product compliance."[46]

COMMENT: A well organised, focused and comprehensive approach to market surveillance that offers benefits to economic operators to demonstrate their desire and ability to comply with the legislative requirements. The approach is in accordance with the Hampton[47] principles of better regulation with a core policy of "soft where possible, hard where necessary".

45 https://english.**nvwa**.nl
46 Netherlands - National Product Market Surveillance Plan for 2015–2016
47 2005 Hampton Report

ASSESSMENT:

1. **Effectiveness**:

   - Design: Market surveillance protocol focusing as much as possible with the front end of the commercial chain - producers, importers and distributors. Proactive market surveillance is risk-based and seeks to influence the behaviour of operators in such a way as to encourage compliance with the law.

   - Evidence of results: No investigation of reduction in dangerous products but an impression has been formed that number of safe products is increasing. An external consultancy company conducted a study economic operators' experience of the system surveillance approach.

   - Costs: No specific budget – part of general MS budget.

   - Duration: 7 years of functional audits

   - Coverage: **National** – Most product sectors are covered but not those dealing in professional use machinery, vehicles or recreational crafts. Large scale producers and importers are targeted.

   - Meets product harmonisation principles: MS protocols designed to ensure that EO only put safe products on market and comply with relevant legislation. New GPSD (2001) was the trigger for more system audit approach market surveillance.

2. **Cost-efficiency**: The auditing is conducted as part of inspection programmes. Costs are higher but advantage is claimed to be higher effectiveness.

3. **Specific elements**:

   - Written procedures to implement the objectives

   - "Auditing" on the basis of risk assessment of the economic operators compliance procedures and product sampling.

   - Audit points are Inspection results, knowledge of legislation, etc**.**

   - EOs get encouraged to adopt a more pro-active approach to product safety (e.g. by installing a product quality system)

   - At least one contact with the EO each year.

   - Change of earlier approaches: much more preparation is needed, deep knowledge of standards, requirements. At least 4 working days per inspection (2 days preparation, 1 day site, 1 day reporting).

   - Use of social media (twitter and apps) to contact stakeholders and keep in touch with them about the market surveillance and the products involved.

   - More traditional forms of consultation and coordination also take place through periodic meetings with stakeholders.

- These consultations are generally organised within sectors.
- Stakeholders may be economic operators or consumers, as well as NGOs and knowledge organisations such as universities.

4. **Ease of replication**: Can be applied by other MSAs if staff have systems analysis qualifications, experience or training.
5. **Earned recognition/impact upon inspection**: EOs that make a demonstrable effort to improve compliance are eligible for reduced surveillance.

TITLE: ***CS4 -*** **MS Quality Management System**

OPERATOR: ILNAS - SURVEILLANCE DU MARCHÉ - MINISTRY OF ECONOMY

COUNTRY: Luxembourg

DETAILS: The Market Surveillance departments in Luxembourg were previously scattered over the country. In 2008, by the creation of ILNAS[48], the competences had been regrouped to harmonise their operations and to put them together in one place. An ISO 9001 Quality Management System [QMS] complete with electronic database, quality policy, quality manual, documented procedures and programmed working was introduction of to deliver an improved inspection regime and to seek ensure client satisfaction. MS activity is enhanced through creating a QMS that integrates the legal requirements and an internal structure. Activities are revised every year in accordance with the ISO 9001 requirements. The overall intention was to design and introduce an operational system capable of meeting national and EI requirements.

COMMENT: Accurate and readily accessible information about the inspection history of economic operators, the products they trade and the systems that they use is the prerequisite of accurate EO risk assessment and the development of an information-led inspection programme that recognises and benefits those who have the means and desire to comply.

ASSESSMENT:

1. **Effectiveness**:
   - Design: A management tool based upon an electronic database of historical inspection information operating within a Quality Management System. This allows a more sophisticated inspection regime to be adopted and based upon accurate and accessible information.
   - Evidence of results: KPIs & annual audit. Increase in RAPEX/ICSMS notifications and participation in ADCO/Prosafe. Credibility amongst stakeholders improved.

48 https://portail-qualite.public.lu/fr/index.html

- Costs: Development of the QMS over 2 years period and the internal electronic database included:
    - 500 person days (2 staff in QMS and 1 staff in software for the database)
    - 5,000 euro: Audit cost
    - 5,000 euro: IT equipment
    - 15,000 euro: extension of existing ILNAS database of ILNAS
    - 5,000 euro: staff training
- Duration: Database 2011, QMS Since 2013.
- Coverage: **National** Wide range of products {3-11, 13-15, 17-20, 23, 25, 31, 33}
- Meets product harmonisation principles. Better data & quick access to it – Improves decision making - More consistent approach by MSAs.

2. **Cost-efficiency**: Clear benefits over time but costs are front-loaded and can involve high initial resource depending upon starting position. Claims of improved efficiency – too soon for definitive evidence but there has been recognition of improved market surveillance and enhanced credibility.

3. **Specific elements**:
    - Classification of risk rating used for economic operators
    - Transparency of operation through documented strategies and procedures
    - Key performance indicators are in place that cover:
        i. Rate of closed files of imported products;
        ii. Rate of closed files of products found on the field (shops, distributors, manufacturers);
        iii. Number of field inspections;
        iv. Number of national/European campaigns per category;
        v. Number of information campaigns;
        vi. Number of complaints by external stakeholders.
    - Quick transfer of information to database – contains economic operator's data plus MS inspection and sampling data
    - Accurate and upto date information provides for good decision making and supports an effective market surveillance regime
    - Good collaboration with Customs Service

- Information provided to EOs via website, factsheets for 25 product sectors & a quarterly newsletter plus specific product alerts

- This approach complements and has parallels with product safety compliance where conformity assessment modules require manufacturers to apply quality assurance systems. It is relevant to all products under 765/2008 and provides "best practice" to help MSA's meet the needs and approval of all stakeholders.

4. **Ease of replication**: Could be implemented by all MSAs if budgets allow.

5. **Earned recognition/impact upon inspection**: EOs are classified through risk assessment - Too soon to measure impact upon inspection demands.

3.11. Compliance Assistance

TITLE: ***CA1 -*** **Regulatory and Scientific Advice Office & Guide**

OPERATOR: **NATIONAL AUTHORITY OF MEDICINES AND HEALTH PRODUCTS,**

COUNTRY: **Portugal**

DETAILS: THE GUIDE FOR REGULATORY AND SCIENTIFIC ADVICE (RSA**)** provides information regarding legal requirements applicable to Cosmetic Products and Medical Devices to economic operators through an advice office and training sessions**.** The Regulatory and Scientific Advice Office (GARC), provided by Infarmed[49], has the competence to advise on issues arising with the preparation of documentation for:

- clinical trial, marketing authorisation, submission of variations, renewals or other subjects related to medicines for human use;

- EC marking or complementary procedures;

- notification or registration of medical devices and cosmetic products;

- licensing and good practices procedures;

GARC's final goal is that applications are submitted in accordance with current regulatory and scientific requirements thus allowing for a quicker validation and assessment.

COMMENT: Advice can be sought during initial development stages of medical devices and cosmetic products (pre-submission) and during post-marketing. The guidance will be regularly updated to reflect the scientific and regulatory evolution, in accordance with new legislation and applicable guidelines. It will also mirror the experience gained in the process.

49 www.**infarmed**.pt

ASSESSMENT:

1. **Effectiveness**:

   - Design: Expert advice for EOs to enable them to achieve compliance by building it into their products from conception to production. Advice is also available on the procedures necessary to be completed before a product is placed on the market.

   - Evidence of results: None provided but as because of the services available it is believed that fewer non-compliant products will be placed on the market

   - Costs: No information provide but fees are only charged for medicines

   - Duration: Since 2008

   - Coverage: **National** - Medical devices and cosmetics [Product sectors 1 & 2]

   - Meets product harmonisation principles: By making it easier and more straightforward for EOs to be compliant and helping them to build in compliance.

2. **Cost-efficiency:** Less time should be taken up by MSAs in inspecting cosmetic products and medical devices on the market and this time could be used for other priority market surveillance work.

3. **Specific elements**:

   - For cosmetics, information is provided in respect of the:

     - regulatory framework for cosmetic products in Portugal
     - steps to be taken to place a cosmetic product on the market
     - steps to be taken to import cosmetic products
     - requirements needed by a technician
     - cost of marketing cosmetic products in Portugal
     - requirements for manufacturing cosmetic products in Portugal.

   - For medical devices:

     - Several training sessions per year regarding legal requirements
     - information regarding medical devices placed on the market;
     - Preparation of documentation for:
       - clinical studies;
       - EC marking or complementary procedures;

- notification or registration of medical devices and cosmetic products;
- licensing and good practices procedures
- Information on technical files and product registration

➢ INFARMED, I.P., will not provide advice whenever the same advice has been requested to EMA's Scientific Advice Working Party (SAWP).

➢ The advice provided by INFARMED, I.P., will only refer to questions to which no clear answer can be found on national regulation or in national or European guidelines, including European and Portuguese Pharmacopoeias.

4. **Ease of replication**: Further detailed information would need to be established.

5. **Earned recognition/impact upon inspection**: No information provided.

TITLE: ***CA2 -*** **Market Surveillance protocols**

OPERATOR: **AGENTSCHAPTELECOM**[50]

COUNTRY: **Netherlands**

DETAILS: The MSA works between the economic operators and the Notified Body to provide high quality information upon the application of legislation, the appropriate means of compliance & relevant risk assessment strategies and procedures. The website provides Guidelines for equipment providing relevant background information, documents and forms as well as access to the relevant laws and regulations on the marketing of electrical appliances. Specific information about the R & TTE and EMC Directive is provided. Major objective is to make inspections more effective.

COMMENT: Good example of co-operation between the MSA and a Notified Body to provide consistent and comprehensive information to economic operators.

ASSESSMENT:

1. **Effectiveness**

➢ Design: Assistance in understanding the application of legislation especially for EO associations to produce more effective market surveillance

➢ Evidence of results: Objectives not formulated, no quality manual, specific indicators are still in development.

➢ Costs: Budget cannot be defined. MS system is budgeted as a single entity.

➢ Duration: Since 2010

50 https://www.agentschaptelecom.nl

- Coverage: **National** - Compliance assistance (related to directives 18, 19), awareness (Dutch "voorlichting" for 17, 18, 19)

- Meets product harmonisation principles: Harmonisation of methods for compliance

2. **Cost-efficiency**: More effective MS should be cost effective.

3. **Specific elements**: Providing good information to EOs for them to better formulate the risk analysis of their products. Information is provided through a website and through trade associations in the relevant product sectors.

4. **Ease of replication**: Depends upon the degree of co-operation between the MSAs and Notified Bodies.

5. **Earned recognition/impact upon inspection**: None - reduction in inspections.

TITLE: ***CA3 -*** **Ensuring the Safety of Toys**

OPERATOR: **COMPETITION AND CONSUMER PROTECTION SERVICE**[51]

COUNTRY: Cyprus

DETAILS: Expert knowledge and guidance on toy safety is provided for Market Surveillance inspectors through an internal single point of contact that also informs the inspection planning process and oversees the targeted sampling that is co-ordinated with EU joint actions.

Due to the size of the economy within which the MSA operates it has been possible to perform effective toy safety surveillance by allocating the responsibility to one senior manager who influences and oversees toy safety inspection outcomes across all inspection activities. Implementation has been based on need and takes account of the risks nationally posed by this product sector compared to other product sectors perceived to be of lower risk.

Key to its success is that the person tasked with the responsibility is up to date with all matters concerning toys and toy safety, including enforcement requirements, complaints statistics, accident trends and known problem areas. The position within the organisation held by the post-holder is at an appropriate management level for this approach to be effective. The post-holder has the necessary delegated power to oversee and inform all the inspection planning process and to tailor it to suit the organisational needs. This oversite by a single person includes the development of sampling programmes and participation in EU joint actions which provides sampling opportunities that would otherwise be unavailable or hard to secure.

COMMENT: A considered approach to compliance assistance to ensure that consistent and accurate information is provided to economic operators and underpins the inspection planning and sampling activities. In addition, the practice also seeks to align activities with EU joint actions. Prioritising toy safety activities and allocating specific responsibility has been an effective way of increasing effectiveness of inspections and targeted sampling. It has also led

51 http://www.mcit.gov.cy/mcit/cyco/cyconsumer.nsf/page22_en/page22_en?OpenDocument

to a higher profile being given to the issue of unsafe toys found on the market and interactions with key stakeholders.

Such an approach provides MSA's, with a valuable expertise resource which can be utilised to inform, train and coach the inspectorate, to educate and inform economic operators and through the media and dedicated proactive enforcement, to inform citizens.

This approach has the potential to be successfully implemented in larger member states where organisation of MSA responsibilities is performed at a regional or local level. However, it is important that attention is given to effective co-ordination and cooperation and to the analysis of both risk (product and EO) and the appropriate level of resources required for effective service delivery.

ASSESSMENT:

1. **Effectiveness**

   - Design: To make better use of limited resources by providing staff with a designated source of information regarding specific product sectors.

   - Evidence of results: Increase in non-compliant products being withdrawn from the market. Injuries currently not being monitored.

   - Costs: Included with overall service budget

   - Duration: 2 years

   - Coverage: Safety of toys and all child care products covered by GPSD

   - Meets product harmonisation principles: Raised inspection levels from a previous low level and provides accurate and consistent information to EO's through fully informed and more confident staff. Now there is effective coordination of activities, standard forms and documents, increase in visibility, increase in both quality and number of inspections, and establishment of a sampling programme.

2. **Cost-efficiency**: Better use of inspection resource - Increase inspection of targeted products.

3. **Specific elements**: Single person responsibility to oversee the service delivery on a day to day basis including overseeing sampling, Prosafe joint actions, RAPEX, Information is also utilised to guide inspection programmes and for visibility opportunities with key stakeholders.

4. **Ease of replication**: Could work within any product sector given staff with high level of product specific knowledge and experience. Lower risk products with less indications of general non-compliance may not warrant such an approach.

5. **Earned recognition/impact upon inspection**: None - currently no risk rating of premises.

TITLE: *CA4 -* **PPE Compliance brochure**

OPERATOR: **SWEDISH CONSUMER AGENCY**

COUNTRY: **Sweden**

DETAILS: Provision of technical assistance through a product sector specific publication. The objective is to meet the needs of the various economic operators dealing with PPE on the Swedish market. Many of these economic operators deal with a wide spectrum of products and do not fully understand the specific requirements of the PPE directive. The brochure entitled "Almost everything you need to know about PPE" gathers together into a single publication useful information upon the directive reuirements for economic operators.

COMMENT: Focused information provided in a durable format that should result in more well educated economic operators placing compliant products on the market. This type of approach to compliance guidance is resource and quality demanding as the legal and safety requirements often varies from time to time resulting in the given information needing to be updated in time.

ASSESSMENT:

1. **Effectiveness**

   - Design: An information source available both as a printed brochure and as electronic document to download. The main objective was to enable economic operators with easy access for accurate and quality assured information about PPE in a single place.

   - Evidence of results: The brochure has been available for almost a year and will be evaluated later.

   - Costs: The brochure was produced within the normal service delivery which is provided through Governmental funding

   - Duration: Since 2015

   - Coverage: **National** - All economic operators trading in PPE

   - Meets product harmonisation principles: National authorities have a duty to inform stake holders about product regulations & rules

2. **Cost-efficiency**: When economic operators call requesting advice, responding is resource and quality demanding. The brochure provides economic operators with option of direct access to vital information regarding product rules and market surveillance. Less internal resources spent on individual communication with economic operators compared with small budget for printing

3. **Specific elements**: The brochure gathers all useful information for economic operators. The title is "Almost everything you need to know about PPE." The objective was to be able to deliver quality assured information in a resource efficient manner.

4. **Ease of replication**: Current practice already in many MSAs/Member States

5. **Earned recognition/impact upon inspection**: No – None

TITLE: ***CA5 -*** **Market Surveillance protocols**

OPERATOR: **SOIVRE INSPECTION SERVICE**

COUNTRY: Spain

DETAILS: SOIVRE Inspection Service has legal base on the border to carry out safety controls on specific products in application of Regulation 765/2008 and specified national legislation. This MSA has sought collaboration by providing importers with technical assistance and co-operation with Spanish Customs Service and other Spanish MSAs to develop mutual understanding. The main objective of the practice is to help importers comply with the requirements of the legislation when they import goods from third countries. Importers can address enquiries to any of the MSA's offices or send an e-mail to get information about controls and applied legislation. In addition, the MSA has conducted public presentations about import and safety requirements.

COMMENT: Close co-operation between MSAs, the Customs Service and economic operators provide the basis to ensure more consistency in the information provided and enforcement actions taken. This type of approach can be very successful when there is a low knowledge base among stakeholders regarding the safety legislations and safety standards.

ASSESSMENT:

1. **Effectiveness**:

   - Design: Control of imported products through information provision to importers to correct any ignorance of essential safety requirements. Importers provided with clear access and contact details if they import these categories of product and need information.

   - Evidence of results: Importers informed about product safety and compliance requirements previously to the import have less non-conformities in their products. There have been no impact studies, but it is assumed an improvement in the safety of the products placed on the market.

   - Costs: There is no additional budget for this practice – no cost analysis

   - Duration: Since 2008

   - Coverage: **National** - Imported toys, personal protective equipment, furniture, timber products, small electrical equipment, textile products and footwear at all border points

   - Meets product harmonisation principles: Control of products from third countries

2. **Cost-efficiency**: A single authority responsible for import control and co-operation with other internal MSAs offers cost and strategic benefits.

3. **Specific elements**: Technical assistance to assist importers comply the legal requirements when importing products through from third countries.

4. **Ease of replication**: Could be easily replicated by MSAs who wish to provide accurate and accessible information relating to importers' obligations and the products they import and have a good working co-operation with the Customs Service.

5. **Earned recognition/impact upon inspection**: No - When inspections identify non-compliant products, importers are included in a specific filter in the risk assessment tool that increases the number of inspections.

TITLE: ***CA6 -*** **Web based information for economic operators**

OPERATOR: **SWEDISH CONSUMER AGENCY**

COUNTRY: Sweden

DETAILS: A web based information provision of the legal requirements for products accessible by economic operators and designed to suit the needs of various kinds of economic operators.

The main objective is to inform economic operators and their respective trade associations about the legal requirements for placing products on the market and to provide guidance about achieving safe products and fair competition on the market. The site contains information not only about product safety but also about consumer rights in general.

COMMENT: This website is designed to be used by economic operators only, consumers and others are directed to other websites. Using a website to inform economic operators ensures easy access and a consistent response as they can always receive an answer and that all economic operators receive the same answer.

ASSESSMENT:

1. **Effectiveness**:

   - Design: Website is designed to be used by economic operators only and input of EOs was sought during development of the site covering both structure and content. The information about rules and advice on how to act is general and can be used by stakeholders in all sectors. Other information is directed to the following sectors: Toys, PPE and the non-harmonised area. The objective was mainly to be able to deliver quality assured information in a resource efficient manner

   - Evidence of results: Too soon for evaluation

- Costs: 1800 person hours & 2,000 euros [20,000SEK] for 10 months' development of content –exclude technical platform & development tools costs. The costs were provided through Government funding

- Duration: Operational since 2015 and intended to operate for many years

- Coverage: All economic operators in general and, in particular, those trading in toys, personal protective equipment (for private use) and non-harmonised products.

- Meets product harmonisation principles: Proactive information provision to deliver quality assured information in a resource efficient manner.

2. **Cost-efficiency**: Economic operators that need information often call for advice. This is resource demanding and a website can provide much of the information, thus freeing up staff resources for other tasks. The quality of the information given is easier to control via a website and provides consistent advice to EOs with direct access 24/7. Less internal resources are spent on individual communication with economic operators but more well educated economic operators on the market.

3. **Specific elements**: Information about this site was provided to larger industry associations. Consumers and others are directed to other websites.

4. **Ease of replication**: Most MSAs operate websites but aspects of the development could be followed by others

5. **Earned recognition/impact upon inspection**: No – None

3.12. Awareness Raising

TITLE: ***AR1 -*** **Market Surveillance protocols**

OPERATOR: DEPARTMENT OF LABOUR INSPECTION

COUNTRY: Cyprus

DETAILS: The scheme is based on providing appropriate and timely advice and support to all key stakeholders in areas identified as the cause of high numbers of accidents in the workplace. In addition, the scheme supports stakeholders where there is a change or introduction of new safety legislation. The aim is to provide all the necessary support to ensure that those responsible for the safety of products under the control of the department are fully aware of their duties and responsibilities, so that accidents in the workplace can be minimised. Regular consultation with stakeholders is undertaken to identify where awareness of the relevant safety requirements needs to improve, including issues of concern that have been identified during the practical application of the requirements in the workplace. To complement this work, compliance assistance is provided by means of technical guidance documentation specifically aimed at products presenting a higher risk and requiring a greater understanding by economic operators to implement further safety improvements. The aim is to provide the necessary technical information to secure compliance with legislation that

presents specific technical challenges. In addition, general guidance is provided on the website of the Department.[52]

COMMENT: Covers aspects of both awareness raising and compliance assistance and the awareness events are very valuable for economic operators. They are promoted proactively and seek to provide economic operators with a formal opportunity to ensure that their knowledge of new legal requirements is correct and up to date. Because consultation takes place on a regular basis between the MSA and economic operators this develops good working relations and a shared purpose which can be otherwise difficult to achieve. As the provision of such awareness campaigns is at the request of stakeholders, input and outcomes are higher than would otherwise be achieved.

ASSESSMENT:

1. **Effectiveness**:

   - Design: Targeting key stakeholder groups - aimed at Trade Associations, Employers and Chambers of Commerce. Driven by need to address the high numbers of accidents involving foreign workers

   - Evidence of results: KPIs – number of accidents & numbers of non- compliant products identified. But no formal review yet

   - Costs: No specific budget as cost included in overall budget of department

   - Duration: Since 2014

   - Coverage: Lifts, machinery, pressure equipment, simple pressure vessels, PPE, ATEX, noise emissions- outdoor equipment.

   - Meets product harmonisation principles: Encourages compliance where there may be a lack of understanding by EOs of technical requirements.

2. **Cost-efficiency**: Not measured but claimed to be reasonably effective due to blanket coverage which is possible due to low numbers of EOs

3. **Specific elements**: In advance of changes to legislation, relevant stakeholders are contacted and an awareness event organised on the topic.

4. **Ease of replication**: Possible for all product sectors

5. **Earned recognition/impact upon inspection**: None – Inspection levels have remained constant

52 http://www.mlsi.gov.cy/mlsi/dli/dliup.nsf/pageh6_en/pageh6_en?OpenDocument

TITLE: *AR2 -* **Be Smart – Build Safe Campaign**

OPERATOR: **CONSUMER RIGHTS PROTECTION CENTRE**[53]

COUNTRY: **Latvia**

DETAILS: A campaign to raise awareness of the legislation controlling the safety of construction products, and how to identify safe construction products. Helpful advice and assistance is provided to economic operators. Economic operators and consumers are informed about the importance of purchasing and using only safe construction products. How safe products can be identified and distinguished from potentially unsafe products is also explained. The practice was introduced by CRPC in response to an urgent need for effective action following a major incident that involved the collapse of a supermarket roof in 2013.

COMMENT: When economic operators are unaware about the requirements for construction materials, non-compliant construction products can be incorporated into a building and are then unable to be inspected. This is a good example of how the MSA can be proactive in assisting an industry in improving its compliance within a specific product sector. Subject to translation this practice could be transposed into different countries and the approach is valid across all product sectors. It changes the status of the MSA from just being an enforcement authority to being part of the "solution to the problem".

ASSESSMENT:

1. **Effectiveness:**

   - Design: To inform economic operators (manufacturers and builders) and consumers about the requirements of Regulation 305/2011 and national legislation on construction products. Specific awareness programme aimed at professionals & EOs in the building industry and provided through TV, Radio, Web page, Brochures and Seminars

   - Evidence of results: 9200 viewings on the website, 160 seminar registrations, 2000 leaflets distributed, recorded increase in business contacts.

   - Costs: Part of CPRC's annual budget plus €45,000 to cover advertisements on TV

   - Duration: The practice was introduced and pushed hard in 2015. It is still running - although not as intensely as in the first year.

   - Coverage: National – Construction products and building industry

   - Meets product harmonisation principles: MS surveillance response to accidents and injury information

2. **Cost-efficiency**: Data on the percentage of non-conformances found at construction sites is being collected and the results will be available from the beginning of 2017. Current feedback from businesses has shown that economic operators now have a better understanding of the laws relating to construction products

53 https://www.em.gov.lv/en/sectoral_policy/construction/regulation_of_circulation_of_construction_products/

3. **Specific elements**: A targeted response to major incident involving a structural failure in supermarket in November 2013

4. **Ease of replication**: A good practice example of a comprehensive response to identified non-compliances in a specific product sector

5. **Earned recognition/impact upon inspection**: The results of the practice will be used as part of the CRPC's risk assessment procedure. No immediate reduction in visits but it has reduced the amount of time needed to be spent inspecting reputable businesses because they now have fewer non-compliances needing to be dealt with by CRPC. This enables more businesses in the sector to be inspected by CRPC and results in improved targeting of resources.

TITLE: ***AR3*** **- Good Communication**

OPERATOR: **DANISH MARKET SURVEILLANCE COMMITTEE**

COUNTRY: **Denmark**

DETAILS: An interactive best practice communication catalogue for the use of MSAs across all product sectors. The catalogue contains ideas, examples and practical tools that MSAs can use when developing market surveillance communication activities directed at businesses. The catalogue was developed to assist MSAs that do not have their own separate communication units. When a MSA wants make awareness raising activities, inspiration, checklists and good examples can be found in the best practice catalogue. The catalogue was made with the assistance of external consultants and in close cooperation with MSAs and their needs. Stakeholder organizations and businesses were also involved in the development.

INITIAL COMMENT: Seeks to ensure that awareness campaigns benefit from best practice and are effective. It should make it easier to initiate and develop communication activities, particularly for smaller MSAs.

ASSESSMENT:

1. **Effectiveness**:

   - Design: Practical communication material developed by the market surveillance committee for MSAs across sectors to improve their awareness raising.

   - Evidence of results: Too early to evaluate but at a round-table discussion in the market surveillance committee, there has been overall positive feedback from MSAs regarding the use of the catalogue in practice.

   - Costs: The development of the catalogue had a budget of approximately €40.000

   - Duration: Since 2016.

   - Coverage: **National** - across all product sectors.

- Meets product harmonisation principles: Enables MSAs the means to become better communicators and engage with EOs more effectively.

2. **Cost-efficiency**: Saves individual MSAs from "re-inventing the wheel" and benefits smaller MSAs and those without experience in awareness raining initiatives.

3. **Specific elements**: An interactive best practice communications toolkit of best practice containing ideas, examples and practical tools that MSAs can make use of when developing markets surveillance communication activities directed at businesses.

4. **Ease of replication**: Good practice, easily replicated across Member States.

5. **Earned recognition/impact upon inspection**: No – None.

TITLE: ***AR4 –*** **Market Surveillance protocol**

OPERATOR: **DEPARTMENT OF JOBS, ENTERPRISE AND INNOVATION**

COUNTRY Ireland

DETAILS: The MSA has developed various guidance documents and provides advice regarding Explosives and Pyrotechnics legislation aimed at the explosives and fireworks industry. It also provides guidance regarding the operation of the Department's import licensing system. Website & press releases are used to raise awareness and are targeted at Halloween, the main period for the use of fireworks. Information is issued via the national print media as well as through web sites and social media.

COMMENT: Timely and targeted information is provided for economic operators and is linked with public awareness campaigns covering safety and non-compliance This practice provides a comprehensive approach to safety within a specific product sector. Both guidance for economic operators and information for consumers benefit from the expertise and experience of the MSA staff.

ASSESSMENT:

1. **Effectiveness**:

   - Design: A three track approach to firework safety that includes -

     - Guidance Documents / Advice: To assist importers/economic operators/ professional users understand the requirements of the legislation in so far as it applies to explosives/pyrotechnics and the import licensing procedure.

     - Publicity campaign: To raise awareness that only Category F1 fireworks are legal for sale to the public. All other fireworks can only be part of a display provided by professional users.

- Publicity campaign: To raise awareness among the general public about the safety aspects when using Category F1 fireworks.

- Evidence of results: Hospital inpatients statistics show a decreasing trend over past six years. Evidence of less availability of non-CE marked products.

- Costs: Included with overall ministry budget – specific cost not disclosed.

- Duration: Since 2009

- Coverage: National - Pyrotechnics

- Meets product harmonisation principles: Provides economic operators with regulatory compliance guidance and informs the public – making them better able to use fireworks safely and to report non-compliance.

2. **Cost-efficiency**: Co-ordinated campaigns for economic operators and consumers that can be very cost effective.

3. **Specific elements**: Based upon the national legal background that includes an import licensing system and allows only category F1 fireworks to be legal for sale to the general public. Links guidance to EOs with public safety information.

4. **Ease of replication**: Easily replicated in targeted safety campaigns. In relation to fireworks the national restriction upon the sale of fireworks makes compliance easier to control when the sale and use by consumers is strictly controlled

5. **Earned recognition/impact upon inspection**: None, but as inspection is risk-based, so information of non-compliance activity will result in more enforcement action.

3.13. Legal Requirements and Best Practice for Market Surveillance

A criterion set for the analysis of the compliance practices identified through the study was to determine "if the practices are consistent with the principles underlying EU product harmonisation legislation (notably the so-called New Approach legislation) and market surveillance legislation (Regulation (EC) 765/2008)". EU Member Countries are given considerable discretion under the subsidiarity rules when it comes to determining the nature and detail of their market surveillance activities. In particular, there is very limited requirement upon MSA' in respect of advice and guidance to Economic Operators.

Regulation (EC) 765/2008 has:

- ***Article 19 (2) Second sub paragraph****: (Market surveillance authorities) "shall cooperate with economic operators regarding actions which could prevent or reduce risks caused by products made available by those operators."*

General Product Safety Directive 2001/95/EC has:

- ***(24)*** *The safety of consumers depends to a great extent on the active enforcement of Community product safety requirements. The Member States should, therefore, establish systematic approaches to ensure the effectiveness of market surveillance*

and other enforcement activities and should ensure their openness to the public and interested parties.

However, there is a considerable body of best practice guidance which states:

- ***"Market surveillance authorities** must be organised and equipped to cope with their obligations but the EU legal framework does not prescribe how the Member States are to implement the directives or how the legislation should be enforced. How the requirements in the treaties are to be fulfilled is up to the Member States, since market surveillance is a national responsibility and falls under the principle of subsidiarity.[54]"*

- ***"Market surveillance** does not formally take place during the design and production stages, which is before the manufacturer has taken formal responsibility for the conformity of the products, usually by affixing the CE marking. However, nothing prevents market surveillance authorities and economic operators to collaborate during the design and production phase. Such collaboration may help taking preventive actions and identifying as early as possible safety and conformity issues.[55]"*

- ***"For market surveillance to be efficient**, resources should be concentrated where risks are likely to be higher or non-compliance more frequent, or where a particular interest can be identified.[56]"*

- ***"Better regulation** sets out to ensure**:** regulatory burdens on businesses are kept to a minimum.[57]"*

- ***"Risk assessment –** though widely recognised as fundamental to effectiveness – is not implemented as thoroughly and comprehensively as it should be. Risk assessment should be comprehensive, and should be the basis for all regulators' enforcement programmes. Proper analysis of risk directs regulators' efforts at areas where it is most needed, and should enable them to reduce the administrative burden of regulation, while maintaining or even improving regulatory outcomes. I am therefore recommending that:*

    - *comprehensive risk assessment should be the foundation of all regulators' enforcement programmes;*

    - *there should be no inspections without a reason;*

    - *resources released from unnecessary inspections should be redirected towards advice to improve compliance;" [58]*

3.14. Review of Compliance Practices identified by the Study

Consideration of the various elements that underpin the operation of the compliance practices identified through the study has allowed the Study team to highlight some general similarities

54 EMARS – Best Practice Techniques in Market Surveillance
55 Blue Guide - page 95
56 ibid
57 EU "Better regulation: why and how" - http://ec.europa.eu/info/strategy/better-regulation-why-and-how_en
58 Reducing administrative burdens: effective inspection and enforcement. Philip Hampton - March 2005: The Hampton Review – Final Report

as well as the strengths and weakness that can be used to inform "best practice" considerations for future practices.

General:

- Although only nine member countries provided sufficient evidence that indicated that their MSA's utilised all three types of compliance practices, it could be wrong to conclude that such practices are not a regular feature of many market surveillance enforcement programmes.

- The constituent elements of awareness raising, compliance assistance and compliance schemes are often seen by MSA's as a well organised, focused and comprehensive approach to market surveillance but they do not necessarily recognise the specific terms or consider them as stand-alone activities.

- The difference between awareness raising and compliance assistance often appears to be very minor – awareness raising often centred upon consumers and end users of products.

- A considered approach to awareness raising and compliance assistance ensures that consistent and accurate information is provided to economic operators for them to achieve compliance by building it into their products from design to production and one that underpins the MSA's inspection planning and sampling activities.

- There is a generally agreed approach by MSA's that assistance provided to economic operators and trade associations to assist them in understanding the application of legislation will produce more effective market surveillance.

- Despite a general lack of evidence of effectiveness, a number of MSAs expressed an impression that the number of unsafe products is decreasing as a result of compliance practices.

Strengths:

- Many of the practices have been designed to address specific market surveillance issues such as poor level of economic operators' knowledge in a product sector or as part of a general inspection reform.

- Significant elements include:

    - Availability of detailed and expert knowledge

    - Dependable advice and guidance

    - Targeted information upon specific trades or product sectors

    - Single point of contact

    - Easy access for accurate and quality assured information in a single place.

    - A variety of access points and information channels

- ❖ Information sources available both as a printed documents and as on-line electronic documents available to download.

- ➢ Most compliance practices identified do appear to be easily transferable to other product sectors, MSA's and Member Countries.

Weaknesses:

- ➢ Very few compliance practices where specifically aimed at SME's. Most compliance assistance and awareness raising was designed to have a universal appeal to all economic operators with a rather simplistic "one box fits all" approach.

- ➢ Many compliance practices are of long standing, five years plus, without a comprehensive review of their continuing need and effectiveness.

- ➢ A serious lack of objective evidence of effectiveness:

  - o Objectives not formulated, goals not set;
  - o Assumptions based upon belief/professional experience;
  - o Key Performance Indicators not set;
  - o Performance not measured;
  - o Programmes not reviewed on a regular basis;
  - o Very little evidence of monitoring of accidents and injuries;
  - o Very little evidence of a measured reduction in dangerous products.

- ➢ A belief by some MSA's that risk assessed inspection programming alone can be an incentive for EOs to improve compliance measures.

- ➢ Inspection levels remaining constant despite compliance practices being used.

- ➢ No measurement of opportunity cost of resources being used for compliance practices.

- ➢ The true costs of compliance practices are often hard to quantify as they are accounted for as part of general MS budget.

- ➢ Very little cost/benefit analysis.

- ➢ High cost of campaigns involving TV advertising.

Compliance Schemes:

- ➢ There are legality issues[59] surrounding the implementation of compliance schemes in some Member Countries without changes to the existing national legislation.

59 It has been suggested that national legislation in some countries may restrict the ability of MSAs to "favour" economic operators in respect of reductions in scope, frequency or intensity of inspections. This issues has not been researched as part of the study.

- There can be an issue with the extra income provided by a "primary authority" type scheme becoming a funding dependency should the MSA's general budget be cut due to economic considerations.

- There is an argument that national and multi-national economic operators already have the resources to determine product compliance and such schemes do not benefit SME's sufficiently.

- There may be a need for systems analysis qualifications, experience or training within the MSA for its staff to able to meet the requirements of national and multi-national EOs.

- The need for detailed and effective policies and procedures to safeguard the ability of the MSA to be responsible for the advice given whilst retaining its independent and transparent duty to take enforcement action in appropriate circumstances.

3.15. Compliance Practices identified by other studies

Guidelines for Coordinated and Effective Ecodesign Market Surveillance[60]

In addition to the monitoring, verification and enforcement activities, many MSAs arrange proactive and preventing activities to inform manufacturers and their representatives or importers about the eco-design requirements that are in force or coming into force:

- Most commonly is for the MSAs to hold information meetings, send out newsletters and publish guidelines on how to comply.

- Some MSAs issue brochures, guides and leaflets.

- Some MSAs work in cooperation with other public bodies such as Chambers of Commerce and national agencies to disseminate information about the eco-design requirements of products.

- MSAs can make public announcements beforehand to inform manufacturers and their representatives or importers about planned market surveillance action(s), by e.g. publish their yearly market surveillance programme on their website. The publication of the results of market surveillance activities can be a way of discouraging possible improper behaviour by other economic operators.

- MSAs can also cooperate with national customs authorities in market surveillance of the Ecodesign Directive in order to prevent non-compliant products entering the EU-market.

3.16. Recommendations

The study is charged with providing a set of recommendations that could serve as a toolkit for improving Member States performance in relation to compliance practices. Many of the examples used in this report are based upon activities that have been common place in some MSAs for many years, and in this sense, it is somewhat surprising that more MSAs did not respond and cite these types of activities. The Study Team did not identify any pattern or

60 ECOPLIANT - European Ecodesign Compliance Project

obvious reason to explain why the use of compliance practices and the coverage of product sectors within the compliance practices varied from country to country and from MSA to MSA. As very few of the compliance practices have specific features that would be difficult to replicate and as all countries would benefit from adopting the highlighted practices, the real issues would seem to be resources, both human and financial, a lack of good service management that understands the benefits of a proactive approach, a reluctance to engage in inspection reform and the lack of an EU legal requirement that such practices are mandatory, or indeed supported. Therefore, the following recommendations do not represent new or novel ideas but rely heavily upon tried and tested principles.

Based upon the results of the study survey, interviews with MSA's using compliance practices, interviews with economic operators and trade associations and generally available public information, the Study Team would recommend:

1. Compliance practices should not be considered as special activities additional to the more traditional or "classical" styles of enforcement but rather be integral components of a comprehensive market surveillance regime. To encourage this approach, it is considered important for the relevant EU Directorates General to support a wider definition of market surveillance and to provide clear guidance that compliance practices are an expectation within market surveillance.

2. Compliance practices are best adopted as part of an inspection reform programme based upon a quality management format including enforcement policies, comprehensive databases of economic operators' details, previous inspection and product sampling results, consumer complaints, accident and injury data & statistics that inform a risk-assessed inspection and sampling programme with documented procedures, product examination and sampling and auditing of the economic operator's quality assurance procedures.

3. Compliance practices are best adopted as part of strong co-operative partnerships between the relevant Market Surveillance Authorities in each product sector or sectors and including Customs Services and other law enforcement bodies as appropriate. This approach should contribute to accuracy of advice, consistency of enforcement, reduction of duplication and cost-efficiency.

4. Trade associations can be valuable partners in compliance practices as they aid the distribution of information amongst their members, make access to information concentrated in a single point of contact and can inform the MSA upon the needs and preferences of their members.

5. Compliance practices should encourage economic operators to adopt a more pro-active approach to legal compliance and product safety (e.g. by installing quality management or assurance systems) Wherever possible, there should be an element of "earned recognition" linked to the practices, so that the resources deployed by the economic operator can be justified through reduced inspection scope or frequency.

6. Compliance practices should contain the specific elements that have been identified as essential for the success of compliance practices and which lead to improved compliance with regulation and market surveillance efficiency;

- Compliance practices need to be well designed and developed to maximise efficiency and effectiveness through a co-ordinated approach of all MSA's involved in the selected product sector(s);

- Compliance practices need to meet the basic requirement of encouraging compliance through encouraging and facilitating better understanding of the legal and safety requirements by Economic Operators;

- Compliance practices should not be limited to the product sector of the originating authority if capable of being rolled out across other product sectors with beneficial impact;

- Compliance practices need to include clear, quantifiable and measurable Key Performance Indicators of success that should be set in advance and supported by baseline statistics;

- The performance of compliance practices should be measured and reviewed at defined intervals to determine their efficiency and effectiveness;

- Specific schemes and practices should be full costed if possible, including the measurement of resource usage and opportunity costs. Without a true resource and financial cost of implementation and impact assessment together with post implementation monitoring against accurate pre-implementation compliance rates and accident and injury statistics; an accurate cost-efficiency assessment is very difficult;

- Compliance practices should be designed and developed to meet the researched and clearly identified requirements of the intended economic operators through an awareness of:

    - Needs in different product sectors – *especially those of SMEs*

    - Reactive assistance v proactive assistance – *a researched balance*

    - Suitable access channels

        - Inspection visits – *often preferred by SME's*

        - Hotlines – *can provide easy access but at a cost*

        - Internet – *24/7 information provision*

        - Social media – *Blogs, Twitter, Facebook, YouTube*

        - Product sector – *Separate channels for different product sectors*

        - Industry only - *Separate channels for industry & consumers*

    - Suitable medium for the advice

        - Verbal advice

        - Written advice – fact sheets, leaflets

- Digital downloads
- Interactive

3.17. Other examples of best practice

➢ **Lessons from other sectors**

- **<u>Business Awareness Raising</u>**[61]

❖ **Develop a unified set of guidelines:**

Often there is no central information point for business operators to gain an overview of their legal obligations. Such information overviews should combine input from various stakeholders, include relevant legislation and highlight issues of responsibility in the supply chain. The ACCC's Business Guide to Selling Online to Consumers in Australia, is considered to be a good practice in this respect.

❖ **Product requirement legislation in understandable terms:**

Keeping track of new and amended legislation can be complicated and as a result, business operators sometimes violate product requirements unintentionally. Regularly informing operators of the changes to relevant legislation is a useful practice that could again yield benefits by preventing non-compliant and unsafe products from entering the market to begin with. In the case of Estonia, the Consumer Protection Board has implemented this practice effectively; regular updates are sent around on legislation that is relevant to operators.

❖ **Interactive information provision:**

Interactive methods of information provision tend to lead to a more active way of absorbing and remembering information. This is demonstrated in the Dutch case for instance, where the "TradeRouteAsia" website uses e-learning modules and quizzes to involve and test business operators on their knowledge. In a non-digital manner, the seminar series organised in Malta also forms a more interactive, real-life method of providing information.

Business awareness raising		
Estonia	Regular updates for business operators on new relevant legislation	Consumer Protection Board of Estonia & Information Letters
Australia	Centralised information on selling online in a given country	The Australian Competition and Consumer Commission (ACCC) business guide to selling products online to

61 "*Good Practice in Market Surveillance Activities related to Non-Food Consumer Products sold Online" - Authors: Jacqueline Snijders (Panteia), Amber van der Graaf (Panteia) & Mike Coyne (CSES) for Austrian Institute of Economic Research (WIFO)*.

		Australian consumers
The Netherlands	Raising business operator awareness on how to import safe goods from Asia	The Dutch Authority (NVWA) - the information and learning website TradeRouteAsia.nl

- **Austrian Institute of Construction Engineering [OIB]**

  The Austrian Institute of Construction Engineering (OIB) is the coordinating platform of the federal states for construction products and construction technology and performs the following tasks:

  - The OIB is a European technical assessment body and national approval body for construction products;
  - It issues the OIB guidelines, in order to enable federal states to harmonise the technical requirements in the building regulations;
  - As market surveillance authority, the OIB ensures that the construction products on the Austrian market fulfil all legal requirements and do not endanger health and safety;
  - As a product contact point, the OIB provides information about the currently valid technical requirements for construction products in Austria.

- **Proof of Age schemes**: joint action between enforcement agencies and economic operators to restrict the supply of age-restricted products through the issue of proof of age cards to those young people who have recently attained the correct age to able to purchase legally. Responsible economic operators can support such schemes and aid compliance across the retail sector. Schemes cover products such as fireworks, knives, alcohol and tobacco that present safety concerns if supplied to young children. These schemes can provide examples of best practices in respect of multiple enforcement agencies cooperating together and working with commerce. [https://www.citizencard.com]

- **Food Hygiene Rating Scheme - Food Standards Agency**: The food hygiene rating or inspection result given to a business reflects the standards of food hygiene found on the date of inspection or visit by the local authority. At the end of the inspection, the business is given one of the six ratings from 0-5. The top rating of '5' means that the business was found to have 'very good' hygiene standards. Economic operators can display stickers at the entrance to their establishments stating the rating given, "scores on the doors". The information provided on businesses is held by FSA on behalf of local authorities and is searchable online by consumers. [https://www.food.gov.uk/business-industry/hygieneratings]

- **Business Companion – CTSI & BEIS:** Free, impartial legal guidance for businesses and individuals that need to know about product safety and consumer protection legislation. The guidance is divided up into 15 broad Quick Guides and

each one contains a number of more detailed In-depth Guides. [www.businesscompanion.org.uk]

- **Compliance Advice Centres – Environmental Protection Agency USA:**

  Compliance advice centres (CAC's) serve different sectors of the US economy and have been developed in partnership with trade associations, academic institutions, environment groups and relevant stakeholders to identify the support needs of economic operators and to develop materials for compliance and performance improvement. The service is web-based and provides a one-stop-shop and user friendly source of advice for SME's. The agency (EPA) is instrumental to their success in providing non-financial support in the form of staff time, expertise, use of facilities and the provision of alerts to new sector specific regulations. [https://www.epa.gov/compliance]

➢ **Adopt, collaborate or sign-post**

- There is much professionally developed compliance guidance prepared in collaboration between enforcement agencies and industry that is already available and perhaps does not need to be duplicated but economic operators would benefit if its content was endorsed and its availability was more widely advertised by a wider range of enforcement and guidance bodies.

- Recommendations and guidance from Administrative Cooperation groups (ADCOs) that support the implementation of EU product legislation is made available on the European Commission's website.

- Other examples would include:

  - Euro Safe Child PRODUCT SAFETY GUIDE [WWW.CHILDSAFETYEUROPE.ORG/PUBLICATIONS/INFO/PRODUCT-SAFETY-GUIDE.PDF]

  - Product Safety Focus Group Joint Guidance with the British Blind and shutter Association (BBSA) on INTERNAL WINDOW BLINDS [HTTPS://BBSA.ORG.UK/TRADE/CHILD-SAFETY-2]

  - CANDLEMAKERS ADVICE SHEET - Joint advice from Trading Standards and the British Candlemakers Federation [www.britishcandles.org/documents]

  - TOY SAFETY – Examples of **a**dvice and guidance that is freely available:

    - TOY SAFETY DIRECTIVE 2009/48/EC - *AN EXPLANATORY GUIDANCE DOCUMENT*

      EUROPEAN COMMISSION, ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

    - GUIDANCE ON TOY SAFETY - *17 GUIDANCE DOCUMENTS*

THE EUROPEAN COMMISSION AND THE EXPERT GROUP ON TOY SAFETY

- TOY SAFETY IN THE EU - *A PRACTICAL GUIDE TO THE LEGAL OBLIGATIONS OF MANUFACTURERS, IMPORTERS AND DISTRIBUTORS*

  TOY INDUSTRIES OF EUROPE (TIE) - *part of an education campaign financed by the European Commission*

- TOY MANUFACTURERS, IMPORTERS AND DISTRIBUTORS: YOUR RESPONSIBILITIES - *HOW TO PRODUCE AND LABEL TOYS FOR CHILDREN TO COMPLY WITH SAFETY AND WARNING REGULATIONS*

  DEPARTMENT FOR BUSINESS, INNOVATION & SKILLS - *UK Ministry*

- INTRODUCTION TO THE TOY SAFETY DIRECTIVE

  BRITISH TOY & HOBBY ASSOCIATION – *UK Trade Association*

- REVISED TOY SAFETY DIRECTIVE 2009/48/EC - *SAFETY UPDATE*

  BRITISH TOY & HOBBY ASSOCIATION– *UK Trade Association*

- EU TOY SAFETY DIRECTIVE 2009/48/EC - *FREQUENTLY ASKED QUESTIONS*

  UL-STR - G*lobal independent safety science company*

- EU TO SAFETY DIRECTIVE 2009/48/EC: *TECHNICAL DOCUMENTATION REQUIREMENTS*

  BUREAU VERITAS - G*lobal provider of Testing, Inspection and Certification (TIC) services*

- HOME TOY PRODUCERS – *BASIC GUIDANCE FOR TRADERS*

  HAMPSHIRE COUNTY COUNCIL - *Web advice from one of UK's 200+ MSA's for toy safety*

➢ **Finally**

Many of the principles and methods of providing advice and guidance to economic operators present in the compliance practices detailed in this study have been practised by market surveillance authorities for many years. Therefore, it is very surprising that more MSA appear not to have already benefitted from these good practices. Just a few examples would include:

- Business advice packs provided during inspection visits. [UK – 1990]
- On-line information. [Latvia – 2004]
- POLISH ENTERPRISE IN THE EUROPEAN UNION - Products subject to conformity

  assessment and CE marking. [Poland – 2005]
- TV/Radio/Poster product safety awareness raising campaign. [Romania – 2006]
- MACHINERY, ELECTRICAL EQUIPMENT, PERSONAL PROTECTIVE EQUIPMENT, CHEMICALS & SIMPLE PRESSURE VESSELS - Market Control in Finland
- [Guidance leaflet - 2008]
- Website "traderouteasia.com". [Netherlands – 2008]
- Product Safety Guide for Business. [Australia – 2012]

3.18. The List of other Practices that were identified for further analysis

The table below presents an overview of the other practices which have been identified as containing elements of good practices but are not included in the "best practice" list. They have been split into the three categories, compliance schemes, compliance assistance and awareness raising. Some practices were categorised into good market surveillance and good awareness raising practices, since they do not fit into the three categories of compliance schemes, compliance assistance and awareness raising practices but may provide useful information.

COMPLIANCE SCHEMES

TITLE	TYPE	TERM	PRODUCT SECTORS[62]	MSA	COUNTRY	No
Regulatory Compliance protocol	CS	10	14, 15	INSPECTOR OF EXPLOSIVES	Cyprus	CS5
DETAILS: *A MS programme designed to ensure that all imports of explosives for civil use are fully compliant with relevant national legislation. This is achieved by control of the whole of the supply chain. Control from the point of entry into the country via customs control and licensing controls over all Economic Operators in the supply chain. Because the control of explosives at all points in the supply chain is strongly regulated this has presented the MSA with the opportunity to intervene at any point within the supply chain to perform compliance checks. All legitimate suppliers are known to the MSA through a licencing regime which*						

62 See Annex for "Reference List of Product Sectors as per the ToR"

eases the task. Any product not found to comply is removed from the market before it reaches the end user. This approach avoids having to remove defective products once they have been sold to the end user which can be particularly challenging. Success is aided by working in cooperation with Customs and the Police.

INITIAL COMMENT: *A well-focused approach to ensuring control of a specific product sector through good information of the economic operators and co-ordination. Tight control of the whole supply chain is aided by the fact the product category is highly regulated.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Covers importation and the whole supply chain*
   - Evidence of results: "*Accident statistics for pyrotechnics are at a low level. No issues with civil explosives"*
   - Costs: *Part of overall budget – no breakdown.*
   - Duration: *Since 2006*
   - Coverage: *Restricted to explosives - product sectors 14 & 15*
   - Meets product harmonisation principles: *Inspection protocol that starts with the importer and includes working in cooperation with other partners*
2. Cost-efficiency: *Control at import and co-operative working should bring operational cost benefits but no figures available.*
3. Specific elements: *Use of licensing, involvement of Police, Customs Service, EO's employees and public. Monitoring of accident statistics*
4. Ease of replication: *May be limited by the licencing element of the scheme. Also, the number of EO's is small in a very specialised product sector.*
5. Earned recognition/impact upon inspection: *No reduction in inspection levels.*

COMPLIANCE ASSISTANCE

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	CA	13	2	PUBLIC HEALTH AUTHORITY	Slovak Republic	CA7

DETAILS: *The Public Health Authority has competence on the territory of the Slovak Republic and is the supreme office for the regional public health authorities. It manages, controls and coordinates them. The execution of state administration carried out by regional public health offices. Information gathered from MS activities, questions from economic operators, consumer complaints and changes in legislation is used to address problems in the market by providing advice and guidance through a series of lectures, workshops and direct advice. This proactive approach has increased the willingness of Economic Operators to seek advice from the MSAs. The measure of success is based upon a reduction in the number of non-compliant products available on the market. A similar programme operates in the Czech Republic. Slovakia cooperates with Czech Republic through the exchange of information and market surveillance activities.*

INITIAL COMMENT: *A comprehensive approach to market surveillance that uses the results of inspection to highlight specific problems and then utilises compliance assistance across a number of access channels to seek to reduce non-compliance. The programme is operated nationally whilst the enforcement is regionally based. This approach should ensure consistency of advice across the market sector*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *To provide information to EOs and monitor the sale of cosmetic products via the internet*
   - Evidence of results: *No performance indicators but overall reduction in the number of non-compliant cosmetic products found during inspection.*
   - Costs: *Covered within overall budget that also includes market surveillance of food products.*
   - Duration: *13 years*
   - Coverage: ***State organisation*** - *Cosmetic products*
   - Meets product harmonisation principles: *Market surveillance provision. Results published in Annual Report of Market Surveillance Programme.*
2. Cost-efficiency: *Unable to measure due to no specific costing or performance*

measurement

3. Specific elements: *Responds to a variety of information inputs, works with Customs Service and Testing Laboratories*

4. Ease of replication: *Yes, a similar programme is being operated in the Czech Republic*

5. Earned recognition/impact upon inspection: *No – Less non-compliance reported*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Industry sectoral agreements	CA	-	3, 4, 31	SWEDISH CONSUMER AGENCY	Sweden	CA8

DETAILS: *IF the Swedish Consumer Agency and the economical operators (sometimes represented by an industry association) agree that an existing standard for certain products (often non-harmonised) does not fully comply with the national regulation and if it is not possible to amend the standard; then an industry sectoral agreement could be signed. This agreement acts to amend the standard and is valid for those economic operators on the national market who signed the agreement.*

INITIAL COMMENT: *Close co-operation between MSA and economic operators to ensure a more consistent approach to agreeing solutions to issues. Since standards have evolved, the activity in this area is less frequent but signing agreements is still a valid tool for compliance assistance.*

FURTHER ASSESSMENT:

1. Effectiveness

   - Design: *Technical assistance for EOs when there is a lack of harmonised standards.*
   - Evidence of results: *No specific indicators are used to monitor performance but instead of being regarded as a threat, the authorities are now more regarded as experts that could be consulted.*
   - Costs: *The negotiating phase is the most time consuming and budget involves travel and accommodation costs*.
   - Duration: *Activity in this area is less frequent now since standards have evolved*.
   - Coverage: ***National*** *– Across Toys, PPE & GPSD*
   - Meets product harmonisation principles: *Encourages the use of standards as the means of compliance*

2. Cost-efficiency: *This activity with agreements is declining in the product safety area*

3. Specific elements: *Industry sectoral agreement signed with trade associations to agree the means of compliance in the absence of harmonised standards.*

4. Ease of replication: *Application is still valid across a range of non-harmonised products but the challenge is that new economic operators can enter the market who are not part of the agreement.*

5. Earned recognition/impact upon inspection: *No – None*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Market Surveillance protocol	CA	8	U	CONSUMER RIGHTS PROTECTION CENTRE	Latvia	CA9

DETAILS: *This practice is a modern approach to market surveillance and operates in accordance with the principle that 'prevention is better than cure'.*

CRPC works with economic operators and provides them with information and support, rather than just leave them to their own devices and only contact them after something goes wrong. CRPC and businesses believe this approach makes a lot of sense.

The practice is to inform economic operators about legal requirements as an integral part of the CRPC's MS activity. The approach seeks to help reputable economic operators to be compliant and enables them to take the necessary corrective actions if necessary. This then enables CRPC to focus resources on non-compliant businesses.

INITIAL COMMENT: *Compliance assistance is provided as an intrinsic part of the market surveillance.*

FURTHER ASSESSMENT:

1. Effectiveness

   - Design: *A MS approach that seeks to help reputable economic operators to be confident that they are compliant and in some cases enables them to take the necessary corrective actions. This enables CRPC to focus resources on non-compliant businesses.*

   - Evidence of results: *Reduction in non-compliances found on inspection – year on year aggregates – no data provided*

   - Costs: *Contained within annual service budget*

   - Duration: *Since 2009*

- Coverage: ***National*** *- All categories of non-food products excluding medical devices and cosmetics*

- Meets product harmonisation principles: *Economic operators need to be aware of the legal regulations – assists compliance*

2. Cost-efficiency: *Because of limited market surveillance resources, and as the number of economic operators is huge, there is a need for an innovative and cost efficient approach to market surveillance.*

3. Specific elements: *This is part of the CRPC's usual MS activity. Depending on the product sectors there is collaboration with other regulators such as the State Building Control Agency and with trade associations.*

4. Ease of replication: *Should be part of all MSAs*

5. Earned recognition/impact upon inspection: *Yes - Visits reduced where a large number of economic operators were involved and could be notified and advised as a group.*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	CA/CS	6	1, 2, 21, 22, 24, 25, 30	FEDERAL PUBLIC SERVICE OF HEALTH, FOOD CHAIN SAFETY & ENVIRONMENT (FASFC).	Belgium	CA10

DETAILS: *Market Surveillance procedures that influence inspections through risk assessment and co-ordination with national and regional campaigns. The market surveillance procedures include both active and passive response protocols designed to deal with the range of issues faced and work in co-operation with other inspection units from other federal public services.*

INITIAL COMMENT: *Market Surveillance protocols that combine elements of awareness raising and compliance assistance with procedures for risk assessing economic operators and thus influencing inspection frequency or scope.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *EOs are controlled on short notice (e.g. less than 4 weeks) on proportional basis regarding the EO.*
   - Evidence of results: *None provided although KPIs are claimed to be in place. Number of consumer complaints have increased – suggesting better consumer awareness as opposed to EO awareness.*
   - Costs: *Part of 160,000 Euros operating costs budget for the federal public service – no individual cost*
   - Duration: *Since 2006*
   - Coverage: ***National*** *- Medical devices, Cosmetics, Chemical substances, Other chemicals, Efficiency-hot boilers, Tyre labelling & Fertilisers*
   - Meets product harmonisation principles: *Provides information for EOs via website and uses risk assessment to determine status of EOs.*
2. Cost-efficiency: *No data re impact upon market compliance/safer products*
3. Specific elements: *Risk analysis on basis of public health, environment concerns, specific problems, effectiveness of the action of EOs, Written procedures, co-ordination with regional level activities.*
4. Ease of replication*: Appears designed to meet specific product sector requirements but is a multi-product approach that can be transferred*
5. Earned recognition/impact upon inspection: *No – but successful campaigns did result in a reduction of inspections (e.g. batteries are not controlled anymore because there was a synergy with BEBAT who had organised awareness campaigns)*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	CA	20	17	MINISTRY OF ECONOMY OF THE REPUBLIC OF LITHUANIA, EU INTERNAL MARKET COORDINATION DIVISIONS	Lithuania	CA11

DETAILS: *The practice aims to inform economic operators about the legal requirements pertaining to the product sector as an integral part of the legal metrological supervision activity. The approach covers the market surveillance of measuring instruments assigned to legal metrology, pre-packed products and the instruments for pre-packed products and measuring containers by seeking to share information and organize joint events of consultations and meetings for the economic operators involved.*

INITIAL COMMENT: *Compliance assistance is provided as an intrinsic part market surveillance protocol and was was devised specifically to address the problems of legal metrology.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Market surveillance via inspection visits (4,000 per annum)*
   - Evidence of results: *Decline in the number of violations each year compared to 2014 - 2015 offenses decreased by 24%*
   - Costs: *Included within overall inspection budget*
   - Duration: *Since 1966*
   - Coverage: ***National*** *- Measuring instruments, pre-packed products and measuring containers*
   - Meets product harmonisation principles: *Meets MS obligation with accreditation of competence to carry out tests, calibrations and sampling.*
2. Cost-efficiency: *No data provided other than the reduction in non-compliance and reduced inspection visit duration*
3. Specific elements: *LST EN ISO / IEC 17025: 2005 standard accredited Inspection Measurement and Research Division.*
4. Ease of replication: *This practice is appropriate to legal metrology*
5. Earned recognition/impact upon inspection: *The number of inspections each year has remained the same, but their duration has decreased.*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Training Programme for Authorised Officers	CA	3	23	DEPARTMENT OF COMMUNICATIONS, ENERGY & NATURAL RESOURCES (DCENR)	Ireland	CA12

DETAILS:

The practice was developed as the central core of the planned service delivery arrangements when the inspection process was out-sourced by the department to and external agency and include the following:

1. *Provision of a training programme for authorised officers to ensure those appointed to carry out market surveillance operations understand the provisions of the applicable legislation, their powers under the legislation and best practice in carrying out inspection activities.*

2. *Development and delivery of awareness raising programmes for relevant economic operators and stakeholders*

3. *National inspection programme*

INITIAL COMMENT: *A considered and well managed approach to ensure that all stakeholders receive accurate information delivered according to best practice and that enforcement is both well planned and delivered by well trained staff.*

FURTHER ASSESSMENT:

1. Effectiveness

   - Design: *Provision of training programmes for authorised officers, inspection programme & awareness raising for economic operators*
   - Evidence of results: *Initial small inspection programme over three phases has defined a baseline for compliance and inspection protocols*
   - Costs: *Subject to public tender for outsourcing – Ministry budget.*
   - Duration: *Since 2013 & 2011 respectively*
   - Coverage: ***National*** *– Eco-design & Energy Labelling (Directives 2009/125/EC and 2010/30/EC*
   - Meets product harmonisation principles: *Ensure those appointed to carry out market surveillance operations and those supplying goods understand the provisions of the applicable legislation, their duties/powers under the legislation and best practice in carrying out inspection activities or placing products on the*

market

2. Cost-efficiency: *Better information & enforcement benefits both EO's and consumers*

3. Specific elements: *Enforcement was outsourced. Training was provided for the newly authorised officers employed by the external service provider to ensure compliant and consistent enforcement.*

4. Ease of replication; *Could be useful in Member States where market surveillance enforcement activities are out sourced or provided by other government/regional/local agencies*

5. Earned recognition/impact upon inspection: *No – None*

AWARENESS RAISING

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	AR/CA	12	22B	MINISTRY OF ENVIRONMENT AND WATER	Bulgaria	AR5

DETAILS: *Information is provided to economic operators and certification bodies through an annual workshop that is promoted through the MSA website, e-mail, direct mailing and via relevant NGO's AND as part of the MS protocol through direct contact via telephone, e-mail.*

INITIAL COMMENT: *Covers aspects of both AR & CA and the annual workshop is a very valuable asset as it provides economic operators with a regular opportunity to ensure that their knowledge of their legal requirements is correct and up to date.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Workshops on the bans and restrictions for placing on the market of paints, fluorinated greenhouse gases and ozone depleting substances plus response to direct requests from EOs*
   - Evidence of results: *Reduction in the number of non-compliant chemical products found.*
   - Costs: *Funded for one workshop per year*
   - Duration: *Since membership of EU*
   - Coverage: ***National*** *- 22/B Other chemicals (Paints, Fluorinated greenhouse gases, Ozone Depleting Substances): Directive 2004/42/EC, Regulation (EU) 517/2014, Regulation (EC) 1005/2009*
   - Meets product harmonisation principles: *Awareness raising of legal requirements plus partnership working with Customs Service*
2. Cost-efficiency: *No performance data provided*
3. Specific elements; *Contact with branch Chambers of Commerce & Trade Associations together with direct contact with EOs & Website*
4. Ease of replication: *Yes, for all product sectors in all member states*
5. Earned recognition/impact upon inspection: *Reduced inspection of low-risk EOs*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocols	AR/CA	-	4, 9, 10, 17, 18, 22	DEPARTMENT OF JOBS, ENTERPRISE AND INNOVATION HEALTH AND SAFETY AUTHORITY	Ireland	AR6

DETAILS: *Awareness raising provided to economic operators through website, lectures, articles in e- journals and visits to premises and trade shows. Compliance assistance through answers to individual queries and normal enforcement activities.*

INITIAL COMMENT: *A good example of how the MSA can be proactive in assisting an industry in improving its compliance across a number of product sectors by embedding awareness raising and compliance assistance into its normal market surveillance procedures.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Awareness raising and compliance assistance incorporated as part of market surveillance protocols. Proactive contributions to e-journals and trade shows*
   - Evidence of results: *N/A*
   - Costs: *Contained within service budget*
   - Duration: *N/A*
   - Coverage: ***National*** *- Machinery, Lifts, PPE, PED, TPED, ATEX, REACH + Classification and Labelling, Detergents - some product sectors have the MS enforcement duty split between HSE & CCPC along occupational/recreational lines*
   - Meets product harmonisation principles: *Provides AR/CA within MS activities*
2. Cost-efficiency: *Combination of advice and enforcement across linked enforcement duties can make good use of scarce resources*
3. Specific elements: *Combining a joint enforcement responsibility for market surveillance of machinery with occupational health and safety in the workplace. Seeks to work through trade associations to widen influence. Works well within a very small market.*
4. Ease of replication: *Would expect most MSAs to already replicate most of these activities*
5. Earned recognition/impact upon inspection: *No – None*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	AR	-	5	MINISTRY OF LOCAL GOVERNMENT AND MODERNISATION. NORWEGIAN BUILDING AUTHORITY (NBA) IS A SUBORDINATE AGENCY	Norway	AR7

DETAILS: *Economic operators are targeted through 7-8 campaigns per year informed by regular consultations with professional bodies, notified bodies, technical assessment bodies and the screening of complaints plus risk assessments of products*

INITIAL COMMENT: *Targeted information to economic operators based upon consultation, risk assessment and complaint analysis.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Comprehensive MS protocol in specific product sector*
   - Evidence of results: *No information provided*
   - Costs: *Containing with MS budget that also contains a testing budget*
   - Duration: *Unknown*
   - Coverage: ***Two National networks*** *– covering consumer & industrial construction products*
   - Meets product harmonisation principles: *Wide consultation with professional organisations, Notified Bodies and technical Assessment Bodies to identify products to control, as well as screening the complaints from previous years*
2. Cost-efficiency: *Working closely with Notified Bodies can reduce costs*
3. Specific elements: *Combination of proactive and reactive market surveillance activities, risk assessment and co-operation with 4 Notified Bodies and Customs Service.*
4. Ease of replication: *A member state's solution to its local situation that would not necessarily be helpful to others although it does contain some MS good practice.*
5. Earned recognition/impact upon inspection. *No – None*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	AR	7	14,17,18,20,21,23	TECHNICAL REGULATORY AUTHORITY CONSUMER PROTECTION BOARD	Estonia	AR8

DETAILS: *Manufacturers, importers and distributors are informed of the legal requirements for measuring instruments by information booklets and other PR activities. Decreasing interest for seminar type events probably because majority of the information can be nowadays found quite easily from our homepage and similar internet sources.*

INITIAL COMMENT: *Targeted information to economic operators through a number of access channels across a range of product sectors*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Comprehensive approach to the provision of information to EOs through face to face discussions, training days, information booklets & website.*
   - Evidence of results: *Not known. Main outcome is likely to be an overall rise in the level of knowledge*
   - Costs: *No additional funds – contained within normal MSA budget.*
   - Duration: *Since 2008 – Training days have now ceased except for events for Pyrotechnics every 2 years*
   - Coverage: ***National -*** *LVD, EMC, ROHS, Eco-design applicable products + Measuring Instruments, Non-automatic weighing, Pre-packaged products + Pyrotechnics 2013/29/EC*
   - Meets product harmonisation principles: *Informed EOs are better placed to produce/import compliant products*
2. Cost-efficiency: *Minimum cost approach but no measurement of effectiveness or efficiency. Printed booklets used in areas of little change*
3. Specific elements: *Focused upon on-line access to information + printed booklets for MI distributed during inspection visits – Pyrotechnics booklets mainly aimed at consumers with the training days targeted on importers and retailers.*
4. Ease of replication: *Normal MS activity*
5. Earned recognition/impact upon inspection: *No – None*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	AR		5	EAST AYRSHIRE TRADING STANDARDS SERVICE	United Kingdom	AR9

DETAILS: *An information sharing initiative by the MSA to the economic operators in a specific product sector.*

COMMENT: *Targeted information to economic operators in local area based upon a direct and proactive approach to an identified issue.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Raise awareness amongst business of the legal requirements and provide guidance on the steps to be taken to achieve compliance.*
   - Evidence of results: *61% found to be compliant or actively seeking compliance on first contact - Informal review after year one indicated that some businesses were still slow to comply through lack of understanding of requirements. Project was continued for another year*
   - Costs: *Contained within MS budget*
   - Duration: *2 years*
   - Coverage: *Small number of local business re Construction Products Directive*
   - Meets product harmonisation principles: *Combats EOs lack of knowledge of regulations and consequent failure to comply.*
2. Cost-efficiency: *No information provided*
3. Specific elements: *Information provided to a specific section of a product sector – Steel construction – to meet a local need*
4. Ease of replication: *The project was taken up by a number of MSAs in the West of Scotland – could be replicated to deal any local compliance issue.*
5. Earned recognition/impact upon inspection: *Yes, businesses that responded to the initial letter were not inspected if they were able to send documentary proof of compliance.*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	AR	2	2,3,22,32	Ministry of Health, Department for Objects of Common Use and Noise Protection	Croatia	AR10

DETAILS: *An information provision initiative by the MSA to the economic operators in a specific product sector.*

COMMENT: *Information on toy safety, cosmetics and chemicals made accessible for economic operators via website and e-mail response.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *To inform economic operators of the legal requirements and provide feedback guidance on the steps to be taken to achieve compliance.*
   - Evidence of results: *No indicators set or review conducted*
   - Costs: *Started with EU funding and continued with Chamber of Commerce funding – no amounts detailed*
   - Duration: *2 years*
   - Coverage: *National & local*
   - Meets product harmonisation principles: *Combats EOs lack of knowledge of regulations and consequent failure to comply.*
2. Cost-efficiency: *No information provided*
3. Specific elements: *Information provided to a number of a product sectors – Toys, cosmetics, chemicals, biocides & REACH*
4. Ease of replication: *Would normally be considered by all MSA's*
5. Earned recognition/impact upon inspection: *None*

GOOD MARKET SURVEILLANCE PRACTICE

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Regulatory Compliance protocol	AR,CA	16	17	METROLOGY INSTITUTE OF THE REPUBLIC OF SLOVENIA (MIRS)	Slovenia	MS1

DETAILS: *MS system based upon the systematic monitoring of the level of compliance in specific product sectors through risk assessment and classification of the supervised economic operators based upon inspection results.*

INITIAL COMMENT: *A comprehensive market surveillance system that seeks to risk assess economic operators and classifies them for inspection planning. This should encourage economic operators to improve their procedures and influence to scope or frequency of their inspections.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Increase the effectiveness of the market surveillance/inspection through risk assessment-led inspection*
   - Evidence of results: *The comparison between the supervised fields at the beginning of surveillance/inspection in year 2000 and today*
   - Costs: *Market surveillance budget*
   - Duration: *6 years*
   - Coverage: NATIONAL
   - Meets product harmonisation principles; *Well-designed risk-based market surveillance planning and procedures*
2. Cost-efficiency: *Seeking to develop successful surveillance activities with limited resources*
3. Specific elements: *The basic goal of eliminating non-compliant measuring instruments & pre- package products from the market/ use*
4. Ease of replication: *Should already be part of all market surveillance systems*

5. Earned recognition/impact upon inspection: *Yes – Numbers of inspections reduced*

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Market Surveillance of Medical Devices	AR,CA, CS	14	1	CYMDA	Cyprus	MS2

DETAILS: A *comprehensive MS programme including inspections, complaint investigation, sampling, inspection check sheets, seminars, visibility mailing list, patient group feedback and cooperation with customs. This approach to market surveillance uses a wide range of tools available to any MSA and is an example of effective controls being implemented using existing established methods delivered in an appropriate way to match service delivery needs.*

INITIAL COMMENT: *A comprehensive market surveillance system that seeks to utilise a full range of information inputs and which benefits from co-operation with the customs service. This has the potential to encourage importers to improve their procedures and influence to scope or frequency of their inspections. This has the potential to encourage importers to improve their procedures and influence the scope or frequency of the MSA inspections*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *Within modest resources, implementing a comprehensive MS programme*
   - Evidence of results*: Increased detection of non-compliant products*
   - Costs: *Budget is part of overall budget of Authority (exact figures not available)*
   - Duration: *Commenced in 2002*
   - Coverage: *Medical devices*
   - Meets product harmonisation principles; *Regular inspection, complaint investigation and product sampling*
2. Cost-efficiency: *No measurable results*
3. Specific elements: *Rolling 3 monthly programme of inspections of manufacturers, importers, distributors, retailers and workplaces*
4. Ease of replication: *Normal Market Surveillance activity – should be implemented in all Member States by all MSAs*
5. Earned recognition/impact upon inspection: *None - No reduction in inspections*

GOOD PRACTICE FOR AWARENESS CAMPAIGNS

TITLE	TYPE	TERM	PRODUCT SECTORS	MSA	COUNTRY	No
Piki's room	AR	1.5	U	FINNISH SAFETY AND CHEMICALS AGENCY TUKES	Finland	AR GP1

DETAILS: *Children's safety game and TV-programme series for children. Both aimed at 3-5-year-old children to increase their safety awareness and teach them safe ways of behaving. The ultimate goal is to reduce accidents.*

INITIAL COMMENT: *An excellent example of the potential to deliver information to specific audiences through the use of methods and access channels that are favoured by or more suited to the selected audience.*

FURTHER ASSESSMENT:

1. Effectiveness
   - Design: *To increase children's safety awareness and to reduce accidents and injuries caused by unsafe behaviour and misuse of products.*
   - Evidence of results: *Piki's room games are played by approx. 2000 children daily at the hugely popular Pikku Kakkonen website for children*.
   - Costs: *So far 41000 Euros*
   - Duration: *Starting from February 2015, undefined duration. First 3 games were published in February followed by 5 more games in August 2015*
   - Coverage: *National across electrical appliances, personal protective equipment, toys and chemicals.*
   - Meets product harmonisation principles:
2. Cost-efficiency: *Long term plan to change behaviours and reduce accidents and injuries over many years*
3. Specific elements: *It offers children a fun way to learn about safety, avoid patronizing tone and get the message through without even noticing it.*
4. Ease of replication: *Very much transferable, only needs to be translated to the language of the region. It is suitable to all product groups used by consumers, also for consumer services and other types of safe behaviour education.*

5. Earned recognition/impact upon inspection; *N/A*

3.19. Annexes

Reference List of Product Sectors as per the project ToR:

	Product Sectors	Relevant legislation
1	Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	Directives 93/42/EEC, 98/79/EC and 90/385/EEC
2	Cosmetics	Regulation (EC) 1223/2009
3	Toys	Directive 2009/48/EC
4	Personal protective equipment	Directive 89/686/EEC
5	Construction products	Regulation (EU) 305/2011
6	Aerosol dispensers	Directive 75/324/EEC
7	Simple pressure vessels and Pressure equipment	Directives 2009/105/EC and 97/23/EC. Directives 2014/29/EU and 2014/68/EU
8	Transportable pressure equipment	Directive 2010/35/EU
9	Machinery	Directive 2006/42/EC
10	Lifts	Directive 1995/16/EC - Directive 2014/33/EU
11	Cableways	Directive 2000/9/EC
12	Noise emission for outdoor equipment	Directive 2000/14/EC
13	Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	Directive 1994/9/EC - Directive 2014/34/EU
14	Pyrotechnics	Directive 2007/23/EC - Directive 2013/29/EU
15	Explosives for civil uses	Directive 93/15/EEC - Directive 2014/28/EU
16	Appliances burning gaseous fuels	Directive 2009/142/EC
17	Measuring instruments, Non-automatic weighing instruments, Pre-packaged products and Units of measurement	Directives 2004/22/EC and 2009/23/EC - Directives 2014/32/EU and 2014/31/EU; Directive 2007/45/EC, 75/107/EEC and 76/211/EEC; Directive 80/181/EEC
18	Electrical equipment under EMC	Directive 2004/108/EC - Directive 2014/30/EU
19	Radio and telecom equipment under RTTE - RED	Directive 1999/5/EC - Directive 2014/53/EU
20	Electrical appliances and equipment under LVD	Directive 2006/95/EC - Directive 2014/35/EU
21	Electrical and electronic equipment under RoHS and WEEE and batteries	Directives 2011/65/EU, 2002/96/EC and 2006/66/EC
22	A) Chemical substances under REACH and Classification and Labelling Regulations	Regulations (EC) 1907/2006 and 1272/2008/EC
22	B) Other chemicals (Detergents, Paints, Persistent Organic Pollutants, Fluorinated greenhouse gases, Ozone Depleting	Regulation (EC) 648/2004, Directive 2004/42/EC, Regulation (EC) 850/2004, Regulation (EC) 842/2006 and Regulation (EU) 517/2014, Regulation (EC) 1005/2009

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

Primary Authority – Cost recovery

A key element of Primary Authority is that MSAs acting as primary authorities have the discretion to recover their costs. Section 31 of The Regulatory Enforcement and Sanctions Act 2008 states: *'The primary authority may charge the regulated person such fees as it considers to represent the costs reasonably incurred by it in the exercise of its functions under this Part in relation to the regulated person.'* This makes it very clear that MSAs are not expected to make money out of Primary Authority, but cost recovery allows an MSA to operate a primary authority partnership whilst retaining the ability to provide a proficient and effective market surveillance service. Businesses in primary authority partnerships benefit in lots of ways including having access to assured legal advice provided to them at cost price.

Cost recovery is a concept that has caused much discussion and debate in the UK around the ethics of charging businesses for advice and support:

- Some businesses argued that, as they were already paying business rates and taxes, they should not be charged additionally for the advice services provided by MSAs.

- Some MSAs were concerned that businesses paying for services would be seen to be paying for immunity from prosecution. Furthermore, they were concerned that their own integrity might be questioned, and their reputation for fairness and even-handedness tarnished.

The taxes and business rates (community charges) paid by businesses for market surveillance, are in reality a very small proportion of the overall taxes and business rates that they pay. The

operation of a Primary Authority partnership is over and above the basic service level provided and the cost is not therefore included in these basic charges. The cost has to be accounted for in a different way.

Many businesses in the UK want a higher than basic level of service from their MSAs that will give them assurance that they were compliant, and that would reduce uncertainties caused by inconsistent legal interpretations of the law. This enables them to have a degree of confidence when investing in compliance and helps them to grow their businesses. An important added benefit is because MSAs have confidence that a business in a primary authority partnership with an MSA will have received good, sound advice from their partner MSA and will therefore be compliant. They will have access to see what advice has been given and will therefore need to spend less time on inspecting those businesses.

Most MSAs cannot normally afford to provide such a high level of service out of their normal annual service budget without reducing their capacity to carry out other high priority work. The ability for them to recover their costs is therefore very important for product safety, and for market surveillance in general. This is only true however if the MSA is allowed to retain the costs recovered within their own budget. If the recovered costs are not 'ring fenced' in this way, and are absorbed into other wider budgets, the benefits to product safety and market surveillance generally outlined above would be lost.

4. DIGITAL COMPLIANCE

4.1. Introduction

Many instruments of Union harmonisation legislation oblige the manufacturer or the importer to ensure compliance, to keep documentary evidence of the compliance process. Firstly, many instruments of Union harmonisation legislation oblige the manufacturer to draw up technical documentation containing information to demonstrate the conformity of the product to the applicable requirements. The technical documentation is usually quite voluminous and contains very valuable technical information which could contain essential elements protected by intellectual property rights and the legislation on trade secrets. Therefore, technical documentation or parts of it is often only shared with market surveillance authorities, upon their request, and not with any other actors in the supply chain. The latter include distributors, other intermediaries and possibly conformity assessment bodies. In order to assess the compliance of a product, these actors should rely, partly on the markings on the product but primarily on the EU declaration of conformity. Secondly, these instruments of Union harmonisation legislation also oblige the manufacturer to draw up and sign an EU declaration of conformity before placing a product on the market. By drawing up and signing the EU declaration of conformity, the manufacturer assumes responsibility for the compliance of the product. Where several pieces of Union harmonisation legislation apply to a product, the manufacturer or the authorised representative has to provide a single declaration of conformity in respect of all such Union acts. The EU declaration of conformity must be made available to the surveillance authority upon request. The EU declaration of conformity must be translated into the language or languages required by the Member State in which the product is placed or made available on the market. It should be noted that Union harmonisation legislation relating to machinery, equipment in potentially explosive atmospheres, radio and terminal telecommunication equipment, measuring instruments, recreational craft, lifts, high-speed and conventional rail systems and constituents of the European Air Traffic Management network require products to be accompanied by the EU

declaration of conformity. However, some instruments of Union legislation do neither provide for technical documentation, nor for a declaration of conformity.

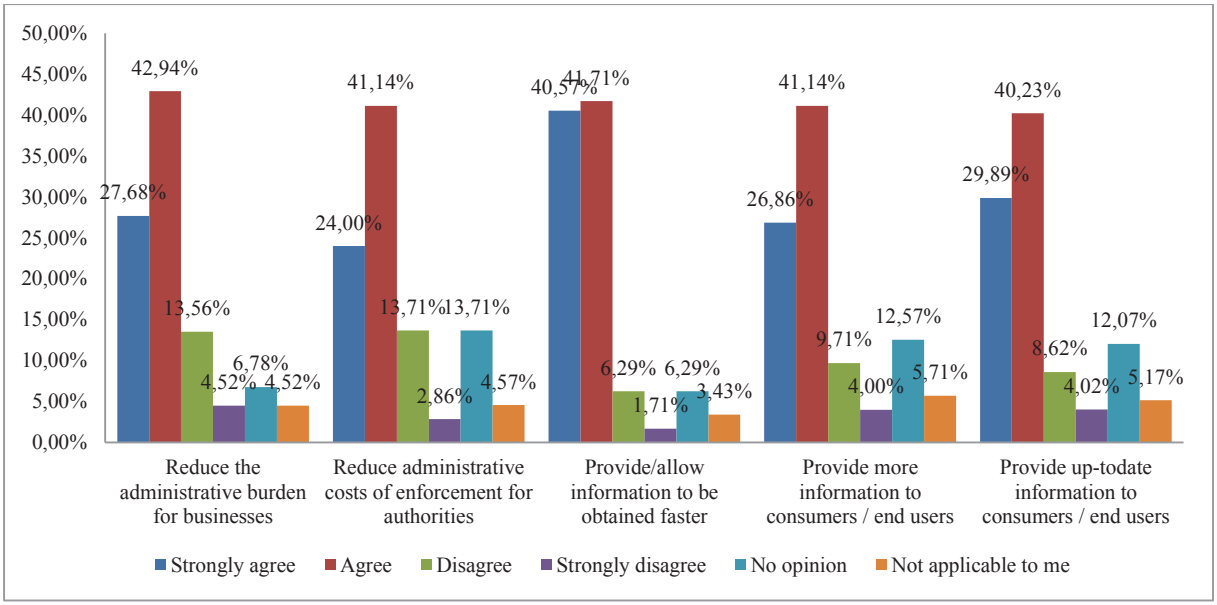
Union legislation that provides for technical documentation and for a declaration of conformity allows market surveillance authorities to request the technical documentation or the declaration of conformity either in paper or in electronic form, as they prefer. Each of both forms of transmission has its own problems of transparency:

- The transmission in paper should not make a major difference for the manufacturer or, as the case may be, the authorised representative, especially to market surveillance authorities, although an electronic transmission might be more efficient. The major drawback of paper is that the declaration of conformity is, in most cases, not readily accessible to other economic operators in the supply chain, for example distributors, except in the cases where the products must be accompanied by the declaration. This might cut them off from important compliance information. In theory, they could ask their suppliers to provide them with a paper copy for all deliveries but this would create a challenging administrative burden for all actors in the supply chain, especially in the light of the obligation for the manufacturer or the authorised representative to continuously update the declaration of conformity. In practice, however, requesting and keeping a paper version of the EU declaration of conformity constitute a fairly important administrative burden for distributors and other intermediaries. Furthermore, where the paper copy was not transmitted by the manufacturer to other economic operators in the supply chain, the latter cannot provide it to the consumer when he or she would seek it.

- Electronic transmission is less easy than it would seem. Firstly, the transmission in electronic form to market surveillance authorities depends essentially upon the latter's willingness to accept electronic documentation. This would then concern scanned versions of signed declarations in paper form. Secondly, the transmission in electronic form to other actors in the supply chain is not a very widespread practice in the EU: only 18% of the respondents of the public consultation always or often publish their declarations of conformity on their site. Thirdly, the electronic signature on declarations of conformity, in accordance with the first eSignatures Directive 1999/93/EC and its replacing Regulation (EU) No 910/2014 on electronic identification and trust services for electronic transactions in the internal market (eIDAS Regulation), seems to be rarely used, notwithstanding the fundamental legal rule that all electronic signatures and verification services must be admissible as evidence in legal proceedings. Fourthly, the electronic seals introduced by eIDAS cannot be used for EU declarations of conformity which require the name and the function of the natural person who signs on behalf of the manufacturer or his authorised representative. Electronic seals are similar to electronic signatures but only available to legal persons such as corporate entities in order to minimize the importance of the “authorized signer” for a particular entity. The electronic seal is associated with that entity and any use of that seal is presumed to be binding on that entity.

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

consumers/end users (68.00%) and provide up-to-date information to consumers/end users (70.11%).



In addition, Union product legislation obliges economic operators to inform the national competent authorities of risks to the health, safety and other public interests posed by products they market. Such information must be made available to consumers.

In particular, according to Article 12 of the General Product Safety Directive[63] (GPSD) and Article 22 of Regulation (EC) No 765/2008[64], voluntary measures[65] taken by economic operators against dangerous products (e.g. a company itself recalls a dangerous product it placed on the market) are to be reported to Member States' authorities and, through them, to the Commission and to the other Member States through the RAPEX system. Moreover, according to Article 23 of Regulation (EC) No 765/2008, voluntary measures against harmonised products posing a less than serious risk need to also be reported to Member States authorities and, through them, to the Commission and the other Member States. As regards non-harmonised products posing a less than serious risk, Member States are not requested by the GPSD to report such voluntary measures to the Commission. For any notification in the RAPEX system, the competent authorities of the Member States must take responsibility concerning the information transmitted therein.

This procedure takes necessarily a certain amount of time due to the various steps described in the legal framework. For example, according to the RAPEX Guidelines[66], Member States have 10 days as of the receipt of information on voluntary measures from the economic operator to notify the Commission in the RAPEX system. This time lapse may be necessary

63 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance), OJ L 11/4 of 15.1.2002

64 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 OJ L 218 of 13.08.2008

65 RAPEX also covers compulsory market surveillance measures adopted by competent authorities in respect of dangerous products. Such measures are outside the scope of this analysis since they fall entirely under the responsibility of the Member States as of their initiation.

66 Commission Decision of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive), OJ L 22/1 of 26.1.2010

for national authorities to make their own assessment of the risk at stake, independently of the level of risk alleged by the economic operator. The Commission has, afterwards, 5 days to validate the notification and distribute it to the other Member States. Notifications sent in languages other than English, also need to be translated. The publication of the notification on the Commission's RAPEX website after its validation can take in practice several days. Consequently, publication of a voluntary measure (e.g. a recall of a passenger car due to safety issues of the airbags) happens weeks after the measure was taken. Thus, RAPEX, which serves a central point of reference in terms of measures against dangerous products in the EU, and even beyond, cannot be a "just in time" system in passing the information about risks posed by products in such cases to consumers and businesses.

Moreover, notice by the economic operators of such voluntary measures will not necessarily reach all consumers that bought the product.

4.2. Existing Technologies

This section is built on *G. Baldini et al.; Enforcers and brand owners' empowerment in the fight against counterfeiting* (updated version of Baldini G. and Cano Pons E., Enforcers and brand owners' empowerment in the fight against counterfeiting, EUR 28400 EN, doi:10.2760/135671) and was adapted for enforcement of Union harmonisation legislation.

Different techniques have been proposed to fight against counterfeiting. These techniques include identification and authentication technologies, processes to control supply chains and technologies to track and trace products. A technique can be based on various tools and equipment. In this report, we will pay special attention to the use of the smartphone and other portable devices as tools to empower law enforcers and . The same techniques could be used for the purpose of compliance: the analysed techniques can also be an important element in supporting Due Diligence practices and Supply Chain Integrity, because the different categories of users can authenticate goods in different parts of the supply chain and report the presence of non-compliance.

Definitions

This section provides the operating context and definitions of key terms used in this report.

- Empowerment: For the aim of this section, the term empowerment indicates the act of enabling law enforcers (e.g. customs and market surveillance authorities) and manufacturers through techniques on the basis of available information, visual inspection and validation through tools 'readily' available. The term 'readily' refers to techniques and tools that are widely available on the market and do not need sophisticated technological solutions and systems or complex training.

- Users: While in literature and elsewhere, empowerment is associated with the concept of the 'consumer' in its widest sense (to encompass private citizens, enforcers and businesses purchasing products), in this report, law enforcement authorities, manufacturers and enterprises — including small to medium-sized enterprises (SMEs) — are all considered as users. Enterprises cannot implement sophisticated or expensive controls for the goods provided by the supplier, such as forensic labs or responsible supply chain management while retailers and distributors may want to check that the received products comply with the law.

Techniques

Two main categories of 'readily' available techniques based on different tools or equipment have been identified.

1. The first category is represented by the modern smartphone (or similar device, such as a tablet). The modern smartphone is equipped with a high-resolution camera (e.g. 5 megapixels and above), support for different standards for wireless connectivity, a powerful processor able to support the implementation of sophisticated algorithms and support for Near Field Communication (NFC) and Radio Frequency Identification (RFID) readers. In addition, the smartphone can be integrated and augmented with a wide range of plug-in devices and tools (e.g. a USB microscope). This category will be the main focus of this report.

2. The second category is represented by the wider domain of portable products (e.g. portable spectrometers), which have already appeared on the market. In many cases, these portable products implement systems that have been available until only recently in forensic labs. An example of this is represented by the category of portable spectrometers. This report will also provide an overview of these systems, without specifying the product or the manufacturer.

In addition to the abovementioned tools, this category also includes low-cost tools, such as readily available chemical reagents or polarised filters.

The focus is on techniques to be used in the 'field', where field is the physical area where the user operates and where the goods are either exposed or in transit. In other words, it refers to physical locations, which are different from forensic labs, where goods that may need to be verified are placed, and that can coincide with the enterprise's premises, the marketplace, the customs area etc. This section does not relate to empowerment techniques for e-commerce as the user does not have physical access to the goods.

Empowerment via Use of a Smartphone

Capabilities of a smartphone

A description of the approach to empowerment via use of a smartphone is presented below.

The centre of the suggested approach would be a smartphone, that is to say, a tool used nowadays by all relevant users. The smartphone acts as a field sensor (to detect optical features, read RFID tags, geolocations etc.), telecommunication gateway (to obtain real-time information on the object or to allow direct interactions between the object and a remote verification system) and notification system (to provide information to the track and trace supply chain system).

Furthermore, the smartphone can be connected to other systems and components, such as the producer's supply chain, the law enforcer's reference database and other systems.

More precisely, nowadays a smartphone (June 2016) has the following capabilities:

1) A high-resolution camera. It is now commonplace to buy a smartphone with a 5 megapixel (MP) camera for under EUR 100 and the trend will continue, so we can envisage that new cameras will have an even higher resolution.

2) Wireless connectivity through different wireless communication standards: Wi-Fi, GSM, Universal Mobile Telecommunications System (UMTS), Long Term Evolution (LTE) and with broadband capacity. This ensures that data can be sent quickly to a remote server (e.g. cloud database) or a remote application.

3) High-performance computing platform. Today's smartphones have similar computational power and capabilities to the older desktop computers, and this trend is likely to continue.

4) Near field communication (NFC) readers to read high-frequency (HF) RFIDs, which both operate at the 13.56 MHz frequency.

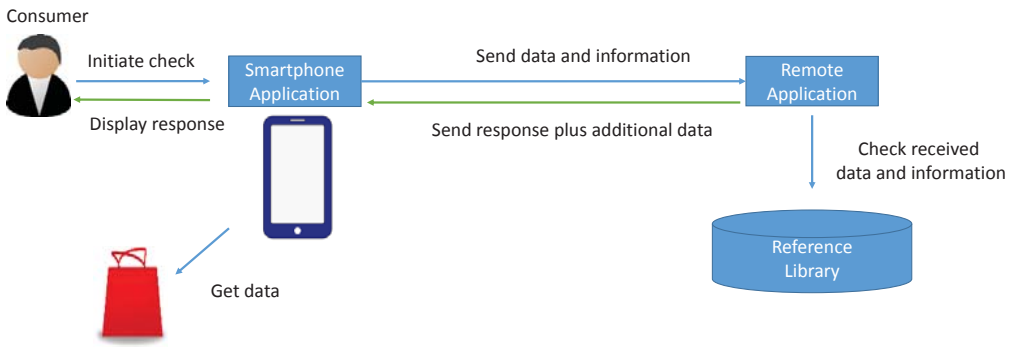
5) Global Navigation Satellite Systems (GNSS), which can record the time and space when goods are being evaluated.

6) Plug-ins of different components through the USB interface. For example, visual augmentation equipment (e.g. USB microscope) or a DVB dongle (e.g. to collect radio frequency emissions) can be added to a smartphone.

7) Installation and activation of applications on a smartphone.

Most of these capabilities were not present in smartphones until recently. The new capabilities mean that it is possible to implement various techniques, which will be described here.

In the context of assessing compliance, the smartphone itself is the component (in the hand of the law enforcement official or the representative of a manufacturer, namely the 'users') of a wider system, which can include an application, a communication protocol, a reference library, a manufacturer database of the product features, or a database linked to the supply chain and other elements. The smartphone is used to collect data (e.g. images, RFIDs) from the goods to be evaluated. This data can be processed in the smartphone itself (e.g. to extract features) to generate additional information from the raw data using an application. The application sends the data and the information to a remote application using wireless connectivity and a specific communication/data protocol. Additional information can also be sent from the smartphone, such as its position if the privacy settings defined by the user allow this. The remote application uses a reference library or a supply chain database to match the data and information received from the smartphone. The matching information and related data (e.g. for which market the product is produced) is then sent back to the smartphone. Then, the application in the smartphone displays this information and data to the user. This generic workflow is represented in the following figure:



The users only see and use the smartphone, but adequate infrastructure must be built to implement the underlying technique. This is described in the following paragraph.

Main components of a smartphone-based approach

Beyond the smartphone, a complete solution must include the following elements.

1) **Smartphone application**. This is the application running on a smartphone, which implements a Graphical User Interface (GUI) to the user to receive requests. The smartphone is connected to the main sensors of the smartphone to collect the required data (e.g. images). The application can also implement specific algorithms to process the data. For example, it could extract statistical features from the retrieved image. The smartphone application is also responsible for sending the data and any additional

information (e.g. features, position or privacy settings) to the remote application using a well-defined communication protocol.

2) **Communication protocol**. This communication protocol is responsible for sending the data and information from the smartphone application to the remote application and sending back the response from the remote application to the smartphone application.

3) **Remote application**. This is the remote application hosted on a remote server, which also uses the communication protocol to exchange data with the smartphone application. The remote application uses the information from a reference library to evaluate whether the received data and information from the smartphone identify the products.

4) **Reference library**. This is the database of the matching information (e.g. track and trace or fingerprinting for product identifications), which can be created by manufacturers or by other organisations that collect the information that identifies valid goods from several manufacturers. The reference library is a generic term, which can include many different types of information, for example, the fingerprinting of goods or the serialisation number of an overt/covert tag. Note that the reference library can also be used to insert additional information useful for the different categories of users.

Specific empowerment techniques

One can distinguish different empowerment techniques based on smartphone information, how the reference library is created and what type of information is stored or collected by the smartphone.

1) **Reference library created by the manufacturer during the manufacturing process**. The reference library is created by the manufacturer itself or by a company working for it and the specific information on the single product is collected and stored in the reference library during the manufacturing phase. In other words, the manufacturing plan of the manufacturer is equipped with systems and devices to collect the unique fingerprinting of the product and/or the package, which is then stored for future use. Note that the fingerprinting information can be in different forms: it can be a serial number represented in the barcode or QR code, it can be a fingerprinting of the product itself on the basis of its physical or chemical properties, or it can be the RFID applied to the product and/or the package. It can also be a serial number embedded in an overt or covert tag. In fact, a combination of these fingerprinting methods can also be used to improve authentication accuracy and resistance to the threat of cloning. In this case, the reference library must store the correlation of the set of data used to identify the package and/or the product uniquely.

2) **Reference library created by a commercial third party, which works with the manufacturer**. In this case, the reference library is created by a third party, which works with the manufacturer to insert its own tags. The tag is applied to the product after the manufacturing process. As a consequence, it is not an intrinsic property of the

product. The difference with the previous case is that a correlation between the tag identifier and the product must be done before the product is distributed on the market. This can increase the risk of cloning or removal of the tag. The advantage is that the manufacturer does not need to invest in technology if it lacks skills, competences or economic capabilities (e.g. because it is a small company with a limited budget), as the commercial third party will perform this activity.

3) **Reference library created by another third party**. In this case, the reference library is created by another party different from the manufacturer, even if it may collaborate with the manufacturer. For example, the third party can be a public body that collects information from different manufacturers with the aim of helping competent authorities detect non-compliant products on the basis of specific features.

Law enforcement authorities in particular might have direct access to information when they have suspicious products in front of them in the course of their front-line activities in customs areas and the marketplace. Through scanning or reading codes or other technologies placed on the product or its packaging, an application may submit the results stored in the reference library. In principle, this functionality might also be extended to external users of the reference library, such as enterprises acting in the supply chain that need to verify the authenticity and details of goods they are dealing with, as well as to private consumers at a point of sale. Through appropriate technical solutions based on interoperability between databases, the reference library might be connected to other similar repositories available on the market (e.g. GS1 database for barcodes); it might also host reference libraries created by manufacturers, in order to integrate the reference library accessible to users.

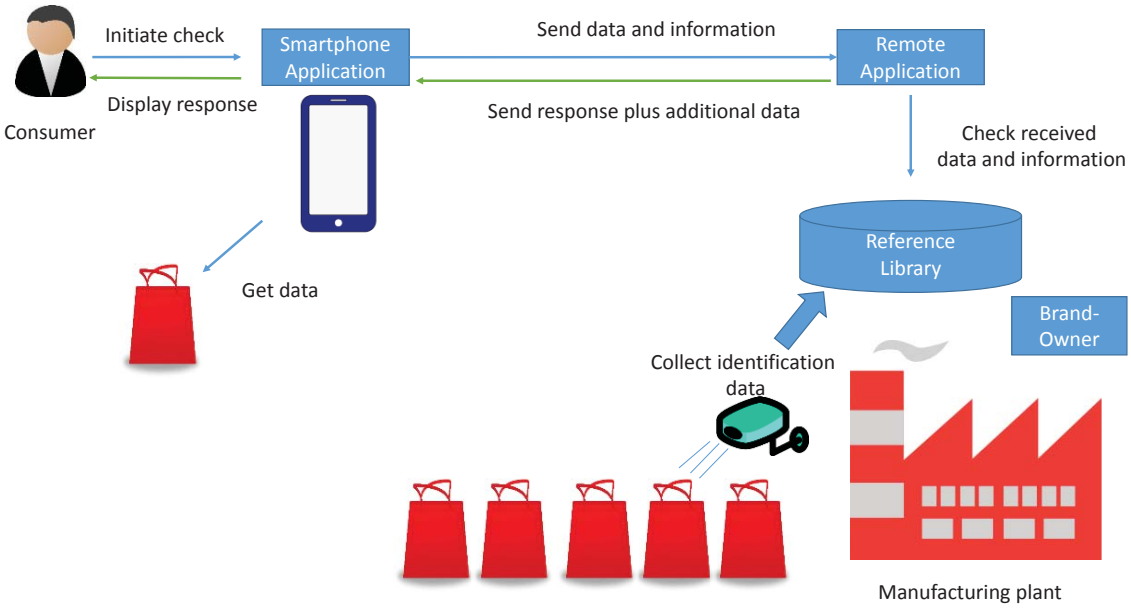
Reference library created by a manufacturer during the manufacturing process

In this case, the manufacturer collects the data to identify the goods in the supply chain or manufacturing process itself. The data can be defined and extracted using different authentication technologies. For example, it can be the specific signature of the paper of a packet of cigarettes (taken with an image) or it can be the identifier of an RFID embedded in the product.

The choice of the serialisation and authentication technology is really dependent on many factors: the type of goods, the impact of the authentication technology in the manufacturing process, the associated costs and so on. For many consumer goods, barcodes, QR codes or simple overt/covert technologies can be used, while more sophisticated and expensive goods can use RFID or more complex authentication technologies.

The goal is to collect and store identification and authentication information, which can be correlated with the data extracted by a smartphone in the field. This means that the data generation and collection process in the manufacturing plant must be designed together with the definition of the application in the smartphone or the related protocol.

A pictorial description of the process is provided below:



Supply chain information, such as the tracking and tracing of data, can also be used for this purpose if the manufacturer so desires. In this case, we must distinguish between closed-loop track and trace supply chains.

- A **closed-loop** supply chain is when the manufacturer, retailer and distributor are the same entity and the tracked goods are controlled by the same business entity (either directly or indirectly).

- An **open-loop** supply chain, meanwhile, is where the tracked goods can be distributed to different business entities, each of them equipped with its own back end. This difference is quite relevant to supporting the empowerment concept because in closed-loop, the ICT infrastructure is not designed to share information on the tracked goods with external entities. In open-loop, the extension to the end user is relatively straightforward and the associated costs are similar to the implementation of an Android application and connected to a remote back-end infrastructure (e.g. a cloud infrastructure).

Another aspect to be considered for the development of an empowerment solution is related to information sharing among the different back-end systems, which store the tracking information on the goods. The back-end systems should be capable of exchanging information with similar data formats. In addition, security and access control solutions should be developed to protect sensitive data, but also to guarantee access to the end users or the empowerment back-end systems, which are responsible for matching the information collected by end users. All these factors contribute to the overall cost of the empowerment solution.

The authentication information can be collected not only on the goods itself but also on the packages, which store the goods in a recursive way. In other words, the packages containing the goods can be authenticated as well. Recursive means that this process can be repeated for the larger packages storing the smaller packages. In this way, the user can trace the goods better.

An example of this technique is CODENTIFY, developed by the Digital Coding & Tracking Association, which represents some of the world's largest manufacturers of tobacco products. CODENTIFY can support:

- tracking and tracing — enabling the electronic monitoring of products as they move through the supply chain and the tracing backwards of their journey history to identify potential points of diversion;

- product authentication — enabling anyone, anytime, anywhere to immediately verify the authenticity of a product using widely available technologies, such as a mobile phone or the internet;

- digital tax verification — enabling governments to verify and control online the volume of products manufactured and so calculate the commensurate amount of excise and other taxes due.

In the pharmaceutical sector, a similar serialisation and tracking system is going to be set up under Commission Delegated Regulation (EU) 2016/161 of 2 October 2015, which was published, after scrutiny by the European Parliament and the Council, on 9 February 2016. The Delegated Regulation, and the new medicine verification system it lays down, will apply as of 9 February 2019.

This new system is based on a unique identifier, defined as a 2-D Data-Matrix code, developed to ISO standards (GS1).

The key data elements are:

- product code (14-digit)

- randomised unique serial number

- expiry date

- batch number

- (national reimbursement number or other national number (where necessary)).

The serialisation is based on a random number. The validity check (i.e. verification) of the serial number will be done at the point of dispensing (e.g. the pharmacist) by using a central cloud system, which stores and updates the status of the tracked pharmaceutical products. The cloud system will be called EMVO — European Medicine Verification Organisation, responsible for the operation of the European hub.

A Swedish pilot project (designed and deployed in 2009/2010) was implemented successfully to high levels of satisfaction from the stakeholders involved (e.g. pharmacists and wholesalers).

A German pilot project securPharm was implemented successfully. Coding is written in the Data Matrix code in accordance with ISO/IEC 16022. After an operating time of more than three years, the securPharm project is well on its way. The stakeholder associations have

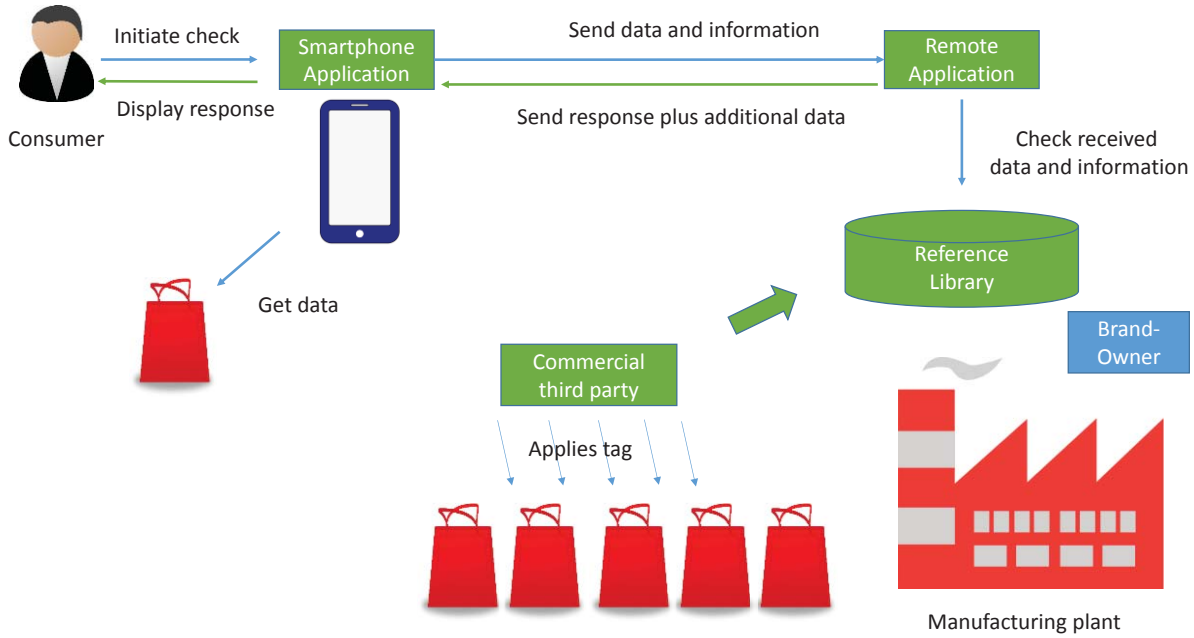
started a system for the verification of pharmaceuticals that meets the requirements of the EU Falsified Medicines Directive and works under real-life conditions.

Another example where the intrinsic features of a product taken during the manufacturing process are used to empower the user is the system developed by the electronics maker NEC. It has developed an authentication system that compares images taken with a smartphone with those in a cloud-based database. Images of the authentic product from the manufacturer would need to be registered beforehand. As described in the report, this can be applied to the retail sector or any other product, which can be identified through augmented visual inspection. NEC stated that the technology is currently in the testing phase and the firm plans to release a commercial version in 2015, but at the time of drafting this report (January 2017), no commercial versions are still available.

Reference library created by a third party working with the manufacturer

In this case, a commercial third party that has developed a technology for authentication or track and trace, works together with the manufacturer to apply identifier tags to the goods during the manufacturing process or after the manufacturing process and prior to distribution. This case is different from the previous one, because the authentication information (e.g. overt tag) is not an intrinsic part of the product but it is applied to it. Note that the identifier tag could be part of the supply chain integrity process and similar considerations of the open and closed supply chain also apply to this case.

The overall workflow is described below. The commercial third party applies its own identification and authentication tags to the goods after they are produced at the manufacturing plant and before distribution to the market. The identification and authentication data is then stored in the reference library. Usually, the commercial third party has also developed a remote application and smartphone application to implement the overall workflow.



This technique is more appropriate for small companies that cannot afford the implementation of more expensive techniques and for the types of product where a tag cannot be inserted during the manufacturing process.

Another advantage of this technique is that the commercial third party, which has developed the technology, can create a single smartphone application, a single communication protocol and a single reference library for different categories of goods and brands, thus facilitating the checks by the user.

Reference library created by a third party other than manufacturers

In this technique, the reference library is created by a third party on the basis of reported information on non-compliant products. For example, a consumer association or law enforcement agency can build a knowledge-based system, which includes a reference library to indicate the most common cases of non-compliance. A user can check the validity of goods by sending relevant authentication data to a remote application linked to a reference library. The response from the remote application will give a probability to the user that the identity of the product is what it claims to be. In a similar approach, the remote application can provide data or digital information (e.g. images) to help the user identify the goods.

The advantage of such reference library is that it can include many different types of goods from different brands and it can process and receive input from many different categories of stakeholders. Another important advantage of implementing the reference library through a public body is that it becomes a central point of contact across Europe and for different private organisations. In this way, the standardisation of the reference library formats and input data processes is easier to achieve. The main disadvantage of this type of option is that the information stored in the reference library may be inaccurate, incomplete or not up to date.

Costs analysis

The costs associated with the design and deployments of technological solutions to empower the smartphone user are structured in the following way:

1) **Design and implementation of the mobile application**. This is the cost of developing a mobile application that can be installed on a smartphone. The application must be designed to interact with the smartphone's sensors, which are needed to collect the requested data, such as images, NFC readings, track and trace information and GNSS position.

2) **Reference library**. This is the cost of developing the reference library, which is used to compare the identification data collected in the field with the database of identification data stored before the goods are distributed on the market. These costs can also be based on different elements: a) the implementation of the means to collect data in the manufacturing or distribution processes, b) the creation of a database to store the reference data, c) the development of the remote application to make available and manage the reference library and d) the publication of the reference library on the web to be accessible by the mobile application. Other associated costs, such as the development of standards or protocols, are described in the other items of this numbered list.

3) **Development of standards**. This is the cost of developing standards for: a) the definition of the protocol between the smartphone and the reference library, b) the format of the data stored in the reference library, c) the serialisation coding to identify the goods in the reference library, d) the back-end systems used to support the supply chain. These should be interoperable and use a similar data format (e.g. based on an OASIS standard).

4) **Open-loop v closed-loop supply chain**. If the empowerment solution has to be built on a closed-loop chain, extensive and costly modifications to the supply chain will be required. This is not the case for an open-loop chain, which is designed to support different entities. As a consequence, one relevant cost can be associated with the integration of the ICT systems used to support the supply chain with the reference library. Note that the integration between the two systems does not need to be complete.

5) **Privacy, security and access control**. This item includes various elements, which address the privacy and security aspects of the empowerment concept. Privacy aspects can be quite important for users. If they are not addressed, citizens could fear that their personal data is at risk when sending data about the goods. In addition, different categories of user (e.g. law enforcers, manufacturers) can have different access to the reference library data. For example, law enforcers can also use data based on covert features rather than on overt features. In addition, access control functions may be required to ensure that only the reference library can be accessed by the web and not other data systems, which store sensitive information.

Authentication technologies

This section briefly describes authentication technologies, which can be used to identify and authenticate the goods in the field against a reference library and which can be supported by the capabilities of the smartphone.

Numeric Identifier/One-dimensional barcode

This was the first technique used to serialise products and, with this information, to track and trace goods in a supply or distribution chain. The first implementation was the Universal Product Code (UPC), which has been a dominant barcode standard in North America since it was established in the 1970s. The UPC has evolved into various versions, for example, UPC-A and UPC-E.

At international level, the Global Trade Item Number (GTIN) is an identification number that may be encoded in UPC-A, UPC-E, EAN-8 and EAN-13 barcodes, as well as other barcodes in the GS1 system.

Numeric identifiers based on barcodes have been used extensively for many years around the world, and they remain the most used track and trace or identification technique.

As extensive literature is available on this technique, we refer the reader to related references.

There are various examples of the smartphone's ability to read and analyse barcodes, therefore this can be considered a very mature technology.

QR codes and other two-dimensional barcodes

The QR (Quick Response) code is a two-dimensional (2-D) barcode.

In comparison to one-dimensional barcodes, the QR code is able to store more information in the same space. QR codes are designed to be read and understood (decoded) by computers, using machine-vision systems consisting of optical laser scanners or cameras and barcode-interpreting software.

Unlike 1-D barcodes, the QR code is a 2-D matrix code that conveys information not by the size and position of bars and spaces in a single (horizontal) dimension, but by the arrangement of its light and dark elements, called 'modules'.

The QR code has a number of advantages in comparison to a one-dimensional barcode. The main advantage is the high-capacity data storage, as a QR code can store hundreds of times more data than a one-dimensional barcode. The QR code is also more robust against curved surfaces or errors due to marks or spots.

There are various examples for the use of the smartphone to read and analyse QR codes, therefore this can be considered a very mature technology.

Physical fingerprint technology on visible spectrum

Physical fingerprints use the specific characteristics of the base material or the packaging. For instance, paper, cardboard, metal and plastic are made up of tiny fibers in random orientations, which are naturally unique in their structure. According to this, every package has its own microscopic structure, its own fingerprint, which cannot be rebuilt and cannot be removed. For authentication to be secure, it is important to use this technology directly on the base material of the smallest packaging available to users; fingerprints of labels, stickers or banderoles will verify the attached strip but not the packaging onto which these are applied. This includes any physical fingerprint technology regardless of the medium (i.e. material) where it is applied: holograms, paper, inks, security threads and regardless of whether it is overt or covert.

For greater security, it is possible to combine a printed unique identifier as the visible element and a physical fingerprint of a package as the invisible element of a security feature. On a mass production line, each package can be scanned and its unique fingerprint can be recorded and linked to its specific unique identifier. When checking, regardless of whether a package is genuine or not, the system compares the physical fingerprint on the base material to the digital fingerprint embedded in (or retrieved from) the unique identifier.

The use of the smartphone to read and analyse physical fingerprint technology is a recent development, but it is supported by an increasing number of companies thanks to the smartphone's higher-resolution camera.

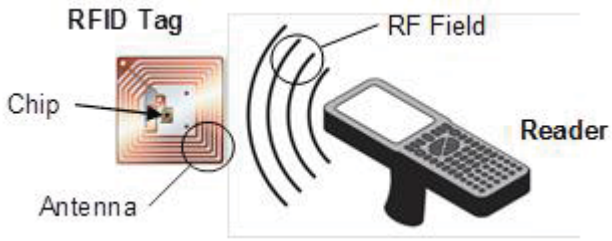
The techniques based on the unique fingerprinting of goods are more accurate and robust against cloning attacks because it is quite difficult for other businesses to reproduce exactly the unique fingerprint of goods. However, it may not be possible to obtain fingerprints of all the different materials using the smartphone features. Furthermore, they could be very

relevant in the context of identifying counterfeited products but they seem much less relevant in the more general context of compliance with EU harmonisation legislation.

Radio Frequency Identifier (RFID)

An RFID tag is basically a device composed of a small chip connected to a coil. The chip is essentially a state machine with a memory, providing limited storage and computational capabilities. To communicate with such devices, an RFID tag reader has to be used. The reader emits a radio frequency (RF) field that by induction through the coil powers the chip. At the same time, the reader itself modulates the field to code commands sent to the chip, which in turn replies to the reader modulating the same field, so establishing a bi-directional communication.

Figure 14-4: Radio Frequency ID



The main purpose of an RFID tag is to memorise data and release it when queried by a reader; usually, at least a unique identifier (ID) is stored in the chip. According to this peculiarity, one of their main applications is item labelling.

RFID tags can be stuck onto or embedded in items to track their position, reading the tags at different places, and to receive information about them easily, storing specific item-data in each applied tag. The information gathered from a tag can also be related to additional item data stored in a back-end system.

A smartphone with an NFC reader can read some types of RFIDs but not all of them, even if various RFID readers connected to USBs are available on the market. Passive RFID tags primarily operate at three frequency ranges:

- low frequency (LF) 125-134 kHz
- high frequency (HF)13.56 MHz
- ultra high frequency (UHF) 856 MHz to 960 MHz.

Near-field communication devices operate at the same frequency (13.56 MHz) as HF RFID readers and tags. The standards and protocols of the NFC format are based on RFID standards outlined in ISO/IEC 14443, and the basis for parts of ISO/IEC 18092.

The RFID can be inserted in the product if the type of product and its material composition allows. For example, an RFID can be inserted in the fabric of a luxury bag, but it is more difficult to insert an RFID in a semi-conductor chip. In other words, RFID technology can be used both by the manufacturer in the manufacturing process or applied to the product in the distribution phase using a tag.

Analysis of the different techniques

The advantage of the barcode or QR code is its cost-effectiveness and simplicity. It can be applied to the material using special inks or as a tag. The clearest disadvantage is that it is clonable, as it is relatively easy to reproduce a barcode or QR code. The threat of cloning can be mitigated through the empowerment solution itself: the smartphone can send the identifier of the barcode or QR code to a remote application attached to the reference library, which can check the presence of duplicated identifiers and duly inform the user.

The advantage of the barcode or QR code and other overt or covert techniques in comparison to the RFID-based technique is the cost of the token itself, even if the cost of RFID has decreased considerably in recent times. Barcode labels cost less than USD 0.02 per label, while RFID tags are at least three times more expensive per tag. The precise cost of RFID tags varies, depending on the underlying RFID technology, but active RFID tags are usually priced between USD 20 and USD 70, whereas passive RFID tags are between USD 0.07 and USD 0.20.

The disadvantages of the barcode and QR code in comparison to RFID are that a direct line of sight is requested between the reader and the code. In addition, the presence of visible light is needed with nothing obstructing the light path between them. RFID tags can be read at a distance; moreover, UHF and BAP RFID can be read at even greater distances and can be scanned much faster.

Regarding the different categories of users, the techniques are mostly clear and easy to understand, even if they can be complemented to increase the security of each specific class. In other words, the empowerment technique can be implemented in such a way that the smartphone provides specific data to the average citizen, and other data to manufacturers, retailers and law enforcers. For example, covert data could be used for manufacturers and law enforcers while only overt data is used for average citizens and retailers.

The analysis of the different techniques is shown in the next table:

Metrics	**Law Enforcers**	**Manufacturers**	**Enterprises (especially SMEs)**
Requested resources	**Barcode and QR code** Low, because a smartphone is already equipped with NFC, a high-resolution camera and communication systems. **RFID** Low, similar to barcode and QR code if the smartphone is equipped with an RFID reader, otherwise High.	**Barcode and QR code** Low, if the solution is based on an extension of an existing **open-loop** track and trace infrastructure. Medium, if the solution is based on an extension of an existing **closed-loop** track and trace infrastructure. High/Very high, if a new track and trace infrastructure must be	**Barcode and QR code** Low, because a smartphone is already equipped with NFC, a high-resolution camera and communication systems. **RFID** Low, similar to barcode and QR code if the smartphone is equipped with an RFID reader, otherwise High.

		created. **RFID** Same considerations as barcode and QR code with the additional cost of RFID components.	
Need for adaptation to organisations and existing processes	**Barcode and QR code** Low, because the checking of the barcode or QR code can be easily automated. **RFID** Medium, because the procedure is very simple for RFID-enabled smartphones, but these specific models must be purchased as they may not be available in the mass consumer market.	**Barcode and QR code** Low, if the solution is based on an extension of an existing **open-loop** track and trace infrastructure. Medium, if the solution is based on an extension of an existing **closed-loop** track and trace infrastructure High/Very high, if a new track and trace infrastructure must be created. **RFID** Same considerations as barcode and QR code with the additional cost of RFID components.	**Barcode and QR code** Low, because the checking of the barcode or QR code can be easily automated. **RFID** Medium, because the procedure is very simple for RFID-enabled smartphones, but these models must be purchased.
Requested level of training	**Barcode and QR code** Low, because the checking of the barcode or QR code can be easily automated. **RFID** Low, because the procedure is very simple for RFID-enabled smartphones.	**Barcode and QR code** Low, because the checking of the barcode or QR code can be easily automated. **RFID** Low, because the procedure is very simple for RFID-enabled smartphones.	**Barcode and QR code** Low, because the checking of the barcode or QR code can be easily automated. **RFID** Low, because the procedure is very simple for RFID-enabled smartphones.
Robustness and adaptability to environmental conditions	**Barcode and QR code** High, because the checking of the barcode or QR code has been	**Barcode and QR code** High, because the checking of the barcode or QR code has been	**Barcode and QR code** High, because the checking of the barcode or QR code has been used for years in many different

	used for years in many different environmental conditions and manufacturers are able to produce environmentally robust tags and labels. **RFID** High, because the RFID is not or is slightly impacted by rain or darkness, as it uses low-frequency radio communication.	used for years in many different environmental conditions and manufacturers are able to produce environmentally robust tags and labels. **RFID** High, because the RFID is not or is slightly impacted by rain or darkness, as it uses low-frequency radio communication.	environmental conditions and manufacturers are able to produce environmentally robust tags and labels. **RFID** High, because the RFID is not or is slightly impacted by rain or darkness, as it uses low-frequency radio communication.
Flexibility to support multiple applications	**General** As described in the rest of the report, it is possible that these techniques may be implemented using different applications and slightly different standards. This is the current situation at the time of writing this report even if current activities, such as the WCO and the IPM Connected program, can mitigate this issue. At least, this is the case for barcode and QR code based techniques. This issue is particularly relevant for law enforcers rather than other types of customers, who have to deal with a specific set of products. **Barcode and QR code** Medium, because there are currently many applications for checking barcode and QR code. Current initiatives, such as IPM Connected, can mitigate this issue (then the Medium level).	**General** The manufacturer will likely use a specific technique and implementation for their products. As a consequence, the multi-use capability will be high because there is a single technique. **Barcode and QR code** High, because there will be only one implementation of the technique. **RFID** High, because there will be only one implementation of the technique. .	**General** An enterprise is usually interested only in a specific set of products. In other words, the multi-use capability is less requested than the law enforcer, but it is still needed for a set of products. As a consequence, a Medium level is suggested for all the techniques. **Barcode and QR code** Medium. **RFID** Medium.

	RFID Low, as similar considerations for barcode and QR code apply, with the difference that as yet, IPM Connected and similar initiatives do not address RFID.		
Upgrade capability	**Barcode and QR code** High, unless the barcode or QR code structure must be changed. **RFID** High, because RFID technology is quite stable, at least for the physical layer.	**Barcode and QR code** High, unless the barcode or QR code structure must be changed. **RFID** High, because RFID technology is quite stable, at least for the physical layer.	**Barcode and QR code** High, unless the barcode or QR code structure must be changed. **RFID** High, because RFID technology is quite stable, at least for the physical layer.
Original set and deployment cost (CAPEX)	**Barcode and QR code** Medium. The smartphone must be purchased but the technology is already implemented. **RFID** Medium/High. A smartphone with an RFID reader must be purchased.	**Barcode and QR code** Medium. The smartphone must be purchased but the technology is already implemented. **RFID** Medium/High. A smartphone with an RFID reader must be purchased.	**Barcode and QR code** Medium. The smartphone must be purchased but the technology is already implemented. **RFID** Medium/High. A smartphone with an RFID reader must be purchased.
Operational Cost (OPEX)	**Barcode and QR code** Low. **RFID** Low.	**Barcode and QR code** Low. **RFID** Low.	**Barcode and QR code** Low. **RFID** Low.
Market and standardisation support	**Barcode and QR code** Medium. While there are many applications on the market, a common standard must still be defined even if there are available	**Barcode and QR code** High. Many manufacturers have built and deployed their own version of the technique.	**Barcode and QR code** Medium. While there are many applications on the market, a common standard must still be defined even if there are available drafts.

	drafts. **RFID** Medium. While there are many applications on the market, a common standard must still be defined even if there are available drafts.	**RFID** Medium/High. Many manufacturers have built and deployed their own version of the technique even if it less deployed than barcode and QR code because of the costs.	**RFID** Medium. While there are many applications on the market, a common standard must still be defined even if there are available drafts.
Interoperability with existing open tools	**General** Law enforcers can use existing activities, such as IPM Connected, to bridge the techniques to ICT systems already deployed. For techniques already deployed, the level of interoperability can be high, while it is low for techniques that have limited deployment in the market. **Barcode and QR code** Medium **RFID** Low/Medium	**General** Manufacturers have usually designed and deployed track and trace solutions to support their production and distribution chain. Then, they have a high degree of interoperability because the techniques used are an evolution of the existing systems. **Barcode and QR code** Very High **RFID** Medium	**General** Enterprises must build up a new system in many cases, even if they already have distribution channels with suppliers. As a consequence, the degree of interoperability is less for the manufacturers but slightly higher for the law enforcers, at least for some techniques. **Barcode and QR code** Medium/High **RFID** Medium

Techniques using smartphones have now reached maturity and they can be both cost-effective and highly accurate in identifying and authenticating a product. These techniques can be applied by the manufacturer as part of the product itself, or they can be applied to the product depending on the feasibility of applying intrinsic features.

With its high-resolution camera and wireless connectivity, the smartphone also has the capability to support the various techniques.

One potential issue is the variety of technical solutions present on the market, which requires a standardisation effort to avoid complex validation procedures by the various categories of users, which may limit the validity of these techniques. For example, a law enforcer may be obliged to use many different smartphone applications for each technique or brand.

Issues and Challenges

Privacy aspects

This section addresses the problem of a consumer's privacy in the context of empowerment. This issue potentially impacts on only consumers, as the other categories will use empowerment techniques as part of their professional duties. By contrast, consumers may be rightfully worried that empowerment techniques could provide a remote application with their personal data when checking products.

Privacy aspects can be addressed easily, using the two privacy protection techniques that follow in the design of the application on the smartphone.

1. Application of anonymisation technology, before sending data to the remote application to check if goods comply. The term 'anonymisation' refers to the process to render the data sent to the remote application 'anonymous' as regards the consumer's identity. For example, the smartphone user's identity, or other identifying data (e.g. location), is removed from the set of transmitted data.

2. Use of informed consent. In this instance, the consumer accepts that the transmitted data contains personal information through informed consent, which is registered electronically on the smartphone and sent together with the application data.

More sophisticated Privacy Enhancing Technologies (PET) can be used to protect the privacy rights of citizens, but these technologies come at a cost. Furthermore, the economics related to the deployment of PET or more sophisticated forms of informed consent can undoubtedly be an obstacle to the deployment of empowerment techniques.

Market fragmentation

There are many empowerment technologies on the market. Such technologies can use the smartphone, which is today a consumer mass market device (and whose cost will decrease even further in the future), or other devices that are either simpler or more sophisticated.

One significant issue is the variety of techniques in the different domains and sectors, which can become a hurdle for the users that belong to the professional categories, such as law enforcers and retailers or distributors.

While manufacturers work in their specific sectors and may adopt only one or two empowerment techniques, law enforcers have to evaluate many different types of goods in their daily activities. The availability of many different empowerment techniques and applications may become a hindrance rather than an effective supporting tool, because law enforcers will have to use a separate technique for different types of goods and even different types of brands. It is easy to imagine that such an approach is impractical and may have a negative impact on the deployment of empowerment techniques in the law enforcer community and in other categories as well (e.g. retailers and distributors). Consumers citizen can also be adversely affected by the availability of empowerment techniques, but for this category, the adoption of these techniques is on a voluntary basis rather than required by their professional activities. Thus, it can be less relevant.

Actions must be taken to support law enforcers and retailers or distributors to overcome these issues. Various approaches are possible.

1) A common standard for identification and authentication is defined for brands belonging to the same sector or across different sectors. Then, applications are developed on the basis of this standard in such a way that a single application is able to evaluate goods of different brands in a specific sector. While this is not an easy task, there are already standardisation efforts in place, which can be a valid basis for further development (REF).

2) Foster a collaborative cooperation from law enforcement authorities, EU institutions, and industry associations to use a common reference library in the EU, so that convergence efforts are concentrated in one single library. If accompanied by (a) developments intended to enable law enforcers and manufacturers to use smartphones to access the information contained in the database securely; and (b) a standardisation process at EU level.

Training

The empowerment techniques presented in this section do require some basic level of training. Training and knowledge on how to use each empowerment technique are important elements in their successful deployment, as a lack of training can reduce accuracy in identifying goods. A lack of accuracy and the consequent frustration from users when using the techniques could lead very quickly to a complete rejection of the empowerment technique. Training should be provided by the companies (e.g. manufacturers) or technological implementers of the technique.

The operational effort needed to develop training practices for empowerment solutions can be considerable and it is preferable that the empowerment techniques develop automatic support mechanisms. For example, a wizard or an automated sequence of steps is implemented to guide the user in the proper acquisition of a product's data.

4.3. Data carrier technologies and architectures

4.3.1. General technologies for automatic identification (AutoID)

Automatic identification (also commonly referred to as "auto-ID") refers to the methods of automatically (i.e. without human involvement) identifying objects and determining their belonging to a certain type or class of objects or their individual identity that differs from all other objects. In addition, it often includes automatically collecting data about them ("automatic data capture").

Objects may include people, animals, goods and products in transit. Automatic identification of objects may use a characteristic or unique property of the object itself (like e.g. the voice or fingerprint of a human being) or of an affixed coding device (e.g. a label or tag), which encodes the object related data. The identification device is normally connected to a data processing or computer system for further processing and manipulation of the object data.

Technologies typically considered as part of auto-ID include barcodes, Radio Frequency Identification (RFID), smart cards, magnetic stripes, machine vision, biometrics, touch memory, optical character recognition (OCR), and voice recognition[67].

In recent years automatic identification procedures (Auto-ID) have been introduced in many service industries, purchasing and distribution logistics, industry, manufacturing companies and material flow systems.

Optical systems (Barcode and Data Matrix)

A **barcode** is a machine-readable, optical representation of data formed by combinations of high and low reflectance regions on the surface of an object according to a predetermined, geometrical pattern. Barcodes are read by optical laser scanning, i.e. by the different reflection of a laser beam from the dark (low reflectance) bars and light (high reflectance) gaps. Barcode scanners and interpretive software have become available on many devices including desktop printers and smartphones.

Barcodes may be distinguished according to the geometry of the optical data representation[68]: A linear or **one-dimensional (1D) barcode** is a binary code comprising a field or sequence of lines (bars) and gaps arranged in a parallel configuration. The data is represented by the varying widths and spacing within the sequence of wide and narrow bars and gaps and can be interpreted numerically and alphanumerically.

Most barcode systems identify only class of products, not individual items. The most widely used barcode is the EAN-13 (International Article Number, formerly named European Article Number) code. The EAN-13 uses 13 digits to code a combined country identifier, company identifier and item (or object) type number as well as a check digit. The UPC (Universal Product Code) from the USA represents a subset of the EAN code, and is therefore compatible with it. Other barcode systems in common use are Code Codabar, which is used for medical applications as well as fields with high safety requirements, Code 2/5 interleaved, Code 39 and GS1-128 (formerly named UCC/EAN-128).

Two-dimensional (2D) barcodes use geometric patterns in two dimensions, like e.g. rectangles, dots, or hexagons, to code information, so it can represent more data per unit area. A Data Matrix code is a two-dimensional matrix barcode consisting of dark and light "cells", little squares arranged in either a square or rectangular pattern that represent bits. The information to be encoded can be text or numeric data (see Figure 14-5). Compared to one-dimensional barcodes, they can represent more data per unit area. Usual data sizes range from a few bytes up to 1556 bytes. They need a scanning device capable of simultaneous reading in a vertical and a horizontal direction.

Figure 14-5: Illustration of ECC200 Data Matrix code

67 Agarwal, V.: Assessing the benefits of Auto-ID Technology in the Consumer Goods Industry. Cambridge University Auto-ID Centre Report, 2001. URL: http://cocoa.ethz.ch/downloads/2014/06/None_CAM-WH-003.pdf, Access: 2015/10/19.

68 Kato, H.; Tan, K.; Chai, D. (2010): Barcodes for Mobile Devices. Cambridge University Press, Cambridge a.o.

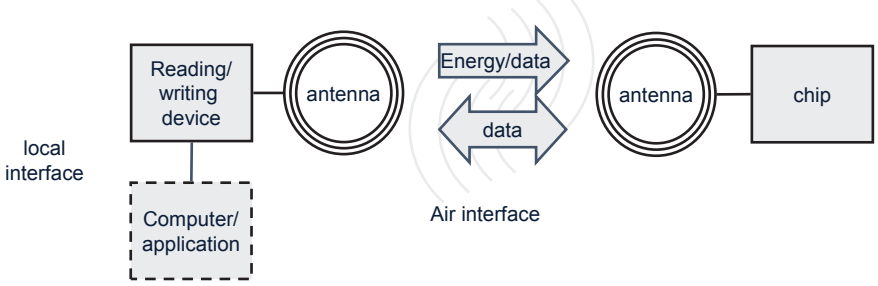
Radiofrequency-based systems (passive RFID in HF and UHF band)

In Radio Frequency Identification (RFID), an object is identified via an attached electronic device (Transponder, or tag) that uses radio frequency or magnetic field variations to communicate to a reading device.

First, transponders contain an integrated circuit or an electronic microchip for storage of data and processing data and modulating and demodulating a radio-frequency (RF) signal, collecting DC power from the incident reader signal. The tag information is stored in a non-volatile memory. Second, they contain a coupling element, such as a coiled antenna, used to communicate via radio frequency waves by receiving and transmitting the signals. The data capacities of RFID transponders range from a few bytes to several kilobytes. In addition, 1-bit transponders are used in electronic article surveillance, e.g. to protect goods in shops. Depending on their power supply, transponders may be either active or passive. Passive transponders obtain all their power from the interrogation signal of the reader. Conversely, active transponders incorporate a battery or a solar cell, which supplies all or part of the power for the operation of a microchip.

The reading device (transceiver, interrogator or reader), which may be a read or write/read device., consists of a radio frequency module, a control unit, and a coupling element to interrogate electronic tags via radio frequency waves for information stored on them. The readers can communicate their received data to the data processing subsystem via a fitted interface. Readers emit an interrogation signal, which forms an interrogation zone within which the transponders may be read. The size and geometry of the interrogation zone is a function of the transceiver and transponder characteristics. The general system configuration is presented in the following Figure 14-6:

Figure 14-6: General system configuration of RFID



Numerous different RFID systems and RFID transponders systems are available on the market. The technical parameters of these systems are often optimised for specific fields of application, e.g. industrial automation or access control. The technical requirements of different fields of application however often partially overlap, making clear distinction between different systems difficult at times.

One of the most important characteristic of an RFID system is its operating frequency, which is the frequency at which the reader transmits. The transmission frequency of the transponder is in most cases the same as the transmission frequency of the reader (load modulation, backscatter). However, the transponder's 'transmitting power' may be set several powers of ten lower than that of the reader. The different transmission frequencies are classified into the three basic ranges, LF (low frequency, 30–300 kHz), HF (high frequency)/RF radio frequency (3–30MHz) and UHF (ultra-high frequency, 300MHz–3 GHz)/microwave (>3 GHz). According to range RFID systems can be subdivided into close-coupling (0–1 cm), remote-coupling (0–1 m), and long-range (>1m) systems. Passive RFID transponders can be read at small to medium distances and active RFID tags at small to large distances. For more information on each range class, see Table 14-5:

Range class	Frequency range	Operating frequencies	Range	Data speed	Basic characteristics regulations
low frequency (LF)	30–300 kHz	0–135 kHz	~ 10 cm	Low	
high frequency / radio frequency (HF / RF)	3–30MHz	13.56 MHz	10 cm - 1 m	Low to moderate	most common frequency
ultra-high frequency (UHF)	300MHz–3 GHz	433 MHz	1-100 m	moderate	Active transponders
		865-868MHz in Europe 915MHz in the US	up to 6m	Moderate to high	ISM band Backscatter systems
microwave	>3 GHz	2.45 GHz 5.8 GHz 24.125 GHz	~ 100-300 m	high	

Table 14-5: RFID operating frequency classes

RFID transponders can be classified according to their possibility of writing data to the transponder. In non-writable transponders, the transponder's data record, usually a simple (serial) number, is incorporated when the chip is manufactured and cannot be altered thereafter.

In writable transponders, the reader device can write data to the transponder. Three main procedures are used to store the data: in passive RFID systems **EEPROMs** (electrically erasable programmable read-only memory) are dominant. Data stored in an EEPROM is retained for several years without a power supply. The energy required for writing to or reading from a transponder using EEPROM technology is transmitted by inductive coupling. The guaranteed number of write access operations to a memory address is typically around 105 cycles.

FRAMs (ferromagnetic random access memory) have recently been used in isolated cases. The read power consumption of FRAMs is lower than that of EEPROMs by a factor of 100 and the writing time is 1000 times lower. Over 1010 write cycles have been being achieved.

Particularly in active microwave systems, **SRAMs** (static random access memory) are used for data storage as well. They allow very rapid write cycles. However, data retention requires

an uninterruptible power supply from an auxiliary battery, as SRAM memory cells require a constant power supply to retain stored data. Therefore, transponders using this memory technology always have their own battery. Data transmission between reader and transponder employs either inductive coupling or the backscatter procedure (microwave). SRAM memory can be reprogrammed any number of times with high write speeds. However, the integral battery limits the temperature range of this transponder to 0–60 ◦C.

Further identification systems

Optical character recognition (OCR) uses special fonts with stylized characters so that they can be read automatically by machines. One application example is the registration of cheques in banking, where personal data, such as name and account number, is printed on the bottom line of a cheque in OCR type.

Advantages of OCR systems are the high density of information and the possibility of reading data visually. However, OCR systems have failed to become more universally applied because of their high price and the complicated readers that they require in comparison with other ID procedures.

In the context of identification systems, **biometrics** refers to all procedures that identify people by comparing unmistakable and individual physical characteristics. In practice, these are fingerprinting and hand printing procedures, voice identification and retina (or iris) identification. Voice identification converts the words spoken by an individual human being into a computer linked microphone to into digital signals, which are evaluated by the identification software in order to check the speech characteristics of the speaker for correspondence to an existing reference pattern. Biometrics is mostly suited to identifying human beings.

A **smart card** is an electronic data storage system, possibly with additional computing capacity (microprocessor card), which is normally incorporated into a plastic card the size of a credit card. Smart card systems are similar in characteristics and often considered a subclass of RFID systems. Their main difference from other RFID systems however is their small reading range due to contact based reading. Smart cards are placed in a reader, which makes a galvanic connection to the contact surfaces of the smart card using contact springs. Like a passive RFID transponder, the smart card is supplied with energy and a clock pulse from the reader via the contact surfaces. Data transfer between the reader and the card takes place using a bidirectional serial interface (I/O port). It is possible to differentiate between two basic types of smart card based upon their internal functionality: the memory card and the microprocessor card. In memory cards the memory is accessed using a sequential logic (state machine). Microprocessor cards contain a microprocessor connected to a segmented memory.

4.3.2. AutoID technologies

4.3.2.1. Comparison of the basic capabilities

The AutoID technologies differ in their basic characteristics, which makes them more suitable or less suitable for the intended purpose of providing unique identification of maritime

equipment. A comparison of the basic capabilities of the different auto-ID technologies, as included in Table 14-6, shows the particular suitability of either barcode or RFID technologies:

System parameters	1D Barcode	2D Barcode	OCR	Biometry	Voice recognition	Smart card	RFID systems
typical data quantity (bytes)	1–100	10-~5 k	1–100	–	–	16–64 k	16–64 k
data density	medium	medium	Low	High	High	Very high	Very high
machine readability	Good	Good	Good	Expensive	Expensive	Good	Good
readability by people	Limited	Limited	Simple	Difficult	Simple	Impossible	Impossible
influence of dirt/damp	high	high	Very high	–	–	Possible (contacts)	No influence
influence of (optical) covering	Total failure	Total failure	Total failure	Possible	–	–	No influence
influence of direction and position	Low	Low	Low	–	–	Unidirectional	No influence
degradation/wear	Limited	Limited	Limited	–	–	Contacts	No influence
purchase cost/reading electronics	Very low	Very low	Medium	Very high	Very high	Low	Medium
operating costs (e.g. printer)	Low	Low	Low	None	None	Medium (contacts)	None
unauthorized copying/modification	Slight	Slight	Slight	Impossible	Possible* (audio tape)	Impossible	Impossible
reading speed (including handling of data carrier)	Low ~4 s	Low ~4 s	Low ~3 s	Very low >5–10 s	Very low >5 s	Low ~4 s	Very fast ~0.5 s
maximum distance between data carrier and reader	0–50 cm	0–50 cm	<1 cm Scanner	Direct contact**	0–50 cm	Direct contact	HF. 0-1 m, UHF: 0–12m, 0-100 m (microwave, active systems)

* The danger of 'replay' can be reduced by selecting the text to be spoken using a random generator, because the text that must be spoken is not known in advance. ** This only applies for fingerprint ID. In the case of retina or iris evaluation direct contact is not necessary or possible.

Table 14-6: Comparison of different RFID systems showing their advantages and disadvantages[69]

Depending on their power supply, transponders may be either active or passive. Considering RFID systems, active transponders need to incorporate a battery or a solar cell, which supplies all or part of the power for the operation of a microchip, and need regular replacement (in case of battery) or at least regular check (in case of solar cells). Microwave systems have a significantly higher range than inductive systems, typically 2–15 m. However, in contrast to inductive systems, microwave systems require an additional backup battery. The transmission power of the reader is generally insufficient to supply enough power for the operation of the transponder.

4.3.2.2.Passive UHF-RFID

An Active Reader Passive Tag RFID system has an active reader, which transmits interrogator signals and also receives authentication replies from passive tags.

The required range of an application is dependent upon several factors:

69 Finkenzeller, K. (2010): RFID Handbook - Fundamentals and Applications in Contactless Smart Cards, Radio Frequency Identification and Near-Field Communication. Third Edition, Giesecke & Devrient GmbH, Munich, Germany, p. 7. Summary assessment (last line) added by authors of this report.

– The positional accuracy of the transponder.

– The minimum distance between several transponders in practical operation.

– The speed of the transponder in the interrogation zone of the reader.

Passive UHF-RFID transponders are produced and used in many different varieties, differing in many important properties. Some different properties of such transponders are listed in Table 14-7.

Aspect	**Options**
protection classes	IP66: Dust tight, Powerful water jets IP67: Dust tight, Immersion up to 1 m IP68: Dust tight, Immersion beyond 1 m IP69K: Dust tight, Powerful high temperature water jets
temperature resistance	Operating temperature: - 50°C up to 100°C Storage temperature: up to 240°C for 30s
materials	polyamide PVC PPS + epoxy PVC, OEM stainless steel fiberglass FR4 copper/polyimide (CU/PI) silicon poly-oxymethylene glass acrylonitrile butadiene styrene (abs) aluminium and polymer polypropylene
designs	disk disk sticker tag disk with hole disk with 2 holes screw dry inlay wet inlay smart card rod smart label glass rod key fob coin tag half lens form
dimensions	L/⌀: 2,6mm-126mm, H: 0,5mm-22mm L/⌀: 3,15mm, W: 13,3mm

Aspect	Options
mounting	self-adhesive magnetic screws or rivets zip-ties wire sticky foam
environment	readable in wet environments shock resistant resistant against chemicals screwable in metal

Table 14-7: alternative characteristics of transponders

Transponders with different properties may be chosen for different products o applications within the tagging of maritime equipment.

Transponders must be resistant against different environmental conditions. These conditions may be challenging or even haphazard. Protection Classification societies standardize against which environmental properties a transponder is safeguarded, so they will not destroy it or hinder its functional performance. More information on different tag protection Classification societies and the kind of protection they offer is provided in Table 14-8:

Protection classes			
IP66	Dust tight	Powerful water jets	can be installed in Ex zones 1, 2, 21 and 22
IP67	Dust tight	Immersion up to 1 m	suited for outdoor use can be used in Ex zones 0, 1, 2, 20, 21 and 22
IP68	Dust tight	Immersion beyond 1 m	suited for outdoor use
IP69K	Dust tight	Powerful high temperature water jets	suited for outdoor use

Table 14-8: Tag protection classes

Transponders belonging to different protection classes may be needed for different applications within the tagging of maritime equipment.

Standards

Relevant standards for UHF-RFID transponders have been issued by International Organization Standards (ISO) and the International Electrotechnical Committee (IEC).

(a) ISO/IEC 18000 is an international standard that describes a series of diverse RFID technologies, each using a unique frequency range. The standard consists of several different parts, under the general title Information technology — Radio frequency identification for item management. The various parts of ISO/IEC 18000 describe air interface communication at different frequencies in order to be able to utilize the

different physical behaviours. The various parts of ISO/IEC 18000 are developed by ISO/IEC JTC1 SC31, "Automatic Data Capture Techniques". The most important parts of this report are the following:

(b) ISO/IEC 18000 Part 1: Reference architecture and definition of parameters to be standardized.

(c) ISO/IEC 18000 Part 6: Parameters for air interface communications at 860 MHz to 960 MHz.

(d) ISO/IEC 18046 defines performance test methods.

(e) ISO/IEC 18047 in its corresponding parts conformance test methods for the various parts of ISO/IEC 18000.

Appropriate Carrier

The primary function of the transponder's carrier and housing is to ensure cohesion of the various components, such as antenna and chip. However, the use of certain materials may also protect against external influences and increase, for example, insulation from metal influences. In addition, the housing may consciously enlarge the transponder to achieve, for example, better capacities for assembly. The antenna is the largest transponder component and determines its size. Different transponder carrier forms are listed in the below table:

Carrier form	**description**
disks and coins	The transponder is housed in a round (ABS) injection moulded housing; Alternatively polystyrol or even epoxy resin may be used to achieve a wider operating temperature range. The diameter of disks/coins is ranging from a few millimetres to 10 cm. Usually contains a hole for a fastening screw in the centre.
glass housing	Used for identification of animals or further processing into other construction formats. Glass tubes contain a microchip mounted upon a carrier (PCB) and a chip capacitor to smooth the supply current obtained. The transponder coil incorporates wire of 0.03mm thickness wound onto a ferrite core. The internal components are embedded in a soft adhesive to achieve mechanical stability. Length of glass tubes normally in range 12–32mm
plastic housing	For applications involving particularly high mechanical demands. Plastic housings can easily be integrated into other products. Greater functional range than glass housings; ability to accept larger microchips and greater tolerance to mechanical vibrations.

Carrier form	description
inductively coupled transponders in metal surfaces	The transponder coil is wound in a ferrite pot core. The transponder chip is mounted on the reverse of the ferrite pot core and contacted with the transponder coil. In order to obtain sufficient mechanical stability, vibration and heat tolerance, transponder chip and ferrite pot core are cast into a PPS shell using epoxy resin.
smart labels	Paper-thin transponder format. The transponder coil is applied to a plastic foil of just 0.1mm thickness by screen printing or etching. The foil is often laminated using a layer of paper and its back is coated with adhesive. Smart labels are thin and flexible enough to be stuck to luggage, packages and goods of all types. They are normally supplied in the form of self-adhesive stickers on an endless roll.
coil-on-chip	Integration of the coil onto the chip is made possible by a special micro galvanic process that can take place on a normal CMOS wafer. The coil is placed directly onto the isolator of the silicon chip. Extreme miniaturisation of transponders is possible using coil-on-chip technology. The size of the entire transponder is just 3 x 3mm. The transponders are frequently embedded in a plastic shell and are among the smallest RFID transponders available.

Possible dimensions

The approximate dimensions of the different transponder carrier forms are compared in in the below table:

Carrier form	Dimensions (diameter x height or length x width x height)
disks and coins	diameter of disks/coins: few mm - 1 0 cm height of disks/coins: few mm – 1 cm
glass housing	length of glass tubes: 12–32mm diameter of glass tubes: 1-5 mm
plastic housing	Length, width: e.g. 12 x 6 mm Height: 3 mm

Carrier form	Dimensions (diameter x height or length x width x height)
inductively coupled transponders in metal surfaces	diameter of disks/coins: few mm height of disks/coins: less than 1 mm
smart labels	Length, width: a few cm each thickness of plastic foil: ~ 0.1mm
coil-on-chip	Length, width: ~3 x 3mm thickness of plastic foil: ~ 0.1mm

Permanent mounting options

Transponders of normal sizes can be mounted in several permanent or removable ways. The mounting options applicable to RFID transponders are compared in in the below table.

method	conditions	benefits
gluing	clean prepared surface	fast, cheap
riveting	sufficient area for receiving the transponder and the ability to bore holes	removal difficult
screws	sufficient area for receiving the transponder to the bore and the possibility of Holes and optionally introduction of threads must be given	easy disassembly removal impossible without tools
hooking	sufficient surface for receiving the transponder and the possibility for attachment appropriate holder must be given	flexible use multiple use of transponders
inserting	sufficient surface for receiving the transponder and the possibility for attachment a tab must be added	flexible use multiple use of transponders
magnetic fixing	sufficient space for accommodating the transponder as well as a magnetic Substrate must be added	flexible use multiple use of transponders

With respect to the durable lifelong usage of transponders on the product, a later implementation guideline could request for permanent mounting options.

Scenarios of counterfeiting

- Attacks on RFID transponders (cf. Figure 14-7) can occur due to the following reasons:[70]

70 Finkenzeller, K. (2010): RFID Handbook - Fundamentals and Applications in Contactless Smart Cards, Radio Frequency Identification and Near-Field Communication. Third Edition, Giesecke & Devrient GmbH, Munich, Germany, p. 215.

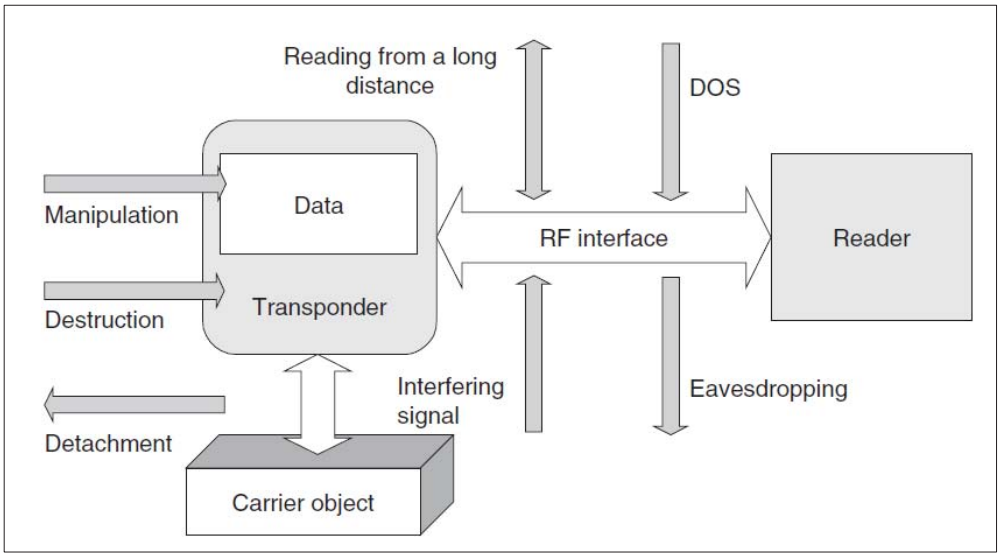
- Spying out: The attacker tries to get unauthorized access to information and data of the active and passive file.

- Deception: The attacker tries to feed incorrect information into the RFID system in order to deceive the active party, i.e. the RFID system operator, or the passive party, i.e. the user of the RFID system.

- Denial of service: This kind of attack affects the availability of functions of the RFID system.

- Protection of privacy: The attacker considers the RFID system to be a threat to her privacy and tries to protect herself with attacks on the RFID system.

Figure 14-7: Some attack options on RFID systems[71]



Often transponders are physically accessible to attackers and can be attacked by varying methods or with varying objectives. Potential attacks and countermeasures are listed in Table 14-9:

Type of attack	Description	Countermeasures
mechanical or chemical **destruction**	The antenna can be easily severed or cut off, for instance. The chip can be easily snapped or smashed.	protected or resistant carrier and mounting
skimming	Removal of a transponder in order to clone and/or modify data.	non-removable mounting of transponders
cloning of read-only transponders	The attacker can replace the PROM containing a	Protection by Cryptographic Measures:

71 Rikcha (2004): Risiken und Chancen des Einsatzes von RFID-Systemen, Studie des Bundesamtes für Sicherheit in der Informationstechnik in Zusammenarbeit mit dem Institut für Zukunftsstudien und Technologiebewertung (IZT) und der Eidgenössischen Materialprüfungs- und Forschungsanstalt (EMPA),November

Type of attack	Description	Countermeasures
	read-only transponder's serial number with a multi-programmable memory (EPROM) and program this serial number into the transponder clone. The transponder clone can send the serial number previously read out from the genuine transponder and thus pretend the presence of this genuine transponder to the reader. The reader is not able to determine whether the currently received serial number was sent by a genuine transponder or a transponder clone. The attacker does not have to have physical access to the transponder, but only needs to use a suitable reader in order to enter the read range of the transponder to be cloned, without being detected.	• Mutual Symmetrical Authentication between reader and transponder via three-pass mutual authentication, in which both participants in the communication check the other party's knowledge of a secret cryptologic key. • Authentication using Derived Keys: Each transponder is secured with a different cryptologic key. A key is calculated using a cryptologic algorithm based on the serial number of the transponder and a master key, and the transponder is thus initialised. Each transponder thus receives a key linked to its own ID number and the master key. Encrypted Data Transfer: During the writing or re-writing process, the transmission data (plain text) is transformed into cipher data (cipher text) using a secret key and a cryptographic algorithm. Without knowing the encryption algorithm and the secret key K a potential attacker is unable to interpret the recorded data. It is not possible to recreate the transmission data from the cipher data.
cloning re-writable transponders	If the memory sections of a transponder can be read or written without any restrictions, i.e. without requiring a password or key, an attacker can manipulate stored data for his personal advantage or produce copies of the attacked transponder by reading data and copying them to other transponders. Cloning of transponders can be efficiently prevented by using authentication and encrypted data transmission.	
eavesdropping	As RFID systems communicate with electromagnetic waves, systems can be generally intercepted with very basic means and the data replayed in order to imitate a genuine data carrier ('replay and fraud').	

Table 14-9: Potential attacks on RFID transponders and countermeasures

4.3.2.3.Data Matrix

Two-dimensional (2D) barcodes use geometric patterns in two dimensions, like e.g. rectangles, dots, or hexagons, to code information, so it can represent more data per unit area. The most relevant matrix barcodes are Aztec, Data Matrix, QR-Code and PDF 417, ECC200 and GS1 Data Matrix. An overview of different two-dimensional barcodes (or matrix barcodes) is given in Table 14-10:

2d barcode	Example symbol	Most relevant standard(s)	Description/comments
Aztec		ISO/IEC 24778:2008	Potential to use less space than other matrix barcodes as no surrounding blank "quiet zone" required
Data Matrix		ISO/IEC 16022:2006— Data Matrix bar code symbology specification	ability to encode fifty characters in a symbol readable at 2 or 3 mm² code can be read with only a 20% contrast ratio highly scalable (300 micro meters (laser etched) to 1 meter square)
QR-Code		ISO/IEC 18004	developed by Toyota subsidiary Denso Wave Can encode music, images, URLs, emails most frequently used type to scan with smartphones
PDF 417		ISO 15438	stacked linear barcode

Table 14-10: Overview of different two-dimensional barcodes

Aztec Code is a type of 2D barcode that was published by AIM, Inc. in 1997 and is public domain. Aztec code has the potential to save space, as it does not require a surrounding blank "quiet zone". The symbol is built on a square grid with a bulls-eye pattern at its centre for locating the code. Data is encoded in concentric square rings around the bulls-eye pattern. The central bulls-eye is 9×9 or 13×13 pixels, and one row of pixels around that encodes basic coding parameters, producing a "core" of 11×11 or 15×15 squares. Data is added in "layers", each one containing two rings of pixels, giving total sizes of 15×15, 19×19, 23×23, etc.

The corners of the core include orientation marks, allowing the code to be read if rotated or reflected. Decoding begins at the corner with three black pixels, and proceeds clockwise to the corners with two, one, and zero black pixels. The variable pixels in the central core encode the size, so it is not necessary to mark the boundary of the code with a blank "quiet zone", although some bar code readers require one.

Additional capabilities that differentiate ECC 200 symbols from the earlier standards include inverse reading symbols (light images on a dark background), a specification of the character set (via Extended Channel Interpretations), rectangular symbols and structured append (linking of up to 16 symbols to encode larger amounts of data).

QR-Code (Quick Response Code) was developed by Denso Wave in 1994. QR-Code is a quadratic matrix code including three corner marks, which can be read even if up to 30% of the mark has been destroyed. QR-Code's (177x177 elements, with error correction level „L") allows to code up to 2953 Byte or 4296 ASCII signs (with 7 Bit per sign).

PDF417 is a stacked linear barcode symbol format used in a variety of applications, primarily transport, identification cards, and inventory management. PDF stands for Portable Data File. The 417 signifies that each pattern in the code consists of 4 bars and spaces, and that each pattern is 17 units long. A symbol consists of 3 to 90 rows, each of which is like a small linear bar code. Each row includes a quiet zone (a mandatory minimum amount of white space before the bar code begins), a start pattern which identifies the format as PDF417 and a "row left" codeword containing information about the row (such as the row number and error correction level). These are followed by 1-30 data codewords: Codewords are a group of bars and spaces representing one or more numbers, letters, or other symbols. The row ends with a "row right" codeword with more information about the row, a stop pattern and another quiet zone.

PDF417 uses a base 929 encoding. Each codeword represents a number between 0 and 928 inclusive. The code words are represented by patterns of dark (bar) and light (space) regions. Each of these patterns contains four bars and four spaces (where the 4 in the name comes from). The total width is 17 times the width of the narrowest allowed vertical bar (the X dimension); this is where the 17 in the name comes from. Each pattern starts with a bar and ends with a space. All rows are of the same width; each row has the same number of code words. Of the 929 available codewords, 900 are used for data, and 29 for special functions. Three different encoding schemes are defined and can be mixed as necessary within a single symbol:

- Text: each codeword represents one or two characters.
- Byte: each group of 5 codewords represents 6 bytes.
- Numeric: groups of up to 15 codewords represent as many as 44 decimal digits.

GS1 Data Matrix is a two-dimensional (2D) matrix barcode which may be printed as a square or rectangular symbol made up of individual dots, cells or squares. This representation is an ordered grid of dark and light dots bordered by a finder pattern. The finder pattern is partly used to specify the orientation and structure of the symbol. The data is encoded using a series of dark or light dots based upon a pre-determined size. The size of these dots is known as the X-dimension.

ECC 200 is the newest version of Data Matrix and uses Reed-Solomon codes for error and erasure recovery. ECC stands for Error Checking and Correcting. ECC 200 allows the routine reconstruction of the entire encoded data string when the symbol has sustained 30% damage, assuming the matrix can still be accurately located. Data Matrix has an error rate of less than 1 in 10 million characters scanned.

Symbols have an even number of rows and an even number of columns. Most of the symbols are square with sizes from 10×10 to 144×144. Some symbols however are rectangular with sizes from 8×18 to 16×48 (even values only). All symbols utilizing the ECC 200 error

correction can be recognized by the upper right corner module being the same as the background colour (binary 0).

Standards

A comprehensive set of matrix barcode related standards has been issued by following standardization bodies the American National Standards Institute (ANSI), International Organization Standards (ISO) and the International Electrotechnical Committee (IEC).

The most relevant standards for Data Matrix barcodes are listed in Table 14-11:

standard	**Topic, description**
ANSI MH10.8.6	Bar Codes and Two-Dimensional (2D) Symbols for Product Packaging
ANSI X12.3	Data Element Dictionary
ISO/IEC 16022:2006	Data Matrix bar code symbology specification
ISO/IEC 15415	Information Technology – Automatic Identification and Data Capture Techniques – Bar Code Print Quality Test Specification – Two-Dimensional Symbols (2-D Print Quality Standard)
ISO/IEC 15416	Information Technology – Automatic Identification and Data Capture Techniques - Bar Code Print Quality Test Specification – Linear Symbols
ISO/IEC 15418:2009	Information Technology - Automatic Identification and Data Capture Techniques - Symbol Data Format Semantics (GS1 Application Identifiers and ASC MH10 Data Identifiers and maintenance)
ISO/IEC 15424:2008	Information Technology - Automatic Identification and Data Capture Techniques - Data Carrier Identifiers (including Symbology Identifiers) [IDs for distinguishing different bar code types]
ISO/IEC 15434:2006	Information Technology – Automatic Identification and Data Capture Techniques - Syntax for high-capacity ADC media (format of data transferred from scanner to software, etc.)
ISO/IEC 15438	Information Technology - Automatic Identification and Data Capture Techniques - Bar Code Symbology Specification – PDF417
ISO/IEC 15459	Information Technology - Automatic Identification and Data Capture Techniques - Unique Identifiers
ISO/IEC 16022:2006	Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification
ISO/IEC 16388	Information Technology - Automatic Identification and Data Capture Techniques - Bar Code Symbology Specification – Code 39
MHIA MH10.8.1	Linear Bar Code and Two-Dimensional Symbols Used in Shipping, Receiving, and Transport Applications
MHIA MH10.8.2	Data Application Identifier Standard

standard	Topic, description
GS1 Data Matrix Guideline	Overview and technical introduction to the use of GS1 Data Matrix. Release 2.2.1, Ratified, July 2015

Table 14-11: relevant standards for Data Matrix barcode

Appropriate Carrier and placement of the mark

In the most general terms, it is required that a Data Matrix applied to an object fulfils the following minimal conditions[72]:

- It remains readable throughout the object's normal life cycle.
- It withstands all environmental conditions to which the object will be exposed under normal operating conditions.
- It does not damage or detriment the functional performance, reliability, or durability of the object.

These minimal conditions should guide the selection of appropriate carriers for the Data Matrix barcodes. In terms of the carrier of the mark, the most important distinction is between non-intrusive marking and intrusive marking.

Non-intrusive marking methods add material to the surface of the item. These material additions can be applied either directly, e.g. by stenciling, laser bonding, or direct ink jet, or indirectly in form of a label or data plate. An intrusive marking method either deforms or removes material from the surface of the item. Methods include dot peening, stamping, abrading, scribing, or etching.

Generally, non-intrusive marking methods should be applied, unless intrusive marking is specifically authorized by quality assurance, safety, and engineering competencies of the relevant program. Often, labelling will be the easiest and cheapest method to implement. However, to determine the best marking solution for a specific type of equipment, many factors about the item to be marked should be considered. These include the function the item has to fulfil and the environment in which the item is stored or operated, the available marking area, material type, colour and mechanical properties of the material (like hardness, surface roughness/finish or surface thickness).

Preliminary advice regarding the data carrier will be included in the preliminary conclusions on data readers.

Placement of the Mark: Where the mark is placed on the item strongly influences the mark's durability and usefulness. Therefore, when determining where to place the mark, many

72 Compare for the analogous minimal requirements set up by: Department of the Navy: Item Unique Identification (Iuid) Marking Guide: Applying Data Matrix Identification Symbols to Legacy Parts.

aspects should be considered. Some useful general advice for placement of marks may be given as follows[73]:

- Apply marks in protected areas, when possible.
- Apply marks on flat areas when possible.
- The mark should be readable when the marked item is in-service.
- The mark should be readable when the marked item is stowed.
- Multiple identical marks can be applied to the same item.

Unless directed to the contrary by the technical authority, marks/labels should not be placed on the following item parts or surfaces:

- On components or pieces authorized to be replaced during field maintenance.
- Over vents and/or air intakes.
- Over other information.
- Covering windows, view ports, access ports, or fastener holes.
- Over seams between separable pieces of the item.
- In direct air streams (for example, leading edge of wings, helicopter rotors, exposed portions of turbine blades, and so forth).
- On sealing surfaces.
- On wearing surfaces.
- Near high heat sources.
- Over lenses, optics, or sensors.
- On surfaces with dimensional tolerance requirements.
- On precision cleaned parts in hermetically sealed packaging.

Other placement considerations become important in specialized circumstances, such as when marking curved, rough, or shiny surfaces or marking items that are sensitive to electrostatic discharge. Many placement considerations stem from a technical understanding of how 2D barcode readers (scanners) decode symbols as well as understanding efforts taken to maximize the reliability of decoding the Data Matrix. For information about mark placement on curved, rough, or irregularly shaped items.

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73 Compare for the analogous advice for placement of marks in: Department of the Navy: Item Unique Identification (Iuid) Marking Guide: Applying Data Matrix Identification Symbols to Legacy Parts.

Scenarios of counterfeiting

Barcodes (in particular two-dimensional barcodes), when applied as labels, can be destroyed or detached from the object to be identified. When using labels, in contrast to direct part marking, the obstacles for reproducing unauthorized pirated copies of products are low, because counterfeiting of tags is simple.

The reading process itself can be seen as relatively unattractive for attacks. However, using backend IT systems for providing further information and making validation of possible codes and their conformity to the predefined code scheme could be of interest.

5. "IMPACTS DIGITAL COMPLIANCE OPTIONS"[74]

5.1. Introduction

This document is the final report for the evaluation of impact of the "Internal Market for Goods – Digital Compliance".

5.1.1. Study objectives

The main purpose of the study is to provide input for the Impact Assessment (IA) accompanying a new Enforcement and Compliance initiative with respect to the internal market for products.

The study aims to achieve this objective by collecting economic data, quantifying benefits/costs and measuring the possible impact of the preliminary options identified by the Commission. Qualitative information will be used to offer a comprehensive understanding of the potential impacts of the different policy options.

5.1.2. Overview of the tasks carried out

The table below provides an update on each of the tasks to be carried out as part of this contract and its current status.

Table 14-12: List of tasks carried out

Phase	Activity	Notes
Task 0 Inception phase	Task 0.1: Internal kick-off	
	Task 0.2: Kick-off meeting	
	Task 0.3: Scoping interviews	
	Task 0.4: EU Literature review	
	Task 0.5: Stakeholder identification	
	Task 0.6: Development of a conceptual impact model	Approved with inception report

74 Study, VVA, draft final report, April 2017.

	Task 0.7: Fine-tuning of the proposed methodology and drafting of inception report	Approved with inception report
	Task 0.8: Approval of the Inception Report	
Task 1 Data collection	Task 1.1: Literature review at the national level	Data collection in parallel with interviews of national stakeholders
	Task 1.2: On-line survey	Market surveillance authorities have either been interviewed or filled in the survey; 66 Notified Bodies have been contacted to fill in the questionnaire in writing. 10 notified bodies took part in the survey.
	Task 1.3: In-depth interviews at the national level	68 interviews completed
	Task 1.4: CATI survey	More than 1700 company interviews completed.
	Task 1.5: Interim Report	Approved
Task 2 Data analysis	Task 2.1 Creation of a single database for analysis	Updated with complete data
	Task 2.2 Cost–Benefit Analysis	
	Task 2.3 Competitiveness Analysis	
Task 3 Reporting	Task 3.1: Develop the baseline scenario	Updated with complete data
	Task 3.2: Conduct the assessment of potential option	Updated with complete data
	Task 3.4: Draft Final report & Final Report	Second revision completed
	Inception meeting	
	Interim meeting	
	Final meeting	

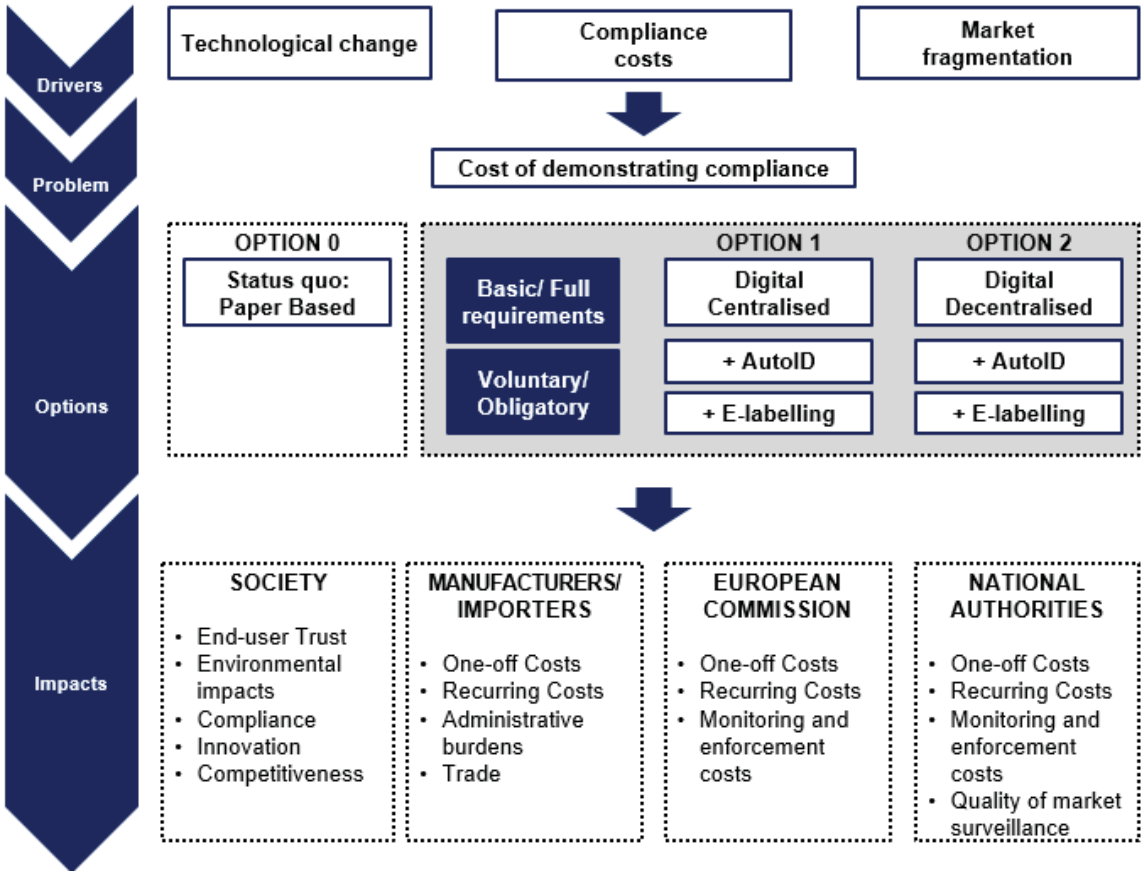
5.2. Methodological framework

5.2.1. Overall impact assessment framework

The figure below presents the conceptual impact assessment framework for this study which focuses on the costs of demonstrating compliance as the main problem to be tackled by the envisaged initiative. For instance, the cost of demonstrating compliance could include administrative burden for answering requests from market surveillance authorities regarding documents needed to demonstrate compliance; displaying (or publishing) the compliance information; updating compliance information for existing products; complying with different compliance procedures across Member States; IT costs; or general labour cost. It should be

emphasised that the costs referred to in this study do not include the actual compliance costs (e.g. product testing, etc). The study focuses instead on the cost of *demonstrating* that a product is compliant.

Figure 14-8: Impact assessment framework



As the figure indicates, the proposed digital compliance initiative aims to address three main problems:

1. Technological and product change;
2. The emergence of differences across countries and sectors in terms of compliance procedures; and
3. The need to reduce compliance costs.

First of all, products have become more complex and incorporate a greater variety of technologies while the product cycles become shorter. There is a clear need to respond effectively to the rapidly evolving needs of industry, society, consumers and other stakeholders. The initiative aims to provide manufacturers with other mechanisms rather than the current paper-based procedure, in order to demonstrate product compliance with the applicable legislation.

Second, there are already (and there are likely to be further) differences in compliance systems across the Single Market, both across countries and across sectors. Even though the participation by relevant stakeholders has improved, it could still be more effective.

Finally, there is a need to reduce costs associated with product compliance processes in line with the EU's Better Regulation objectives. Taking this into consideration, the absence of a Europe-wide and cross-sector mechanism which allows the provision of compliance information electronically could possibly lead to the unilateral development of national systems in the Member States.

This, in turn, could raise the problem of system incompatibility or information asymmetry and therefore encourage fragmentation of the internal market and affect its proper functioning because:

- There are cases where different sectoral legislative acts apply to a specific product;

- Businesses and authorities have to deal with multiple systems at the same time;

A variety of systems will not improve the ability of businesses to comply with EU legislation, on the contrary will create an additional burden and confusion.

Sections 5.3, 5.4 and 5.5 of this report provide an assessment of the costs and benefits of the current (baseline) situation and the policy options that have been put forward to tackle the above problems. Section 5.6 summarises the key findings and conclusions and Section 5.7 sets out recommendations on the basis of these conclusions.

5.2.2. Methodological approach

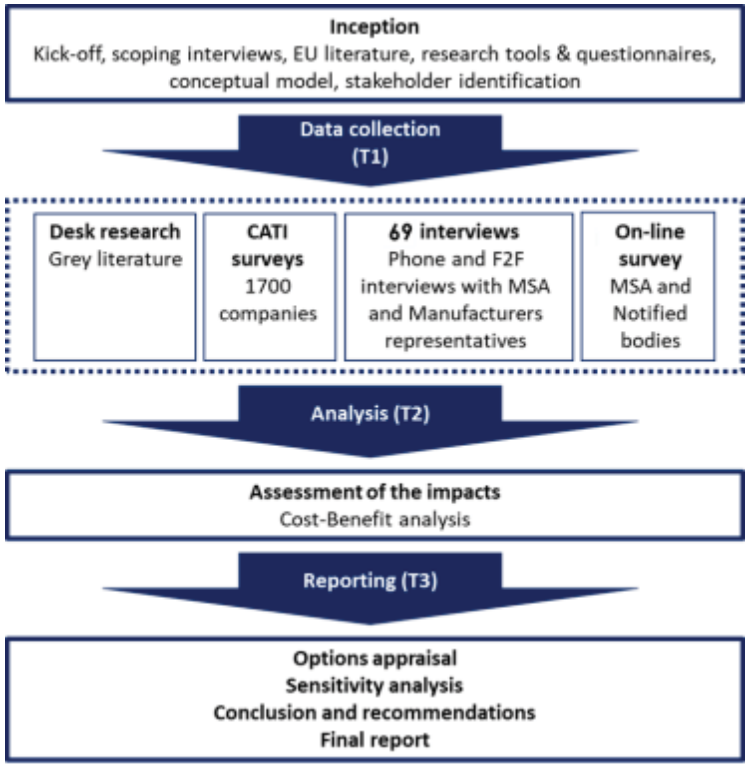
The figure below details the overall methodological approach. Subsequent sub-sections define the methodology used for the data collection in greater detail. The study was divided into three phases: Data collection, Analysis and Reporting:

- Data collection consisted of a combination of desk research, CATI interviews with companies affected by the proposed initiative and a targeted interview programme and online survey with MSAs, Notified Bodies and industry representatives.

- Analysis consisted of the assessment of impacts in a cost benefit model both for the current situation (Baseline) as well as for each of the proposed potential initiatives.

- Finally, reporting included the appraisal of each of the options under consideration, a sensitivity analysis, the development of conclusions and recommendations and the drafting of the present final report.

Figure 14-9: Methodological approach



5.2.2.1. Literature review at national level

The main objective of the literature review was to identify all national information related to **digital compliance schemes at national levels** and the **costs and benefits of demonstrating compliance for businesses and surveillance authorities** under a paper-based and/or digital compliance system.

Other relevant information within the scope of the review included:

- Trends and evolution of manufacturer problems in demonstrating compliance with technical product documentation and EU Declaration of Conformity;
- Trends and evolution of importer problems in demonstrating compliance with technical product documentation and EU Declaration of Conformity;
- Recent developments in improving market surveillance using digital means;
- Trends and evolution in Automatic ID technology and its applications;
- Trends and evolution in E-labelling technology and its applications;
- Cross-border issues in the demonstration of compliance.

The literature review involved the collection of statistics, economic and other literature and studies at national level relevant for the assessment; including complaints data, enforcement decisions and information efforts. A list of references is included in Annex 7.1.

The information gathered served as an input to fine-tuning interview questionnaire and surveys. Mapping country specificities also improved the analysis and interpretation of data gathered in other tasks. The literature review was carried out in preparation and together with interviews and CATI survey.

5.2.2.2. In-depth interviews

In order to build upon and complement the literature review, the research team conducted an interview programme with market surveillance authorities and sector representatives.

69 in-depth interviews were conducted, of which 19 with national market surveillance authorities and 50 with sector representatives and companies. The list of interviewed stakeholders is provided in Annex 7.2.

The **purpose of the interviews** was to gather qualitative and quantitative insights on experiences with the legislation within the scope of the study. To ensure that all relevant issues are covered and that the data collected is comparable, semi-structured interviews were carried out. This type of interviews enables the interviewer to have the flexibility to focus on specific points where the interviewee has particular knowledge.

To facilitate the interview process, **interview guides** (Annex 7.3) were sent to interviewees ahead of the interview to give them the possibility to prepare. As there are two types of respondents, the questions differ slightly to address costs and benefits borne by each stakeholder type. The interview guide includes a section introducing the study and explaining its specificities. Among the information presented to interviewees, the interview guide includes a description of what is meant by digitally demonstrating compliance, an overview of the policy options and the scope of the study (which excludes conformity assessment and CE marking).

A **guidance note** was prepared for the data collection team in order to align interviewers with the objectives of the study, the policy options under consideration and the type of stakeholders interviewed. This was complemented by a **briefing session**, during which the methodology and the approach of the study was discussed with the data collection team.

Interviews were **conducted by phone and face-to-face.** When requested, interviews notes were validated by interviewees. All interviews were stored in a shared folder for subsequent analysis. Interviews were collected simultaneously with the running of the online survey and the CATI survey.

5.2.2.3. Online survey

In addition to the in-depth interviews, the research team launched an online survey targeting public organisations such as notified bodies and market surveillance authorities that could not be reached through the interview programme. The survey questionnaire can be found in Annex 7.4. As the annex illustrates, the foreseen survey questions are simplified versions of the questions in the interview programme. A total of 11 authorities completed the survey, of

which 10 Notified bodies and 1 MSA. The survey data were combined with the data from in-depth interviews and used to determine the costs and benefits of each policy option.

5.2.2.4. CATI survey

The CATI survey was used to **gather quantitative information from individual businesses.** The data gathered were used to carry out the CBA and the CATI survey questionnaire is presented in Annex 7.5

More than **1700 company interviews** were completed in the relevant NACE sectors (Annex 7.7) across the 28 Member States, ensuring geographical coverage and robustness of the analysis.

The CATI company used the Standard Industrial Classification (SIC) codes to identify relevant industries. The conversion table used to convert SIC to NACE codes is provided in Annex 7.8. The two systems do not always match perfectly. As a result, for each NACE code in scope we used data from the best fitting SIC code(s). Sometimes, more than one NACE code fits the same SIC code. In those cases, each interview was counted once for every NACE code that fits the SIC code. After this adjustment, the 1700 interviews constituted a database of 3482 rows. The final database ensures the coverage of businesses of different type and size.

As displayed in the figure below, 90% of respondents are manufacturers, 25% are distributors and 24% importers. The total adds up to more than 100% because a significant number of companies fall into more than one category.

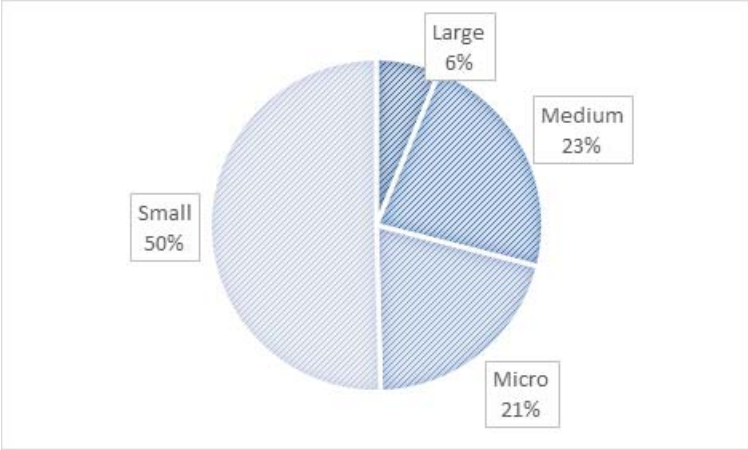
Figure 14-10: Share of responses, by company type

Source: CATI survey

In terms of company size, 94% of the companies interviewed for the CATI are SMEs:

- 21% are micro enterprises (with less than 10 persons employed);
- 50% are small enterprises (with 10-49 persons employed);
- 23% are medium enterprises (with 50-249 persons employed);
- 6% Large companies (with more than 250 persons employed).

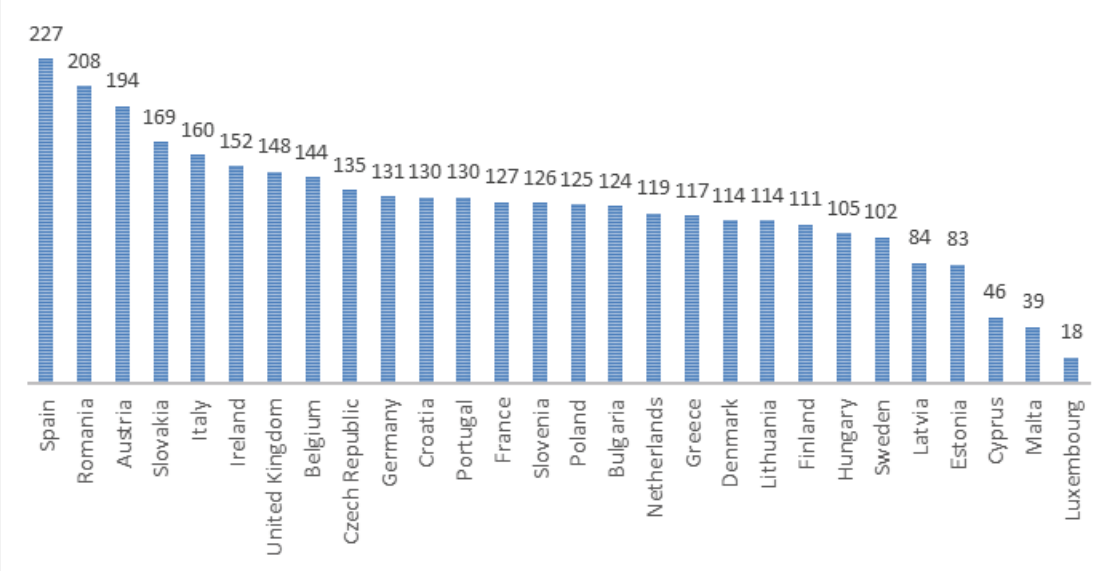
Figure 14-11: Number of responses by company size



Source: CATI survey

The figure below summarizes the geographical coverage after adjusting for NACE code. Interviews have been collected across all 28 MS, ensuring full geographical coverage.

Figure 14-12: Number of responses by country



Source: CATI survey

Further, although sector coverage was agreed with the Commission during the inception phase of the study, it is nevertheless possible that not all companies in the relevant NACE sectors are within the scope of the study. Hence, the survey also included questions for companies to self-report whether they produce any of the documents required for demonstrating compliance. This allowed the team to:

- Compute the share of companies in the relevant sectors for this study that indicate that they demonstrate compliance

- Estimate the total population of enterprises in the EU that demonstrate compliance

- Estimate total costs / benefits at EU level (once combined with interview results)

The CATI survey was carried out over the course of 60 days. An initial fine-tuning phase was performed together with the CATI company to ensure the quality of the questionnaire, a high response rate and a detailed planning of the timeframe.

5.2.3. Structure of the cost benefit analysis

The main analytical tool in this present study is a cost-benefit analysis. The cost benefit analysis shows:

The current costs (and benefits) of the paper based system (see Section 5.3)

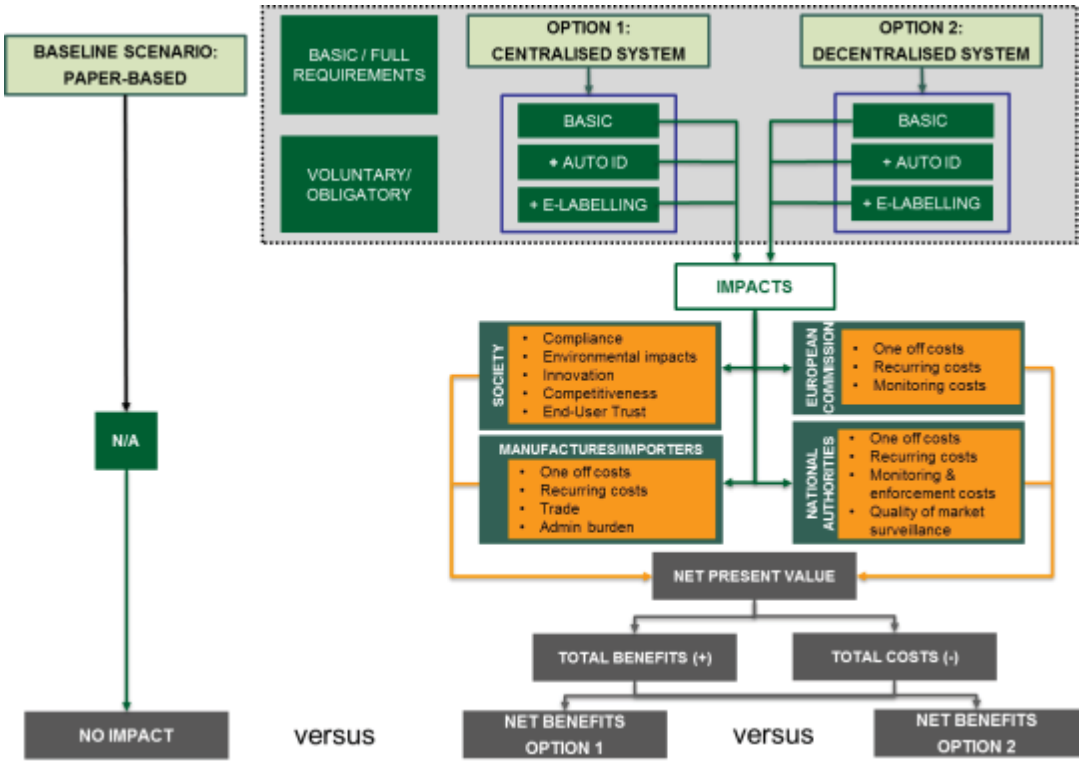
- The projected cost (and benefits) for each of the options and sub-options (see Sections 5.4 and 5.5)

- A sensitivity analysis which indicates how robust the options appraisal is to variations in the underlying parameters of the analysis.

The cost-benefit analysis in this report is based on the results of interviews with enterprises, their representatives and market surveillance authorities as well as the CATI survey described above. The CATI interviews cover all sectors listed in Annex 7.6, a breakdown of CATI responses by country and sector is in Annex 7.7. The results of the CATI survey are weighted by sector to achieve a more representative picture of the European enterprise population.

Where no quantitative data are available the analysis juxtaposes quantitative results with qualitative elements to arrive at a comprehensive picture of the merits of the different options. The figure below provides the final structure for the cost-benefit model.

Figure 14-13: Structure of the cost-benefit model



Note: Impacts in italics will be quantified if possible – otherwise they will be included in the qualitative analysis

The comparison of the options is based on the "net present value" for each of the options (where sufficient quantitative data are available):

$$NPV = \sum_{t=0}^{T} \frac{(B_t - C_t)}{(1+r)^t}$$

Where:

B_t = benefits in Euros received in year *t,* (where available)

C_t = costs in Euros received in year *t* (where available)

r = discount rate

The "paper based" scenario (option 0) constitutes the baseline against which the impacts of the two options are assessed.

5.3. Description and assessment of the baseline

5.3.1. Description of the baseline

Generally, **when a product is placed on the market the manufacturer is obliged to take all measures necessary to ensure that the manufacturing process assures compliance of the products**[75].

Manufacturers have to demonstrate compliance of their products through two main sets of documents:

1. **The technical product documentation** Under Union harmonisation legislation the manufacturer is obliged to draw up a technical documentation which shall contain information that demonstrates the products complies with the requirements. Moreover, the technical documentation has to be available as soon as the product is placed on the market, regardless of its geographical origin or location. One more important aspect is that the technical documentation has to be kept for 10 years starting from the date of the product's placement on the market. Exceptions can be made only if there is applicable Union harmonisation legislation which provides expressly for a different duration.

   The contents of the technical documentation are laid down, in each EU harmonisation act, in accordance with the products concerned. Also, the documentation must include a description of the product and of the way in which it is intended to be used. This must cover the design, manufacture and operation of the product. The documentation must contain the details considered necessary, from a technical point of view, for demonstrating the conformity of the product with essential requirements of Union harmonisation law.

   Frequently, the technical documentation has to contain also an "adequate analysis and assessment of the risk(s)". This consists in the identification of all the possible risks of the product and the determination of the essential requirements applicable. Furthermore, if there are cases where a product has been redesigned and conformity has been reassesed, the technical documentation must provide all versions of the product (this must include the description of the changes, how the various versions of the product can be identified and on the different conformity assessments).

2. **The EU Declaration of Conformity**. The manufacturer or the authorised representative established within the Union must also devise and sign an EU Declaration of Conformity. The EU Declaration of Conformity must contain all relevant information to identify the Union harmonisation legislation according to which it is issued, as well as all relevant information concerning the manufacturer, the authorised representative, the Notified Body (if applicable), the product, and where appropriate a reference to harmonised standards or other technical specifications. Only a single declaration of conformity is required where a product is covered by several pieces of Union harmonisation legislation requiring an EU Declaration of Conformity.

3. **Manufacturers have to meet and fullfil the traceability requirements of the products**. This is done by indicating the name, registered trade name or registered trade mark and the address at which they can be contacted. This information must be displayed on the product, on its packaging or in a document which accompanies the

75 See COM Notice (2016) 1958 final "The 'Blue Guide' on the implementation of EU product rules 2016" of 05/04/2016, section 3.1, p 28-31 on ec.europa.eu/DocsRoom/documents/12661/attachments/1/.../pdf

product. The address must indicate a contact point for the manufacturer. Likewise, importers have to indicate their name, registered trade name or registered trade mark and the address at which they can be contacted, on the product or, where that is not possible, on its packaging or in a document accompanying the product. On top of this, manufacturers must also make sure that their product bears a type, batch, serial or model number or other element allowing their identification (if the nature or size doesn't allow it, it must be provided on the packaging or in a document accompanying the product).

If there is a grounded request, the manufacturer must provide the competent national authority with all the information and documentation needed to demonstrate the conformity of the product. This must be done in a language accessible for the authority. Moreover, if the products placed on the market present any risk, the manufacturer must cooperate with the authority to address this risk. Manufacturers must also identify any economic operator to whom they have supplied the product if the market surveillance authorities request it. They must be able to present this information for a period of 10 years after they have supplied the product.

5.3.2. Interview results regarding the baseline

Results of interviews with market surveillance authorities (MSAs) and manufacturer associations, found that different Member States (MS), have different ways of dealing with market surveillance. For instance:

1. Market surveillance can be a national (ex. Slovenia) or a regional (ex. Germany) level competence.

2. MSAs can be organised along industry sectors (i.e. more than one authority dealing with market surveillance, but with different sector competencies) or they can be more centralised.

3. MSAs have different approaches to market surveillance. They can:

    - Be primarily proactive: the MSA initiates inspections and checks whether products are compliant according to the relevant Directives, requiring the CE marking. Certain MSAs perform random checks (i.e. Belgium), while others select specific product/ companies/ sectors based on a risk a based approach (i.e. Netherlands);

    - Be primarily reactive: the MSA reacts to complaints from consumers, associations, competitors or following an accident (i.e. Germany); or

    - Feature a mix of both of these approaches. For instance, the Slovenian MSA states that they perform 80% proactive and 20% reactive activities.

Under both the reactive and proactive approaches, if preliminary assessment leads to *initial suspicion*, the MSA approaches manufacturers, importers and resellers for additional information. The request is usually rather specific (not limited to making documentation available but explaining parts within it) and MSAs get directly in touch with

the investigated economic operator, either via a telephone call or via a visit. During this phase, most of the exchanges of documents happen digitally via e-mail.

According to the interviews, most MSAs stated that they are equipped to **send and receive official documentation in digital form** (such as with electronically signed PDF), even if in certain countries paper documentation is still required. Most MSAs report that paper-based exchanges are rare compared to digital communication and most documentation is produced and stored electronically and printed only if needed. For instance, in Austria, demonstrating compliance is done digitally, except for the Declaration of Conformity which remains paper based because it needs to be signed. In Sweden exchanges of paper documentation have been abolished.

Further, in the construction industry, the Construction Products Regulation (CPR) incentivises a digital Declaration. The Regulation changes the way in which a manufacturer declares compliance. The manufacturer's 'declaration of conformity', now becomes a 'declaration of performance'. The document must contain actual performance data in relation to the essential characteristics. This must be 'made available' to the end user and the Regulation allows for this to be by electronic means, for example by posting on a website. Additionally, some information must be marked on the product and/or its packaging. According to industry representatives, this digital approach has been adopted by most manufacturers in Europe, except for specific SMEs for whom the change away from paper-based demonstration of compliance is not as easy to make.

Finally, even outside construction, representatives noted that the big international manufacturers, frequently already operate voluntary decentralised databases for internal use, to quickly provide compliance documentation worldwide. The key drivers behind this phenomenon include:

- cost minimisation,
- flexibility,
- workflow tools,
- support for multiple compliance requirements worldwide, and
- geographic dispersion of the relevant services.

At the same time, for smaller manufacturers, the economies of scale for setting up a digital compliance system may not exist.

Overall levels of compliance are difficult to estimate given the different approaches to market surveillance across the EU. In addition, such an estimate is outside the scope of this particular study which focuses on the cost and benefits of *demonstrating* compliance only – not on the compliance requirements themselves. However, German authorities for instance estimate an average 30% level of non-compliance across all sectors following the initial request by the MSA.

The majority of concerns arise with respect to imported goods (mainly from Asia/China) rather than manufacturers within the EU. At the same time, market surveillance

authorities pointed out that sometimes it can be difficult to receive technical files from importers because they are not able to obtain the file from the manufacturer abroad. While digital identification of each product (identity of the manufacturer, involved Notified Body, Declaration of Conformity, and a unique identification number of the product which links it to a specific batch) could help EU market surveillance authorities with their requests for further information from third country (e.g. Chinese) authorities, such a system would still require that the underlying information that is fed into it by the third country manufacturer is actually correct.

5.3.3. Share of companies in relevant sectors that fall under the current paper based compliance regime

The remainder of this section provides first results of the CATI survey regarding the current paper based system of demonstrating compliance. Results have been weighted by sector where appropriate.

5.3.3.1. Incidence rate in the sectors covered by the study

The first questions in the CATI survey related to whether the company produces at least one of the documents required to demonstrate compliance (section 5.3.1). Companies that do not produce these documents do not incur the associated costs. There could be different reasons why companies – though classified as operating in one of the sectors covered by this study – do not produce such documentation, including the activity of the company which may not require them to produce any of the relevant documents, lack of awareness of the need to demonstrate compliance or simply a lack of compliance with existing rules.

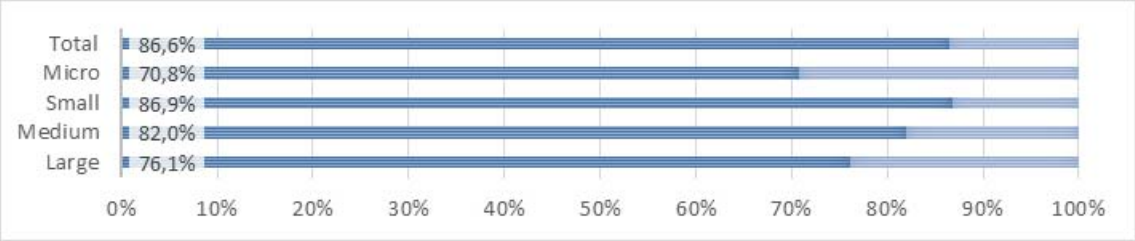
Annex 7.7 provides the incidence rates[76] for all NACE sectors included in the study. The CATI survey results show that there is a significant variation in the incidence rate across sectors. Given these differences, as well as differences in the size (number of companies and turnover) and the structure of these sectors, it is important that CATI findings in the final analysis are weighted by sector.

The figure below presents the overall incidence rate weighted by sector for companies of different size. **The overall incidence rate across the population of enterprises in the sectors covered by this study is 86.6%.**[77] Incidence levels are lower for micro companies (70.85) and higher for small companies (86.9%).

76 The incidence rate reflects the percentage of companies, classified to operate in one of the sectors in the scope of the study, that after accepting to participate in the interview stated that they produce at least one the requested documents: technical documentation and/or declaration of conformity

77 67.4% of companies contacted in the fieldwork said that they produce at least one of the documents within the scope of the research. The overall incidence rate of 86.6% is based on this figure, weighted by sector. Interviews were only taken forward with companies that do produce at least one such document. Other than in this sub-section, all further results presented in this report only cover the companies that produce at least one document (i.e. the companies that do demonstrate compliance), unless otherwise indicated.

Figure 14-14: Incidence rate, by company size

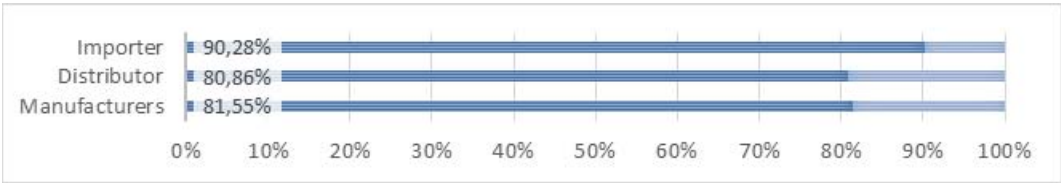


Source: CATI survey, data weighted by NACE code

Among the documents covered, the technical file is the costliest to produce and also the most commercially sensitive. Based on the CATI results and sector weighting, **it is estimated that 81% of all companies in the sectors covered by this study produce a technical file**.

The figure below shows the share of companies by type, size and sector which produce such a technical file. These figures are particularly important in the context of this study because they relate directly to one of the sub-options to be considered (inclusion of the technical file in the digital compliance demonstration system).

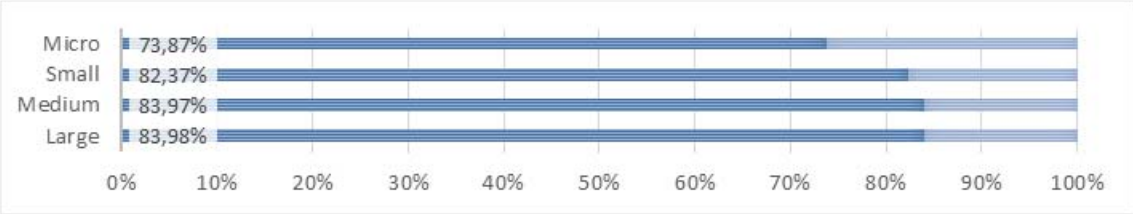
Figure 14-15: Share of companies which demonstrate compliance with the technical file, by company type



Source: CATI survey, data weighted by NACE code

Although 90.28% of importers stated that they produce a technical file compared with only 80.86% of distributors and 81.55% of manufacturers, the vast majority of companies in the sample were in the latter two groups and the results for these two groups are very close to the overall sample mean of 81%. The focus of this report is therefore on sector and company size differences.

Figure 14-16: Share of companies which demonstrate compliance with the technical file, by company size



Source: CATI survey, data weighted by NACE code

In contrast, there is a significant difference in the use of technical files between micro companies and larger companies. Micro companies (the largest group of in the population of companies) are less likely to use the technical file to demonstrate compliance than companies

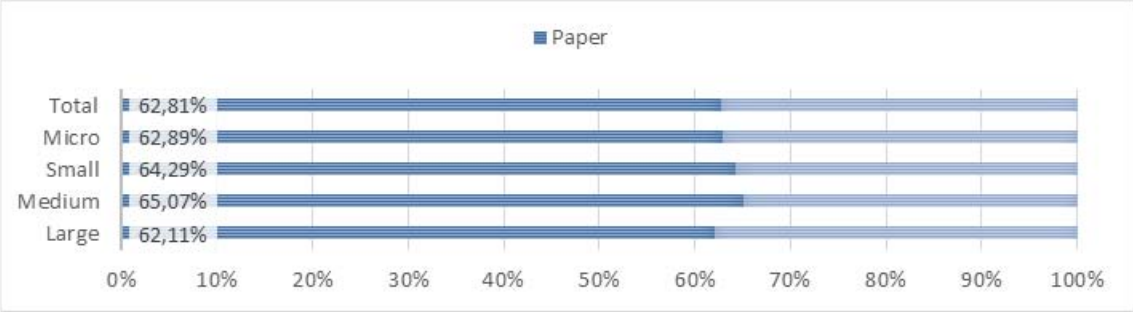
in any of the larger size categories. Differences between small, medium and large companies in the use of the technical file are not significant.

5.3.3.2. Prevalence of paper based compliance demonstration

Among those companies that produced compliance documentation, **62.8% said that they still produce and exchange paper documents with authorities, compared with 38.2% who indicated that they use only digital means to produce and demonstrate compliance to authorities, such as electronically signed PDFs**.

After weighting the data by NACE code, **there is little difference in terms of company size**: Medium companies are most likely to rely on paper (65%) compared with large companies which are more likely to use a digital means for demonstrating compliance (62% paper based).

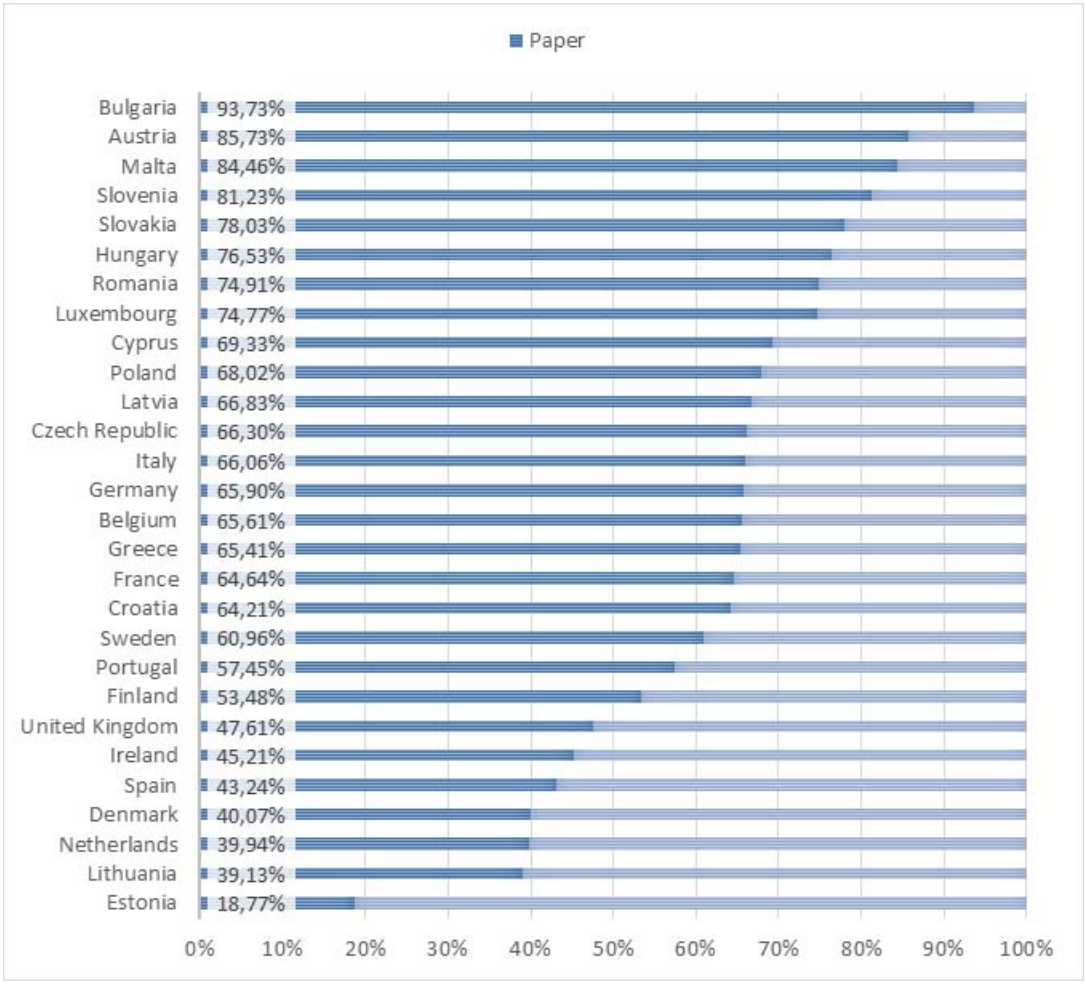
Figure 14-17: Share of companies that use a paper v digital means for demonstrating compliance, by company size



Source: CATI survey, data weighted by NACE code

Across countries, paper based compliance demonstration is the main channel in Bulgaria, Austria, Malta, Slovenia, Slovakia, Hungary, Romania, Luxembourg (more than 70% paper based). In comparison, Denmark, Estonia, Ireland, Lithuania, Netherlands, Spain and the United Kingdom have the greatest prevalence of digital systems to date (more than 50% digital). Estonia specifically is by far the most digital country when it comes to compliance demonstration: according to our survey only 18.8% of companies in Estonia use a paper-based procedure to demonstrate compliance.

Figure 14-18: Share of companies that use a paper v digital procedure for demonstrating compliance, by country



Source: CATI survey, weighted by NACE code.

5.3.3.3. Prevalence of MSA inspections

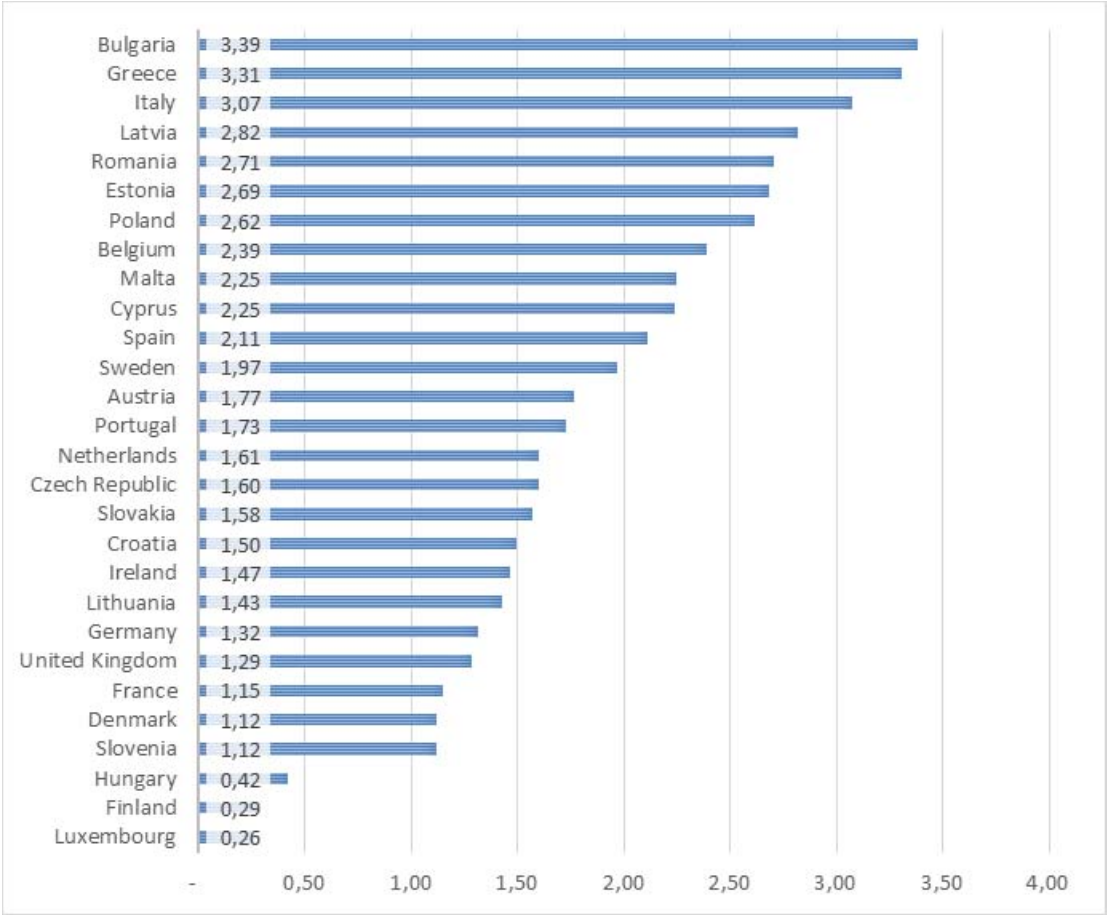
Finally, among those companies that produce compliance documents, **41% indicated that they had been subject to an inspection by a market surveillance authority in the last 5 years**. Responses ranged from a low of 15% in Hungary to a high of 76% in Cyprus.

On average, on the basis of the responses to the CATI, across all relevant sectors we estimate that **there are 1.41 inspections per company every 5 years**. However, this is a global average and differences between countries are significant.

- In Bulgaria, Greece and Italy, frequent inspections are reported – i.e. 3 every 5 years
- In Hungary, Finland and Luxembourg, inspections are reported much less frequently (less than one every 5 years).

It should be noted that the average of 1.41 every 5 years considers all companies, including those that have not been subject to any inspection over the past 5 years.

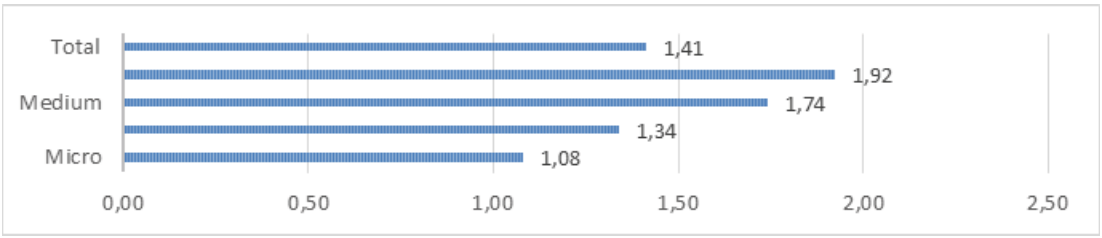
Figure 14-19: Estimated average number of MSA inspections per company every 5 years, by country



Source: CATI survey, weighted by NACE code.

In terms of company size, **inspections are more frequent in bigger companies**. Large companies receive on average 1.92 inspections every 5 years. This number goes down to 1.74 for medium companies, 1.34 for small companies and 1.08 for micro companies. In other words, large companies receive on average almost twice as many MSA inspections compared with micro companies. Finally, 52% Of large companies are likely to receive at least one inspection every 5 years. This number goes down to 47% for medium companies, 40% for small companies and 34% for micro companies.

Figure 14-20: Estimated average number of MSA inspections per company every 5 years, by company size



Source: CATI survey, weighted by NACE code.

5.3.4. Costs of demonstrating compliance under the current regime for demonstrating compliance

5.3.4.1. Cost estimate for companies

According to the result of the CATI interviews, the median respondent reported that the cost of demonstrating compliance (i.e. administrative burden for answering requests from market surveillance authorities regarding documents needed to demonstrate compliance; Displaying (or publishing; updating compliance information for existing products; Complying with different compliance procedures across Member States; IT costs; General labour cost) amounts to 10% of their overall cost of compliance with Union harmonisation legislation. Furthermore, based on the Evaluation of the Internal Market Legislation for Industrial Products[78], the total cost of compliance with such legislation for a firm is approximately 0.48% of its turnover. **We can therefore estimate the cost of demonstrating compliance to be approximately 0.048% of turnover**.

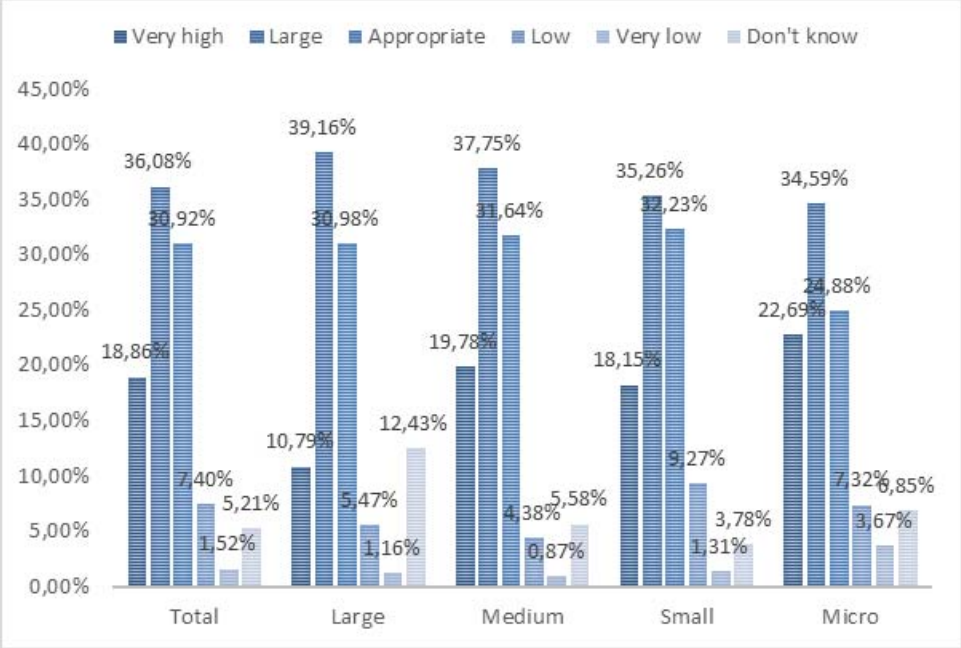
Considering Eurostat data from 2013[79], the turnover of the almost 350,677 companies within the scope of the study (see Annex 7.6) is € 2.03 trillion (€2,026,565.10 million). Given this, a preliminary estimation shows that the total cost of demonstrating compliance is approximately **€ 842.374 m** per year (€ 2.03 trillion * 0.48%*10%*86.6%incidence rate) or **€1,807.41 per company** per year on average.

5.3.4.2. Company perceptions of the level of costs

To put the above cost estimates into context, the CATI survey also asked companies about their perceptions regarding the appropriateness of the current costs of demonstrating compliance. About **55% of respondents believe that today's cost of demonstrating compliance are either high or very high** (Figure 14-21) compared with about one third who considered the costs appropriate and about 9% who thought the costs were low. **Only 11% of large company believes today's cost of demonstrating compliance are very high, compared to twice as many micro enterprises.**

78 http://ec.europa.eu/smart-regulation/evaluation/search/download.do?documentId=9966151
79 Eurostat: http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=sbs_na_sca_r2&lang=en

Figure 14-21: Perceived level of cost under the current regulations and business practices, total and company size

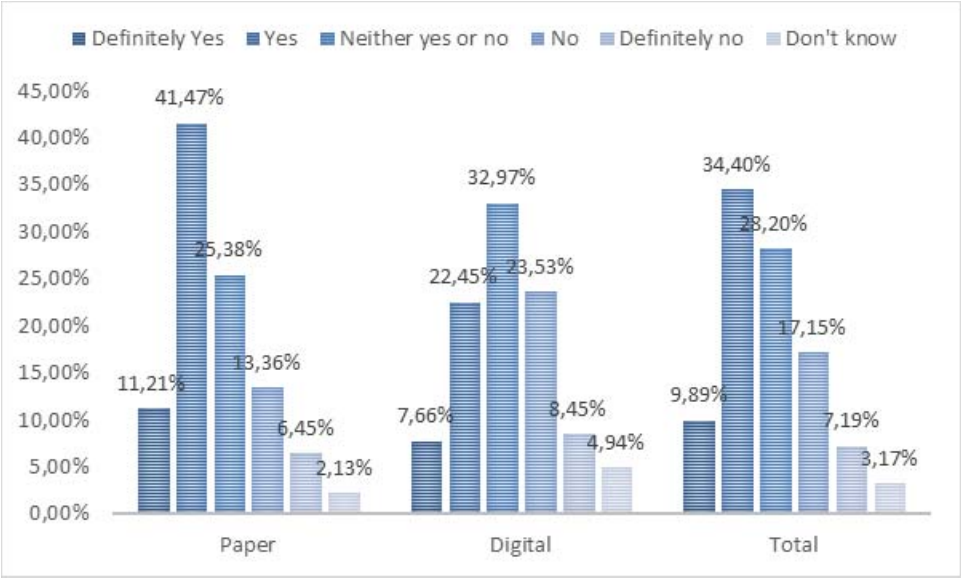


Source: CATI survey, weighted by NACE code

5.3.4.3. Overall company assessment of the current procedures

Finally, regarding the need for change, two fifths of companies considered the paper based procedures to be efficient or very efficient (44.3%) with 31.4% not having a strong opinion either way and **24.3% of respondents considering the current paper based system as inefficient**. There are no significant differences in perceptions of overall efficiency by company size. However, companies that are fully paper based in their demonstration of compliance were overall more satisfied with the status quo than companies which indicated that they demonstrate compliance digitally. This result suggests that companies that have the resources to demonstrate compliance digitally (or that have already invested in digital systems) would like the regulatory environment to "catch up", whereas companies that do not currently have these means are more likely to want to preserve the paper based system.

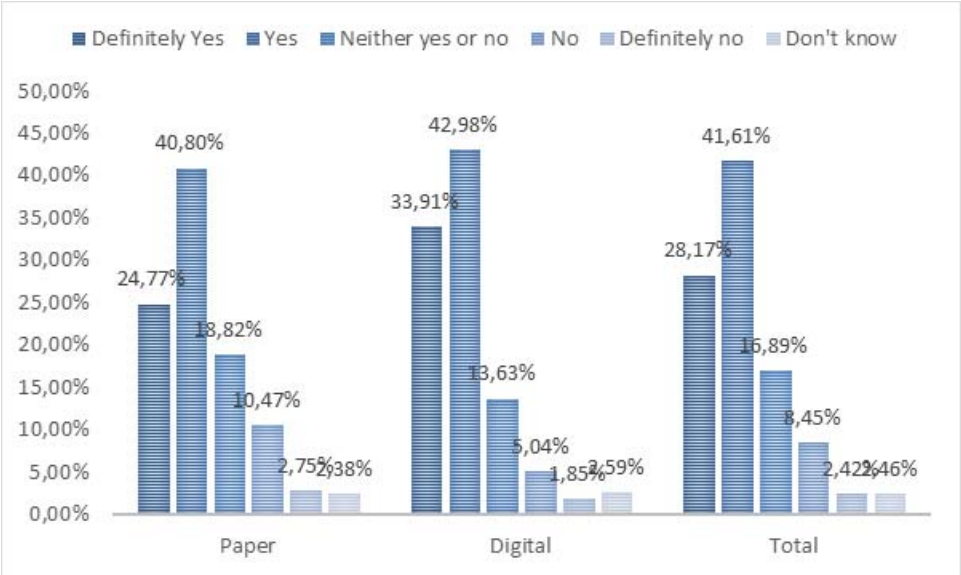
Figure 14-22: Overall, do you find today's paper based procedure of demonstrating compliance efficient?



Source: CATI survey, weighted by NACE

Finally, despite overall rather favourable perceptions of the current paper based system, there is a strong preference among companies for digitalisation. Overall, **more than 69% of respondents think a digital system would be an improvement**, compared with slightly more than 10% who think such a system would be worse than the current one. Like for the previous diagram, preferences for a digital procedure are particularly strong among companies that already do part of their compliance activities digitally.

Figure 14-23: Do you think a digital compliance system would be an improvement compared to todays' procedure of demonstrating compliance?



Source: CATI survey, weighted by NACE

5.3.4.4. Market surveillance authorities and Notified Bodies' costs

Beyond the company's costs, market surveillance authorities also provided (mostly qualitative) information regarding their costs.

Overall, costs of individual activities are very difficult for MSAs to estimate because they work with a fixed budget that cuts across all their activities and it cannot easily be broken down. For this reason, most MSA did not provide data on costs but they specified that this is usually limited to personnel costs and a budget for tests and for acquiring products at point of sale.

In certain countries, the law allows the MSA to ask for products from manufacturers for free (e.g. Germany). However, anecdotal evidence shows that outlays vary widely between countries and sectors:

- The Dutch centralised MSA has a yearly budget of € 12 million, which is being used both for current expenses and for the testing of 6000 products a year on average. The authority has a yearly capacity of 100 FTE divided in:
    - 40 FTE in inspection activities;
    - 30 FTE in testing activities;
    - 30 FTE in strategy and facilitating the infrastructure.
- The Danish Safety Technology Authority estimated an average cost of 2 hours (FTE) for each inspection related to one product and one company.
- The Slovenian MSA for toys, cosmetics, hygiene, and personal care products has a yearly budget of € 4.4 million. With a staff of 88 inspectors, the authority carries out 30,000 products checks a year.
- The Romanian MSA estimated a cost of €14,000 a year for market surveillance of construction products in the category of fixed fire-fighting equipment
- The Estonian MSA estimated a cost of €4000 just for radio equipment

To overcome lack of quantitative data, the research team tried to collect information on how much time is spent on the different activities carried out by MSA and Notified bodies, and to understand which activities require most of the authority's resources.

The table below shows typical responses from MSAs in relation to the costs associated with different market surveillance activities related to demonstrating compliance as well as the results for the 10 Notified bodies who participated in the online survey. As the table shows, MSAs spend most of their resources on carrying out core activities such as inspections and testing. It is important to note that most MSAs highlighted difficulties in interacting with third parties and MSAs in other countries. Even if these activities do not take most of the time, the answers collected suggest possible margins for improvements in those areas.

Table 14-13: Perceptions of costs among MSAs and Notified Bodies for activities related to demonstrating compliance

Type of activity	Cost for MSA	Cost for Notified Bodies (as a percentage of the time spent by the institution on the different activities)
Assessing/collecting the information showing compliance from companies	This is a core activity for MSAs and therefore it takes most of the time and budget	19%
Interacting with market surveillance authorities in other Member States to assess information showing compliance	Very burdensome activity that often leads to no answers.	6%
Interacting with third parties (e.g. consumers, other public bodies, courts, etc) regarding the search for information showing compliance[80]	Very burdensome and time consuming	12%
Costs for archiving/handling of documents showing compliance[81]	Often impossible; EU importers cannot get the required information from manufacturers (intellectual property).	Not significant.
Training of new/existing employees on the process of verifying compliance[82]	No specific training costs were provided	Training is usually provided and it is between 4 and 15 days a year.
Other activities related to searching for information showing compliance	Finding and identifying the batch to which non-compliant product belongs	NA

Finally, MSA costs depend also on the authority's strategy. For example, MSAs that use a reactive approach may have a higher incidence of non-compliance as a percentage of the inspections carried out. For example, the Ministry of Rural Affairs and Consumer Protection of Baden-Württemberg estimated that 30% of all the inspections carried out by the local MSA result in non-compliance. The reason for such a high percentage is that the initiating of checks is triggered by *initial suspicion*.

80 This refers to the costs of producing and distributing copies of compliance documents to other parties when they request them. In the Digital Compliance scenarios (OPTION 1 and OPTION 2), such interaction would most often mean referring third parties to the location of the documents.

81 This includes post stamps, costs for paper and printer ink supplies, costs for handling storage and archiving, as well as costs of discarding documents.

82 This includes trainings, external advice and assistance to staff from other public agencies.

5.3.5. Benefits of demonstrating compliance under the current paper based regime

As expected, in terms of benefits, information provided by both companies and MSAs was mostly qualitative in nature. Most benefits that both companies and market surveillance authorities could name were related not to *demonstrating* compliance but to the system of Union harmonisation legislation in general, which is out of scope of the current study. The benefits of the process to demonstrate compliance are more difficult to isolate but key elements cited included:

Cited by companies

- End-user trust;
- Familiarity with the current system (i.e. the system's benefit is that it has been around for a long time and everyone knows how to deal with it);
- Creation of a level playing field for companies across the EU;

Cited by market surveillance authorities:

- The fact that there is extensive technical documentation but this does not have to be made public and control of technical knowledge, confidentiality and business know-how are maintained within the firm.
- The fact that manufacturers using Harmonised Standards listed under respective EU legislation in the OJEU, benefit from the so-called 'presumption of conformity' until the moment that non-compliance is proven by the Market Surveillance Authorities.
- Ex-post checks by market surveillance authorities are quite specific and usually MSA requests are quickly solved in bilateral communication and exchange of emails or electronic documents with the company, even in the absence of a systematic digital procedure.

5.4. Overview of the policy options

Following the assessment of the baseline in the previous section, this section presents the proposed policy options to address the problems identified with the current paper based approach.

5.4.1. Aim of the potential policy intervention

The immediate objective of a possible Digital Compliance system should be to facilitate the demonstration of product compliance through the digital transmission of compliance information to market surveillance authorities and to reduce the costs of providing/accessing compliance information for manufacturers (especially SMEs), Notified Bodies and authorities, while maintaining the necessary high level of protection of public interests.

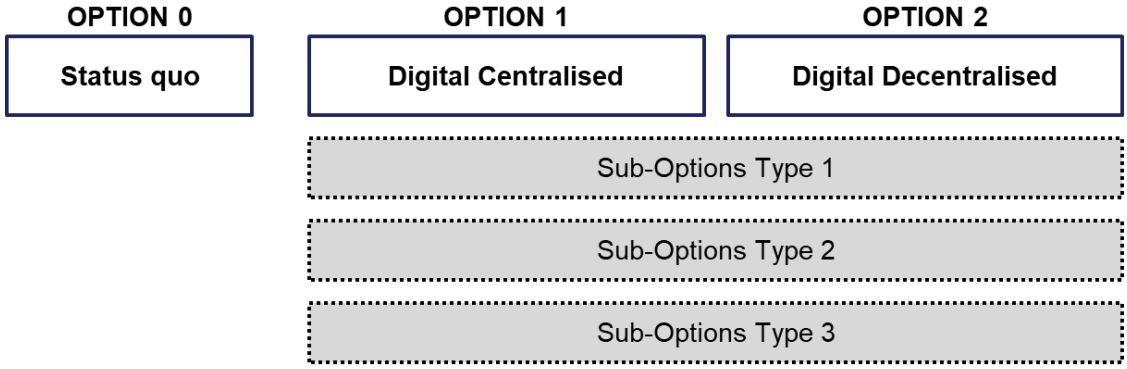
In a Digital Compliance system, manufacturers and Notified Bodies would share information digitally regarding the compliance of a product with the applicable legislation enabling the drafting of the necessary documentation. Market Surveillance authorities would be able to access the required information. Confidentiality issues would need to be taken into account.

It needs to be reiterated that this study deals only with demonstration of compliance. The conformity assessment procedures themselves, covering e.g. testing and affixing of the CE marking, are outside the scope of the study.

5.4.2. Description of each policy option

This section briefly presents the key elements of the policy options, in the form of a "decision tree". The "decision tree" is a decision support tool that uses a tree-like graph that serves as a guide through a sequence of scenarios.

Figure 14-24: Overview of the policy options



Three main policy options will be considered in the cost benefit analysis (see Figure 14-24).

1. **The "status quo" option (Option 0)**: manufacturers are solely responsible for the compliance of their products with the applicable legislation. The demonstration of compliance with Union legislation is done through two main sets of paper based documents:

   b. the EU Declaration of Conformity.

   Upon a reasoned request, the manufacturer has to provide the competent national authority with all the information and documentation necessary to demonstrate the conformity of a product.

2. A **centralised digital compliance procedure** (Option 1): a central database will be developed, owned and maintained by the European Commission and have the form of an electronic repository of information. Manufacturers can upload information regarding the conformity of a product with the applicable legislation. Notified Bodies can upload information regarding the certificates of conformity. Market surveillance authorities will be able to access this information; and

3. A **decentralised digital compliance procedure** (Option 2): all relevant data will be collected in decentralized databases operated by the individual companies (or on the products themselves). The database can consist of dedicated sections located on the websites of the economic operators, responsible for developing and maintaining their own dedicated websites. Manufacturers will upload and maintain up-to-date information regarding the conformity of a product with the applicable legislation to a dedicated section of their websites. Notified Bodies will upload to a dedicated section of their websites information regarding the certificates they issued, suspended or recalled, and the certificates they refused to issue. Market surveillance authorities will be able to access this information.

For both options (1 and 2), three specific sub-options will be considered.

- The **first sub-option** considers only the introduction of the **digital compliance procedure**, centralised in the case of Option 1 and decentralised in the case of Option 2.

- The **second sub-option** considers the introduction of the digital compliance procedure together with an automatic identification process (**AutoID**) such as barcodes, Radio Frequency Identification devices, smart cards and magnetic stripes, etc.

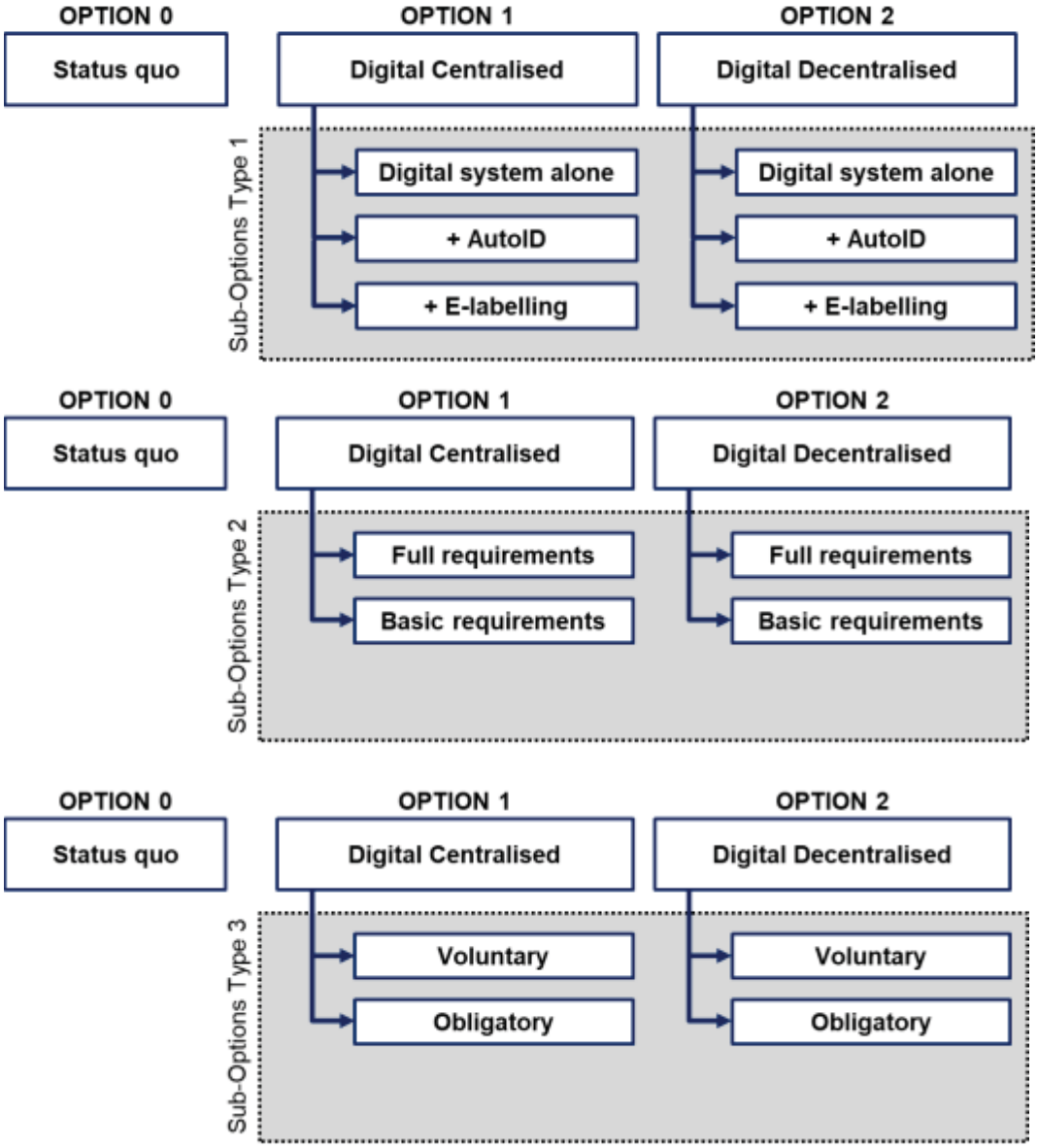
- The **third sub-option** considers the introduction of the digital compliance procedure as well as **e-labelling** to allow manufacturers of electronic devices with a screen to show compliance information electronically through a display rather than on a label affixed to the device (similarly to what has been introduced in the USA with E-LABEL Act in 2014).

For both Options 1 and 2 we will also take into consideration two additional possibilities:

- Digital compliance covers either only the EU declaration of conformity (DOC), contact data of the manufacturer and the certificate of the Notified Body, if such a body has been involved (**Basic**), or also includes the technical file (**Full**) (sub-options Type 2 – see figure below).

- Implementation of the new digital procedure is either **voluntary** or **obligatory** (sub-options Type 3 – see figure below).

Figure 14-25: Sub-options overview



5.5. Assessment of the policy options

This section presents the assessment of the different policy options and sub-options under consideration, including a sensitivity and a brief competitiveness analysis.

5.5.1. Option 1: centralised digital compliance procedure

Under option 1, a database of compliance related documents would be developed, owned and maintained by the European Commission. Manufacturers would be responsible for uploading information regarding the conformity of a product with the applicable legislation. Notified Bodies can upload information regarding the certificates of conformity. Market surveillance authorities would be able to access this information

The simulation first assumes that the centralised digital compliance procedure becomes the mandatory and only way to demonstrate compliance, thus eliminating the current paper based approach and any national databases or repositories of information regarding certificates of conformity. A second estimation considers the possibility that the centralised digital compliance procedure remains voluntary and co-exists alongside the current procedure.

5.5.1.1. Costs to companies

As shown in Figure 14-26, **most economic operators do not think that there will be considerable additional costs in case of basic compliance under Option 1**. As explained above, basic compliance refers to the option where the technical file would not be included in the centralised database and current paper-based procedures would continue to operate for the technical file.

In interviews, only few manufacturing associations were able to estimate their costs but there were a number of indications that should be taken into account in the further design of the option if this is carried forward.

1. There would be a **one-off setup cost** to create an in-house database with electronic versions of the documents to be uploaded into the centralised database as well as a new process for demonstrating compliance. In particular, this database would impose potentially significant costs related to security.

2. The significance of these costs would depend to a large extent on the system that would be implemented under option 1 and how **compatible** it is with each company's current procedures. For instance, the centralised database would require companies to provide information according to a pre-defined format which may not be compatible with the software used in-house at the moment to produce compliance documentation.

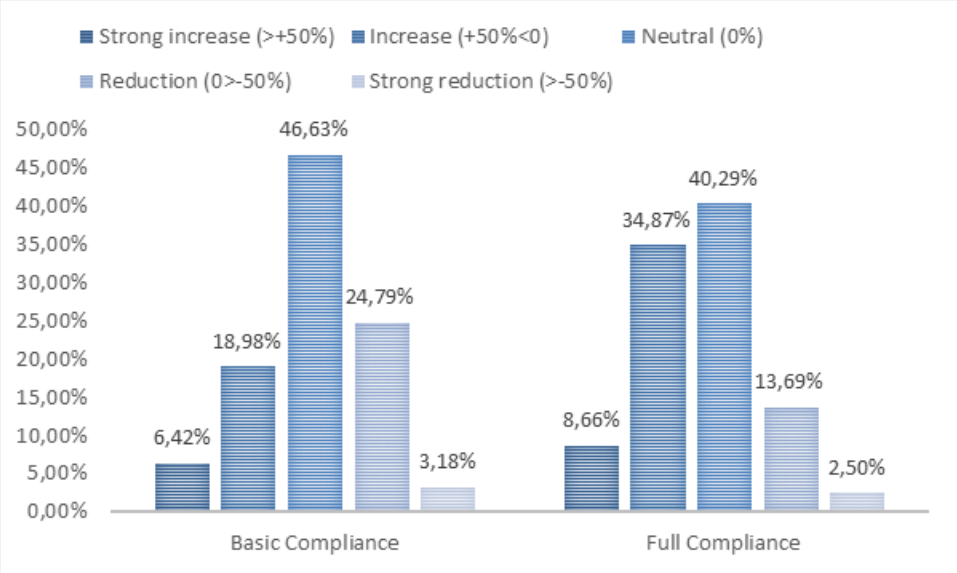
3. **Recurring costs** would differ depending on the number of products in each company's portfolio, the user friendliness of the database, and the product life cycle. By way of illustration, in the electric appliances sector there is a turnover of approximately 30% new/ changed models a year which would thus generate significant recurring costs. Regarding user-friendliness, experience with other

European portals (ex. ECAS) were not positive due to technical problems and the lack of a functioning helpdesk.

4. If the centralised database requires uploading the technical file, **security costs** would be significantly higher as sensitive information is shared with a third party (the MSA). Interviews showed that under full compliance, this option would be difficult for economic operators to accept.

Overall, business perceptions are that costs would be significantly higher if the digital centralised database were to include the technical file due to the need for higher security and confidentiality standards. Under basic compliance about 25.4% of respondents expected a cost increase, versus 43.5% if the technical file were included in the option. The vast majority of respondents do not expect option 1 to lead to a reduction in costs under either the full or basic scenarios. However, during the interviews, both manufacturers and their associations were unanimous in opposing full compliance due to data sensitivity and the risk of industrial espionage.

Figure 14-26: Option 1 – change in cost of demonstrating compliance, under a "full" or "basic" digital compliance system



Source: CATI survey, weighted by NACE

To turn the above results into quantitative point-estimates, the thresholds specified in the answer options were used. Thus, where a respondent indicated for instance a "strong increase > +50%" this lower bound was used to develop the cost estimate (+25% for respondents who replied "increase", 0% for respondents who replied "neutral", -25% for all respondents who replied "reduction", -50% for respondents who replied "strong reduction").

The Table below breaks down these results to estimate the change in the cost of demonstrating compliance by company size. These results illustrate the importance of distinguishing between company size. Indeed, **small and medium companies, on average expect a small decrease in the costs of demonstrating compliance under the basic scenario (without the technical file), while micro-companies expect an increase in costs of 6.15%**. There is unanimity among companies of all sizes that including the technical file

would lead to a significant increase in the costs of demonstrating compliance of between 6.95% (large companies) and 9.52% (medium sized companies).

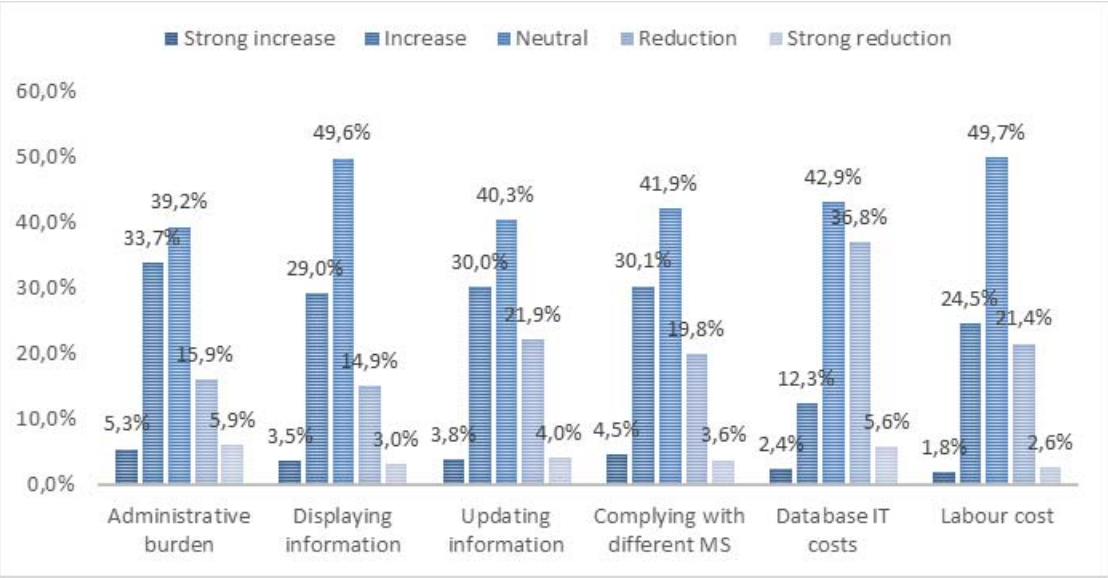
Table 14-14: Estimated percentage change in cost of demonstrating compliance per company size

	Basic	Full
Size	**%**	**%**
Large	1.93%	6.95%
Medium	-2.02%	9.52%
Small	-0.51%	7.98%
Micro	6.15%	7.99%
TOTAL	0.17%	8.37%

Source: CATI survey, weighted by NACE

The figure below provides a further breakdown of the kinds of cost changes companies expect under option 1 (basic compliance). The key cost categories where increases are expected are administrative burden, complying with different Member States, displaying and updating information. In contrast, reductions in costs are expected primarily in database / IT costs.

Figure 14-27: Key cost impacts as a result of Option 1 (basic compliance)



Source: CATI survey, weighted by NACE

Finally, in order to arrive at a monetary cost estimate, we assume that all companies which comply with Union harmonisation legislation under the paper based approach would continue to do so under a centralised digital compliance procedure. Taking the average cost increase under each of the options, it can be estimate that the total additional cost of Option 1 would be

as shown in Table 14-15 below. Starting from the baseline calculated in section 5.3.4.1 to estimate the costs of Option 1 we consider:

- Estimated percentage change in cost of demonstrating compliance
    - Basic compliance: 0.17%
    - Full compliance: 8.37%
- Voluntary uptake: 81.87% (as per CATI survey results)
- Incidence rate of technical file: 80.89%

Annex 7.9 summarises the calculation used to estimate the overall costs of demonstrating compliance as well as its NPVs.

Adopting Option 1 would lead to an average increase in recurring costs between € 2.52 and € 122.37 per year.

Under a basic compliance system, the average yearly increase would be between €2.52 (with voluntary uptake) and €3.07 (with mandatory uptake). Under a full compliance system (including the technical file), the average yearly increase would be between €100.18 (with voluntary uptake) and €122.37 (with mandatory uptake). Thus, the increase in recurring costs is significantly lower in case of adoption of a centralised database with basic compliance.

Table 14-15: Company costs under Option 1

Cost of demonstrating compliance			Total	Company Level
Baseline			€ 842,374,938.53	€ 1,807.41
Option 1: Centralised database	Basic Compliance	Voluntary	€ 843,547,347.54	€ 1,809.93
		Mandatory	€ 843,806,975.92	€ 1,810.48
	Full Compliance	Voluntary	€ 889,067,568.70	€ 1,907.60
		Mandatory	€ 899,407,588.05	€ 1,929.78
Change in cost of demonstrating compliance			Total	Company Level
Option 1: Centralised database	Basic Compliance	Voluntary	€ 1,172,409.02	€ 2.52
		Mandatory	€ 1,432,037.40	€ 3.07
	Full Compliance	Voluntary	€ 46,692,630.17	€ 100.18
		Mandatory	€ 57,032,649.53	€ 122.37
NPV over 10 years			Total	Company Level

Option 1: Centralised database	Basic Compliance	Voluntary	€ 10,681,696.35	€ 22.92
		Mandatory	€ 13,047,143.46	€ 27.99
	Full Compliance	Voluntary	€ 525,916,461.60	€ 1,128.41
		Mandatory	€ 642,379,945.77	€ 1,378.30

According to stakeholders, given the relatively low number of updates to compliance documentation, micro companies would be unlikely to set up a system to automatically feeddata into a centralised database. As a result, feeding and updating a centralised database would be a more labour-intensive activity for such companies, as compared to Option 2.

In terms of one-off costs, interviewees where reluctant to provide estimations. Business associations are concerned that big companies would face high one-off cost to adapt their existing compliance software to feed a centralised database. According to business associations big multinational companies invest considerably in setting up compliance software to manage specific and geographically dispersed supply chains that stretch across the European Union and beyond. Feeding a centralised database may require changes in terms of IT structure, IT security and information format. No major one-off costs were highlighted for smaller companies, apart from training costs. Due to security concerns, business associations highlighted that one-off costs would be significantly higher in case of full compliance.

5.5.1.2. Benefits to companies

The figure below shows the key benefits identified by companies as a result of option 1, for both the sub-options with basic and full (i.e. including technical file) compliance. Under basic compliance, improvements are expected by a majority of respondents in terms of market surveillance, transparency, compliance levels, product safety and environmental impacts. Very few respondents (<5% in all cases) expect a negative impact of the option on any of these aspects. The results are very similar for the full compliance scenario (including the technical file) which suggests that companies do not expect much added value from the inclusion of the technical file.

Figure 14-28: Impact of option 1 (basic and full compliance) on benefits of demonstrating compliance

Source: CATI survey, weighted by NACE

5.5.1.3. Costs and benefits to MSAs

For MSAs, the information provided in interviews on costs and benefits was mostly qualitative. The following key conclusions can be drawn:

Overall, MSAs expect that option 1 will increase their costs, including recurring and one-off costs:

1. To introduce a new database will require an increase in the operational budget of the MSA and newly trained personnel to deal with the database and share relevant information with inspectors.

2. In terms of recurring costs, under today's system, the economic operator must provide all the required information in case of an investigation. If they don't do this, the product is judged non-compliant. As mentioned above, requests for information from

MSAs are usually quite specific and there is no need to require the full documentation. Under the proposed centralised database, MSAs believe that this would make them responsible for identifying the relevant information in the database themselves. For complex products, this would be very time-consuming and lead to an increase in operating costs.

On the benefits side, the picture for MSAs is rather unclear. The main advantage for MSAs under a compulsory, centralised database including all compliance documents (i.e. with the technical file), is that it **facilitates access to information**[83].

1. While 40% of the MSA interviewed do not believe that a digital system would improve market surveillance from an operational point of view, there may be benefits for the planning of MSA activity (i.e. knowledge of the market, new products, selection of products for investigation, etc.). One MSA noted that there may be lower risk of non-compliance if the technical file is included in the digital database. Another noted that a digital compliance system could ease access to information.

2. One advantage of the centralised database compared to all other options is the availability of information even if a company does not exist anymore and, compared to paper-based systems, a centralised digital system also has better traceability.

3. If use of the database is compulsory for companies, this would make access to information faster. Indeed, according to one manufacturing association, it currently takes MSAs approximately 6 weeks today to access documentation from economic operators. On the other hand, if the database is not mandatory and if it does not include the technical file then it would be of little use as MSAs would still need to go the manufacturers to access the complete documentation.

4. Finally, MSAs suggested that, while the centralised database should include the technical file, this should only be accessible to the MSA. However, all other documents for demonstrating compliance should be accessible to other companies as well since they do not contain any confidential information and access by competitors may lead to a level of "self-policing" and therefore greater compliance.

5.5.2. Option 2: decentralised database

Under option 2, each manufacturer, importer or distributor would be responsible for uploading information regarding the conformity of a product with the applicable legislation to a website developed and maintained by the company. Notified Bodies and market surveillance authorities would be able to access this information.

As for Option 1, the simulation in Section 5.5.2.1 assumes, first, that the decentralised digital compliance procedure becomes the mandatory and only way to demonstrate compliance, thus eliminating the current paper based approach and any national databases or repositories of information regarding certificates of conformity. A separate simulation assuming a voluntary decentralised database is provided alongside the mandatory option.

83 A similar result could perhaps be reached if a decentralised database is introduced together with an Auto-ID system. See also Section 5.3

5.5.2.1. Costs to companies

As shown in the figure below, **most economic operators do not think that there will be considerable additional costs for basic compliance under Option 2**. Under basic compliance about 30% of respondents expected a cost increase (compared with only 25.4% in option 1), versus 43.6% if the technical file were included in the option (similar to the result under option 1). The vast majority of respondents do not expect option 2 to lead to a reduction in costs under either the full or basic scenarios. However, a significant share of respondents perceives greater additional costs under the full compliance option.

As for Option 1, a number of elements should be taken into account in the design of the option:

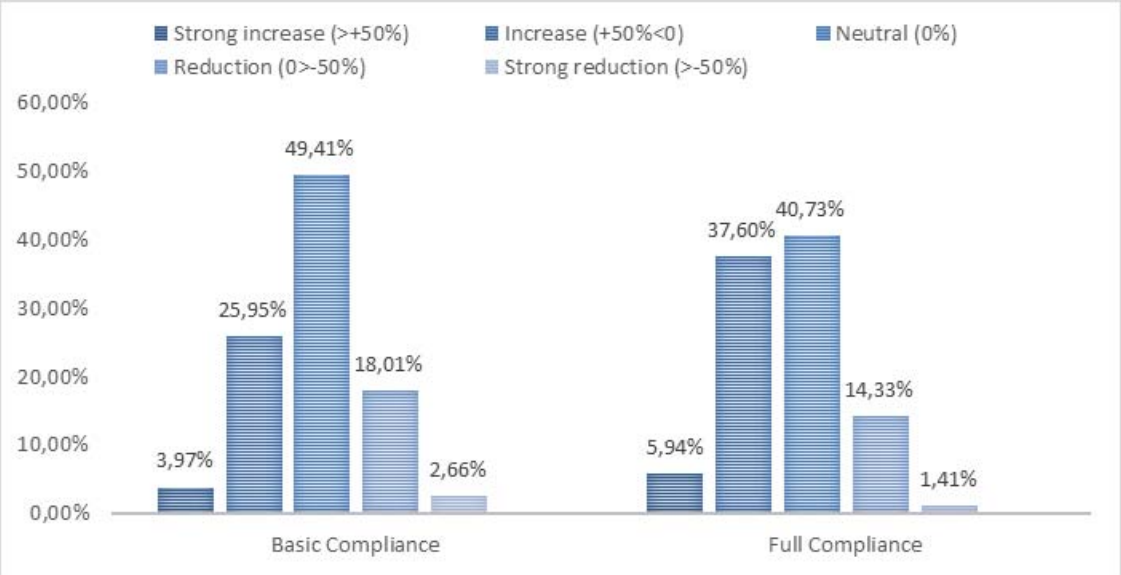
1. There would be a one-off setup cost to create an in-house database with electronic versions of the documents to be uploaded.

2. However, this one-off cost would be lower as compared to Option 1 (according to interviews) since each company would have greater control and knowledge over their own IT system and there would be no compatibility issues.

3. Overall, costs would be higher if the digital decentralised database were to include the technical file. Indeed, as for option 1, manufacturers and manufacturers association were unanimous in opposing full compliance including the technical file due to the confidential nature of the data included in that file.

4. Indeed, interviews suggested that such security risks would be even higher under Option 2 than under Option 1, since access would have to be granted to the MSAs and the full compliance version of option 2 seems to assume that either the technical file would be publicly available or that it would be made available via a restricted account to the MSA which would carry further costs for both companies and the MSA.

Figure 14-29: Option 2 – change in cost of demonstrating compliance



Source: CATI survey, weighted by NACE code

The table below breaks down the above results to estimate the change in the cost of demonstrating compliance by company size.

Unlike under option 1, companies of all sizes expect, on average, a cost increase under option 2 with the largest increases expected by micro-companies (5.64%) and the lowest increases among larger companies (0.79%-1.90% for medium and large companies respectively). It should be noted that the **estimated costs for micro -companies (the largest enterprise population) are lower under this option than under Option 1 and there is almost no difference between the options for large companies.** However, there is unanimity among companies of all sizes that including the technical file would lead to a significant increase in the costs of demonstrating compliance of between 6% (large and medium size companies) and 12% (micro companies).

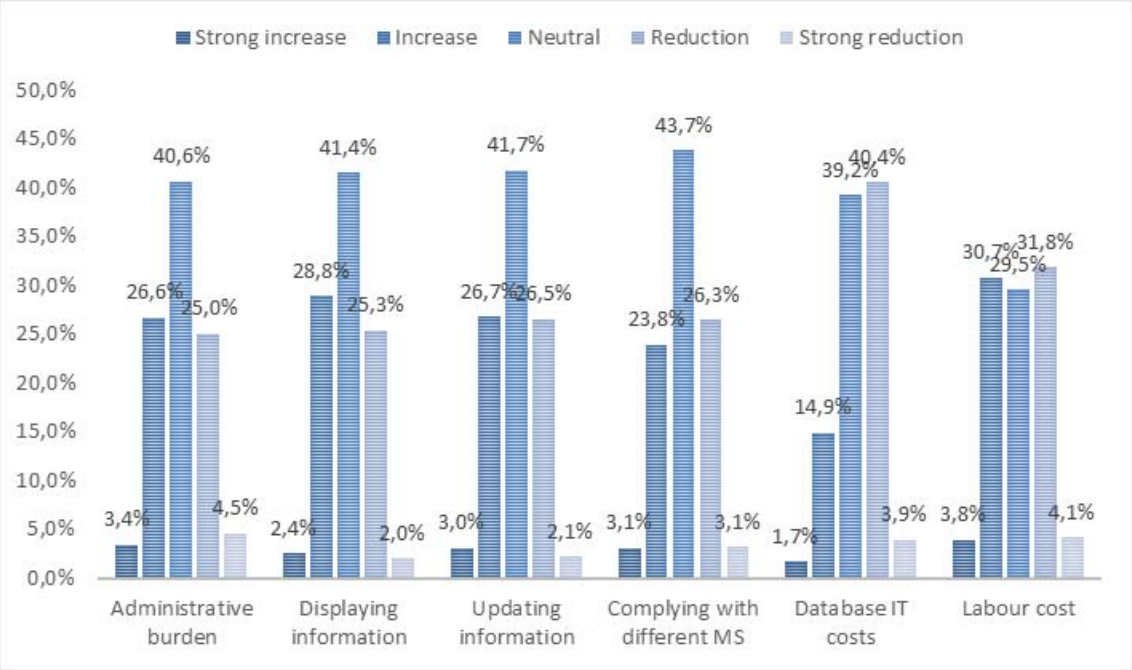
Table 14-16: Estimated change in cost of demonstrating compliance per sector, per company size

	Basic	Full
Size	**%**	**%**
Large	1.90%	6.53%
Medium	0.79%	6.28%
Small	2.89%	8.43%
Micro	5.64%	12.27%
TOTAL	**2.64%**	**8.08%**

Source: CATI survey, weighted by NACE code

The figure below provides a further breakdown of the kinds of costs that are likely to change under option 2. The results here are very similar to option 1 in that the key cost categories where increases are expected are administrative burden, displaying and updating information. In contrast, reductions in costs are expected primarily in database / IT costs. The impact of this option on labour costs is balanced between those who expect a reduction in costs, those who expect an increase and those who expect the option not to lead to any change in this type of costs.

Figure 14-30: Key cost impacts as a result of Option 2 (basic compliance)



Source: CATI survey, weighted by NACE code

Like for option 1, in order to arrive at a monetary cost estimate, we assume that all companies which comply with Union harmonisation legislation under the paper based approach would continue to do so under a decentralised digital compliance procedure. Taking the median cost increase under each of the options, it can be estimate that the total additional cost of Option 2 would be as shown in the table below. Starting from the baseline calculated in section 5.3.4.1 to estimate the costs of Option 2 we consider:

- Estimated percentage change in cost of demonstrating compliance
    - Basic compliance: 2.64%
    - Full compliance: 8.08%
- Voluntary uptake: 74.65%
- Incidence technical file: 80.89%

Annex 7.9 summarises the calculation used to estimate the overall costs of demonstrating compliance as well as its NPVs.

Adopting Option 2 would lead to an average increase in recurring costs of demonstrating compliance between € 39.06 and € 118.13 per year.

Under a basic compliance system, the average yearly increase would be between € 39.06 (with voluntary uptake) and € 47.72 (with mandatory uptake). Under a full compliance system, the average yearly increase would be between € 96.71 (with voluntary uptake) and € 118.13 (with mandatory uptake). The increase in recurring costs is lower in case of adoption of a decentralised database with basic compliance.

Table 14-17: Company costs under Option 2

Cost of demonstrating compliance			Total	Company Level
Baseline			€ 842,374,938.53	€ 1,807.41
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 858,976,126.87	€ 1,846.48
		Mandatory	€ 864,613,636.91	€ 1,855.13
	Full Compliance	Voluntary	€ 883,474,696.33	€ 1,904.13
		Mandatory	€ 897,431,546.43	€ 1,925.54
Change in cost of demonstrating compliance			**Total**	**Company Level**
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 16,601,188.34	€ 39.06
		Mandatory	€ 22,238,698.38	€ 47.72
	Full Compliance	Voluntary	€ 41,099,757.80	€ 96.71
		Mandatory	€ 55,056,607.91	€ 118.13
NPV			**Total**	**Company Level**
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 151,251,696.77	€ 355.92
		Mandatory	€ 202,614,463.18	€ 434.73
	Full Compliance	Voluntary	€ 374,455,609.88	€ 881.14
		Mandatory	€ 501,615,016.59	€ 1,076.27

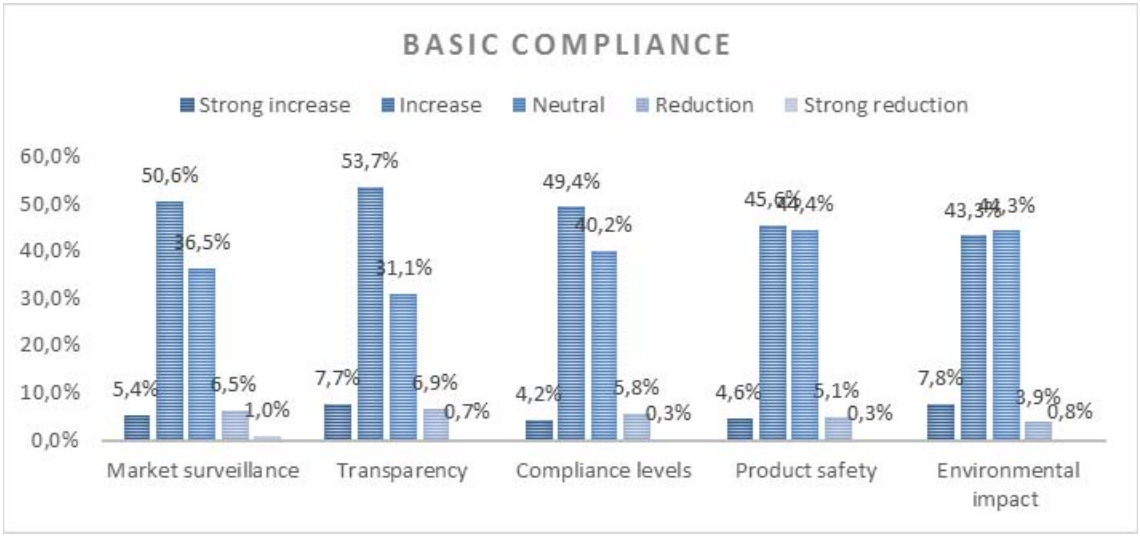
In terms of one-off costs, interviewees were reluctant to provide estimations. Business associations are concerned that small companies would face higher one-off cost when no pre-existing IT structure was set up – even though micro companies estimated the cost of this option to be lower than that of Option 1. Large companies instead, could create profiles for the authorities to allow them limited access to pre-existing databases which are already in use internally. As for Option 1, due to security concerns, business associations highlighted that one-off costs would be higher in case of full compliance.

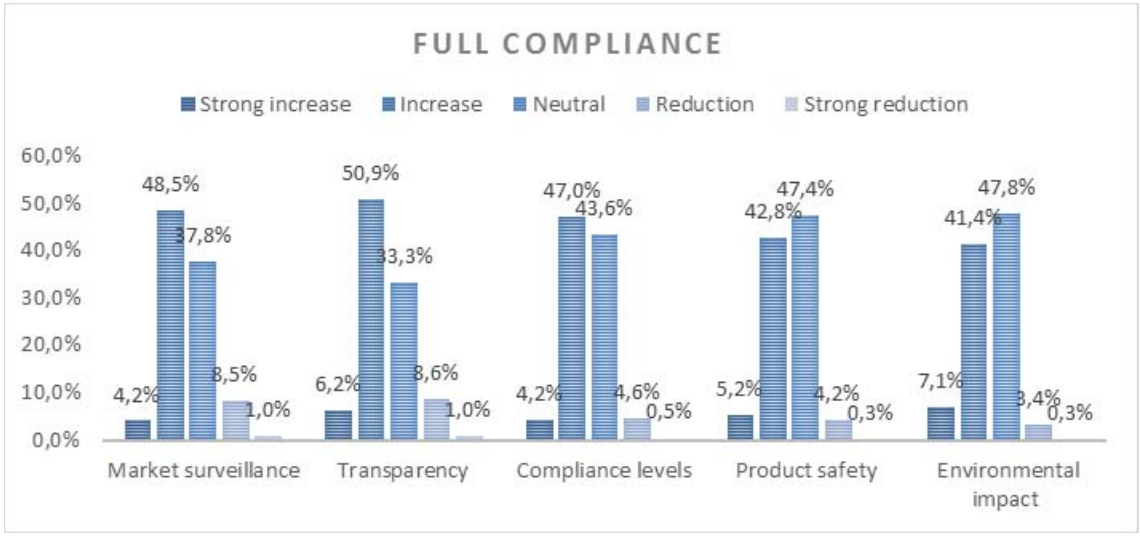
5.5.2.2. Benefits to companies

The figure below shows the key benefits identified by companies as a result of option 2, for both the sub-options with basic and full (i.e. including technical file) compliance. Like for option 1, under basic and full compliance, improvements are expected by a majority of respondents in terms of market surveillance, transparency, compliance levels, product safety and environmental impacts. While very few respondents expect a negative impact of the option on any of these aspects, the results are – on the whole – slightly less positive than they were for option 1. Like for option 1, the results are relatively similar for the full compliance

scenario (including the technical file) which suggests that companies do not expect much added value from the inclusion of the technical file.

Figure 14-31: Impact of option 2 (basic and full compliance) on benefits of demonstrating compliance





Source: CATI survey, weighted by NACE code

5.5.2.3. Costs and benefits to MSAs

With regard to this option there are likely to be very few costs or benefits for MSAs.

This is because a decentralised database would effectively still require MSAs to contact the company to retrieve the relevant documents and to point to the answer to the MSA's specific request within the documents on the manufacturer's website.

This would be even more the case if option 2 was voluntary, since the lack of completeness and the uncertainty regarding whether the documents on the manufacturer's website are fully

updated would further reduce the incentive for MSAs to try and find the desired compliance information on the company website before contacting the manufacturer directly.

As a result, from the MSA's perspective this option would impose potential additional burdens on companies (i.e. creation of a website and uploading of documents in electronic form) without any benefits in terms of time saved during investigations by the MSA.

However, one MSA pointed out that the use of an Auto-ID or e-labelling system could have a significant impact on the costs and benefits of this option from an MSA's perspective since it would greatly facilitate access to relevant and updated information. Introduction of Auto-ID and the potential use of e-labelling for devices with a screen is examined further in the next section.

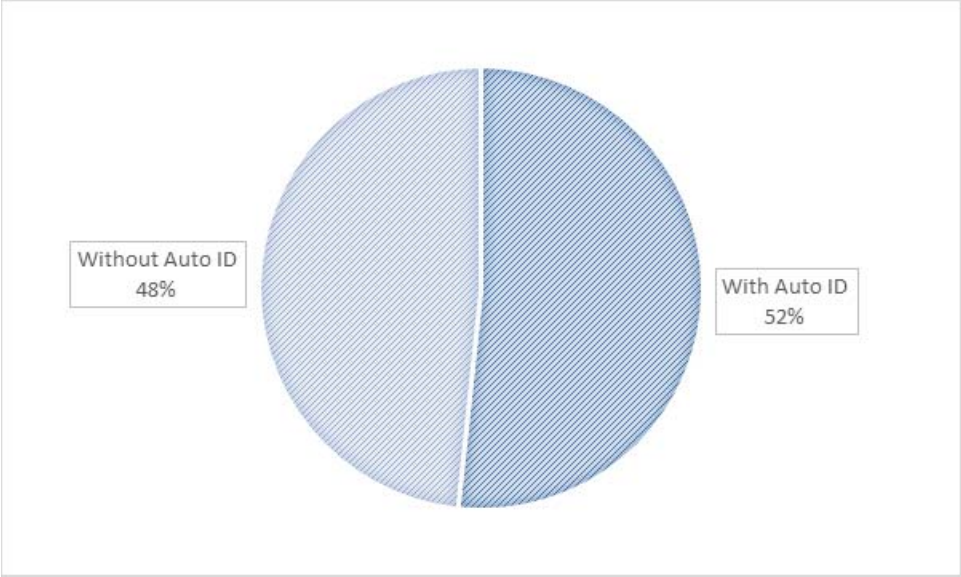
5.5.3. Auto ID and E-labelling

5.5.3.1. Auto ID

Auto ID refers to the method of automatically identifying objects, collecting data about them, and entering them directly into computer systems, without human involvement. Because the process is automated, information is gathered quickly and accurately. The most common technologies used to identify and capture data are barcodes, QR codes, Radio Frequency Identification, smart cards and magnetic stripes.

The technology finds a multitude of applications and it is often used to optimise logistics and supply chain. As a result, according to the CATI survey respondents, **about half of the firms interviewed, stated to currently produce, distribute and import at least one item in their product portfolio already equipped with an automatic identification tag** as shown in the figure below.

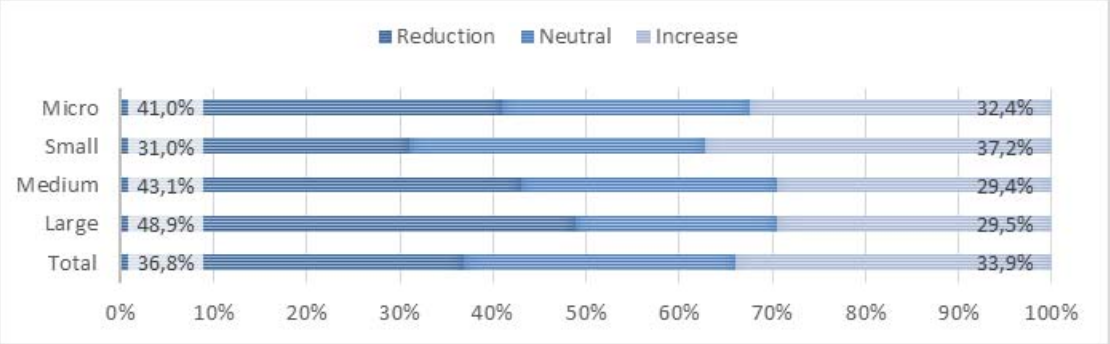
Figure 14-32: Firms currently producing/importing/distributing at least one item equipped with an automatic identification tag



Source: CATI survey, weighted by NACE code

Figure 14-33 summarizes the change in the cost of demonstrating compliance expected by companies if Auto ID technologies were included in the procedure for demonstrating compliance digitally. The overall opinion is fragmented with slightly more than one third of respondents expecting a reduction in cost, about one third expecting an increase and about one third not expecting much change at all. The reason behind this fragmentation may be due to the different impact that the sub-option would have on the different options.

Figure 14-33: Auto ID - change in cost of demonstrating compliance, by size



Source: CATI survey, weighted by NACE code

According to the interviews, stakeholders expect **Auto ID to be particularly useful in case of a decentralised digital compliance system**, since it could contain information on the exact URL where stakeholders can find compliance documentation on the manufacturer's website. For example, producers could add a QR code on the product that stakeholders could use to directly access the appropriate URL on the producer website. In case of Option 1 where information would be stored centrally, there would be little additional benefit from Auto-ID. There were no differences in the impact of Auto ID technologies under full/basic compliance or in terms of the mandatory/voluntary uptake of the different options.

The main benefits identified in the use of Auto-ID technologies are:

- Rapid and accurate identification of items by custom duty, notified bodies, market surveillance authority and consumers
- Potential support in addressing counterfeiting more efficiently
- Effective management of product recalls for manufacturers, distributors and resellers (outside the scope of this study).

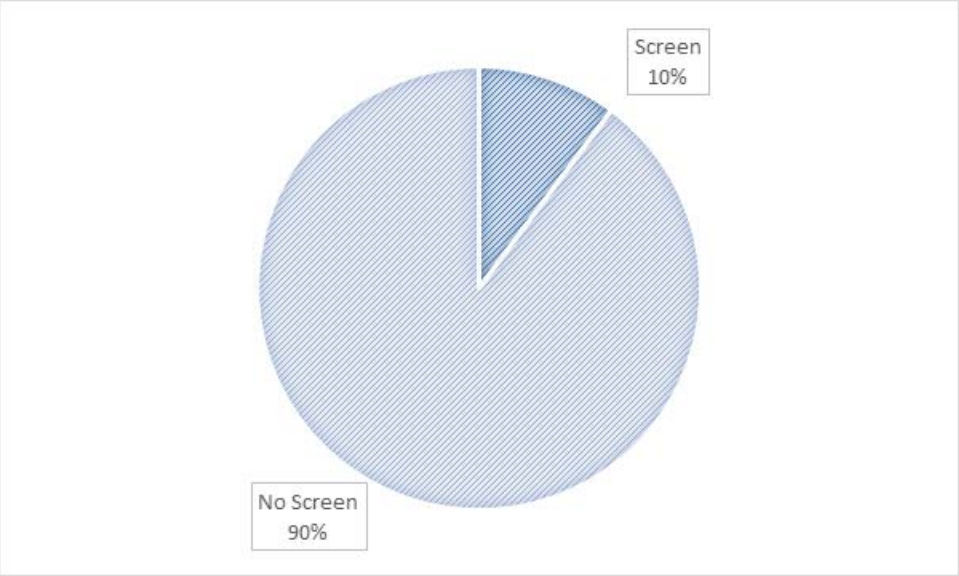
5.5.3.2. E-labelling

E-labelling refers to displaying compliance information in the integral screen of the product (if the product has a screen), whereby no access code or permissions should be required for accessing all the information needed to demonstrate compliance. The information would have to be accessible in no more than three steps in a device's menu.

At the moment, the only legislative EU instrument that provides for e-labelling is Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28). It establishes the conditions under which the instructions for use of medical devices may be provided in electronic form instead of in paper form. It also establishes certain requirements concerning instructions for use in electronic form which are provided in addition to complete instructions for use in paper form relating to their contents and websites. For specific medical devices, the provision of instructions for use in electronic form instead of in paper form can be beneficial for professional users. It can reduce the environmental burden and improve the competitiveness of the medical devices industry by reducing costs, while maintaining or improving the level of safety.

By definition, the use of an e-labelling system would only impact products that contain a screen (computer, smartphone, tablet, etc.). According to the CATI survey, 10%[84] of respondents across all sectors, stated that within their product portfolio they produce, distribute or import electronic devices with a screen that could display information digitally on the screen rather than on a label affixed to the device.

Figure 14-34: Firms currently producing/importing/distributing at least one item currently equipped with a screen

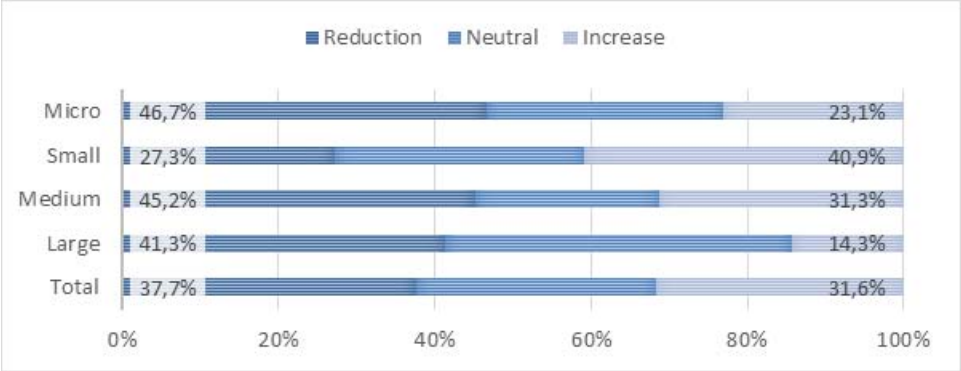


Source: CATI survey, weighted by NACE code

Figure 14-35 summarizes the change in the cost of demonstrating compliance expected by companies in case e-labelling technologies were introduced alongside the main options under consideration. Regardless of company size, the majority of companies believe e-labelling to reduce or have a neutral effect in terms of costs. The benefit seems to be higher for large, medium and micro companies and somewhat smaller for small companies (though this may simply be due to the sector/size make-up of the CATI sample). According to the interviews, stakeholders believe that the impact of e-labelling would be the similar across all options and sub-options.

84 Data weighted by NACE code

Figure 14-35: E-labelling - change in cost of demonstrating compliance, by size



Source: CATI survey, weighted by NACE code

The advantage of E-labelling in terms of costs is not clear, nevertheless during the interviews potential advantages were highlighted:

- E-labelling can include a greater amount of information than regular labels. This would give the possibility to certain companies to display a greater amount of information than today, such as the contacts of the different national offices.

- Reduction in paper used for labelling and manuals.

- Information could be provided in all the official languages avoiding logistical barriers that arise today.

- Possibility (for products that can be updated remotely) to avoid recalls associated with incorrect label information

5.5.4. Options comparison

5.5.4.1. Cost comparison

Following the methodology highlighted in section 5.5.1.1 and 5.5.2.1, Table 14-18 summarises the costs of demonstrating compliance for companies under Option 1 and 2. For all options we observe an increase in costs compared to the baseline. Cost increases are sensibly higher in case of full compliance both for Option 1 and 2 (more than € 100 a year at company level), with Option 1 being slightly higher than Option 2.

With basic compliance, the estimated cost of a centralised database (Option 1) is lower than for a decentralised one (Option 2). At company level, the yearly cost of Option 1 with basic compliance is € 3 or less, while with Option 2 with basic compliance the price goes up to € 39 – 47. Between voluntary and mandatory uptake there is no significant difference on a per company basis though the total cost of the option would be lower since a smaller percentage of the population would incur the cost of switching to the digital compliance demonstration procedure.

Nevertheless, it is important to consider, as mentioned before, that micro companies would be unlikely to set up an automatic feeding of data into a centralised database, given the relatively low number of updates to compliance documentation required from them. As a result, as

described in section 5.5.1.1, feeding and updating a centralised database would be a more labour-intensive and costly activity for micro companies compared with Option 2.

Table 14-18: Cost of demonstrating compliance to companies (Cost comparison)

Cost of demonstrating compliance			Total	Company Level
Baseline			€ 842,374,938.53	€ 1,807.41
Option 1: Centralised database	Basic Compliance	Voluntary	€ 843,547,347.54	€ 1,809.93
		Mandatory	€ 843,806,975.92	€ 1,810.48
	Full Compliance	Voluntary	€ 889,067,568.70	€ 1,907.60
		Mandatory	€ 899,407,588.05	€ 1,929.78
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 858,976,126.87	€ 1,846.48
		Mandatory	€ 864,613,636.91	€ 1,855.13
	Full Compliance	Voluntary	€ 883,474,696.33	€ 1,904.13
		Mandatory	€ 897,431,546.43	€ 1,925.54
Change in cost of demonstrating compliance			Total	Company Level
Option 1: Centralised database	Basic Compliance	Voluntary	€ 1,172,409.02	€ 2.52
		Mandatory	€ 1,432,037.40	€ 3.07
	Full Compliance	Voluntary	€ 46,692,630.17	€ 100.18
		Mandatory	€ 57,032,649.53	€ 122.37
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 16,601,188.34	€ 39.06
		Mandatory	€ 22,238,698.38	€ 47.72
	Full Compliance	Voluntary	€ 41,099,757.80	€ 96.71
		Mandatory	€ 55,056,607.91	€ 118.13

Table 14-19 summarizes the NPV of the costs of demonstrating compliance to companies under Option 1 and 2. The NPV is calculated based on a 10-year period and a social discount rate of 4%, as suggested by the European Commission Better Regulation "Toolbox"[85].

$$NPV = \sum_{t=0}^{T} \frac{(B_t - C_t)}{(1+r)^t}$$

Where:

85 http://ec.europa.eu/smart-regulation/guidelines/toc_tool_en.htm

B_t = benefits in Euros received in year *t*

C_t = costs in Euros received in year *t*

r = discount rate

Table 14-19: Net Present Value of the different options (cost to companies)

NPV			Total	Company Level
Option 1: Centralised database	Basic Compliance	Voluntary	€ 10,681,696.35	€ 22.92
		Mandatory	€ 13,047,143.46	€ 27.99
	Full Compliance	Voluntary	€ 425,411,687.11	€ 912.77
		Mandatory	€ 519,618,525.85	€ 1,114.90
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 151,251,696.77	€ 355.92
		Mandatory	€ 202,614,463.18	€ 434.73
	Full Compliance	Voluntary	€ 374,455,609.88	€ 881.14
		Mandatory	€ 501,615,016.59	€ 1,076.27

According to business associations, one off costs are always higher in case of full compliance due to security concerns, while there is no apparent difference in one off costs between the voluntary/mandatory sub-options (except that these costs would only be incurred by those companies that take up the option in the voluntary scenario).

As described in section 5.5.1.1 and 5.5.2.1, one off costs are higher for larger companies in the case of Option 1 due to need to adapt company IT systems to be compatible with the centralised database, while they can potentially affect more smaller businesses in the case of Option 2 due to the need for each business to set up its own IT system.

From the European Commission perspective, the introduction of a centralised database would be costlier, both in terms of recurring and one-off costs since the Commission would need to set up the database, maintain it, ensure security as well as provide assurance that documents available on the database are fully up to date. Under full compliance (i.e. with the technical file), the centralised database option would be even costlier due to security concerns.

Furthermore, both the centralised and decentralised database options would effectively still require MSAs to contact the company to retrieve the relevant documents and to assist the MSA in identifying the answer to the its specific query within the compliance documents.

This would be even more the case if the option was voluntary, since lack of completeness and uncertainty regarding whether the documents on the manufacturer's website are fully updated would further reduce the incentive for MSAs to try and find the desired compliance information on the company website (or in a centralised database) before contacting the manufacturer directly.

Furthermore, for MSAs the introduction of a new centralised database would require an increase in the operational budget and newly trained personnel to deal with the database and share relevant information with inspectors. However, one MSA pointed out that the use of an Auto-ID or e-labelling system could potentially have a significant impact on the costs and benefits of option 2 from the authority's perspective since it would greatly facilitate access to relevant and updated information.

5.5.4.2. Benefits comparison

Table 14-20 visually compares the benefits highlighted in section 5.5.1.2 and 5.5.2.2, as well as the inputs received from the interviews conducted with MSAs and industry representatives. While it was not possible to quantify the magnitude of the benefits generated by the proposed options (because those benefits are – for the most part – not quantifiable), the table compares the different options with one another to identify which option would lead to the greatest benefits. For companies, due to the use of a structured survey questionnaire in the CATI with 1700 companies across the sectors within scope, it was possible to quantify the benefits (though not to monetise them). For each option, the estimate is the sum of the average benefits estimated for each category of potential benefits included in the survey questionnaire (i.e. access to information; transparency; compliance levels, etc.). Each response was code using a Likert scale from -2 (strongly negative) to +2 (strongly positive). The first result is that, even for companies, all proposed options have a overall positive impact on the types of potential benefits that were investigated. Furthermore, Option 1 scores higher than Option 2 and in both cases companies declared that introducing a basic compliance system would have greater benefits for them than a system that also includes the technical file.

Option 1 (centralised database) improves access to information as well as transparency of that information under both the basic and full compliance scenarios. Option 2 also improves access to information as well as transparency, but to a smaller extent. The difference between the two options is highlighted both by the CATI survey, as well as by the interviews. According to MSAs, if compliance information is not centralised it might be harder to access and monitor it, even though the use of Auto ID technology could fill this gap. Decentralised data are also harder to compare and analyse since they might be stored using different data formats. Furthermore, in the case of a decentralised database with full compliance, the commercial sensitivity of the technical file would require strict access limitations which would lower the benefit in terms of ease of access to information and transparency.

Finally, according to companies and MSAs both Option 1 and 2 could have a small benefit in terms of compliance levels, product safety and environmental impact.

For all categories of benefits, the voluntary sub-option would reduce the overall impact of the proposed option.

- For access to information and transparency, the reduction is due to lack of comprehensive and reliable information that is fully updated.

- For compliance levels and product safety, the reduction is due to the fact that companies that fail to comply or do not respect product safety regulation would be less likely to switch to a digital compliance procedure.

- The lower environmental impact is explained by the lower share of companies adopting a digital procedure for demonstrating compliance.

Table 14-20: Benefits comparison, assuming adoption of Auto ID

Benefits comparison			Access to information	Transparency	Compliance levels	Product safety	Environmental impact	Overall estimate of benefits according to companies
			Interviews with MSA, Notified bodies and industry representatives					*CATI company survey**
Option 1: Centralised database	Basic Compliance	Voluntary	**	**	**0**	**0**	*	2.47
		Mandatory	***	***	*	*	**	
	Full Compliance	Voluntary	**	**	**0**	**0**	*	2.06
		Mandatory	***	***	*	*	**	
Option 2: Decentralised database	Basic Compliance	Voluntary	**	**	**0**	**0**	*	1.48
		Mandatory	***	***	*	*	**	
	Full Compliance	Voluntary	**	**	**0**	**0**	*	1.18
		Mandatory	*	*	*	*	**	

Note: * the quantitative estimate is based on the average across all categories of benefits and for all companies. It ranges from -2 (strongly negative impact) to +2 (strongly positive impact)

5.5.4.3. Conclusions of options comparison

The table below shows the comparison between cost and benefits according to companies. It is important to highlight that the cost structure does not include one off costs, which could potentially alter the outcome.

The results show that based purely on the responses of companies consulted in the CATI survey, the centralised database with basic a compliance solution (i.e. without the technical file) would bring the highest benefit per euro cost. Including the technical file in the option would, in turn lead to a much worse return in the perception of businesses.

Overall, Option 1 and Option 2 under basic compliance present the best cost/benefit ratio, with Option 1 Basic being overall the cheapest. Consistent with the quantitative results below, the "basic compliance" option is far less costly than "full compliance" including the technical file.

It is important to highlight that the results below are driven by the recurring cost differential between the options for companies. The comparison does not take into account one -off costs or the costs and benefits for other stakeholders (Commission, MSAs, notified bodies, and customs bodies).

Table 14-21: Cost-benefit comparison (company perspective)

NPV		NPV Company Level (based on the mandatory option)	Overall estimated benefits of the option for companies	Overall assessment (i.e. Benefit/cost)
Option 1: Centralised database	**Basic Compliance**	**€ 27.99**	**2.47**	**0.08825**
	Full Compliance	€ 1,114.90	2.06	0.00185
Option 2: Decentralised database	Basic Compliance	€ 434.73	1.48	0.00340
	Full Compliance	€ 1,076.27	1.18	0.00110

The above quantitative conclusions only cover the perceptions of companies. For the full options appraisal, one-off costs and the input of other stakeholders, which was mostly qualitative, need to be considered alongside that of companies.

According to the qualitative data collected, **one off costs are potentially higher for large companies under Option 1 and potentially higher for micro companies under Option 2**. Large companies tend to have more complex and globalised supply chains for their production process. Technological products can sometimes be made-up of more than a thousand different components produced worldwide. This results in large enterprises developing different tools, software, and procedures to manage complexity and ensure compliance. In order to automatically feed a centralised database, large companies would have to sustain a significant one-off adaptation costs to ensure safe data transmission in the correct format. Large companies would also have to initially invest to mitigate any security risk as a result of feeding an external database. Companies and sector representatives agreed that to set up and to manage a decentralised database would be cheaper for large companies as it would be easier to adapt it to today's procedures. On the contrary, micro companies do not usually have complex procedures to demonstrate compliance and they lack complex pre-existing structures (IT, management of global supply chains and internal procedures). In this case a decentralised database system could imply higher one off-costs due to the need to set up an internal database which did not exist before.

According to the qualitative data collected, **ongoing costs are expected to be lower for micro companies under Option 2 than under Option 1**. Given the lower number of updates to compliance documentation, micro companies would be unlikely to set up a system to automatically feed data into a centralised database. As a result, feeding and updating a centralised database would be a more labour-intensive activity for micro companies compared to updating the decentralised database under Option 2. As a result, ongoing costs for micro companies are expected to be lower under Option 2.

One off and recurring costs would be higher for the European Commission under Option 1 (a centralised database managed by the Commission). From the perspective of the European Commission, the introduction of a centralised database would be costlier, both in terms of recurring and one-off costs, since the Commission would need to set up the database, maintain it, ensure its security, as well as to provide assurance that documents available on the database are fully up to date. Under full compliance (i.e. with the technical

file), the centralised database option would be even costlier due to security concerns. The Commission's involvement in database management is not foreseen under Option 2.

According to MSAs, both a centralised and a decentralised database would effectively still require them to contact the company to retrieve the relevant documents and to point to the answer to the MSA's specific request, regardless of the level of compliance (full/basic). As of today, companies have to reply to specific MSA' requests. Even if provided with the technical documentation, it would be very expensive for MSAs to retrieve specific information without the involvement of the manufacturing companies.

Both MSAs and manufacturers agreed that the MSA's cost of accessing data under a decentralised system would be lower if Auto ID technology was combined with the digitisation of the process for demonstrating compliance.

As a result of the above considerations, option 2 (decentralised database) with basic compliance supported by Auto-ID technology emerges as the most desirable option.

5.5.5. Competitiveness analysis

According to the Better Regulation toolbox (Tool #17)[86], EU initiatives are likely to impact competitiveness when they affect at least one of the following:

- A sector's capacity to produce products at a lower cost and/or offer them at a more competitive price (cost/price competitiveness). The cost of an enterprise's operations includes the cost of inputs (including resources and energy) and production factors which may be directly or indirectly affected by the policy proposal;

- The quality or the originality of a sector's supply of goods or services (innovative competitiveness) - technological development and innovation (of products and/or processes) are of primary importance for both the cost of inputs and the value of outputs;

- Effective market competition and undistorted access to markets including inputs and materials, public procurement, etc.;

- The sector's market shares on international markets.

In order to measure the extent to which an initiative affects competitiveness three aspects therefore need to be considered:

- **Cost competitiveness** (i.e. the extent to which a proposal affects competitiveness by raising costs for some companies but not for others)

- **Innovation competitiveness** (i.e. the extent to which a proposal affects the propensity of / the likelihood of success of innovation among some companies but not others)

- **International competitiveness** (i.e. the extent to which a proposal affects the ability of European companies to compete with non-European companies)

86 http://ec.europa.eu/smart-regulation/guidelines/tool_17_en.htm

What is important to keep in mind when assessing competitiveness (and what makes it different from the cost benefit analysis above) is its focus on systematic *differences* in costs and benefits across different groups of companies rather than the focus on the *level* of costs and benefits that forms the core of the cost-benefit assessment.

Cost competitiveness

As reported in section 5.5.1.1, 5.5.2.1 and summarised in the table below, the options could affect cost competitiveness because they impact companies differently depending on their size. Overall, micro companies tend to be the most affected by changes in compliance demonstration procedures If the proposed options do raise costs for the smallest companies more than they do for larger firms (as shown in Section 5.5.1.1 and 5.5.2.1) then this will result in a deterioration of cost competitiveness for the smallest companies.

At the same time, the cost impacts identified in this report are not likely to be significant enough to substantially alter the market position of companies depending on their size. Furthermore, in the longer term, the benefits of digitisation would accrue faster to smaller firms if they adopt these tools now rather than only in the future. Finally, it has also been argued that one off costs for large companies could be very high (e.g. for option 1, the centralised database) due to the need for such a database to be interrogable with the compliance management software that larger companies have already invested in.

On the whole, therefore, this report concludes that cost competitiveness implications of the proposed initiatives would **not be significant.**

International competitiveness

In terms of international competitiveness, since the new procedures on demonstrating compliance would apply to European manufacturers, distributors and importers of products from outside the EU, there would not be an international impact. It would be expected that any costs in terms of demonstrating compliance (minimal though they might be) would be passed on by importers to foreign manufacturers. However, for European companies that sell their products both in the EU and in third countries, recurrent and one-off costs to switch to a digital procedure for demonstrating compliance would put them at a disadvantage compared to local manufacturers in third countries which do not sell into the EU. However, given the limited magnitude of costs estimated under all of the options in this report, any such disadvantage would **not be significant.**

Innovation competitiveness

No innovation competitiveness impacts are expected under any of the options since these are unlikely to lead to fundamental changes to products that are currently on the market.

5.6. Conclusions and recommendations

5.6.1. Conclusions

The analysis presented in this report has led to the following conclusions:

- Most companies (86.6%) in the sectors concerned by Union harmonisation legislation do demonstrate compliance via technical product documentation, the declaration of conformity or product traceability.

- About half of companies (41%) in the relevant sectors in Europe are subject to a market surveillance inspection every 5 years and about 38.2% indicated that they already use digital means for demonstrating compliance (e.g. exchanging documents with MSAs electronically) – though there are large differences across countries.

- The overall costs of demonstrating compliance are significant at €1,807.41 per company or over €800 million per year on average across the EU economy.

- More than half of companies believe these costs to be "high" or "very high" and more than 69% think a digital system for demonstrating compliance would be an improvement, compared with only about 10% who think such a system would be worse than the current one.

- Both the proposed options are unlikely to lead to very significant changes in the cost of demonstrating compliance for companies, especially if the basic sub-option (without the technical file) is chosen.

    - In terms of recurring costs:

        - Option 2 is the least costly for micro-companies, the largest share of the enterprise population under study

        - Option 1 is the least costly for large companies – though the difference between the options is not very significant for these larger companies

    - In terms of one-off costs:

        - Smaller companies may incur initial set-up costs to develop an in-house compliance demonstration database under option 2.

        - Larger companies would incur initial costs to ensure interoperability between their existing in-house regulatory compliance systems and that of the centralised database under option 1.

- From the Commission's perspective, there would be additional costs under option 1 (centralised database) assuming this database would be managed by the Commission. There would be no additional costs under option 2 (decentralised database).

- There is strong opposition from companies to including the technical file in any digital system due to confidentiality and security concerns.

- If the technical file were included in the proposed options, these cost increases would be significantly higher due to the complexity of the document and its sensitive nature.

- If the options were made **voluntary**, a large share of respondents indicate that they would take up the digital procedure for demonstrating compliance (excluding the technical file) (82% for option 1 and 75% for option 2).

- On the **benefits** side, for MSAs a mandatory centralised database could facilitate and speed up access to information, especially regarding traceability (e.g. for companies that do not exist anymore). Such a centralised databased would also support the exchange of information with MSAs in other countries, which is currently a source of frustration and delay.

- However, benefits would be limited by the fact that MSAs usually need to contact the manufacturer directly with very specific requests and questions and this would still be required under a digital system which only makes full documents available.

- In addition, the digital system would only be useful to MSAs if it was complete and always up to date which would not be the case under the voluntary sub-option.

- **Auto-ID** technology would help improve a decentralised database system, since allows to rapidly and accurately identify data stored in a decentralised structure. 52% of companies in the sectors covered by Union harmonisation legislation already include an automatic identification tag.

- In combination with Auto-ID technology the decentralised database option (option 2) would offer similar access to information for MSAs as the centralised database.

- Finally, **e-labelling** can help increase the amount of information compared to regular labels and can help improve logistics (since it can store more languages than regular labels). However, it would only apply to about 10% of companies in the sectors covered by Union harmonization legislation.

5.6.2. Recommendations

Considering the high cost of full compliance (i.e. including the technical file) under both options, significant initial set-up costs especially for the smallest companies under the centralised database (option 1), and possible compatibility difficulties in feeding such a centralised database (option 1), the results of the study suggest that the **decentralised database for basic compliance** would be the best option among those considered in this assessment.

The fact that this option exhibits somewhat higher recurring costs for larger companies is counterbalanced by the fact that it is less costly for the largest group of companies (micro-businesses) and the lower costs for the Commission which does not need to be involved in database management under this option. From the perspective of MSAs there is little difference in the costs of option 1 and 2 (or the benefits assuming the option is supplemented by the adoption of Auto-ID technology).

Furthermore, introduction of **Auto ID technology** could greatly help the adoption of such a decentralised database for basic compliance, since it would improve speed and ease of access to information for authorities.

While the full benefits of this option would only materialise under the mandatory scenario (i.e. if all companies used the digital procedure for demonstrating compliance) the transition to a digital procedure would be facilitated if the option were initially made voluntary for companies. This would allow all stakeholders (MSAs, companies, notified bodies, and other authorities) to familiarise themselves with the system, develop the required in-house skills and put in place a digital compliance demonstration system in their own time.

Indeed, three quarters of companies have indicated that they would be likely to take up a voluntary decentralised database option. However, voluntary take-up by businesses should be monitored to assess whether a move to a mandatory scenario might be required in the future.

5.7. Annexes

5.7.1. List of references from the literature review

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58. European Commission, Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 – Sector 19 Radio and telecom equipment under RTTE;

59. European Commission, Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 – Sector 20 Electrical appliances and equipment under LVD;

60. European Commission, Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 – Sector 21 Electrical and electronic equipment under RoHS, WEEE and batteries;

61. European Commission, Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 – Sector 22 Chemicals (Detergents,

Paints, Persistent organic pollutants) (Regulation 648/2004, Directive 2004/42/EC, Regulation 850/2004);

62. European Commission, Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 – Sector 23 Ecodesign and Energy labelling;

63. European Commission, Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 – Sector 24 Efficiency requirements for hot-boilers fired with liquid or gaseous fuels;

64. European Commission, Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 – Sector 25 Recreational craft;

65. European Commission, Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 – Sector 26 Marine Equipment;

66. European Commission, Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 – Sector 27 Motor vehicles and tyres;

67. European Commission, Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 – Sector 28 Non-road mobile machinery;

68. European Commission, Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 – Sector 30 Other consumer products under GPSD;

69. SWEDAC, SE comments on the Commission paper on eCompliance (ENTR.C.1 ZB/el D (2014)3653472), 2014;

70. EuroCommerce, Digital compliance system, 2017;

71. European Commission, The 'Blue Guide' on the implementation of EU product rules 2016;

72. CEPS, Final report – Assessing the costs and benefits of regulation, 2013;

73. CSES, Final report – Evaluation of the Internal Market Legislation for Industrial Products, 2014

74. European Commission, The future of market surveillance in the area of non-food consumer product safety under the General Product Safety Directive - SANCO/2009/B3/012, 2011;

75. BALance Technology Consulting GmbH, The possible introduction of an electronic tag as a supplement or a replacement of the wheel mark in marine equipment, 2016;

76. European Commission, Brief factual summary of the public consultation on enforcement and compliance, 2016.

77. PTC, Cumplimiento normative: Garantía de que los productos y procesos cumplen as normas del gobierno, del cliente y terceros

5.7.2. Stakeholder list

SH mapping.xlsx

5.7.3. Interview guides

Interview guide - manufacturers repre

Interview guide - market surveillance

5.7.4. Online survey

Online survey - market surveillance

5.7.5. CATI survey questionnaire

CATI questionnaire.docx

5.7.6. List of sectors covered, number of enterprises, employment and turnover

NACE CODE	Number of enterprises (Eurostat SBS - data as of 2013)	Number of persons employed (Eurostat SBS - data as of 2013)	Turnover or gross premiums written (Eurostat SBS - data as of 2013) - million Euro
NACE 13.92 Manufacture of made-up textile articles, except apparel	24,334.00	175,000.00	14,865.10
NACE 15.20 Manufacture of footwear	20,337.00	288,100.00	26,110.40
NACE 20.51 Manufacture of explosives	549.00	17,300.00	

NACE CODE	Number of enterprises (Eurostat SBS - data as of 2013)	Number of persons employed (Eurostat SBS - data as of 2013)	Turnover or gross premiums written (Eurostat SBS - data as of 2013) - million Euro
NACE 22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	1733 (2011)	125,600.00	43,418.80
NACE 22.19 Manufacture of other rubber products	5,983.00	208,000.00	
NACE 22.21 Manufacture of plastic plates, sheets, tubes and profiles	7,000.00	257,600.00	58,976.50
NACE 22.23 Manufacture of builders' ware of plastic	12,628.00	243,300.00	32,000.70
NACE 24.20 Manufacture of tubes, pipes, hollow profiles and related fittings, of steel	2,000.00	117,800.00	31,510.00
NACE 24.51 Casting of iron	1,870.00	96,400.00	14,814.00
NACE 24.52 Casting of steel	500.00	32,900.00	4,276.50
NACE 25.11 Manufacture of metal structures and parts of structures	n/a	691,400.00	86,406.40
NACE 25.21 Manufacture of central heating radiators and boilers	2,124.00	57,000.00	10,991.00
NACE 25.29 Manufacture of other tanks, reservoirs and containers of metal	3,096.00	73,500.00	9,611.00
NACE 25.30 Manufacture of steam generators, except central heating hot water boilers	n/a	42,000.00	8,308.20
NACE 25.99 Manufacture of other fabricated metal products n.e.c.	38,878.00	356,900.00	44,258.70
NACE 26.11 Manufacture of electronic components	7,259.00	201,000.00	44,040.70

NACE CODE	Number of enterprises (Eurostat SBS - data as of 2013)	Number of persons employed (Eurostat SBS - data as of 2013)	Turnover or gross premiums written (Eurostat SBS - data as of 2013) - million Euro
NACE 26.12 Manufacture of loaded electronic boards	3,137.00	87,500.00	14,484.50
NACE 26.20 Manufacture of computers and peripheral equipment	5,932.00	81,700.00	
NACE 26.30 Manufacture of communication equipment	n/a	180,200.00	
NACE 26.40 Manufacture of consumer electronics	2,690.00	62,100.00	21,144.50
NACE 26.51 Manufacture of instruments and appliances for measuring, testing and navigation	11,112.00	386,800.00	70,507.10
NACE 26.60 Manufacture of irradiation, electromedical and electrotherapeutic equipment	1,934.00	54,100.00	
NACE 27.12 Manufacture of electricity distribution and control apparatus	n/a	402,400.00	81,408.70
NACE 27.40 Manufacture of electric lighting equipment	7,265.00	154,800.00	28,162.60
NACE 27.51 Manufacture of electric domestic appliances	2,094.00	177,200.00	38,424.90
NACE 27.52 Manufacture of non-electric domestic appliances	2,109.00	47,400.00	5,182.50
NACE 27.90 Manufacture of other electrical equipment	n/a	187,900.00	28,956.20
NACE 28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	1,735.00	242,500.00	85915.3 (2011)

NACE CODE	Number of enterprises (Eurostat SBS - data as of 2013)	Number of persons employed (Eurostat SBS - data as of 2013)	Turnover or gross premiums written (Eurostat SBS - data as of 2013) - million Euro
NACE 28.12 Manufacture of fluid power equipment	1,909.00	114,200.00	20,615.10
NACE 28.13 Manufacture of other pumps and compressors	2,326.00	146,700.00	32,529.30
NACE 28.14 Manufacture of other taps and valves	2,326.00	138,900.00	29,728.20
NACE 28.15 Manufacture of bearings, gears, gearing and driving elements	2,825.00	199,300.00	36,191.50
NACE 28.21 Manufacture of ovens, furnaces and furnace burners	2,109.00	47,400.00	8,990.00
NACE 28.22 Manufacture of lifting and handling equipment	8,991.00	263,300.00	54,271.50
NACE 28.23 Manufacture of office machinery and equipment (except computers and peripheral equipment)	1,135.00	20,000.00	4,017.80
NACE 28.25 Manufacture of non-domestic cooling and ventilation equipment	8,581.00	230,100.00	43,325.00
NACE 28.29 Manufacture of other general-purpose machinery n.e.c.	14,902.00	335,700.00	68,023.50
NACE 28.41 Manufacture of metal forming machinery	4,325.00	145,900.00	45,096.80
NACE 28.49 Manufacture of other machine tools	4,085.00	81,700.00	12,000.00
NACE 28.91 Manufacture of machinery for metallurgy	2,706.00	49,700.00	10,217.80
NACE 28.92 Manufacture of machinery for mining, quarrying and construction	3,514.00	161,300.00	40,064.20

NACE CODE	Number of enterprises (Eurostat SBS - data as of 2013)	Number of persons employed (Eurostat SBS - data as of 2013)	Turnover or gross premiums written (Eurostat SBS - data as of 2013) - million Euro
NACE 28.93 Manufacture of machinery for food, beverage and tobacco processing	6,017.00	123,300.00	22,384.80
NACE 28.94 Manufacture of machinery for textile, apparel and leather production	2,121.00	55,300.00	11,072.80
NACE 28.95 Manufacture of machinery for paper and paperboard production	900.00	n/a	
NACE 28.96 Manufacture of plastics and rubber machinery	2,545.00	63,700.00	13,693.40
NACE 28.99 Manufacture of other special-purpose machinery n.e.c.	10,735.00	261,200.00	50,655.30
NACE 29.10 Manufacture of motor vehicles	n/a	1,041,600.00	600,000.00
NACE 29.31 Manufacture of electrical and electronic equipment for motor vehicles	n/a	207,000.00	28,092.10
NACE 30.12 Building of pleasure and sporting boats	4,307.00	45,900.00	8,061.50
NACE 32.30 Manufacture of sports goods	4,476.00	40,100.00	5,928.20
NACE 32.40 Manufacture of games and toys	5,043.00	53,000.00	
NACE 32.50 Manufacture of medical and dental instruments and supplies	60,000.00	487,100.00	63,145.70
NACE 32.99 Other manufacturing n.e.c.	28,500.00	140,500.00	14,686.30
TOTAL	**350,677**	**9,501,300**	**2,026,565.10**

5.7.7. List of NACE sectors and description

NACE 2	Description	Incidence rate[87]
13.92	Manufacture of made-up textile articles, except apparel	59.85%
15.2	Manufacture of footwear	100.00%
20.51	Manufacture of explosives	48.28%
22.11	Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	51.11%
22.19	Manufacture of other rubber products	48.77%
22.21	Manufacture of plastic plates, sheets, tubes and profiles	69.93%
22.23	Manufacture of builders' ware of plastic	100.00%
24.2	Manufacture of tubes, pipes, hollow profiles and related fittings, of steel	100.00%
24.51	Casting of iron	83.33%
24.52	Casting of steel	100.00%
25.11	Manufacture of metal structures and parts of structures	54.20%
25.21	Manufacture of central heating radiators and boilers	93.43%
25.29	Manufacture of other tanks, reservoirs and containers of metal	55.87%
25.3	Manufacture of steam generators, except central heating hot water boilers	55.87%
25.99	Manufacture of other fabricated metal products n.e.c.	69.52%
26.11	Manufacture of electronic components	67.33%
26.12	Manufacture of loaded electronic boards	64.60%
26.2	Manufacture of computers and peripheral equipment	69.91%
26.3	Manufacture of communication equipment	69.55%
26.4	Manufacture of consumer electronics	93.15%
26.51	Manufacture of instruments and appliances for measuring, testing and navigation	75.28%
26.6	Manufacture of irradiation, electromedical and electrotherapeutic equipment	65.51%
27.12	Manufacture of electricity distribution and control apparatus	77.92%
27.4	Manufacture of electric lighting equipment	69.52%

87 The incidence rate reflects the percentage of companies that after accepting to participate to the interview stated that they do not produce technical documentation and/or declaration of conformity

NACE 2	Description	Incidence rate[87]
27.51	Manufacture of electric domestic appliances	80.46%
27.52	Manufacture of non-electric domestic appliances	93.43%
27.9	Manufacture of other electrical equipment	67.16%
28.11	Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	68.98%
28.12	Manufacture of fluid power equipment	100.00%
28.13	Manufacture of other pumps and compressors	88.07%
28.14	Manufacture of other taps and valves	100.00%
28.15	Manufacture of bearings, gears, gearing and driving elements	48.43%
28.21	Manufacture of ovens, furnaces and furnace burners	87.37%
28.22	Manufacture of lifting and handling equipment	100.00%
28.23	Manufacture of office machinery and equipment (except computers and peripheral equipment)	69.91%
28.25	Manufacture of non-domestic cooling and ventilation equipment	80.46%
28.29	Manufacture of other general-purpose machinery n.e.c.	75.28%
28.41	Manufacture of metal forming machinery	56.78%
28.49	Manufacture of other machine tools	69.52%
28.91	Manufacture of machinery for metallurgy	69.05%
28.92	Manufacture of machinery for mining, quarrying and construction	61.72%
28.93	Manufacture of machinery for food, beverages and tobacco processing	91.67%
28.94	Manufacture of machinery for textile, apparel and leather production	69.40%
28.95	Manufacture of machinery for paper and paperboard production	100.00%
28.96	Manufacture of plastics and rubber machinery	68.65%
28.99	Manufacture of other special-purpose machinery n.e.c.	65.85%
29.1	Manufacture of motor vehicles	70.11%
29.31	Manufacture of electrical and electronic equipment for motor vehicles	69.52%
30.12	Building of pleasure and sporting boats	52.08%
32.3	Manufacture of sports goods	77.78%

NACE 2	Description	Incidence rate[87]
32.4	Manufacture of games and toys	93.15%
32.5	Manufacture of medical and dental instruments and supplies	75.41%
32.99	Other manufacturing n.e.c.	55.13%

5.7.8. SIC to NACE conversion table

NACE mapping.xlsx

5.7.9. CBA methodology and sensitivity analysis.

5.7.9.1. CBA methodology

This annex summarises the calculation used to estimate the overall costs of demonstrating compliance as well as its NPVs.

Option 1/Basic compliance/Voluntary

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + (option 1 basic change as % of baseline * voluntary uptake option 1)*

Option 1/Basic compliance/Mandatory

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + option 1 basic change as % of baseline)*

Option 1/Full compliance/Voluntary

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + (option 1 full change as % of baseline * voluntary uptake option 1)*

Option 1/Full compliance/Mandatory

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + option 1 full change as % of baseline)*

Option 2/Basic compliance/Voluntary

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + (option 2 basic change as % of baseline * voluntary uptake option 2)*

Option 2/Basic compliance/Mandatory

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + option 2 basic change as % of baseline)*

Option 2/Full compliance/Voluntary

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + (option 2 full change as % of baseline * voluntary uptake option 2)*

Option 2/Full compliance/Mandatory

*(cost of demonstrating compliance as % of compliance cost * cost of compliance as % of turnover * turnover * incidence level) * (1 + option 2 full change as % of baseline)*

The NPV values are calculated based on a 10-year period and a social discount rate of 4%, as suggested by the European Commission Better Regulation "Toolbox"[88].

$$NPV = \sum_{t=0}^{T} \frac{(B_t - C_t)}{(1+r)^t}$$

5.7.9.2. Sensitivity analysis

The estimation of the baseline cost of demonstrating compliance is based on several assumptions. While most of the estimation is based on an extensive CATI survey, weighted by NACE sector to reflect the structure of the European enterprise population in the sectors covered by the study, the assumption (H_0) that the total cost of compliance is 0.48% as a

88 http://ec.europa.eu/smart-regulation/guidelines/toc_tool_en.htm

percentage of turnover is based on the Evaluation of the Internal Market Legislation for Industrial Products.[89]

By relaxing the assumption H_0, different scenarios are created:

- Best case scenario: H_0 = 0.24% (-50%)
- Worst case scenario: H_0 = 0.72% (+50%)

Table 14-22 summarises the NPV of Option 1 and 2 for both scenarios. Given the linearity of the model, the impact of the change in assumption affects all options equally. Thus, whether compliance costs are reduced or increased by 50% affects the overall costs of each of the two options but it does not affect the choice of the most appropriate option. Furthermore, even such a significant difference in the cost of compliance would at best lead to a 10-year total saving of €557.45 per company and at worst to an additional cost over 10 years of €557.45

Table 14-22: Sensitivity analysis, impact of best- and worst-case scenarios for the cost of demonstrating compliance under each option

Best Case scenario (H_0 = 0.24%)			NPV, total	NPV, company
Option 1: Centralised database	Basic Compliance	Voluntary	-€ 5,340,848.17	-€ 11.46
		Mandatory	-€ 6,523,571.73	-€ 13.99
	Full Compliance	Voluntary	-€ 212,705,843.55	-€ 456.39
		Mandatory	-€ 259,809,262.93	-€ 557.45
Option 2: Decentralised database	Basic Compliance	Voluntary	-€ 75,625,848.39	-€ 177.96
		Mandatory	-€ 101,307,231.59	-€ 217.36
	Full Compliance	Voluntary	-€ 187,227,804.94	-€ 440.57
		Mandatory	-€ 250,807,508.29	-€ 538.13
Worst case scenario (H_0 = 0.72%)			NPV, total	NPV, company
Option 1: Centralised database	Basic Compliance	Voluntary	€ 5,340,848.18	€ 11.46
		Mandatory	€ 6,523,571.73	€ 14.00
	Full Compliance	Voluntary	€ 212,705,843.56	€ 456.38
		Mandatory	€ 259,809,262.92	€ 557.45
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 75,625,848.38	€ 177.95
		Mandatory	€ 101,307,231.59	€ 217.37

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

	Full Compliance	Voluntary	€ 187,227,804.95	€ 440.58
		Mandatory	€ 250,807,508.30	€ 538.14

Another sensitivity test consists of varying assumptions regarding the take-up time of the sub-options under both the voluntary and mandatory scenarios. Indeed, even under a mandatory scenario, not all companies will comply instantly with requirements. Under a voluntary scenario, take-up will be slower and it will take longer to achieve the estimated take-up as reported in the CATI survey.

Table 14-23 summarises the NPV of Option 1 and 2 for different take-up rates. In this scenario, take-up rate assumptions are:

- Under mandatory compliance it takes 4 years for all companies to comply with the new requirements (t_1 = 40%; t_2 = 60%; t_3 = 90%; t_4 = 100%)
- Under voluntary compliance the full voluntary up take rates (x = 81.87%; 74.65%) are reached after 9 years (t_1 = x*40%; t_2 = x*60%; t_3 = x*70%; t_4 = x*75% t_5 = x*80%; t_6 = x*85%; t_7 = 90%; t_8 = x*95%; t_9 = x*100%;)

Table 14-23: Sensitivity analysis, impact of gradual take-up rate of each option on cost estimates

Up-take			NPV, total	NPV, company
Option 1: Centralised database	Basic Compliance	Voluntary	€ 7,841,413.10	€ 16.82
		Mandatory	€ 10,837,238.28	€ 23.25
	Full Compliance	Voluntary	€ 312,293,915.39	€ 670.06
		Mandatory	€ 431,606,335.57	€ 926.06
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 111,033,584.70	€ 238.24
		Mandatory	€ 168,295,935.65	€ 361.10
	Full Compliance	Voluntary	€ 274,887,155.42	€ 589.80
		Mandatory	€ 416,652,233.14	€ 893.98

As this table shows, reducing the speed of take-up significantly reduces overall costs under all the options but it does not affect the relative position of the options and therefore does not affect the overall decision on which option would be least costly.

The estimation of the baseline costs of demonstrating compliance is based on several assumptions and variables that do not consider the differences in company size. However, as seen throughout the report, company size does matter. The table below shows the main variables used to estimate the cost of demonstrating compliance broken down by company

size. The cast estimates in the baseline and for each option seen previously in this report use only the average across companies of all sizes (the last row in the table below).

Table 14-24: Change in variables by company size

Size	Incidence rate	Technical file	% change in cost Option 1		% change in cost Option 2	
			Basic	Full	Basic	Full
Large	76.1%	84.0%	1.93%	6.95%	1.90%	6.53%
Medium	82.0%	84.0%	-2.02%	9.52%	0.79%	6.28%
Small	86.9%	82.4%	-0.51%	7.98%	2.89%	8.43%
Micro	70.8%	73.9%	6.15%	7.99%	5.64%	12.27%
Total	**86.6%**	**80.9%**	**0.17%**	**8.37%**	**2.64%**	**8.08%**

Source: CATI survey, weighted by NACE code

Disaggregating cost estimates by company size leads to the estimates in the table below. It is important to highlight that figures for turnover and number of companies by size and sector are not available on Eurostat. Therefore, the specific cost estimates in the table below should only be considered as an approximation of the annual cost for companies of different sizes.

But the table does show accurately which option is least/most costly in each company size category. For example, while in the total sample – not considering company size – option 1 appears least costly, this is not the case for micro-companies for whom option 2 is less costly. This result for micro-companies is very important considering that according to Eurostat, 82.94% of manufacturing companies fall within this category.[90]

Table 14-25: Analysis by company size (yearly change in cost of demonstrating compliance compared to baseline)

Analysis by Size (yearly change in cost)	Total	Large	Medium	Small	Micro

90 Eurostat: http://ec.europa.eu/eurostat

Option 1: Centralised database	Basic Compliance	Voluntary	**€ 2.52**	**€ 28.56**	-€ 29.89	-€ 7.55	€ 91.00
		Mandatory	€ 3.07	€ 34.88	**-€ 36.51**	**-€ 9.22**	€ 111.16
	Full Compliance	Voluntary	€ 100.18	€ 86.39	€ 118.33	€ 97.30	€ 87.37
		Mandatory	€ 122.37	€ 105.52	€ 144.54	€ 118.85	€ 106.72
Option 2: Decentralised database	Basic Compliance	Voluntary	€ 39.06	€ 28.11	€ 11.69	€ 42.76	**€ 83.46**
		Mandatory	€ 47.72	€ 34.34	€ 14.28	-€ 52.23	€ 101.94
	Full Compliance	Voluntary	€ 96.71	€ 81.17	€ 78.06	€ 102.79	€ 134.17
		Mandatory	€ 118.13	€ 99.14	€ 95.34	€ 125.55	€ 163.89

Source: CATI survey, weighted by NACE code

5.7.10. Mapping of Union harmonisation legislation by sector

Overview Table - New Version - Proco

5.8. Evaluation

The assessment of the different ways to promote digital compliance show that schemes based on *voluntary* provision of compliance information would perform less in effectiveness than compulsory variants, and would only have very limited to negligible less costs implications on businesses. While voluntary systems have the benefit of flexibility, they would be quite unreliable for interested persons who would consult the database/web-sites, since the absence of a declaration of conformity would not automatically mean that there is no declaration of conformity. The voluntary variants were therefore not further considered in the impact assessment.

The encouragement or prescription *of particular labelling requirements or specific technologies* (e.g. e-labelling, quick-scan / bar-codes) could be problematic due to the variety of the technical solutions present in the market. An important standardization effort would be needed to avoid complex validation procedures by the various categories of user, which may limit the validity of the multiple techniques that are currently available. For example, a law enforcer may be obliged to use many different smartphone applications for each technique or brand. The most significant issue, however, is the variety of techniques in the different domains and sectors, which can become a hurdle for the users, which belong to the professional categories of law enforcers and retailer/distributors.

The option of *e-labelling* furthermore could only apply to products with a display or screen, i.e. essentially appliances, machinery and radio equipment. e-labelling requires that the user be provided with prominent instructions on how to access the required labelling and regulatory information, in either the packaging material or another easily accessible format, at the time of purchase, and that these instructions be available on the product-related website, if one exists. However, when a consumer is considering purchasing a product, he/she cannot usually turn on the product and use the electronic display to access the labelling and regulatory information. Likewise, when distributors and other intermediaries and market surveillance authorities would examine the compliance of the products, they most likely cannot access the electronic display. E-labelling would not address the main problem driver that it should address, i.e. the transparency of compliance information to consumer and traders in the supply chain, nor facilitation of exchange of compliance information with market surveillance authorities. E-labelling is therefore not further considered in this impact assessment.

6. FEEDBACK FROM MEMBER STATES ON "FAST-TRACK" INFORMATION RECEIVED FROM COMPANIES PERFORMING RECALLS

Member States were asked to provide their views on proposals for 5 changes to the publication of RAPEX notifications on the public website[91] as well as on the publication of information received from companies performing voluntary recalls. The feedback received from Member States is summarised as follows:

A majority of Member States fully supported a "fast-track" publication on a central EU website of information received from companies regarding recalls they performed voluntarily with a view to ensuring that the general public is swiftly informed as soon as possible after the measure is taken. They overall agreed that such a system would enable the consumers who have acquired a dangerous product to receive information about the risks that the product poses and to discontinue using it, which will ensure better consumer protection.

At the same time, Member States pointed out that it must be made clear that such voluntary reporting by the companies is different from RAPEX notifications as it does not involve any investigation or approval by the competent authority. Similarly, this voluntary reporting does not exempt economic operators from their obligations under the relevant EU legislation. In addition, a formal validation by the Commission of such voluntary publication of information on recalls should take place. Member States further pointed out that the information published should not include an assessment by the economic operator of the level of the risk posed by the product, as this could lead to confusion for the consumers when there is a disagreement with the assessment carried out by the competent authorities. On the other hand, such voluntary reporting could include factual information useful for consumers, such as clear description of the product, including picture of the product and of the packaging; indication of bar or batch codes; a clear, factual and concise description of the risk to the consumer; clear description of what the consumer needs to do with the contact details of the manufacturer etc.

91 RAPEX Contact Points meeting of 14 October 2016