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PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	20 December 2017
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2017) 469 final PART 2/3
Subject:	COMMISSION STAFF WORKING DOCUMENT REFIT EVALUATION Accompanying the document Proposal for a Regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union harmonisation laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council

Delegations will find attached document SWD(2017) 469 final PART 2/3.

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PART 2/3

COMMISSION STAFF WORKING DOCUMENT

REFIT EVALUATION

Accompanying the document

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

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

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ANNEX 1: PROCEDURAL INFORMATION

1. IDENTIFICATION

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

2. ORGANISATION AND TIMING

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

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

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

3. CONSULTATION OF THE REGULATORY SCRUTINY BOARD

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

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

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

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

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

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

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

ANNEX 2: STAKEHOLDER CONSULTATION

1. OBJECTIVES OF THE CONSULTATION

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

1.1 Consultation methods and tools

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

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

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

2. RESULTS OF THE CONSULTATION ACTIVITIES

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

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

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

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

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

2.2 Meetings of the Customs Expert Group

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

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

2.3 Stakeholder conference of 17 June 2016

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

2.4 Public Consultation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2.4.2 Compliance assistance in Member States and at EU level

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

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

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

2.4.3 Business' demonstration of product compliance

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

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

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

2.4.4 Cross-border market surveillance within the EU

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

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

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

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

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

2.4.5 Market surveillance of products imported from non-EU countries

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

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

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

2.5 Targeted Consultation conducted by the Contractor

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

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

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

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

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

3. FEEDBACK TO STAKEHOLDERS

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

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

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

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

The preferred option (3) includes:

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

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

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

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

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

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

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

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

1. Lack of sufficient resources for market surveillance.

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Workshops with other ADCO Groups

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

3. Cooperation with producer countries, especially China

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

5. More documents to be shared through CIRCA BC

6. Joint actions between directives

7. Feedback on safeguard notifications from the Commission

8. Shorter dates between publication of legislation and guidance

9. Exchange between inspectors across Member States

10. Easier contacts with economic operators abroad

11. Team building, networking, exchange of experience

12. More information on what is happening in other fields

13. Review of notified bodies' certificates

14. Exchange of ADCO members

15. Convergence of ICSMS and RAPEX platforms

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

17. More responsibilities for importers

18. More resources

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

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

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

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

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

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

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

Thirteen Member States provided answers to the above questions.

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

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

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

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

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

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

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

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

4.2.1 Information to economic operators

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

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

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

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

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

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

In addition, the Commission does not have sufficient manpower to handle a **'first port of call'** to address businesses' questions on all areas of product legislation, which would **require a huge amount of work**. An **eLearning system** is proposed for raising awareness and educating economic operators through graphic interfaces, and access to applicable standards and conformity assessment procedures, and a "10-20 questions card" for importers to ask when they buy goods overseas.

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

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

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

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

4.2.3 Coordination of market surveillance at EU level

The need for closer cooperation and exchange of information is generally acknowledged. Specific proposals are made with respect to the use of current tools or to the need for additional forms of cooperation.

4.2.3.1 ICSMS and RAPEX

The importance of the development of the **ICSMS and RAPEX** systems for communication between all authorities involved in market surveillance (market surveillance authorities of all Member States, COM and, where appropriate, customs authorities) is stressed. ICSMS should be used consistently by Member States in all areas of legislation while interfaces with national systems should be provided. The creation of single system for exchange of information has also been requested but also the idea of fusion between ICSMS and RAPEX platforms to avoid the double encoding of data; however, this should take into account the fact that the RAPEX system has been used for a long time by all stakeholders.

The focus of the Commission’s wording on the Single Market Strategy is on working better together, with better sharing of information. In this regard Member States could make better and more consistent use of ICSMS; they recognise that this is a medium- to long-term issue,

and one which might require funding/support from the Commission in order to make it work – in particular for those Member States who do not use the system.

There is a need for closer cooperation between surveillance authorities in Member States and between surveillance and custom authorities, and between surveillance authorities and notified bodies, and suggests it would be good to have a stronger convergence between the the ICSMS and RAPEX platforms.

4.2.3.2 ADCOS and IMP-MSG groups

The role of **ADCOs** should be revisited and clarified (many discuss policy issues rather than focussing on issues related to technical cooperation, for example), and absences from meetings/participation should be marked. The Commission desk officers for the relevant directives should also take a stronger role in encouraging attendance/participation. Furthermore, the European Market Surveillance Forum, which was proposed in the "Regulation on Market Surveillance", would be a positive way of addressing this issue.

Member States welcome the proposal mentioned in section 3.2 above relating to workshops with other ADCOs. Similarly, a Member State suggests a better use of ADCOs to improve coordination, exploit synergies and avoid duplication. Furthermore, it suggests that the **IMP-group** should develop a shared understanding of the horizontal rules and promote more interaction between the market surveillance authorities of the Member States in the different fields of law by means of visits, joint actions, etc.

There is also a proposal devoting an extra IMP-MSG meeting to the exchange of best practice. ADCOs should contribute to the meeting by reporting on experience accumulated during their earlier joint action projects.

4.2.3.3 Cross-border cooperation

The need for consistent implementation of the **guidelines on cross-border–cooperation** is stressed, complemented if necessary by the set-up of additional legal arrangements. Furthermore, under the **safeguard clause procedure** all European market surveillance authorities must take, where necessary, measures to enforce requirements under European law. Furthermore, a Member State suggests that where a public authority prohibits the making available on the national market, this should **automatically apply in all MS,** with the ECJ possibly acting as appeal. Member States should reflect on the possibility of **specialising in specific fields**. In order to achieve an effective market surveillance system, the adaptation of **national legislation** to the EU legislation will be necessary in a number of areas (cross-border cooperation, mutual recognition of activities of the market surveillance authorities of other Member States - for example, recognition of test reports, etc.). The **organisation** of market surveillance **at national level** should be reconsidered in order to reduce the fragmentation of responsibilities.

There is also a need for **guidance on cross-border cooperation** to improve and optimize the results of authorities' actions. To achieve better results in trans-border cooperation between the Member States, in cases of non–compliant products a **contact points list for each product group** should be prepared which could provide fast and easily accessible communication.

A **mandatory harmonized procedure for MSA cooperation** will facilitate cases of cross-border cooperation and will further harmonize existing market surveillance approaches. The administrative burden for MSAs of this procedure should nevertheless be as minimal as possible.

Prior to setting additional requirements for mutual change of information, the Commission should ensure that all Member States **actively use the present procedures** and notes that for example EMC and LVD notifications are made by only a few States.

It would be useful for Member States to receive **more feedback on safeguard notifications**. In general, more cooperation and exchange of information is needed at EU and **national level**.

'Language borders' are considered as the main obstacle to day-to-day cooperation among authorities.

4.2.4 Harmonisation of market surveillance practice across Member States

There is a suggestion developing **common European standards on the quality and quantity** of their market surveillance activities.

The development and publication of **guidelines and best practices** on market surveillance in general is welcomed as a means to achieve the consolidation of the procedures of the EU market surveillance authorities in many problematic areas.

Publication of guidance documents would considerably help the harmonization of market surveillance in Europe as they would help inspectors and economic operators to interpret and correctly apply the directives and regulations. Shorter dates for the publication of guidance documents are required.

In addition, it is proposed to encourage via EU funding the **participation of** more **Member States in common projects** in which different products can be tested in order to achieve more representative results, and the dissemination of all information, analysis, results and decisions taken for this specific product group after a project is completed.

According to feedback from domestic surveillance authorities having taken part in international cooperation projects, they have provided a good overview of the practices of other countries and have contributed to carrying out uniform surveillance in different Member States.

The problem of limited human resources and **training opportunities** has been pointed out **and** a suggestion was made to promote the **exchange of inspectors** across Member States and closer cooperation among surveillance authorities to improve knowledge and exchange experiences.

Training programmes and exchange of experience between Member States' inspectors are also proposed.

The exchange of experience and best practices between inspectors across the Members States is very important to improve the harmonization of market surveillance in Europe. Regular exchanges of officials could be a solution.

Similarly, exchange of inspectors, teambuilding and networking are endorsed by other Member States.

Moreover, the **Product Safety & Market Surveillance Package** has to be finalized, since it will enable better coherence of the rules regulating consumer products and will improve coordination of the way authorities check products and enforce product safety rules across the European Union.

The current delay with revision of the Market Surveillance Regulation is considered to be problematical, and stresses the importance of a **horizontal legislative framework on market surveillance**.

The Commission should provide more information on what **instruments are available to the authorities** and how they are used in practice (frequency, criteria for deciding what tools to use in different cases), so that the barriers for putting non-compliant products on the market might be the same for all Member States.

4.2.5 Better control of products imported from third countries

There is a need to strengthen border controls, where the goods are centralised before being dispatched throughout the EU. This could be achieved either by **reinforcing the role of customs** or by ensuring detailed cooperation with market surveillance authorities.

More effective cooperation between market surveillance and customs authorities should also be achieved via a **clearer definition/better alignment of the tasks performed by the customs authorities** in order to ensure compliance with the European product rules. The need for **improved communication** between the customs and market surveillance authorities is also stressed.

Controls would improve if there was **better communication between authorities**. This might potentially be done through an electronic forum which authorities could use to discuss and agree issues which arise on products, and better guidance on the application of the directives concerned and the procedures which need to be followed.

Both the importance of cooperation between customs and market surveillance authorities and the importance of **cooperation among customs** on market surveillance matters are mentioned.

Customs should be enabled to request **manufacturer and type designation as part of the customs declaration**. Furthermore, combined nomenclature (**CN**) **codes** must be amended to be also useful for market surveillance purposes.

There is a need to improve border control of non–compliant products and to ensure **regular exchange of information** on results of controls and lists of products not released for free circulation.

Another problem is that, while many products come from outside the EU, authorities can do little against those manufacturers. Products are often placed on the EU market through “once only importers” that disappear after one or two years, so even there we can do little. **Strong measures against** these **products** are needed **to target the non EU economic operator**. For

example, a strong message could be sent when all products need to be recalled if there is no technical file present.

A Member State supports the **strengthening of responsibilities of importers**, especially when the manufacturer is outside the EU. For the supervisory authorities it is especially helpful to have a partner in the EU, which has full responsibility and all the technical documentation. According to France this could possibly be done by creating a concept of "first placer on the market", which would need to be an economic operator on the EU territory (manufacturer, agent or importer if the manufacturer outside the EU).

Improving the opportunities for the European market surveillance authorities to impose **penalties on operators in third countries** by means of agreements between the EU and third countries was also pointed out. It was also proposed to have a sustainable **education** strategy on the existing European rules in third countries that export mainly to Europe but also some **guidelines** on how to deal with different types of non-conformity (e.g. should a product be rejected at the border if there are shortcomings in labelling?). Measures must be proportionate and consistent across the EU.

4.2.6 Better control of Internet commerce

E-commerce is a great challenge because it's very difficult to trace products which are imported from non-EU countries, and to get the required information from the economic operators who are responsible for the product. A solution would be to improve **market surveillance organisation and strategies** with respect to internet commerce, as well as **broadening the concept of economic operators**.

There is an agreement on the need to incorporate Fulfilment Houses into new legislation (in particular, this might be achieved by including it in a revised Regulation on Market Surveillance), but also the need for **clarity on market surveillance tools** to be used for products bought online, either through guidance documents or legislative action.

The biggest future challenge in e-commerce is the changeover from imports of big consignments (containers with a number of the same products) sent to a distributer vs. a **high number of small consignments** consisting of only one product sent directly to the end user. In such a scenario, market surveillance authorities can only learn of a case when they are involved by customs.

Stronger border controls are also an important factor in terms of control procedures of products sold online. It is also necessary to improve the way authorities **communicate market surveillance work electronically**.

A Member State stresses the need for **authorities' powers to purchase goods** to be tested and to increase the budget for purchase and test of products found **online**. It also notes that MSAs face similar problems to those presented by Internet sales in cases of sales via catalogues (for example for construction products).

As to the products purchased through e-commerce platforms, the need to **develop a method** covering both border control, testing and cross-border communication between market surveillance and customs authorities is noted.

The Commission should capitalise on the opportunity presented by the **revision of the E-commerce Directive** and submit to the competent service the feedback from ADCOs on the needs of market surveillance over the internet.

4.2.7 More and/or better use of resources; tools to support market surveillance authorities

Lack of resources has prevented some authorities from carrying out sufficient market surveillance in some specific sectors. Often, resources are just enough to cover one part of the total market surveillance activities as initially foreseen, so some specific sectors are neglected.

In the current climate it is unrealistic to expect Member States to attribute more funding to market surveillance and that the emphasis should be on how to **use the existing allocation of resource more effectively**, and to consider better and more effective ways to improve market surveillance. The Primary Authority system is considered as a good example of a model which the Commission and other Member States might wish to adopt more broadly.

The problem of limited resources can only be tackled by **streamlining the whole market surveillance process,** from planning to sanction the use of the latest technologies. The following specific suggestions are put forward:

Carry out studies on the inherent risk of the different product categories under the different directives; as an example, see the preliminary study for the next Ecodesign working plan.

Collect information on the number of product categories on the European market: this is one of the crucial factors in determining the "adequate scale of the checks" stipulated in Art. 19 (1) of Reg. 765.

Consider mandatory registration in a product database, as is done partially under the RED, and is envisaged for energy labelling and adaptation of existing registration obligations (WEEE directive) to make them suitable for market surveillance planning.

Facilitate checks at the border by including information on the manufacturer in customs declarations, and amending CN (Combined Nomenclature) to make it useful for market surveillance purposes.

Facilitate documentary checks via a digital compliance system (see below) and by including compulsory photos in the DoC to enable a positive identification of products, EAN (Bar)-Codes and CN-Codes.

Future standardisation mandates, including affordable preliminary testing: only products exceeding the preliminary limits would deserve full testing.

Simplification of reporting duties by providing an integrated IT solution from planning to documentary checks to product identification and reporting.

Market surveillance should be risk-based and should **focus on the minority of non-compliant products that pose a high risk** to persons, livestock and property, while other non-conformities should be addressed by means of education of businesses (see proposals under section 4.1 above).

The **lack of notified bodies and testing laboratories** in many technical areas is stressed, which makes testing of products expensive. This lack of laboratories might be a problem **in some sectors**, however **not in all**.

For market surveillance authorities without their own laboratories, budget and administration of external testing costs are a major issue limiting the effectiveness of their surveillance. Thus, programs **facilitating sufficient laboratory capacity** would be necessary. **EU-wide agreements with laboratories**, to which market surveillance authorities could send products to be tested on a pro-rata basis, would be a perfect solution.

This option of EU-wide agreements with laboratories is also proposed by another Member State, while another one suggests EU **financial support** from the Commission **for laboratory tests** (rather than for 'joint actions', which imply prohibitive administrative costs for MSAs).

On the other hand, the availability of laboratories is not considered as an issue by other Member States, since they believe they have excellent access to a number of test laboratories (test houses) which are also available for other Member States to use. It is not necessary or proportionate to introduce this at a supranational level.

A Member State also stresses the need for: (i) an on-line database where the national market surveillance authorities would be able to download the **harmonised standards**; (ii) **the c**reation of a **rapid advice forum** at EU level; (iii) **legal assistance** from the Commission.

The simplification of the work of national authorities by means of an **easier administration of joint actions** and an integrated reporting system is suggested.

A very serious reshaping by the Commission of the internal approval procedure for joint actions is needed.

Finally, the need for adequate and **reliable 'facts and figures' on products, volumes and economic operators** is stressed as a necessary basis for developing and improving a risk-based approach. This kind of information is also considered useful in showing the importance of market surveillance.

4.2.8 Stronger measures against economic operators; Penalties

There is a need to take **stricter measures against economic operators** and to apply sanctions against economic operators located in third countries.

The **harmonisation of the levels of penalties** has been considered by one Member State, while keeping the possibility to adapt them on a case by case basis.

However, another Member State considers that penalties must remain the **responsibility of Member States** – it is for the Member State to determine what is effective, proportionate and deterrent. It is therefore also for the **Member State to revise its legislation** if it does not provide a sufficient deterrent.

For SMEs especially, limited financial leeway implies **limited ability to react to more deterrence**.

4.2.9 Digital compliance

There should be a **greater emphasis on e-commerce and e-compliance** as there are many more opportunities to take advantage of new and developing technology and make market surveillance more effective (e.g. using e-labelling whereby relevant information is provided online at the point of purchase).

Studying the impact of a possible e-compliance system, which could be useful for strengthening border controls, is supported: the system could be tried for products manufactured outside the EU, for which the technical documentation is more complicated to obtain.

The need for a database where manufacturers upload their declarations of conformity, technical documentation and instructions for **easy reference by market surveillance authorities** is stressed. This database would facilitate data collection of checked products but also provide an excellent basis for information on new and revised products on the market.

By contrast, other Member States **strongly disagree with the suggestion of** developing **a digital compliance system**. Some of the reasons reported are:

- The main problem for market surveillance authorities is not access to documentation but the fact that the documentation received does not always correspond to the actual product. The problem of falsified certificates etc. will not be solved by a digital system.

- The authorities cannot trust the data in the system, because they are supplied by those they are supposed to check.

- While a voluntary system would provide no added value, a mandatory system would create unjustified administrative burdens for economic operators as well as for market surveillance authorities. Compliant economic operators are already put at a competitive disadvantage vis-à-vis rogue traders, who will either report nothing or report false information to the system. Businesses in third countries would more easily escape the application of a mandatory system.

- It could lead to a practice where authorities allow undue time and resources to checking documentation in the database instead of focusing on the actual compliance of products. There is a fear that the emphasis will shift from checking products to checking the data entered in the system, without consideration of the reality of the market.

- There are many questions regarding the confidentiality of data in such a system.

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

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

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

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

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

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

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

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

Detailed analysis of each method is provided in Annex 4.

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

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

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

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

ABSTRACT (EN)

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

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

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

ABSTRACT (FR)

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

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

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

ABSTRACT (DE)

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

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

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

EXECUTIVE SUMMARY (EN)

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

<u>The evaluation</u>

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

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

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

Effectiveness

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

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

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

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

Efficiency

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

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

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

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

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

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

Relevance

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

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

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

Coherence

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

EU added value

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

RÉSUMÉ (FR)

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

L'évaluation

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

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

Efficacité

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

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

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

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

Efficience

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

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

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

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

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

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

Pertinence

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

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

Cohérence

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

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

Valeur ajoutée de l'UE

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

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

List of abbreviations

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

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

List of countries

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

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

1. INTRODUCTION

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

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

1.1 Scope of the evaluation

The subject of this evaluation is **Regulation (EC) No 765/2008** of the European Parliament and of the Council of 9 July 2008, setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

The scope of the study is defined as follows:

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

1.2 Purpose of the evaluation

The overall objectives of the study are to:

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

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

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

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

1.3 Structure of this report

This final report provides the full results of the analyses.

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

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

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

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

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

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

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

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

2. BACKGROUND OF THE INITIATIVE

2.1 Legislative background

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

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

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

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

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

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

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

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

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

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

Moreover, it lays down rules on:

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

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

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

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

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

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

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

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

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

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

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

2.2 Main provisions of the Regulation

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

Chapter I – General provisions

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

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

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

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

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

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

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

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

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

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

Chapter V – EU financing

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

Chapter VI – Final provisions

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

2.3 Intervention logic framework

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

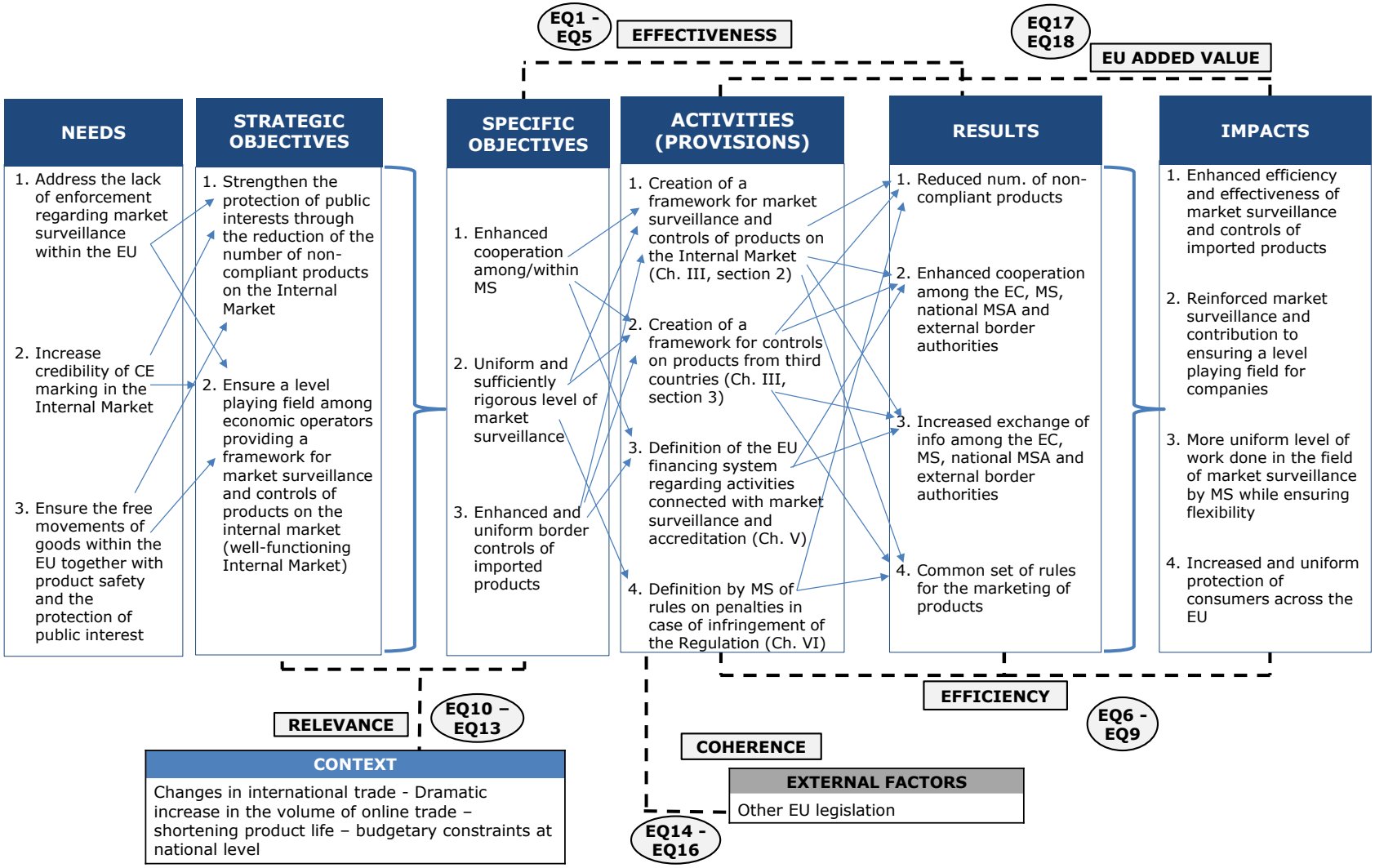
Three main **needs** or drivers led to the definition of the Regulation's strategic objectives: (1) *to address the lack of market surveillance enforcement within the EU*; (2) *to increase the credibility of CE marking in the internal market*; and (3) *to ensure the free movement of goods within the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

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

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

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

Figure 4-1 - Intervention logic of the Regulation



Source: EY

3. EVALUATION QUESTIONS

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

The evaluation criteria were understood to mean:

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

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

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

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

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

Effectiveness

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

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

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

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

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

Efficiency

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

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

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

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

Relevance

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

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

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

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

Coherence

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

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

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

EU added value

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

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

4. METHODOLOGY

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

4.1 Evaluation grids

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

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

All evaluation grids are presented in Annex.

4.2 Overview on data collection and analysis tools

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

4.2.1 Desk research

4.2.1.1 Implementation

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

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

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

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

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

N.	Product sectors	Relevant legislation
22/B	Other chemicals (Detergents, Paints, Persistent Organic Pollutants, Fluorinated greenhouse gases, Ozone Depleting Substances, etc.)	Regulation (EC) 648/2004, Directive 2004/42/EC, Regulation (EC) 850/2004, Regulation (EC) 842/2006 and Regulation (EU) 517/2014, Regulation (EC) 1005/2009
23	Eco-design and Energy Labelling; Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	Directives 2009/125/EC and 2010/30/EU; Directive 1992/42/EEC
24	Tyre labelling	Regulation (EC) 1222/2009
25	Recreational craft	Directive 1994/25/EC - Directive 2013/53/EU
26	Marine equipment	Directive 96/98/EC -Directive 2014/90/EU
27	Motor vehicles and Tractors	Directive 2002/24/EC - Regulation (EU) 168/2013; Directive 2007/46/EC; Directive 2003/37/EC - Regulation (EU) 167/2013
28	Non-road mobile machinery	Directive 97/68/EC
29	Fertilisers	Regulation (EC) 2003/2003
30	Other consumer products under GPSD	Directive 2001/95/EC
31	Biocides	Regulation (EU) 528/2012
32	Textile and Footwear labelling	Regulation (EC) 1007/2011 and Directive 94/11/EC
33	Crystal glass	Directive 69/493/EEC

Source: EC (2016)

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

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

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

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

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

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

4.2.1.2 Market analysis

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

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

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

All data were extracted from three databases:

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

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

In detail, the approach comprised the following steps:

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

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

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

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

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

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

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

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

Table 2 - Indicators for the sector-level analysis

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

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

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

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

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

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

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

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

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

4.2.1.3 Cost-benefit analysis

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

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

The existing data were used for:

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

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

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

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

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

- Measuring the **inputs** (i.e. financial and human resources) used by MSAs in order to meet surveillance obligations deriving from the Regulation. MS should declare budget allocated to market surveillance and enforcement activities, including related infrastructures and projects and measures aimed at ensuring economic operators' compliance with product legislation. These measures should also include communication activities (consumer/business information and education), enforcement, staff remuneration, direct costs of inspections, laboratory tests, training, and office equipment costs. This means that data included in the national reports might be considered as the best source of information in order to estimate the regulatory costs for national authorities. In particular, the following dimensions have been identified as relevant for this purpose:
  - **Financial resources** available for market surveillance activities;
  - **Human resources available** for market surveillance activities.
- Assessing how authorities' market surveillance is meeting surveillance obligations (**results**). National reports were used to verify:
  - Number of inspections performed by year and by sector
  - Number of tests performed by year and by sector
- Evaluating the levels of compliance for harmonised products and the perceived effectiveness of the Regulation in ensuring a level playing field for businesses (**impacts**). Businesses and business associations took part in the targeted survey. In addition, 10 targeted interviews were conducted with these stakeholders to investigate:
  - Whether the Regulation introduced any type of cost on consumers/end-users (e.g. derived from Article 19 stating that the MSAs may require economic operators to make available documentation and information regarding the products, to present test reports, or certificates attesting conformity);
  - Whether introduced costs affect disproportionately a particular category of stakeholders;
  - Whether the measures taken by MSAs are proportionate to their objectives and effective in ensuring product compliance and a level playing field for businesses;
  - Whether any differences emerged across Member States in implementing the Regulation.

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

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

4.2.2 Field research

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

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

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

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

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

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

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

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

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

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

4.2.3 Case studies

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

Notably, the case studies allowed for:

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

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

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

- Identifying best practices and approaches.

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

4.3 Data limitations

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

4.3.1 Data gaps in the desk research

4.3.1.1Data gaps in estimates of product non-compliance

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

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

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

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

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

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

4.3.1.2 Data gaps in the assessment of implementation

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

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

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

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

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

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

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

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

4.3.1.3 Data gaps in national programmes

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

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

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

4.3.1.4 Data gaps in national reports

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

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

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

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

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

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

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

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

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

4.3.1.5 Data gaps related to the market analysis and the CBA

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

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

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

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

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

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

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

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

4.3.2 Data gaps in the field research

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

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

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

4.3.3 Solutions to the problems encountered

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

Table 4-4 - Problems encountered and mitigation measures

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

5. STATE OF PLAY

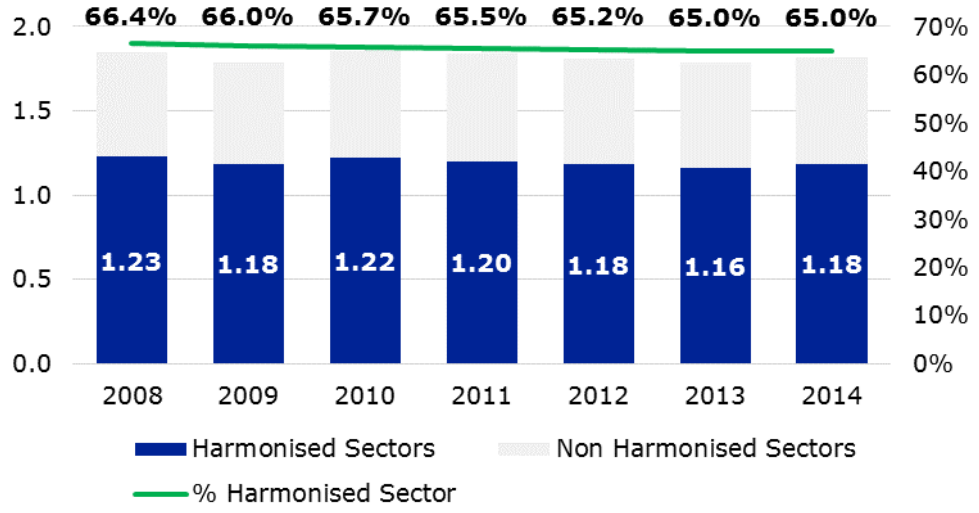
5.1 Market analysis

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

5.1.1 Analysis at sectoral level

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

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

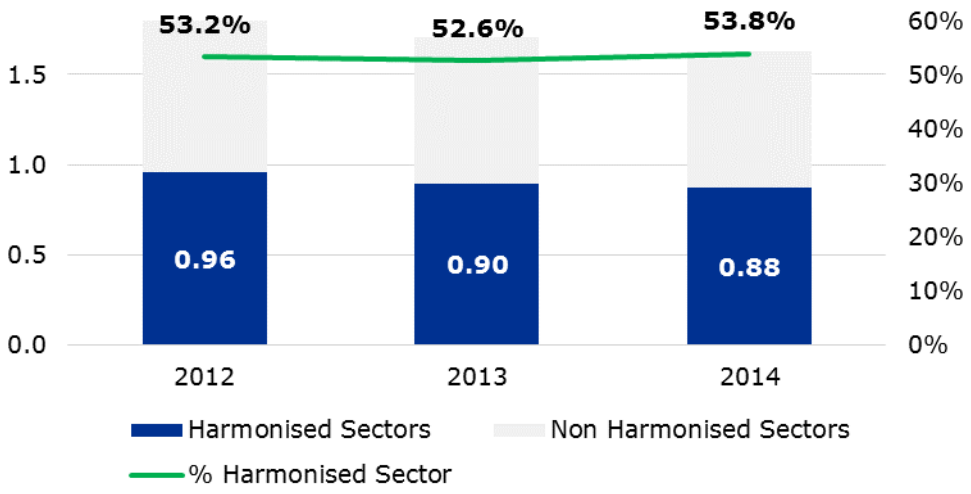


Source: Authors' elaboration on SBS (2016)

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

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

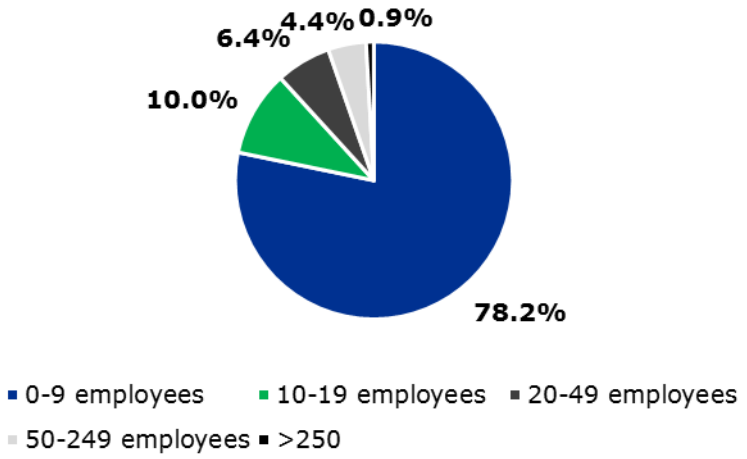
Figure 4-2 - Number of enterprises in harmonised sectors vs. overall manufacturing sectors (2012-2014, EU-28), millions, NACE Digit-3



Source: Authors' elaboration on SBS (2016)

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

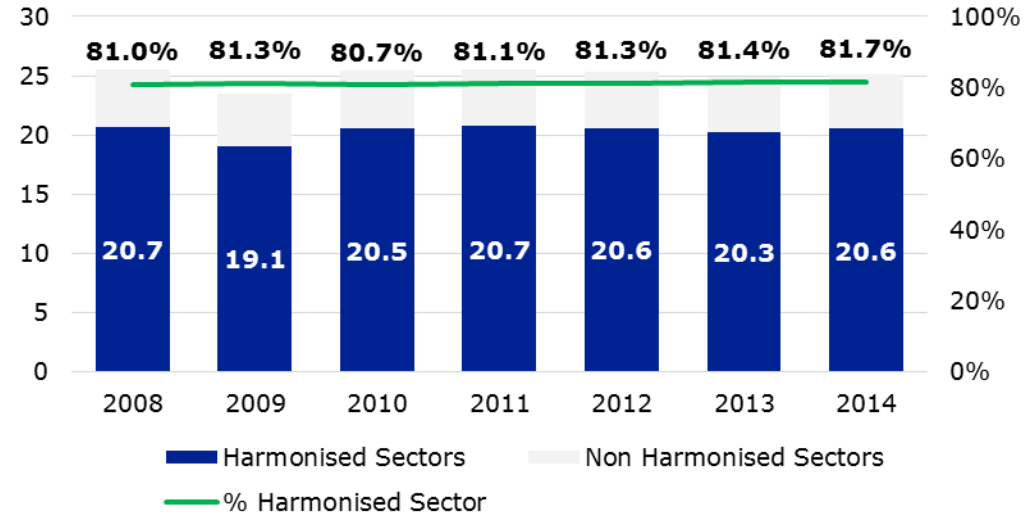
Figure 4-3 - Size of enterprises operating in harmonised manufacturing sectors (2012-2014, EU-28)



Source: Authors' elaboration on SBS (2016)

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

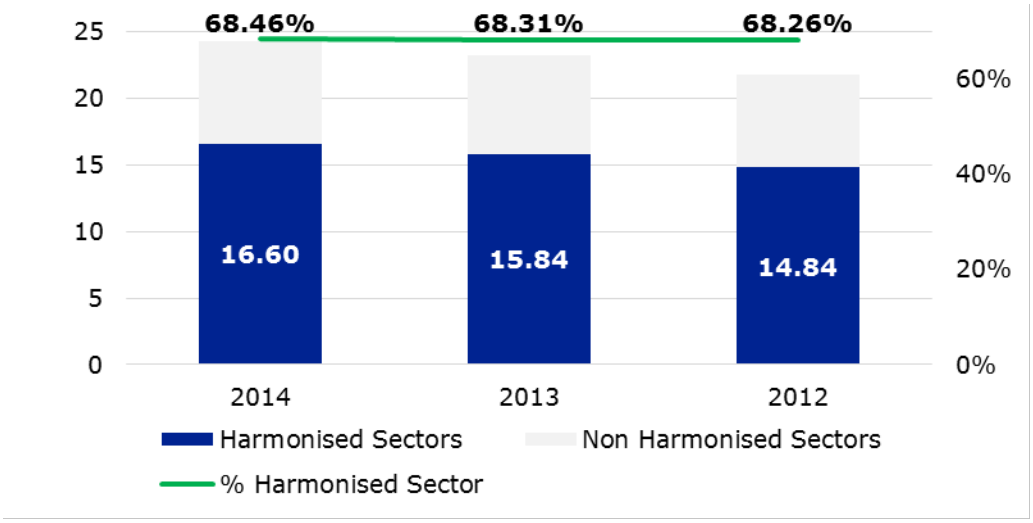
Figure 4-4 - Number of employees: harmonised sectors vs. overall manufacturing sectors (2008-2014, EU-28), millions, NACE Digit-2



Source: Authors' elaboration on SBS (2016)

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

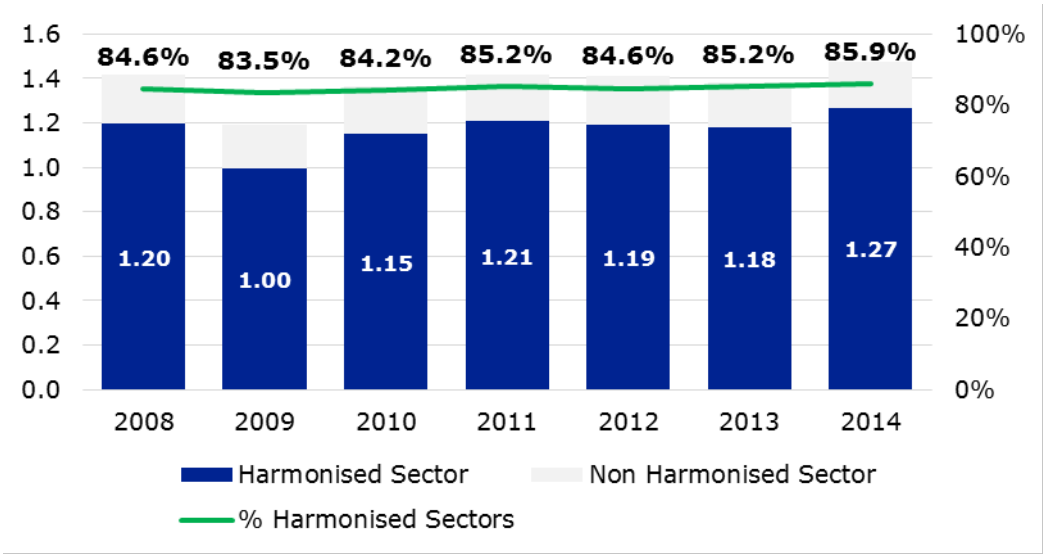
Figure 4-5 - Number of employees: harmonised sectors vs. overall manufacturing sectors (2012-2014, EU-28), millions, NACE Digit-3



Source: Authors' elaboration on SBS (2016)

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

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



Source: Authors' elaboration on SBS (2016)

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

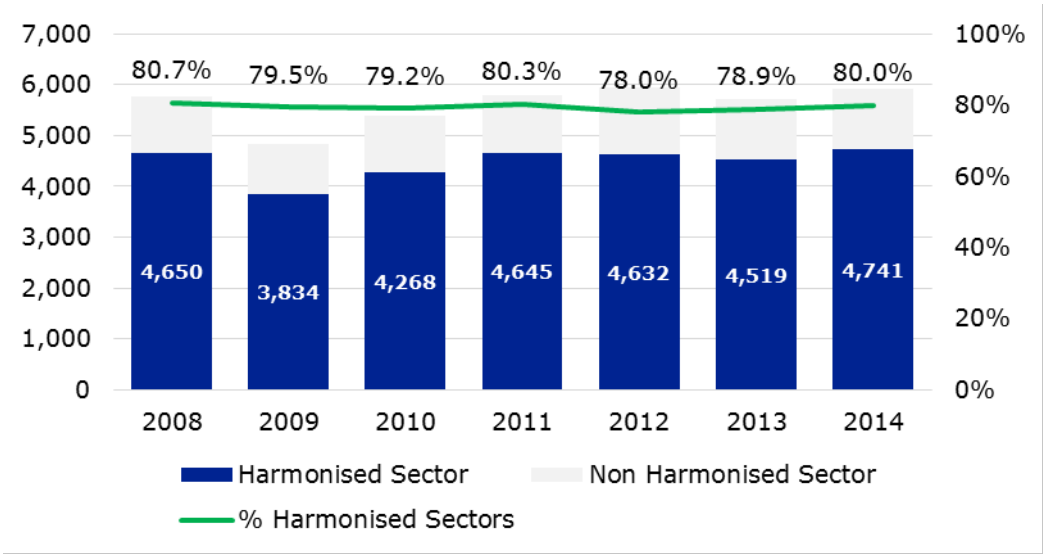
Table 4-5 - Value added at factor cost per size of enterprises: harmonised sectors vs. overall manufacturing sectors (2011-2013, EU-28)

Size of enterprises	*Harmonised sectors*		*Manufacturing*		*a/b*
	Total ***(a)***	*%*	*Total (€b)*	*%*	*%*
Micro enterprises (0-9 employees)	**49.02**	6%	84.64	7%	**4%**
SMEs (10–249 employees)	**323.54**	38%	451.88	39%	**28%**
Large enterprises (> 249 employees)	488.56	57%	627.25	54%	42%
Total	861	100%	**1,164 (b)**	100%	74%

Source: Authors' elaboration on SBS (2016)

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

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



Source: Authors' elaboration on SBS (2016)

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

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

Size of enterprises	*Harmonised sectors*		*Manufacturing*		*a/b*
	Total (€b) (a)	*%*	*Total (€b)*	*%*	*%*
Micro enterprises (0-9 employees)	**146.15**	4%	251.03	5%	**3%**
SMEs (10-249 employees)	**1,091.72**	33%	530.30	34%	**24%**
Large enterprises (> 249 employees)	2,067.94	63%	2,782.93	61%	45%
Total	3,306.81	100%	**4,564.26**	100%	72%

Source: Authors' elaboration on SBS (2016)

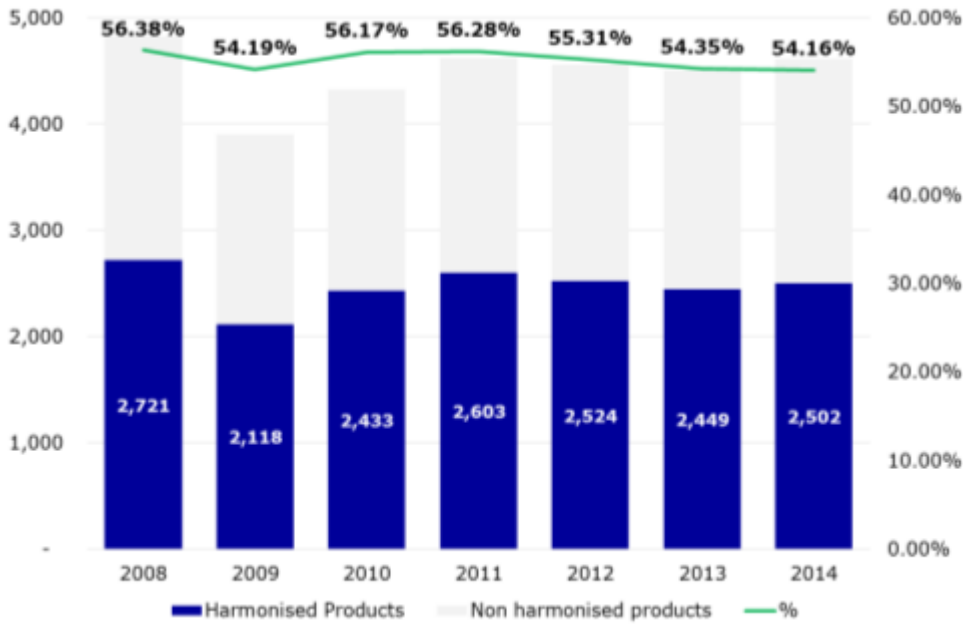
5.1.2 Analysis at product level

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

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

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

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



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

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

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

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

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

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

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

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

- Transport equipment (NACE codes 29 and 30).

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

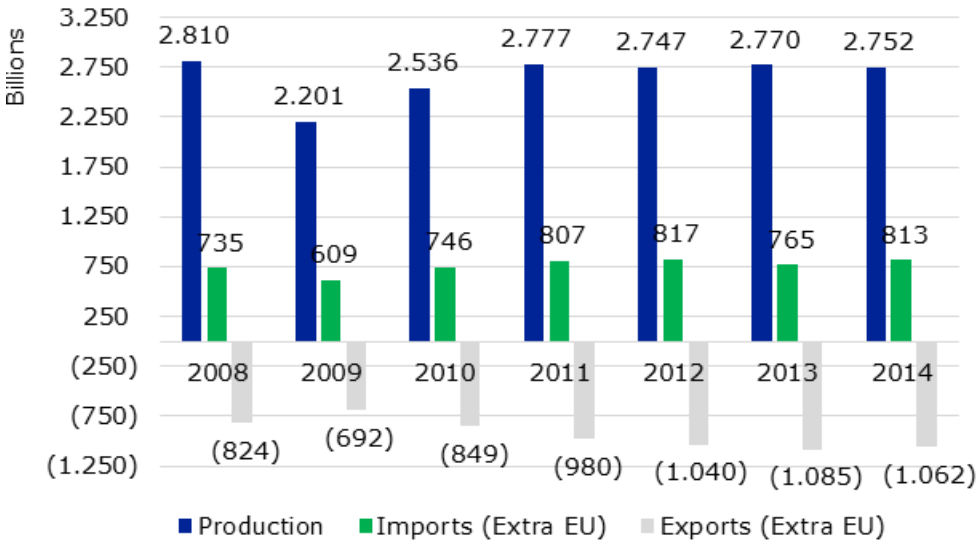
ISIC rev 4	*NACE rev 2*	*Average value (€b) 2008-2014*	*%*
Manufacture of textiles, apparel, leather and related products	13 to 15	120.40	4.9%
Manufacture of wood and paper products, and printing	16 to 18	:	:
Manufacture of coke, and refined petroleum products	19	:	:
Manufacture of chemicals and chemical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

Source: Authors' elaboration on PRODCOM (2016)

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

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

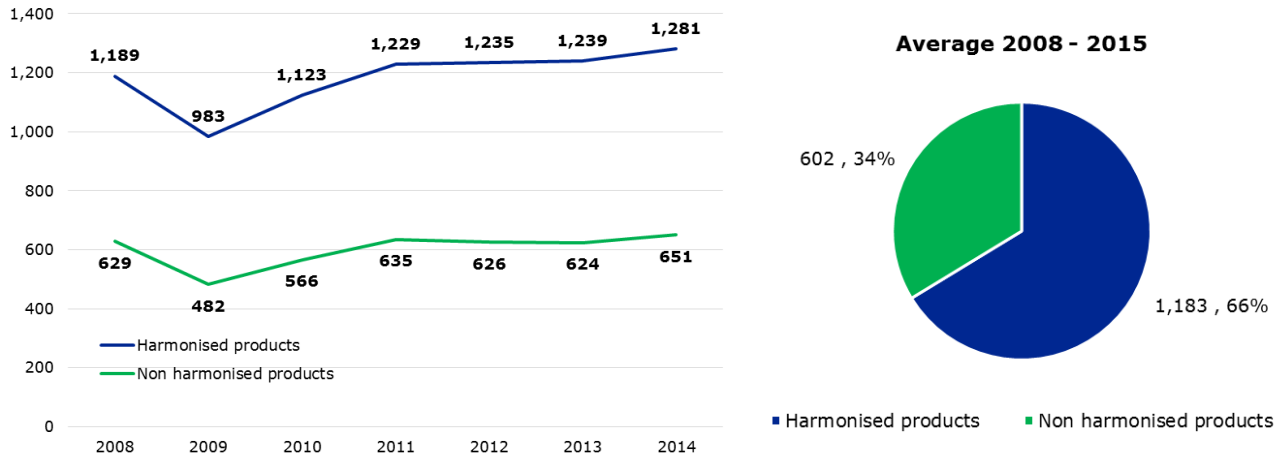
Figure 4-9 - Trade in harmonised products: sold production and trade with non-EU countries (2008-2014, EU-28), €b



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

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

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



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

52 EU trade since 1988 by SITC:, http://ec.europa.eu/eurostat/web/international-trade-in-goods/data/database

53 The value of extra EU trades (used in Figure 9) is only available at EU28 level from PRODCOM database.

5.2 Implementation of the Regulation

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

5.2.1 Organisation of market surveillance at the national level

5.2.1.1 Organisational models

According to Article 16(1) of the Regulation, "*Member States shall organise and carry out market surveillance as provided for in this Chapter [i.e. on General requirements]*". The Regulation does not set explicit obligations on how market surveillance shall be organised at the national level, this being left to Member States' prerogative. Therefore, market surveillance is organised differently at the national level in terms of sharing competences and powers between MSAs. Table 4-8 summarises the organisational structures in place in all EU Member States, as resulting from the national programmes and based on the classification provided by the European Parliament (2009).[54]

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

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

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

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

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

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

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

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

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

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

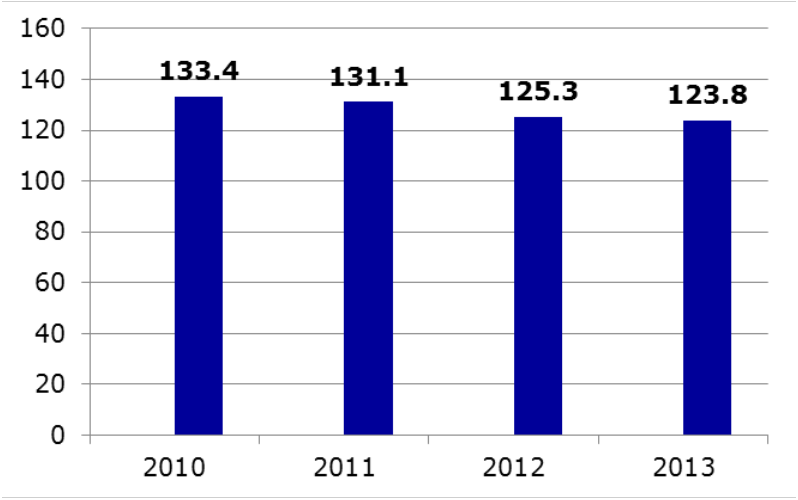
5.2.1.2 Resources available to MSAs at the national level

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

5.2.1.2.1 Financial resources available for market surveillance activities

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

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



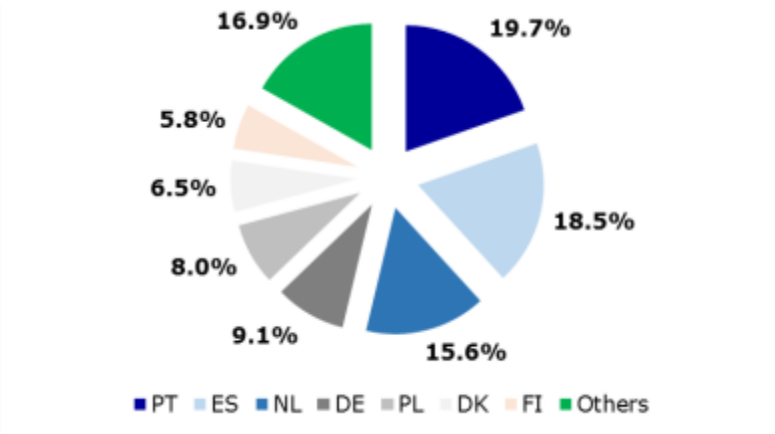
Source: Authors' elaboration on national reports

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

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

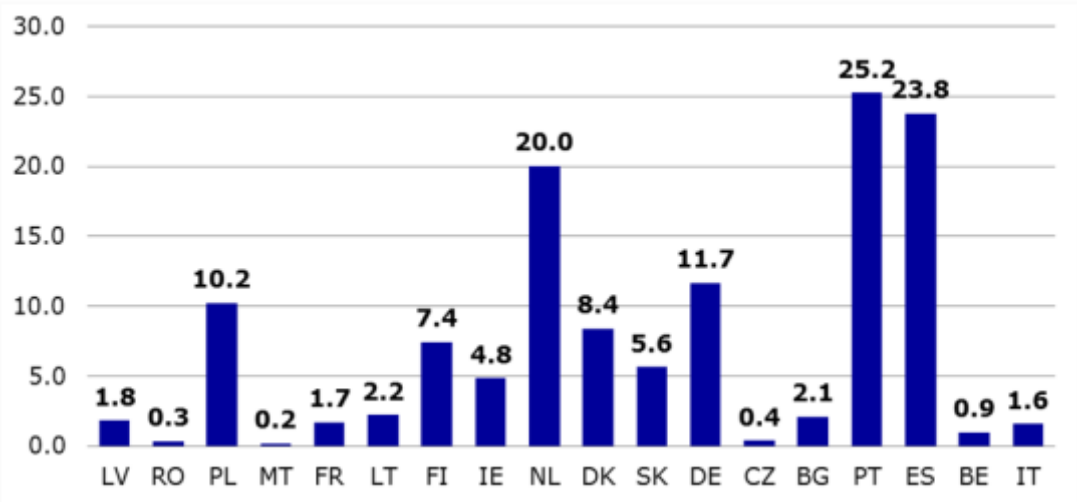
- More than 80% of the total budget available to the 18 MSAs reporting data in nominal terms is concentrated in seven Member States (Figure 4-12);
- More than half of the Member States providing data had an available annual budget of less than €10 million (Figure 4-13);
- Only three countries (Portugal,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

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



Source: Authors' elaboration on national reports

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

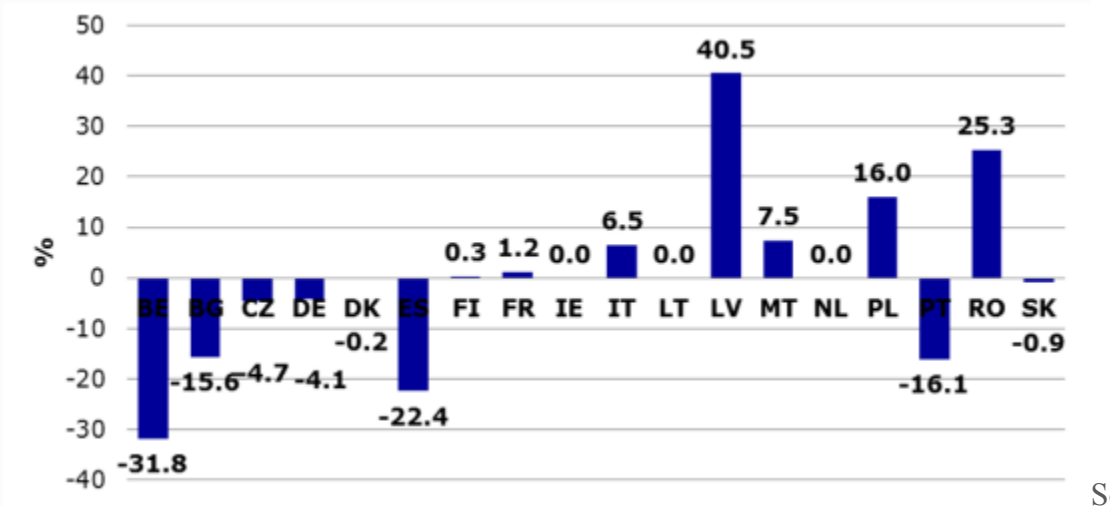


Source: Authors' elaboration on national reports

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

- High in two Member States (Belgium -32% and Latvia +40.5%);
- Moderate in five Member States (increase in Romania and Poland, reduction in Bulgaria, Spain and Portugal);
- Limited in more than half the Member States, i.e. in 12 out of 18.

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



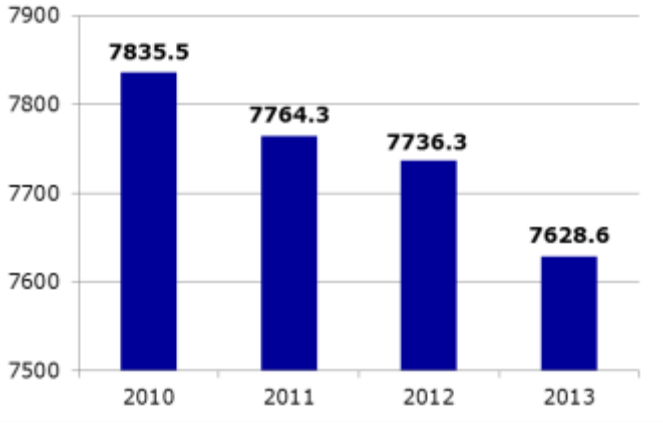
Source: Authors' elaboration on national reports

5.2.1.2.2 Human resources available for market surveillance activities

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

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

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



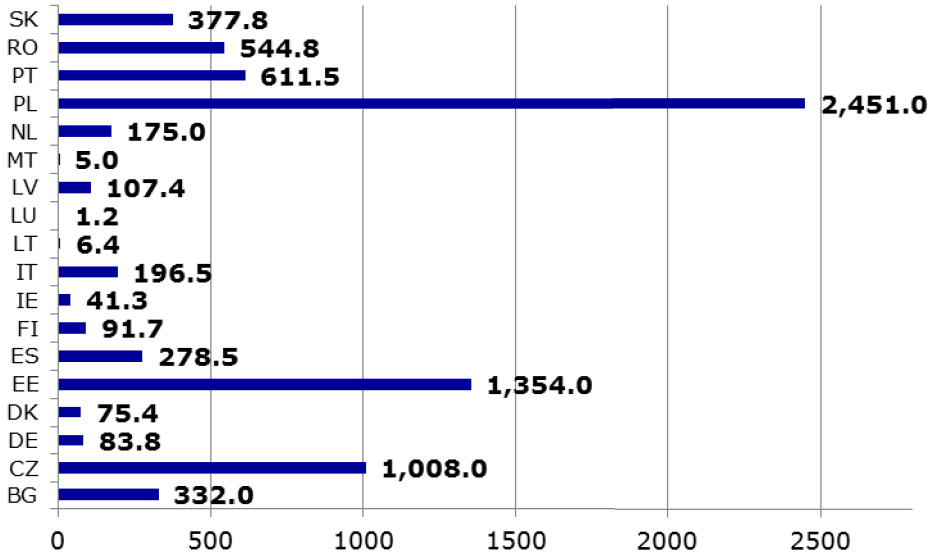
Source: Authors' elaboration on national reports

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

- On average, 7,741 staff resources (FTEs) were available for the MSAs of 18 EU Member States during the period 2010-2013 (Figure 4-15);
- 86.3% of staff resources (6,679) were based in seven Member States (Poland, Estonia, Czech Republic, Portugal, Romania, Slovakia and Bulgaria, Figure 4-17 and Figure 4-18);
- More than 30% of total staff resources were based in one country (Poland, Figure 4-17 and Figure 4-18);
- There were significant differences among countries in terms of total staff resources available over the period 2010-2013. On the one hand, a large number of Member States (15 out of 18) involve less than 1,000 FTEs in market surveillance activities. On the other hand, Poland reported a significantly greater number of FTEs available to the MSAs, more than five times higher than staff resources declared by most countries.

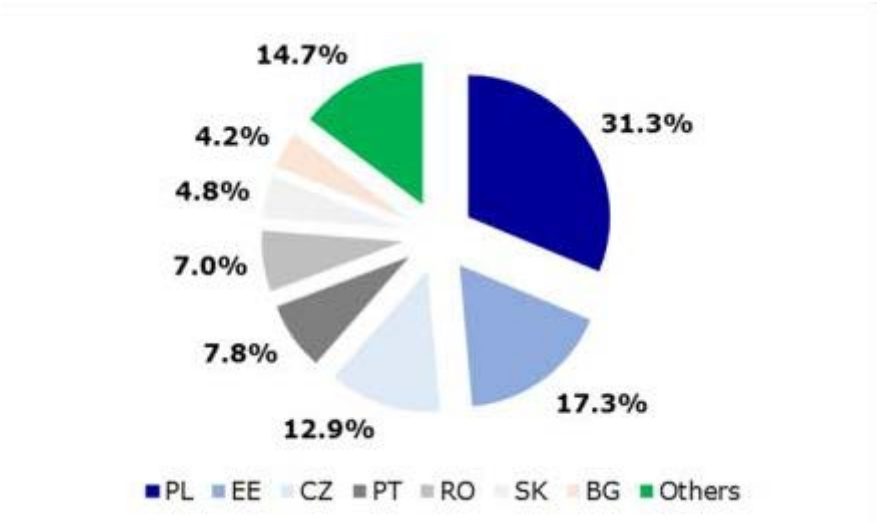
61 The analysis includes: BG, CZ, DE, DK, EE, ES, FI, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE and, SK; the other MS have not provided complete and reliable data.

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



Source: Authors' elaboration on national reports

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



Source: Authors' elaboration on national reports

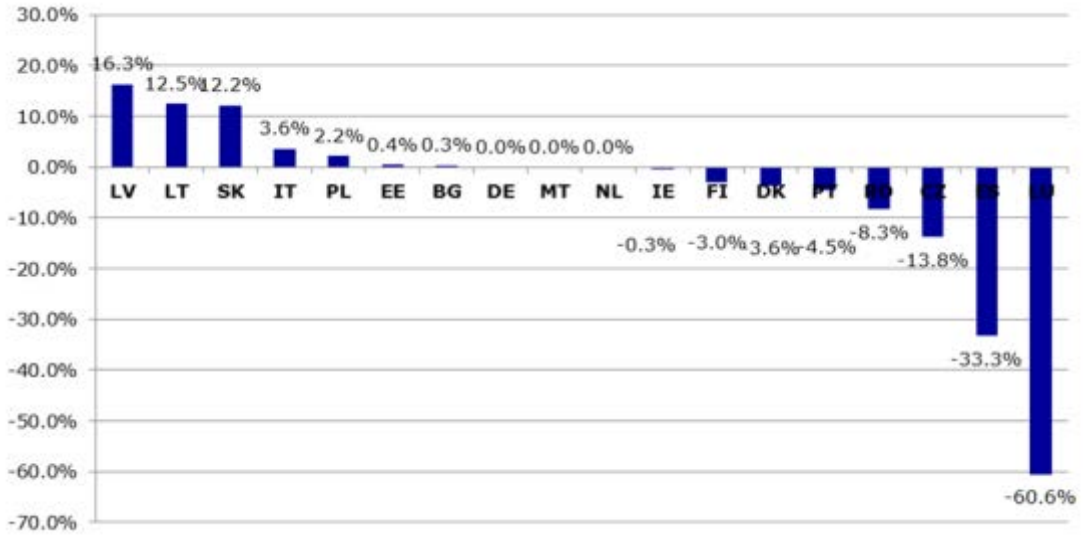
The highlights of the analysis concerning the **variation** in total staff resources available to MSAs (FTE units) over the period 2010-2013 include (Figure 4-18):

- More than half of the Member States considered (11) displayed a relatively stable trend in the number of staff resources available to MSA (FTE units) with a variation of less than 5% of the value registered in 2010;

- Three Member States (Latvia, Lithuania and Belgium) declared an increase between 12.2% and 16.3%;

- The magnitude of total staff reduction was very different: the largest percentage decrease (-60.6% - Luxembourg) was almost twice as high as the second largest percentage reduction (33.3% - Spain) and 202 times higher than the smallest reduction (0.3% - Ireland).

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

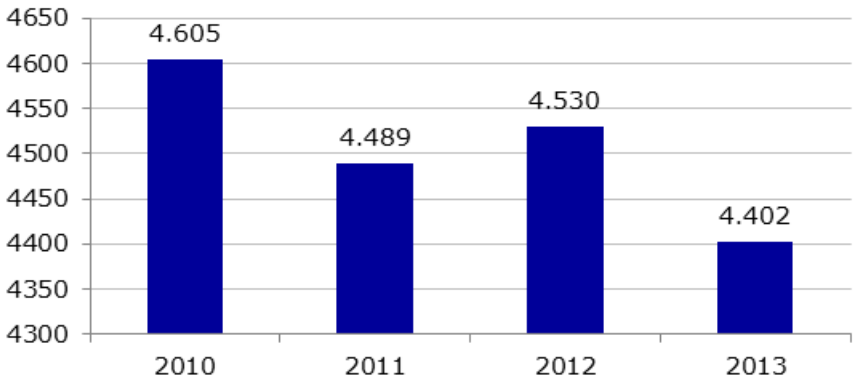


Source: Authors' elaboration on national reports

While at the EU level the budget available for market surveillance activities experienced continuous adjustments and the total staff resources available to MSAs (FTE units) registered a negative trend, the **number of inspectors (FTE units)** followed a fluctuating trend (falling one year, rising in the next, then falling again) which could be translated into fluctuating staff costs during this period (Figure 4-19). In this case, only 16 Member States provided completed data and were included in the analysis.[62]

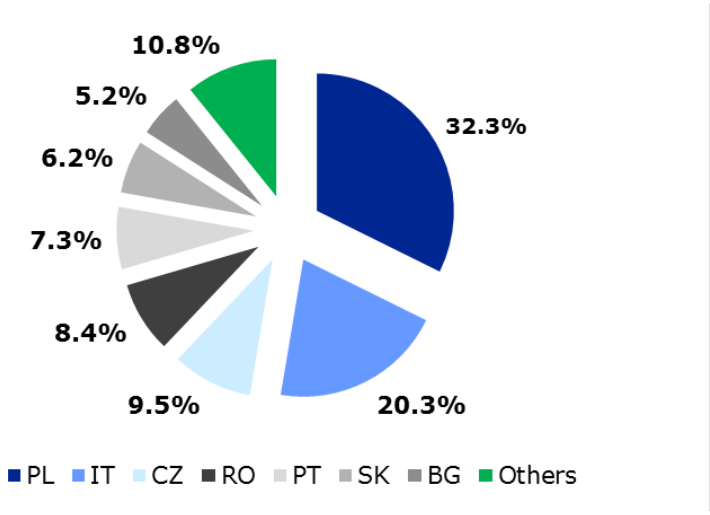
62 BE, BG, CZ, DK, EE, ES, FI, IE, IT, LT, LU, LV, PL, PT, RO, SK.

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



Source: Authors' elaboration on national reports

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



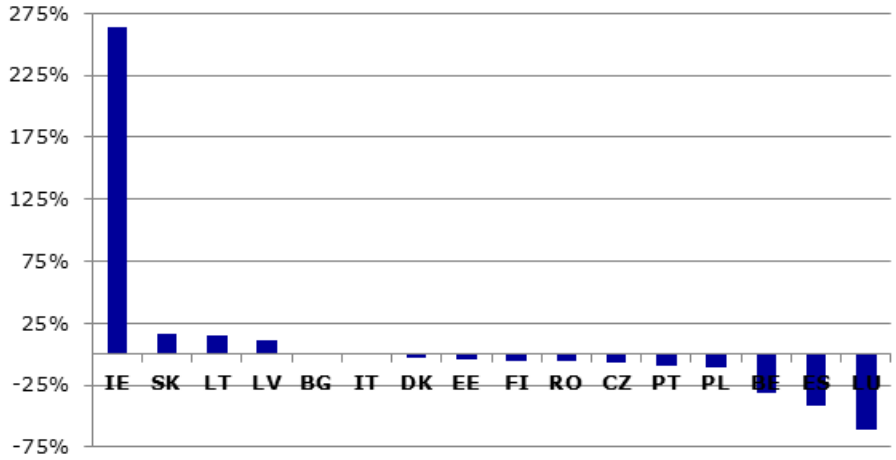
Source: Authors' elaboration on national reports

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

- On average, 4,506 inspectors were available to the 16 Member States considered for inspection activities (Figure 4-19);
- The majority (90%) of inspectors (4,019) were based in six Member States - Poland, Italy, Czech Republic, Romania, Portugal and Slovakia (Figure 4-20);
- Around half (2,372) of the FTEs dedicated to inspection activities were employed in two Member States (Poland and Italy);

- The magnitude of the costs derived from the number of inspectors (FTE units) varies across for instance, in Luxembourg and Lithuania (included in the 'Others' category in Figure 4-20) only 4.6 and 21.74 FTEs, respectively, were allocated to market surveillance activities, while Poland involved 5,822 FTEs.

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



Source: Authors' elaboration on national reports

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

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

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

5.2.1.2.3 Technical resources

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

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

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

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

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

Source: Targeted surveys

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

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

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

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

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

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

Source: Targeted surveys

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

5.2.2 Market surveillance activities

5.2.2.1 Approaches to market surveillance

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

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

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

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

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

Source: National programmes

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

5.2.2.2 MSAs' powers of inspection

According to Article 19(1) of Regulation (EC) No 765/2008, MSAs shall "*perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples*".

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

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

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

68 Stating that MSAs "*shall take account of established principles of risk assessment, complaints and other information*", when deciding to take enforcement measures.

69 AT, BE, DK, EE, IE, NL, PL, RO, SE, SI, SK, and UK.

- **Documentary and visual checks**, "for example, regarding the CE marking and its affixing, the availability of the EU declaration of conformity, the information accompanying the product and the correct choice of conformity assessment procedures. More profound checks may be necessary however to verify the conformity of the product, for example, regarding the correct application of the conformity assessment procedure, the compliance with the applicable essential requirements, and the contents of the EU declaration of conformity";[70]

- **Physical checks of the products**, aimed at verifying basic characteristics of the goods either *in situ* or at commercial, industrial, and storage premises, workplaces or other premises where the products are in use;[71]

- **Inspections of business premises**;

- **Product testing** through laboratory examination, aimed at verifying product compliance with basic health and safety requirements.

However, there are **other powers of inspection** that are attributed differently to national MSAs (and across sectors within the same Member State) as they are based on different national legislative frameworks.

- *Carry out sector inquiries*: based on the information available, this power is granted in most Member States and in the majority of sectors. Irish MSAs are granted this power for the lowest number of sectors (i.e. only in five: medical devices, cosmetics, measuring instruments, electrical and electronic equipment under RoHS and WEEE and batteries, and chemicals). In eight Member States,[72] this power is granted in all sectors (see also Table 4-35 in Annex).

- *Do mystery shopping:* this is the least common power among MSAs and across sectors, since it is only available to 10 of the MSAs and on average is granted in seven sectors in just 11 Member States. The Member States granting it most are the Czech Republic (in 30 sectors), Latvia, Slovenia (in 26 sectors each), and Finland (in 25 sectors). The personal protective equipment sector has the highest coverage by Member States, although only 11 of them grant this power in the sector (see also Table 4-36 in Annex).

- *Request information/cooperation by any possible natural or legal person:* based on the available data, this power is generally granted to half of the MSAs in more than 14 sectors. In particular, in the Czech Republic, Estonia, Poland and Romania it is granted in all sectors, while in Belgium, Lithuania, Luxembourg and Slovenia it is granted in almost all sectors (i.e. more than 30 sectors). In Ireland, this is applied in a limited way (only in five sectors), but there are no Member States where this power is not granted at all (see also Table 4-37 in Annex).

70 COM(2016)1958 final. *The 'Blue Guide' on the implementation of EU product rules*. http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=7326

71 WELMEC (2007), Market Surveillance Guide. http://www.welmec.org/fileadmin/user_files/publications/WELMEC_5.2_Issue_2_final.pdf

72 CZ, EE, HR, LT, LU, PL, RO and SI.

- *Seize and detain products:* based on available information, this power is granted in 14 sectors in a significant number of Member States[73] and in five of them[74] it is available to MSAs in more than 30 sectors; in 12 Member States[75] it is granted in fewer than seven sectors. Personal protective equipment is the sector covered most, with 17 Member States granting this power. In Bulgaria and Ireland, it is not granted in 26 and 29 sectors, respectively (see also Table 4-38 in Annex).[76]

- *Seize documents:* the distribution of this power is similar to the previous one. Based on the information available, it is granted in 14 sectors in more than 12 Member States.[77] In the personal protective equipment and lifts sectors it is granted by the highest number of Member States (i.e. 16). In Bulgaria and Ireland, this power is granted in the lowest number of sectors, i.e. eight and five, respectively (see also Table 4-39 in Annex).[78]

- *Take samples for free:* based on available information, this power is granted in 14 sectors in more than 10 Member States. Those with the highest number of sectors in which MSAs can use it are Estonia, Germany, Poland and Slovenia (granting it in 32, 28, 32 and 29 sectors, respectively). The sectors covered most are toys, radio and telecom equipment, electrical appliances and equipment under LVD, chemicals and crystal glass, where this power is granted in 14 Member States (see also Table 4-40 in Annex).

- *Make use of test reports by MSAs in other EU countries:* as previously noted, the average number of Member States granting this power is 10. Ireland is the only Member State where this power is not granted in a particularly high number of sectors (i.e. 30 out of 33),[79] while MSAs in the Czech Republic, Estonia, Lithuania, Luxembourg and Slovenia can use it in more than 28 sectors. The sectors covered most are toys, machinery, measuring instruments, radio and telecom equipment under RTTE - RED, electrical appliances and equipment under LVD, with 14 Member States granting it (see also Table 4-41 in Annex).

Table 4-12 below presents an overview of the abovementioned powers of inspection granted to MSAs at the national level.

73 i.e. 14 MS: CY, CZ, DE, DK, EE, FI, HR, LU, LV, NL, PL, RO, SI and UK.
74 CZ, EE, LU, PL and RO.
75 AT, BG, EL, ES, FR, HU, IE, IT, LT, MT, PT and SK.
76 In particular, in Bulgaria this power is granted in sectors 2. Cosmetics, 10. Lifts, 17. Measuring instruments, 22. Chemicals, 29. Fertilisers, 31. Biocides. In Ireland, it is granted in sectors 1. Medical devices, 2. Cosmetics, 17. Measuring instruments, 22. Chemicals.
77 CY, CZ, DE, DK, EE, FI, HR, LU, NL, PL, RO, SE SI and UK.
78 In particular, in Bulgaria this power is granted in sectors 6. Aerosol dispensers, 10. Lifts, 11. Cableways, 17. Measuring instruments, 24. Tyre labelling, 30. Other consumer products under GPSD, 32. Textile and footwear labelling, 33. Crystal glass. In Ireland, it is granted in sectors 1. Medical devices, 2. Cosmetics, 17. Measuring instruments, 21. Electrical and electronic equipment under RoHS and WEEE and batteries, 22. Chemicals.
79 In particular, it is granted only in the medical devices, cosmetics and measuring instruments sectors.

Table 4-12 - MSAs' powers of inspection

Powers	*Number of MSAs having this power in more than 14 sectors*	*Number of sectors where this power is granted in a significant number of MS*[80]
Carry out sector inquiries	16	16 sectors (in more than 14 MS)
Do mystery shopping	10	7 sectors (in more than 11 MS)
Request information/ cooperation by any possible natural or legal person	14	15 sectors (in more than 13 MS)
Seize and detain products	14	14 sectors (in more than 12 MS)
Seize documents	13	14 sectors (in more than 12 MS)
Take samples for free	13	14 sectors (in more than 10 MS)
Make use of test reports by MSAs in other EU countries	12	14 sectors (in more than 10 MS)

Source: Targeted surveys

5.2.2.3 Customs and control of imported products

According to Article 27 of Regulation (EC) No 765/2008, external- border-control authorities controls Authorities are endowed with the following main tasks:

- Carrying out appropriate checks on the characteristics of products;
- Suspending the release of a product for free circulation in the internal market when the product: (a) displays characteristics which give cause to believe that the product, when properly installed, maintained and used, it presents a serious risk to health, safety, the environment or any other public interest; (b) is not accompanied by the written or electronic documentation required by the relevant EU harmonisation legislation or is not marked in accordance with that legislation; and (c) the CE marking has been affixed to the product in a false or misleading manner;
- Ensuring efficient cooperation and exchange of information among external- border-control authorities controls Authorities.

Although Customs are responsible for targeting shipments and carrying out physical checks of goods before they gain access to the national market, the final decision on the safety and compliance of products is to be taken by MSAs.

The case of **France** is particularly relevant as Customs are an MSA in their own right. Depending on the applicable legislation, French Customs may take samples of products, have them tested in a laboratory and decide, depending on the results, on the appropriate follow-up,

80 The reference list of sectors is that provided in Table 4-1.

thereby enhancing the overall efficiency of market surveillance procedures.[81] The coordination between French MSAs and French Customs is particularly relevant in light of the role played by the latter, as explained.

Based on the available data, all Customs except the Dutch Customs, have the power to **request businesses to provide information and exhibit documents** on products presented for release. Moreover, according to Articles 197 and 198 of Regulation 952/2013 (the Union Customs Code), Customs are **authorised to destroy products** in and **to recover from economic operators the costs borne to store/destroy products** in all Member States for which information is available. Finally, only six Customs authorities can recover the costs **of testing non-compliant products**.[82] As a potential consequence of this, the guarantees provided are not always sufficient to cover possible costs linked to market- surveillance checks.[83]

Table 4-13 - Customs' powers[84]

MS	*Request business to provide info and exhibit documents on products presented for release for free circulation*	*Recover costs to test products found to be non-compliant*	*Destroy products*	*Recover costs borne to store or destroy products*
AT	√		√	√
BE	√		√	n.a.
BG	√	n.a.	√	√
CY	√		√	√
CZ	√		√	√
DE	√[85]		√[86]	√
DK	√[87]		n.a.	n.a.
EE	√	√	√	√
ES	√	n.a.	√	√
FI	√	√	√	√

81 Panteia and CESS (2014), Good Practice in Market Surveillance Activities related to Non-Food Consumer Products sold Online, Annexes, p. 39.

82 EE, FI, IT, MT, PL and SK.

83 This question received a very low share of responses (i.e. nine). More in detail, Customs in Finland, Latvia and Sweden state that guarantees are sufficient, Customs in Austria, Cyprus, France and Italy deem that they are insufficient, while Customs in Germany and Luxembourg declare that no guarantees exist.

84 A blank cell means Customs do not have the relevant power; 'n.a' means 'information is not available'. No information was available for: EL, IE, LT, SI and UK.

85 Only in cases where the declarant has a legal obligation.

86 Customs may decide to destroy goods where release for free circulation is not allowed by MSAs AND the goods are not placed under a Customs procedure other than free circulation or are re-exported. Customs supervise destruction of goods where it is carried out by the importer (on his own initiative or following a decision from the MSA).

87 Only when required by the MSAs.

MS	*Request business to provide info and exhibit documents on products presented for release for free circulation*	*Recover costs to test products found to be non-compliant*	*Destroy products*	*Recover costs borne to store or destroy products*
FR	√		√	√
HR	√		√	√
HU	√		√	√
IT	√	√	√	√
LU	√		√	√
LV	√		√	√
MT	√	√	√	√
NL			√	√
PL	√	√	√	√
PT	√	n.a.	√	√
RO	√		√	√
SE	√		√	√
SK	√	√	√	√

Source: Targeted surveys

As shown in Table 4-34 in Annex similarly to the situation for the MSAs, **half of Customs[88] do not have in-house testing laboratories**. Only Croatian Customs own in-house laboratories to test products in all sectors covered by the Regulation, followed by Estonian and French Customs, which respectively cover eight and seven sectors, respectively.

Table 4-14 - Availability of test laboratories for Customs authorities' across Member States[89]

MS	*Number of sectors where **Customs have** own test laboratories*	*Number of sectors where **Customs do not** have own test laboratories*
HR	33	0
EE	8	0

88 For which information was available: AT, BE, BG, CY, CZ, DE, DK, ES, LT, LU, LV, PL, RO and SE.

89 No information was available for EL, HU, IT, MT, SK, PT, RO, SI and UK. The number of sectors covered by the table may not add up to 33 due to data availability. The reference list of sectors is that provided in Table 4-1.

MS	*Number of sectors where **Customs have** own test laboratories*	*Number of sectors where **Customs do not** have own test laboratories*
FR	7	22
FI	2	31
NL	1	32
AT	0	33
BE	0	33
BG	0	33
CY	0	33
CZ	0	33
DE	0	33
DK	0	33
ES	0	33
LT	0	33
LU	0	33
LV	0	33
PL	0	33
RO	0	33
SE	0	33

Source: Targeted surveys

If the sector dimension is taken in consideration, the available information indicates that test laboratories are not available in Customs in most Member States. In-house laboratories in the majority of sectors (i.e. 20) are only available in one Member State (Table 4-14).

Table 4-15 - Customs authorities' laboratories across sectors[90]

Sector	*Num. of MS where **Customs have** own test laboratories*	*Number of MS where Customs **do not** have own test laboratories*	*Number of MS for which **no info** was available*
2.Cosmetics	4	15	9

90 The reference list of sectors is that provided in Table 4-1.

Sector	*Num. of MS where **Customs have** own test laboratories*	*Number of MS where Customs **do not** have own test laboratories*	*Number of MS for which **no info** was available*
3.Toys	4	15	9
32.Textile and footwear labelling	3	16	9
4.PPE	2	16	10
5.Construction products	2	16	10
9.Machinery	2	16	10
19.Radio and telecom equipment under R&TTE - RED	2	17	9
20.Electrical appliances and equipment under LVD	2	16	10
21.Electrical and electronic equipment under RoHS and WEEE and batteries	2	16	10
22.Chemicals	2	16	10
29.Fertilisers	2	16	10
30.Other consumer products under GPSD	2	16	10
31.Biocides	2	16	10
1.Medical devices	1	17	10
6.Aerosol dispensers	1	17	10
7.Simple pressure vessels and pressure equipment	1	17	10
8.Transportable pressure equipment	1	17	10
10.Lifts	1	17	10
11.Cableways	1	17	10
12.Noise emissions for outdoor equipment	1	17	10
13.Equipment and protective systems intended for use in potentially explosive atmospheres	1	17	10
14.Pyrotechnics	1	17	10
15.Explosives for civil uses	1	17	10

Sector	*Num. of MS where **Customs have** own test laboratories*	*Number of MS where Customs **do not** have own test laboratories*	*Number of MS for which **no info** was available*
16. Appliances burning gaseous fuels	1	17	10
17.Measuring instruments	1	17	10
18.Electrical equipment under EMC	1	17	10
23.Eco-design and energy labelling	1	17	10
24.Tyre labelling	1	17	10
25.Recreational craft	1	17	10
26.Marine equipment	1	17	10
27.Motor vehicles and tractors	1	17	10
28.Non-road mobile machinery	1	17	10
33.Crystal glass	1	17	10

Source: Targeted surveys

5.2.3 Coordination and cooperation mechanisms

Member States are requested to establish coordination mechanisms between their MSAs (Article 18(1)), and cooperation mechanisms with authorities from other Member States (Article 24) and third countries (Article 26).

As for coordination between national MSAs, **most Member States have a permanent, ad-hoc body** responsible for cooperation and coordination between national MSAs.[91] The coordination body's members are usually **MSA representatives**.[92] Overall, there are **no uniform working practices, and the frequency of meetings** also varies substantially. For instance, in Austria, Cyprus and Lithuania, coordination councils usually meet twice a year, in Denmark three times a year, and in the Netherlands and Sweden five times a year. The Spanish Market Surveillance Committee convenes every 40 to 60 days, while in Poland meetings are held at least once a year. Member States report that coordination bodies are **mainly responsible for**:

- Ensuring and strengthening coordination and cooperation among different MSAs, with Customs Authorities and other national authorities responsible for border controls;[93]
- Ensuring the exchange of information between relevant institutions;[94]

91 AT, BG, CY, DE, DK, EE, EL, FI, FR, HR, IE, IT, LU, LV, NL, PL, RO, SE, SI, and UK. HU and LT did not report on the existence of any permanent body to ensure coordination between MSAs. Where this is not the case (i.e. BE, CZ, ES, SK), there exist different coordinating bodies/working groups or ad-hoc bilateral agreements to enhance cooperation, further discussed below.

92 DE, EE, HR, IE, LU, NL, PL, RO and SE. The remaining MS did not provide any information.

93 AT, DE, DK, EE, HR, LV, and PL.

- Setting market surveillance priorities and strategic objectives, and discussing proposals for improving market surveillance;[95]

- Promoting the establishment of a common approach to market surveillance (e.g. by planning coordinated actions among different inspection bodies, organising exchanges of experience and best practice, and incentivising debate among MSAs);[96]

- Monitoring conformity assessment procedures and planning inspections.[97]

In some Member States, coordination bodies fulfil additional tasks. More specifically, the Austrian coordination body **gathers information** from businesses and consumers about their market surveillance priorities. In Latvia, it focuses on ensuring a clear **division of competences** among MSAs to prevent duplication of activities. Finally, the Polish coordination body **reports on the findings of inspections and maintains public registers** of non-compliant products.

Besides more structured forms of coordination, there are several additional mechanisms at the national level which have the same purpose, such as:

- Ad-hoc bilateral agreements;[98]

- Fora for deeper cooperation and/or dialogue;[99]

- Working groups for the direct exchange of information and experience;[100]

- Regular contacts to coordinate market surveillance activities;[101]

- Joint actions on specific product categories.[102]

Within the same Member State, **almost all MSAs cooperate with Customs** on an ad-hoc basis, through regular dialogue or joint surveillance actions.[103] A few Member States have

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94 DE, EE, LV, PL, and SE.
95 DK, EE, FI, LU, NL, and SE.
96 AT, DK, EE LV, NL, PL, SE, and SI.
97 FI, PL, and SI.
98 BE, CZ, EE, RO, and SK.
99 Fora appear to be a good working tool especially for the UK, where different ones exist, such as: the sub-group of the Market Surveillance Co-ordination Committee (MSCC), which focuses on border controls; the Product Safety Focus Group, acting as the contact point between local authorities, regions, central government and other stakeholders; and the National Trading Standards Board (NTSB), which involves a group of experienced local government heads of trading standards.
100 CZ, EE, FI, SE, SI, SK, and UK. Estonia, for instance, set up an expert working group for borderline products under the Health Board, while Sweden established the permanent 'Forum for Customs-Related Issues'. Finland set up the 'Mativa Network', which meets twice a year and focuses specifically on cooperation related to RAPEX and ICSMS systems. In the UK, the HSE (Health and Safety Executive) Product Safety Team is responsible for enforcing the legislation on workplace goods.
101 BE, NL and SE report that some departments hold regular meetings on surveillance of some product categories. In CY and SI, MSAs frequently exchange communications on daily matters by phone, official letters or electronically. EL created a specific integrated information system presenting multiple information such as names and data of the registered test laboratories, registered products and names of inspectors, annual budgets for inspections allocated by national legislation, risk assessments and planning of costs.
102 BG, CZ, EL, ES, HU, LT, NL and SI.
103 A regular dialogue between Customs and MSAs in Greece is ensured through the exchange of information sheets providing information on product compliance and provide guidance for releasing/suspending products for/from free circulation. Also, the Consumer Protection and Health Board exchanges information on an ongoing basis, and difficulties encountered during inspections are discussed in annual meetings between MSAs and Customs. Information exchange is based on risk analysis to provide an expert assessment of products for Customs' inspection. Similarly, the German MSAs create product-risk profiles in collaboration with

opted to **establish a permanent body** dedicated to cooperation with Customs.[104] Other Member States have introduced **bilateral cooperative agreements**.[105] In some cases, there is cooperation between MSAs and Customs through **regular participation in working groups** at both national and EU levels.[106] Notably, to ensure a close link between all the authorities involved, cooperation mechanisms have been established between French Customs and MSAs. These can be used during inspections carried out by Customs in order to access information collected on the market by MSAs, and vice versa. Moreover, a cooperation protocol exists between Customs and the national MSA (DGCCRF, Directorate-General for Competition, Consumer Affairs and the Combating of Fraud). This protocol specifies the frequency of meetings between the two authorities during which annual control plans are developed. More importantly, the protocol clearly establishes geographical and sectoral competences. By knowing who to address for which purposes, the regional, local and central units of both Customs and the DGCCRF can quickly approach the relevant unit, making the market surveillance activities quicker and more responsive.

As for cooperation with other countries (pursuant to Articles 24 and 26), the majority of Member States[107] engage in some form of **cooperation with other EU countries**, notably by means of joint actions, i.e. specific market surveillance projects carried out simultaneously between MSAs in different countries. However, joint actions co-funded by the EU de facto require external support for the coordination of the MSAs involved and management of the budget. Only a few[108] Member States participate in **cooperation initiatives on market surveillance involving third countries**, although cross-country communication and cooperation is considered useful by nearly all public authorities (PAs).[109]

AdCO groups (Administrative Cooperation Groups) are a relevant example of cross-country coordination mechanisms. They are supported by the EC and involve MSA representatives in

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Customs in order to help the latter to decide on whether to defer the placing of a product on the market and to inform the MSAs. In both Poland and Romania, MSAs support Customs through training courses. An interesting form of cooperation has been set up in Poland since 2011, whereby all Customs appoint product safety coordinators, who are responsible for monitoring the correct and uniform application of market surveillance regulations and cooperation with MSAs to improve the effectiveness of joint actions. Furthermore, Polish Customs usually cooperate with MSAs in the drafting of position papers on new EU legislative proposals. Information on the type of cooperation with Customs was not available for FR, HU, LU, LV and PT.

104 This is the case in Belgium, where an ad-hoc unit, made up of representatives from MSAs and the General Administration of Customs and Excise (AGDA), meets several times a year to discuss potential improvements to market surveillance. For instance, improvements such as checklists to assist Customs' monitoring and a table breaking down the responsibilities among MSAs have resulted from these meetings. Similarly, the UK has established an Intelligence Hub, which acts as a single point of contact for the liaison between all MSAs, Her Majesty's Revenue and Customs (HMRC) and the Border Force for the border controls of unsafe and/or non-compliant products entering the country. The National Clearance Hub, which is responsible for the Customs clearance of products entering the UK, also acts as a single point of contact for importers and other enforcement agencies for freight clearance queries. In Sweden, the Market Surveillance Council also involves the National Board of Trade and the Customs authorities.

105 DK, EL, ES, FR, NL, MT, RO, SI, and SK. For instance, cooperation agreements between Customs and MSAs are implemented systematically in Spain. The Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) is usually engaged in activities relating to the promotion of consumer and user rights regarding goods and services. However, it acts as an MSA and undertakes actions only in cases where Customs authorities request support on the basis of Articles 27 to 29 of the Regulation. Interestingly, there is also another control body, i.e. the Official Service Inspection, Supervision and Regulation of Exports – SOIVRE, operating in Spain. This body is in charge of monitoring a series of products (e.g. through documentary checks, inspections and testing) before they reach Customs' offices. Specific product categories (i.e. toys, textiles, shoes, some personal protective equipment, some electrical products and wood products and their derivatives) must receive formal approval (in the form of a safety certificate) from SOIVRE before Customs can let them entering the country.

106 In particular, in Poland and Sweden, Customs participate jointly with MSAs in the EC Expert Working Group on product safety and compliance checks for imported goods. Furthermore, Sweden has set up a permanent working group for cooperation, the 'Forum for Customs-Related Issues'. This Forum is convened twice a year and is open to all authorities in the Market Surveillance Council, the Swedish coordination body comprising the 16 national MSAs. It has the task of drawing up the national market surveillance plan and promoting cooperation and efficiency in market surveillance activities.

107 AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, IE, IT, LT, LV, MT, NL, PL, PT, RO, SI, and UK.

108 AT, CZ, EE, EL, ES, FI, RO, and UK.

109 i.e. by 56 out of 77 public authorities responding to the question.

a given sector. AdCOs meet regularly to discuss issues in their area of competence and to ensure efficient, comprehensive and consistent market surveillance.[110] Thus, they enable flexible and efficient cooperation between Member States.[111] They are the most frequently used mechanism for market surveillance cooperation related to product categories subject to Union harmonisation legislation.[112]

RAPEX and ICSMS are key tools provided by the Regulation to allow for cross-border exchange of information and possible collaboration between MSAs. According to what was stated in national programmes, **all Member States make use of RAPEX** and **most of them utilise ICSMS**, in accordance with Articles 22 and 23, respectively.

As regards **existing databases for monitoring accidents related to products**, only Bulgaria, Greece, Hungary and Liechtenstein seem to have no national databases to collect data on injuries.[113] The EU Injury Database systems are the most widespread mechanisms for gathering injury information across Europe, as they are available in 16 EU Member States[114] plus Iceland and Norway.

5.2.4 Measures on non-compliant products

5.2.4.1 Restrictive measures

As shown in the table below, which is based on RAPEX data, **the most frequently imposed restrictive measures are withdrawal, recall and ban.** The data show that the use of restrictive measures has grown over the two periods by an impressive 52%. Interestingly, the most significant increases have been registered in the most 'coercive' measures (i.e. seizure, withdrawal, destruction). The use of other measures, such as requests for information or corrective actions, has actually declined.

Table 4-16 - Average number of RAPEX notifications on measures undertaken by Public Authorities (PAs) over 2005-2009 and over 2010-2015

Measure	*'05-'09*	*'10-'15*	*Average Δ%*	Total
Recall	184.4	288	56%	2,648
Withdrawal	428.2	803	88%	6,959
Destruction	11.8	18	55%	169
Ban	242	236	-2%	2,627
Seizure	10	27	167%	210

110 http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups/index_en.htm
111 Four MSAs (DE, FI, 2 SE), the German coordinating authority.
112 COM(2013) 76 final. Product Safety and Market Surveillance Package - Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee. 20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU.
113 No information was reported in national programmes, therefore source for this data is DG JUST (2015). Draft - *Mapping injury and accident databases for market surveillance of products in the EU – Survey Results*.
114 AT, CY, DK, EE, FI, IE, IT, LT, LV, LU, MT, NL, PT, RO, SE, and UK.

Corrective actions	21.2	16	-27%	199
Information	16	2	-91%	89
Total	**913.6**	**1,389**	**52%**	**12,901**

Source: Authors' elaboration on RAPEX database

The national reports do not appear to confirm the data from RAPEX, since overall **MSA restrictive measures** showed a slight fall, averaging -0.33% over the period 2010-2013, although such measures increased in R&T under R&TTe and in the toy sector. However, as noted, data from national reports demonstrated a number of limitations in terms of sectoral and geographical coverage, and covered a smaller time frame when compared to RAPEX. In this case, the low number of both sectors (3) and Member States (19) covered might explain this trend.

Table 4-17 – Number of MSA restrictive measures in three sectors[115]

Sector	*2010*	*2011*	*2012*	*2013*	*Average Δ%*
Electrical appliances under LVD	344	117	82	70	-20%
R&T under R&TTE	877	769	784	952	2%
Toys	1,277	1,433	1,430	1,450	3%
Total	**2,498**	**2,319**	**2,296**	**2,472**	**-0.3%**

Source: Authors' elaboration on national reports

As for **measures undertaken by economic operators**, on average, measures increased between the two periods. From 2005-2009 to 2010-2015, the most significant increase (by nearly 124%) was registered in the average number of notifications relating to product destructions.

Table 4-18 - Average number of RAPEX notifications on measures undertaken by economic operators over 2005-2009 and over 2010-2015

Measure	*'05-'09*	*'10-'15*	*Average Δ%*	Total
Recall	225.8	334.7	48.2%	**3,137**
Withdrawal	334	332.7	-0.4%	**3,666**
Destruction	15.8	35.3	123.6%	**291**

115 Data for 19 MS: AT, BG, CY, CZ, DK, EE, EL, FI, FR, HU, IE, LU, LV, PL, PT, RO, SE, SI and SK.

Measure	*'05-'09*	*'10-'15*	*Average Δ%*	Total
Ban	10.8	15.8	46.6%	**149**
Information	28.8	3.3	-88.4%	**164**
Total	**615.2**	**721.8**	**17.3%**	**7,407**

Source: Authors' elaboration on RAPEX database

Data from national reports partly confirm data from RAPEX. **Indeed, corrective actions taken by economic operators increased slightly** over time, showing a +4% rise at the end of the period. They also grew in the toy sector, but fell in radio and telecommunications equipment under R&TTe.

Table 4-19 - Corrective actions taken by economic operators[116]

Indicator/sector	*2010*	*2011*	*2012*	*2013*	*Average Δ%*
Measuring instruments	415	557	463	515	6%
R&T under R&TTE	734	790	689	588	-5%
Toys	1,116	1,474	1,902	1,517	9%
Total	**2,264**	**2,821**	**3,054**	**2,620**	**4%**

Source: Authors' elaboration on national reports

Table 4-20 presents an overview of the **measures undertaken by both economic operators and PAs per category of product**, comparing the periods 2006-2009 and 2010-2015. If single product categories are considered, the number of notified measures has diminished over time for the majority of these (e.g. notifications of withdrawals diminished for 17 product categories from 2006-2009 to 2010-2015). However, if measures are considered across sectors, the number of notifications always increased over the period, with the exception of 'other' measures. The following sectors were particularly the subject of restrictive measures: chemicals, clothing, textiles and fashion items, communication and media equipment, construction products, jewellery, laser pointers, motor vehicles, pressure equipment/vessels, protective equipment, pyrotechnic articles. For instance, **construction products** and **jewellery** were particularly subjected to higher levels of withdrawals, with increases of 3,167% and of 389%, respectively, from one period to the other. Similarly, notifications of bans related in particular to the **protective equipment** sector showed an increase of 1,167% from 2006-2009 to 2010-2015. **Overall, the number of notified measures rose by 20% only falling in the toy sector**.

From this analysis, it can be concluded that **product non-compliance increased consistently from 2006-2009 to 2010-2015**. Nonetheless, as previously mentioned, these data could be

116 Data for 20 MS: AT, BE, BG, CY, DK, EE, EL, FI, FR, HU, IE, IT, LU, LV, MT, PL, RO, SE, SI and SK.

interpreted in two opposing ways, inasmuch as an increase in RAPEX notifications may also imply that MSAs have become more effective in finding – and thus correcting – non-compliance.

Table 4-20 - Annual average number, total number and percentage increase of notified measures taken by both PAs and economic operators per product category

	Withdrawal				*Ban*				*Recall*				*Other*[117]				*Total*			
	06-09	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*
Chemical products	19	30	257	63	6	13	100	111	5	6	59	14	6	8	71	42	36	57	487	60
Childcare articles and equipment	53	32	405	-38	18	12	143	-33	29	23	255	-22	12	6	84	-52	112	73	887	-35
Clothing, textiles and fashion items	106	400	2,825	278	17	57	409	225	46	150	1,083	225	12	22	180	80	181	629	4,497	246
Comm. and media equip.	2	7	54	225	0	1	9	439	5	9	76	71	1	2	17	24	9	20	156	111
Construction products	0	7	41	3167	0	1	4	100	-	6	35	n/a	0	1	9	439	1	14	89	1945
Cosmetics	47	44	452	-8	18	13	153	-28	15	10	122	-33	6	14	109	123	87	81	836	-7
Decorative articles	12	12	119	0	2	3	27	14	9	4	64	-54	1	5	33	574	25	24	243	-2
Electrical appliances and equipment	109	101	1,040	-8	34	27	299	-22	77	71	735	-8	13	9	105	-33	234	207	2,179	-11
Food-imitating	23	16	187	-33	6	5	56	-19	7	5	59	-31	3	2	24	-8	39	28	326	-29

117 Other measures include notifications of: imports rejected, information and appropriate warnings, corrective actions, suspension of sales, seizure and confiscation, fines and destruction. Please consider that these data were not homogenous across the years.

	Withdrawal				*Ban*				*Recall*				*Other*[117]				*Total*			
	06-09	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*
products																				
Furniture	9	7	78	-25	3	3	28	19	6	6	60	-12	2	0	8	-78	20	16	174	-19
Gadgets	3	2	21	-38	1	1	6	-33	2	0	9	-81	1	1	8	-33	6	3	44	-49
Gas appliances & components	6	3	43	-41	5	3	36	-41	4	5	45	19	2	0	10	-83	17	11	134	-31
Hand tools	2	1	12	-78	1	0	3	-67	1	-	3	-100	1	0	6	-86	5	1	24	-82
Hobby/sports equipment	16	16	164	0	6	7	65	29	16	12	138	-22	4	2	29	-59	42	38	396	-11
Jewellery	5	23	159	389	1	2	15	167	1	3	22	204	0	1	9	136	7	29	205	321
Kitchen/ cooking accessories	8	6	65	-31	2	3	26	80	3	4	35	48	1	1	8	-33	13	13	134	0
Laser pointers	8	11	98	48	1	2	17	389	1	3	22	204	4	4	42	0	13	21	179	58
Lighters	19	16	174	-15	8	4	55	-45	7	2	39	-70	4	2	28	-57	38	24	296	-36
Lighting chains	19	19	193	0	7	7	68	-4	14	11	122	-19	1	2	16	48	41	39	399	-5
Lighting equipment	59	42	488	-28	21	5	113	-75	43	34	373	-22	4	2	25	-48	126	83	999	-34
Machinery	17	11	132	-36	6	2	36	-74	13	9	105	-33	5	2	30	-71	42	23	303	-46
Motor vehicles	11	3	60	-75	5	0	21	-89	11	118	755	944	105	31	606	-70	131	153	1442	16
Other	7	27	189	278	1	5	35	574	5	12	94	123	2	4	29	151	15	48	347	224

	Withdrawal				*Ban*				*Recall*				*Other*[117]				*Total*			
	06-09	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*	*06-09*	*10-15*	*Tot*	*Δ%*
Protective equipment	9	16	130	71	0	3	19	1167	6	10	83	71	2	2	18	4	17	30	250	80
Pyrotechnic articles	-	14	84	-	0	1	6	-	0	0	2	-33	-	-	-	-	1	15	92	2870
Recreational crafts	1	-	5	-100	0	-	1	-100	1	2	14	63	4	0	18	-96	7	2	38	-73
Stationery	7	2	37	-75	1	-	4	-100	3	0	14	-95	1	0	4	-78	12	2	59	-83
Toys	290	267	2,758	-8	82	72	762	-12	131	107	1,164	-19	36	40	384	9	539	485	5,068	-10
Total	867	1,134	10,273	31	251	252	2,516	0	463	623	5,590	34	234	162	1,910	-31	1,815	2,172	20,289	20

Source: Authors' elaboration on RAPEX database

5.2.4.2 MSAs' powers of sanction

According to Article 41 of Regulation (EC) No 765/2008, "*Member States shall lay down rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive […].*"

Penalties are imposed on economic operators by MSAs or by a court and **should act as powerful deterrents for non-compliance**. They may be either administrative or criminal, depending on the seriousness of the offence. **Administrative sanctions** are imposed in cases of infringements of administrative law and include both restrictive measures and monetary sanctions. **Criminal sanctions**, such as imprisonment, are usually imposed in cases of serious infringements and by means of a judicial procedure. As provided for by Article 41 of the Regulation, **all Member States foresee the use of penalties for product non-compliance**.[118] More specifically, they all apply administrative sanctions for non-compliance, while 24[119] recur to criminal law for the enforcement of market surveillance in non-food product sectors. In case of serious infringements, **imprisonment is envisaged** in 21 Member States.[120]

The following table presents a synthesis of penalty mapping set at the national level for product non-compliance. The complete overview is presented in the Annex.

Table 4-21 - Types of penalties and Member States where these are applied

Penalty	*Administrative*	*Criminal*
Definition	Administrative penalties are imposed in cases of infringements of administrative law; they include both restrictive measures and fines	Criminal penalties can be imposed in cases of serious infringements by means of a judicial procedure
Member States	28	24
	All EU MS	AT, BE, BG, CY, CZ, DE, DK, EE, FI, FR, HR, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SI, SK, UK

Sources: National programmes and reports, EC-SOGS N620[121]

As the result of the mapping provided in the Annex, **the level of penalties differs across Member States and sectors.** As for the **administrative sanctions**, for instance, fines for breaching the national legislation on medical devices may vary from €30 to €1,500 in Lithuania and reach €1,802,776 in the Czech Republic. In the toy sector, fines in Romania and Sweden range respectively from €330 to €2,200 and from €500 to €500,000. As for

118 According to the Blue Guide: "*If a product presents a risk to the health or safety of persons or to other aspects of public interests, market surveillance authorities must request without delay to relevant economic operators to: (a) take any action to bring the product into compliance with the applicable requirements laid down in the Union harmonisation legislation; and/or (b) withdraw the product; and/or (c) recall the product; and/or (d) stop or restrict supplying the product within a reasonable period. In case the risk is deemed to be 'serious', market surveillance authorities must adopt a rapid intervention following the specific provisions of Articles 20 and 22 of the Regulation*".

119 AT, BE, BG, CY, CZ, DE, DK, EE, FI, FR, HR, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SI, SK and UK.

120 AT, BE, BG, CY, CZ, DE, DK, EE, FI, FR, HR, IE, IT, LT, LU, MT, NL, PL, SE, SI, UK.

121 http://ec.europa.eu/DocsRoom/documents/6266/attachments/1/translations

construction products, there is no maximum level for monetary sanctions in the Netherlands, while every year Sweden establishes a fixed amount to be paid in case of non-compliance. Infringements regarding measuring instruments are fined up to €50,000 in Germany, €24,000 in Poland and €7,500 in Bulgaria. The variance is particularly high even for **criminal sanctions**. When looking at the medical device sector, Bulgaria does not foresee any criminal prosecutions for non-compliance, Denmark only sets criminal fines, while imprisonment is set from a six-month period in Ireland to up to four years in Cyprus. It is not possible to be imprisoned for breaching the legislation on toy safety in Croatia, although criminal monetary sanctions are available, while Estonia foresees a maximum period of three years in detention. For non-compliance in the measuring instruments sector, imprisonment is not foreseen in Bulgaria, but is in Malta and the UK.

According to data available from the national reports, **application of sanctions and penalties experienced a positive trend,** rising by 34% from 2010 to 2013. This variation was related in particular to an increase in measures taken in the radio and telecommunications equipment under R&TTe and in the toy sector.

Table 4-22 - Applications of sanctions/penalties in three sectors covered by the Regulation[122]

	2010	*2011*	*2012*	*2013*	*Δ%*
Measuring instruments	436	454	415	329	-25%
R&T under R&TTE	163	315	324	328	101%
Toys	1,900	1,814	2,580	2,692	42%
Total	**2,499**	**2,583**	**3,319**	**3,349**	**34%**

Source: Authors' elaboration on national reports

Similarly, **the criteria for setting the amounts of penalties differ** from one Member State to another (e.g. dangers to health and safety in France and Croatia, the seriousness of the offence in Finland and the Netherlands, the Court's decision in the UK).[123]

Furthermore, as shown in Table 4-23, in some countries MSAs have specific **sanctioning powers**. In particular they may:

- *Destroy products:* based on information available, the majority of MSAs can destroy products, most frequently in the personal protective equipment and toys sectors, in 17 and 18 Member States respectively. In Estonia, Romania and Slovenia this power is more diffused, being granted in almost all sectors, except for biocides in Slovenia (see also Table 4-42 in Annex).

- *Impose administrative economic sanctions (without resorting to national courts):* this power is granted in all sectors by five Member States,[124] while Ireland is the country where MSAs have this power in fewer sectors. Indeed, Irish MSAs can impose

122 Data for 19 MS: AT, BG, CY, CZ, DK, EE, EL, FI, FR, HU, IE, LU, LV, PL, PT, RO, SE, SI and SK.
123 Targeted surveys.
124 CZ, EE, LT, RO, SI.

sanctions without resorting to the courts in only two sectors: medical devices and electrical and electronic equipment under RoHS and WEEE and batteries. The sectors covered most are aerosol dispensers and electrical and electronic equipment under RoHS and WEEE and batteries, where this power is available to 15 MSAs (see also

- Table 4-43 in Annex).

- *Impose compensation for consumers/users of non-compliant products:* this power is not particularly widespread, since only Slovenia grants it in all sectors.[125]Electrical appliances and equipment under LVD is the most-covered sector, although in only six Member States (see also Table 4-44 in Annex).[126]

- *Impose provisional measures pending investigations:* this power is available in more than 30 sectors in five Member States,[127] while in Ireland it is granted in only four sectors[128] and Romania does not grant it at all. In five sectors[129] it is granted by 15 Member States, which is the highest coverage for this power (see also Table 4-45 in Annex).

- *Publish decisions on restrictive measures:* based on information available, 14 Member States use this power in more than 14 sectors and it is granted in more than 12 Member States in 15 sectors. The sectors covered most are toys, personal protective equipment, machinery, noise emissions for outdoor equipment, and electrical appliances and equipment under LVD. In Estonia and Slovenia, it is granted in all sectors (see also Table 4-46 in Annex).

- *Recover from economic operators the costs borne to test products found to be non-compliant:*[130] a large number of MSAs for which information could be gathered can make use of this power in the majority of sectors.[131] In 13 Member States this power is granted in more than half of all sectors. Toys, personal protective equipment, simple pressure vessels, machinery and lifts are the sectors covered most, with 16 Member States making this power available to MSAs (see also Table 4-47 in Annex).

- *Sanction economic operators which do not cooperate:* this is the **most common power of sanction** among MSAs, as 15 Member States grant it to MSAs in more than 14

125 In Slovenia, MSAs have the powers to impose compensation for consumers, established in the Consumer protection law in Article 37(c) (OJ RS No. 98/04, 114/06 – ZUE, 126/07, 86/09, 78/11, 38/14 and 19/15). The compensation is imposed on a case-by-case basis. In many cases, MSAs recur to court experts to assess and justify the amount to be refunded by the economic operator.

126 DE, ES, FI, PL, SE and SI.

127 BG, CZ, EE, LT, SI.

128 Medical devices, cosmetics, measuring instruments, electrical and electronic equipment under RoHS and WEEE and batteries.

129 Medical devices, toys, personal protective equipment, measuring instruments, electrical and electronic equipment under LVD.

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

131 For instance, in Croatia, on the basis of the national Law on Administrative Procedure, MSAs can require by administrative decision that economic operators pay for testing costs only where these products were found to be non-compliant. In Slovenia, MSAs have the powers to request economic operators to pay for test costs according to Art. 17 of the Act on technical requirements for products and the conformity assessment (OJ RS, No. 17/2011) (1) stating that MSAs may take product samples for free in order to carry out checks and tests necessary to assess conformity. If the product is not in conformity, the costs incurred shall be borne by the economic operator. The cost recovery is imposed on case-by-case basis. In many cases, MSAs recur to court experts to assess and justify the amount to be paid by the economic operator.

sectors. Six Member States apply it in more than 30 sectors[132] and the most-covered sector is toys, with 18 Member States making it available to MSAs (see also Table 4-48 in Annex).

- *Shut down websites:* this is **the least-adopted sanction**, both across sectors and among Member States. In fact, based on the available information, only Latvian MSAs have this power in more than 14 sectors (see also Table 4-49 in Annex).

- *Remove or require to remove illegal content from a website:* only eight Member States confer MSAs with the power to remove illegal content from websites in more than 14 sectors.[133] Furthermore, only 11 sectors out of 33 are in some way covered by this power across the EU. Toys and electrical appliances and equipment under LVD are the most covered sectors, with 10 Member States granting this power.

Table 4-23 below presents an overview of the abovementioned powers of inspection.

Table 4-23 - MSAs' powers of sanction

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

Source: Targeted surveys

132 BG, CZ, EE, LU, RO and SI.
133 BG, CZ, FI, LU, LV, NL, SI and UK.

Additional differences in the penalty framework also depend on the **procedure to impose economic sanctions.**[134]

First, based on the available data, **not all MSAs can impose administrative fines without resorting to the courts** (for instance in Malta, Ireland and Finland). In Austria, an administrative court intervenes in cases where the non-compliant economic operator disagrees with the sanction imposed by the MSA and appeals against it. In Malta and Finland, MSAs can only impose restrictive measures and cannot recur to administrative monetary sanctions given that only the court has the power to impose fines. Please refer to case study 5 in Annex for more information.

Secondly, the conformity assessment procedures, the evaluation procedures preceding the imposition of sanctions, and the administrative process often require a considerable amount of work and resources.[135]

Thirdly, **the amount of effort and the resources necessary to impose sanctions may not always be coherent with the monetary value of the fines imposed**.[136]

5.3 Figures on non-compliance

As already noted, RAPEX is used to notify products that pose serious risks to consumer health.[137] In an attempt to identify any differences in the number of notifications before and after the Regulation came into force, where relevant, data have been divided into two time frames, 2006-2009 and 2010-2015, respectively. The table below presents **the average number of RAPEX notifications per category of products, per year,** divided into two periods, i.e. 2006-2009 and 2010-2015, where 2010 marks the year of the Regulation's entry into force.

Table 4-24 - Annual average of RAPEX notifications by product category for the periods 2006-2009 and 2010-2015

Product category	*2006-2009*	*2010-2015*	*Average Δ%*
Chemical products	24.5	49.83	103%
Childcare articles and children's equipment	72	62.17	-14%
Clothing, textiles and fashion items	154.5	512.67	232%
Communication and media equipment	7.25	13.50	86%
Construction products	0.75	9.33	1,144%
Cosmetics	66.75	75.83	14%
Decorative articles	18.5	15.17	-18%

134 37% of MSAs report that this procedure is burdensome to a large extent, 34% to a small extent, while 29% of them do not consider it as burdensome.
135 Three MSAs (2 CY, SE), one AdCO member (medical devices).
136 As underlined by a Finnish MSA.
137 Since 2005, only products posing serious risks have been notified. Since 2013, both PAs and economic operators started to report information about actions undertaken against products presenting a lower level of risk. In 2015, these notifications still represented a very small percentage (6%) of total notifications.

Electrical appliances and equipment	158.5	181.33	14%
Food-imitating products	30.25	22.33	-26%
Furniture	12.5	13.00	4%
Gadgets	4.25	2.00	-53%
Gas appliances and components	9.5	8.33	-12%
Hand tools	3.5	0.83	-76%
Hobby/sports equipment	29.75	32.67	10%
Jewellery	6.5	32.67	403%
Kitchen/cooking accessories	10.25	10.17	-1%
Laser pointers	9.25	16.67	80%
Lighters	27	23.17	-14%
Lighting chains	31.75	31.83	0%
Lighting equipment	77	56.50	-27%
Machinery	22.5	20.17	-10%
Motor vehicles	154.75	183.17	18%
Other	10.75	41.83	289%
PPEPPE	13.25	32.17	143%
Pyrotechnic articles	0.5	14.83	2,866%
Recreational crafts	6.5	4.33	-33%
Stationery	7.5	2.17	-71%
Toys	393.75	458	16%
Total	**1,209.25**	**1,927.5**	**59%**

Source: Authors' elaboration on RAPEX database

Overall, these trends are consistent with those reflected in the national reports. As reported therein, MSAs' inspection activities resulting in a **finding of non-compliance registered a positive average annual growth** over the period 2010-2013 (13%), rising from 11,945 in 2010 to 18,316 in 2013. This growth was due in particular to greater non-compliance in the eco-design and energy labelling sector and in the pyrotechnics sector – the latter also registering the highest increase in RAPEX notifications. Discrepancies between the two sources (e.g. an increase in the annual average number of RAPEX notifications in the PPE sector and a decrease in the annual average findings of non-compliance in the same sector) can be explained by the limitations, previously discussed, of data provided by national reports.

Table 4-25 - MSAs' findings of non-compliance[138]

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

Source: National reports

At the **Member State level**, the highest numbers of notifications per year over 2010-2015 came from Hungary, Spain, Germany, Bulgaria and the UK. These were also among the major notifying countries over 2005-2009. Those experiencing the largest variations over the two periods are Luxembourg, Malta and Romania,[139] which also have the lowest average number of notifications per year over the period 2005-2009. Overall, **the average number of notifications has increased from one period to another in most Member States**, with very few exceptions (i.e. Belgium, Greece, Ireland, Poland and Slovakia).

Table 4-26 - Average number of RAPEX notifications per year, per Member State, from 2005 to 2015[140]

MS	*'05-'09*	*'10-'15*	*Average Δ%*	*MS*	*'05-'09*	*'10-'15*	*Average Δ%*
HU	123.4	233.7	89%	SE	21.8	43.0	97%
ES	121.2	210.5	74%	PT	24.4	41.7	71%
DE	158.0	199.7	26%	PL	57.6	38.0	-34%
BG	53.4	170.2	219%	DK	13.6	32.2	137%
UK	84.4	119.8	42%	LV	9.4	26.0	177%
CY	35.2	115.7	229%	SI	18.0	21.7	20%
FR	56.2	114.8	104%	MT	5.2	21.5	313%
FI	55.4	85.0	53%	RO	5.0	18.8	277%

138 Data for 21 MS: AT, BE, BG, CY, CZ, DK, EE, EL, FI, FR, HU, IE, IT, LU, LV, PL, PT, RO, SE SI and SK.
139 It should be noted that the lower level of notifications in Romania over the period 2005-2009 might also be due to its later entry into the EU in 2007.
140 It should be noted that data for BG, HR and RO may experience higher variations given that they entered the EU after 2005.

EL	107.4	75.8	-29%	EE	15.8	17.7	12%
NL	37.8	60.3	60%	AT	13.8	17.3	26%
CZ	38.4	57.3	49%	IE	21.6	17.2	-21%
IT	24.4	53.5	119%	HR	-	14.3	n/a
SK	82.4	48.3	-41%	BE	10.4	9.8	-5%
LT	30.0	44.3	48%	LU	1.0	5.5	450%

Source: Authors' elaboration on RAPEX database

When looking at the **notified products' country of origin** (Table 4-27), it can be seen that notifications increased in 2010-2015 with respect to 2006-2009 for all major countries of origin. Over the period 2010-2015, around **80% of total notifications were related to products from 12 countries**, half of which are EU Member States (DE, ES, FR, IT, PL, UK) and one is Turkey. The **majority of notified products came from China,** equalling 59% of total RAPEX notifications over the period 2010-2015. However, between 2010 and 2015, a considerable number of products notified also came from Turkey (402), Germany (380), the USA (298) and Italy (243).

When looking at the **trends** in the number of notifications over the two periods, a remarkable increase was experienced by products imported from India, Turkey and the USA.

Table 4-27 - RAPEX notifications by products' country of origin

	2006-2009			*2010-2015*		
Country of origin	*Notifications*	*Annual average*	*% of total*	*Notifications*	*Annual average*	*% of total*
China	2,952	738	54%	6,862	1,143.7	**59%**
Turkey	108	27	2%	402	67	**3%**
Germany	271	67.75	5%	380	63.3	**3%**
United States	121	30.25	2%	298	49.7	**3%**
Italy	212	53	4%	243	40.5	**2%**
France	107	26.75	2%	196	32.7	**2%**
United Kingdom	88	22	2%	174	29	**2%**
India	44	11	1%	170	28.3	**1%**
Japan	98	24.5	2%	167	27.8	**1%**
Poland	87	21.75	2%	155	25.8	**1%**
Taiwan	79	19.75	1%	119	19.8	**1%**

Spain	58	14.5	1%	111	18.5	**1%**
Other	1,232	308	23%	2,288	381	**20%**
Total	**5,457**	**1,364.25**	**100%**	**11,565**	1,927.5	**100%**

Source: Authors' elaboration on RAPEX database

6. ANSWERS TO THE EVALUATION QUESTIONS

6.1 Effectiveness

This section focuses on the analysis of the effectiveness of the Regulation in achieving its specific and strategic objectives, as defined in its intervention logic, and the reasons behind the results achieved. Evaluation questions have been aggregated accordingly.

6.1.1 Achievement of the specific objectives

EQ of reference

EQ 1. *Are the results in line with what is foreseen in the impact assessment for the Regulation, notably as to the specific objectives of (i) enhanced cooperation among Member States/within Member States, (ii) uniform and sufficiently rigorous level of market surveillance, (iii) border controls of imported products?*

EQ 2. *How effective was the measure as a mechanism and means to achieve a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security? What have been the quantitative and qualitative effects of the measure on its objectives?*

EQ 3. *How effective was the measure as a mechanism and means to achieve a level playing field among businesses trading in goods subject to EU harmonisation legislation? What have been the quantitative and qualitative effects of the measure on its objectives?*

6.1.1.1 Cooperation and coordination

The current framework of existing cooperation and coordination arrangements is varied as well as complex.

As for **coordination between national MSAs**, various coordinating tools are used, such as ad hoc, permanent bodies for coordinating market surveillance activities and related meetings, committees, working groups, fora, informal arrangements, information systems and websites.

The great majority of Member States, with only a few exceptions,[141] have set up **formal mechanisms**, establishing an **ad hoc permanent coordinating body**. However, the **frequency of the body's coordination meetings** varies, ranging from two – in Austria, Cyprus and Lithuania - to more than five times a year – in Spain. In addition, the body's responsibilities are not uniform, and span from merely operative – e.g. monitoring of conformity assessment procedures – to more strategic, such as setting market surveillance priorities (DK, EE, FI, LU, NL and SE), or ensuring a clear division of competences between national MSAs to avoid duplication of activities (LV). The German coordination body (Zentralstelle der Länder für Sicherheitstechnik – ZLS) analysed in case study 2 is particularly relevant as it is in charge of strategic tasks to avoid overlapping among Land MSAs.[142]

141 i.e. BE, CZ, ES, SK.

142 For instance, ZLS creates product risk profiles to be applied throughout the country, or even enforces market surveillance measures when a case involves several Länder, thus allowing a uniform approach in a highly decentralised organisation of market surveillance.

Nonetheless, it is worth mentioning that coordination and cooperation mechanisms among MSAs in Germany were already in place before the entry into force of the Regulation, thus probably impacting positively on the way the Regulation has been further implemented by German Authorities.

Another interesting example of a particular coordination mechanism is represented by the Italian Medical Device Registration database. Although not yet fully merged with databases on product non-compliance, it allows for information sharing between economic operators and public healthcare agencies (see case study 1 in Annex).

In general, the pre-existence or the absence of an internal cooperation mechanism may be a relevant element of differentiation to be taken into consideration.

In addition to structured arrangements, there are also **informal mechanisms** for coordinating market surveillance activities, such as ad hoc bilateral agreements, fora, working groups, regular contacts, and joint actions. These mechanisms have proven to be effective, allowing, for instance, **to focus on specific market surveillance issues** such as border controls (as it is the case of MSCC in the UK, of a working group in Estonia, and of a forum in Sweden) or the use of RAPEX and ICSMS (as for the Finnish MATIVA network), or **to share experience and knowledge** on specific product categories – as it occurs in Belgium, the Netherlands and Sweden.

Finally, Member State authorities rely also on **information systems** such as ICSMS and RAPEX to exchange information and coordinate market surveillance activities, as well as on **websites** to communicate with economic operators and citizens both within and among Member States. Yet, their use is not at full potential. For instance, very few Member States use institutional websites as the most common tool to alert users on hazards,[143] despite the fact that the effectiveness and inclusiveness of a reporting system is crucial in ensuring stakeholders' involvement and cooperation in market surveillance. As proof, *'European organisations representing the interests of consumers, SMEs and other businesses have not yet been systematically involved in European efforts to improve market surveillance*'.[144] Next to this, the study identified many practical **difficulties in setting up a reporting system aimed at exchanging information between all authorities and economic operators**.[145]

Moreover, statistics[146] and information gathered from stakeholders[147] show that **the use of ICSMS by both MSAs and representatives from the private sector is still limited, or that some Member States do not even use ICSMS at all**.[148] Even within Member States, there is a great variance between MSAs in their use of the system.[149] This hampers the possibility to avoid duplication of effort, which is the case when the system is properly used, as shown by the German practice analysed in case study 2.[150] A number of MSAs indeed report on the

143 AT, BG, CZ, EE, NL, PL, RO, SI, and UK.
144 COM(2013) 76 final.
145 Ibid.
146 No information was found for LT and PT in national market surveillance programmes. Information on Member States' use of ICSMS has been complemented with ICSMS-AISBL (2015). IMP-ICSMS N024. Graph: *Level of use of ICSMS by all EU/EEA Member States (1. half of 2015)*, p.2.
147 Two European industry associations, a Danish industry association, a large Italian product manufacturer/ authorised representative, a large Spanish holding company, a Hungarian civil society association.
148 Such as BG, LT, MT, PT, RO. Source: ICSMS-AISBL (2015). IMP-ICSMS N024. Graph: *Level of use of ICSMS by all EU/EEA Member States (1. half of 2015)*, p.2
149 Source: ICSMS-AISBL (2015). IMP-ICSMS N024.
150 Germany represents a particularly positive case, in light of the fact that ICSMS was designed in Germany and then spread at the European level. Before starting a non-compliance case, German MSAs check on the tool as to whether a product has already been filed in the system.

duplication of work due to the filling-in of both ICSMS and internal/national databases,[151] which create disincentives to use ICSMS, due to compatibility issues. Further frequent issues concern the lack of adaptations to insert sector-specific information into ICSMS[152] and the impossibility to update information on the progress of the case.[153] The **low user-friendliness** to ease data entry,[154] inability to find **instructions about how to use** ICSMS[155] and **linguistic barriers**[156] are also reported as minor issues that could be improved.

As for RAPEX, its use has **significantly increased over the years**, both in terms of the number of notifications and follow-up actions (see case study 4). Moreover, the number of follow-ups outweighed the number of total notifications from 2014, thus possibly indicating that RAPEX **is increasingly recognised and used as an information tool** for enforcing market surveillance. However, **the use of RAPEX across Member States differs**, indicating that some Member States are more proactive while others are more reactive in dealing with notifications (see Figure 4-50). Yet, there are doubts on the full use of RAPEX when considering that the number of notifications made in the system is not proportionate to the size of the national markets.[157] For instance, Cyprus notifies on average more than Poland, Sweden and Romania.[158] Additional obstacles to the use of RAPEX is the perceived redundancy of having different notification procedures and communication tools. As proof, some MSAs think that ICSMS, RAPEX and the safeguard clause should be integrated within a single information system to reduce double work and inconsistencies.[159]

The sub-optimal use of information systems to exchange information also hampers **cooperation between Member States** – this is mainly based on the use of those systems and on European-level initiatives (namely expert groups, AdCOs and joint actions).

Besides the sub-optimal use of information systems, cooperation between Member States faces additional challenges. Even if the majority (77%) of MSAs and Customs consulted state that they cooperate with authorities based in other Member States and the large majority of MSAs declare to notify other Member States (75%),[160] most of **MSAs (78%) responding to the survey rarely restrict the marketing of a product following the exchange of information on measures adopted by another EU MSA against the same product**. Also, the possibility for MSAs and Customs to **make use of test reports drafted by MSAs in other EU countries** seems to be limited.[161] As shown in case study 4, for instance, while some countries used to rely completely on risk assessments provided by other Member States, others prefer to repeat the risk assessment on notified products. Input provided by some stakeholders and case study 4 suggest that the main obstacles to a full follow-up of RAPEX notifications across Member States consist of:

151 20 MSAs (AT, CH, CY, DE, ES, 5 FI, LT, LV, 3 NL, PL, 4 SE) and the Estonian and the Lithuanian coordinating authorities.
152 13 MSAs (AT, CH, 4 DE, 2 FI, LV, 3 SE, UK).
153 A Danish MSA.
154 Three MSAs (DE, LT, UK).
155 Four MSAs (DE, FI, LT, SE).
156 Four MSAs (BG, CH, LT, SE).
157 As regards RAPEX: http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/reports/docs/rapex_annual_report_2015_en.pdf
158 RAPEX database, average of data over the period 2005-2015.
159 Three MSAs (DE, PL, SE) and one AdCO chair.
160 41 MSAs (2 AT, 2 BE, BG, 2 CY, DE, 2 DK, ES, 6 FI, 2 IT, 4 LT, LU, 2 LV, 5 NL, PL, 9 SE) and eight AdCO members (electromagnetic compatibility, explosives for civil use, gas appliances, measuring instruments, medical device, noise, pyrotechnic articles, recreational craft). Source: targeted surveys.
161 Overall, the possibility of using test reports drafted by other EU MSAs is recognised only in BG, CZ, DE, EE, FI, LT, LU, LV, SI, and UK for a considerable number of sectors (i.e. more than 20).

- The lack of risk assessment data and test reports, making it impossible to assess the quality of checks performed by other MSAs;
- The lack of power to make use of test reports provided by other EU countries: as shown in Table 4-12, only 12 MSAs out of 28 have this power in more than 14 sectors. This causes duplication of testing costs and lengthy follow-up procedures;
- Possible disagreements between Member States on appropriate measures to be taken against the same non-compliant product;
- Language barriers;
- Difficulties in understanding the description of adopted measures when these are too generic.

As for EU-level arrangements, participating in AdCO work proves to be essential for coordinating actions[162] and keeping an eye on what MSAs in other Member States do, as well as learning from each other.[163] However, **not all MSAs participate in this form of administrative cooperation**.[164] Furthermore, according to the feedback received by AdCO Chairs, many Member State representatives participating in the meetings do not get actively involved in common discussions and activities. In light of this, the EC has increased its support for these groups, underlining that the chairpersons bear a remarkable burden when organising meetings and that many MSAs cannot attend due to budgetary constraints. Interestingly, however, the **number of AdCO groups has increased** with respect to the period previous to the implementation of the Regulation, rising from 'more than 10'[165] to the current 28.[166] This could possibly indicate an incentive to cooperate on sectoral market surveillance issues due to the introduction of the Regulation. In addition, from the interviews with business representatives it emerged that the cooperation mechanisms in place are not effective in identifying non-compliant products on the market because of limited financial, human and technical resources.

Finally, only few[167] Member States participate in cooperation initiatives on market surveillance **involving third countries**, as reported in the national programmes.

In conclusion, **coordination and cooperation mechanisms are significantly developed,** consisting of an impressive number of initiatives, and all stakeholders recognise them as useful.[168] However, these mechanisms **have not reached a level that can be considered satisfactory, especially considering those existing among Member States.** In particular, **despite the necessary tools being in place to ensure cross-border market surveillance cooperation**, they are not used effectively.

162 29 MSAs (BG, 2 CH, CY, 4 DE, 2 DK, 3 FI, IT, 2 LT, 2 LV, LU, 5 NL, 4 SE, UK), based on the targeted surveys.
163 31 MSAs (AT, BG, 2 CH, CY, 2 DE, 6 FI, 2 IT, 3 LT, 2 LV, 4 NL, PL, 6 SE), based on the targeted surveys.
164 8 MSAs (CY, 2 FI, 2 LT, 2 LV, SE), based on the targeted surveys.
165 SEC(2007) 173, p.34.
166 http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups_en
167 AT, CZ, EE, EL, ES, FI, RO, and UK.
168 45 out of 47 participants to the targeted survey find it useful (2 coordinating authorities, 39 MSAs and 4 Customs).

Based on the analysis undertaken **there is still a need for higher** level **and more transparent cooperation and exchange of information**, consistent with what was also suggested by some stakeholders.[169]

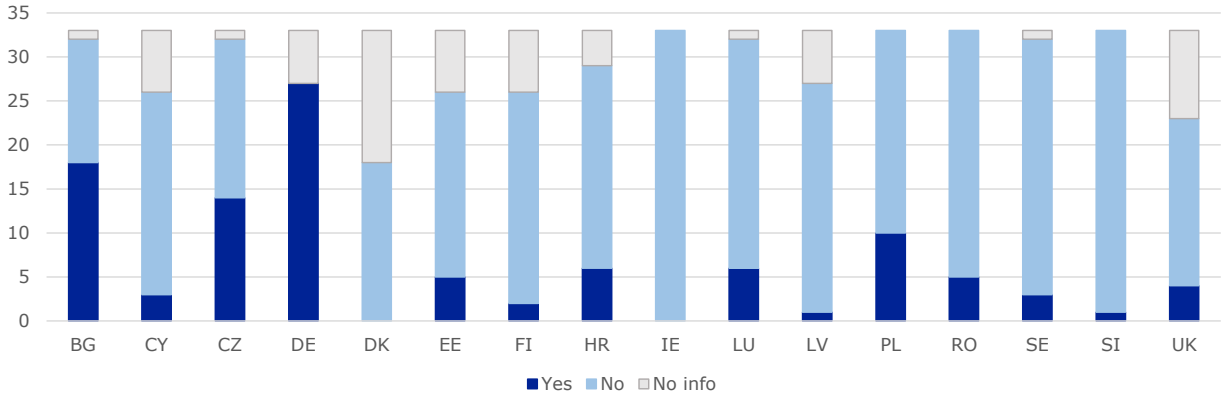
6.1.1.2 Uniform and sufficiently rigorous level of market surveillance

Member States need efficient and well-functioning (i.e. uniform and sufficiently rigorous) market surveillance systems to ensure the effective and efficient enforcement of the legislation and to reduce the number of non-compliant products circulating on the market. Nonetheless, **a satisfactory level of uniformity and rigorousness of market surveillance has not been achieved yet.**

As resulting from the analysis of national reports, there are significant differences across Member States.

Firstly, the **organisation** of market surveillance is different across Member States, in terms not only of level of centralisation of the organisational model, but also in terms of available resources (financial, human, and technical). Although data available from national reports, as discussed in the limitations to the study, are not fully reliable in their precise values, the big picture of a **high level of heterogeneity in the available resources** can be considered reliable, as also confirmed by additional stakeholder input and presented in section 5.2.1.[170] For instance, as shown in the figure below, **the availabilities of laboratories for product testing widely very across Member States**, though a widespread lack can be traced.

Figure 4-22 – MSAs' availability of in-house laboratories for product testing in 33 sectors covered by the Regulation[171]



Source: Authors' elaboration on multiple sources

The availability of resources seems to influence the depth of market surveillance controls. For instance, based on the figure below, Cyprus, Finland, Ireland and the UK perform a lot more physical checks on the product than testing, and also have few in-house

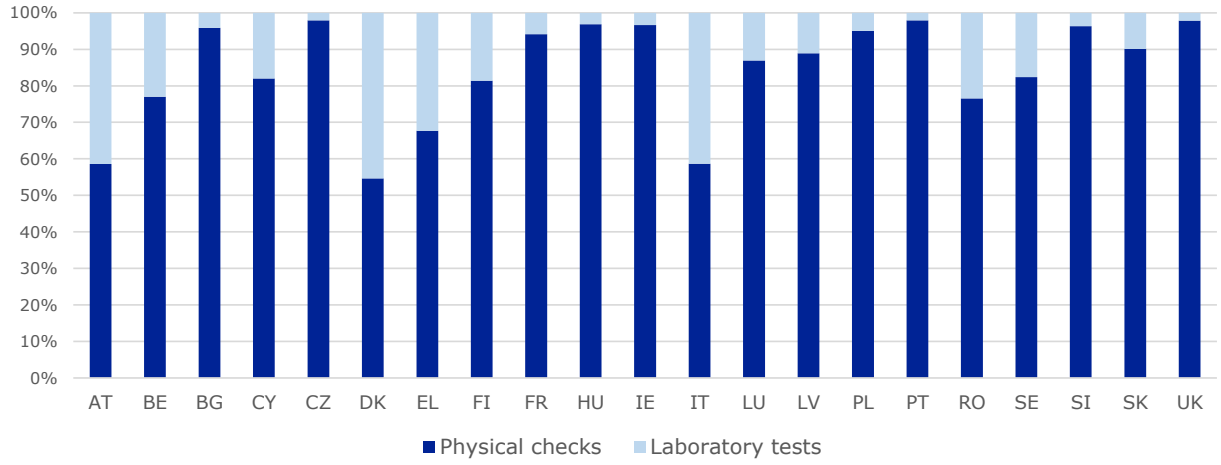
169 13 stakeholders (nine MSAs, three AdCO members, and one Custom Authority) suggest need for higher level of cooperation, 8 (MSAs) for higher transparency. Source: targeted surveys.

170 In the context of interviews, six interviewees from the Ministry of Health and Social Services (ES), the Ministry of Economic Development (IT), ISPRA (IT), REACH – CLP Unit (IT), the Ministry of Economy, Development and Tourism (EL) and a large French economic operator reported this issue, while all German interviewees (three MSAs and one Customs authority) perceive available resources as sufficient.

171 12 Member States have been excluded due to lack of information.

laboratories. In addition, as discussed under section 6.2.1, some Member States give higher importance to administrative aspects than to technical aspects, when checking compliance.

Figure 4-23 –Share of physical checks and of laboratory tests performed on total inspections, average 2010-2013[172]

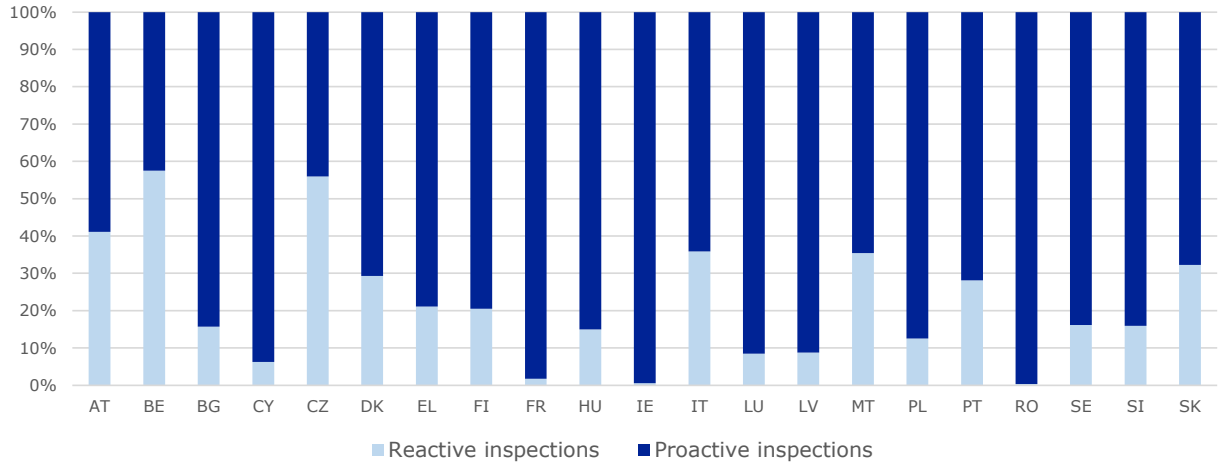


Source: Author's elaboration on data from national reports

Therefore, the **intensity of enforcement activities varies across countries**. As based on the figure above, there are some Member States (i.e. AT, DK, EL, IT) that seem to perform a higher number of laboratory tests – thus involving more in-depth enforcement – instead of merely checking formal compliance.

A second element of differentiation is represented by MSAs' **strategies of market surveillance**. As shown in the figure below, the level of proactivity varies from one Member State to the other.

Figure 4-24 – Average of reactive vs proactive MSAs' inspections between 2010 and 2013



Source: Author's elaboration on data from national reports

172 Data for DE, EE, ES, HR, LT, MT and NL are excluded as incomplete/unreliable. These data also do not include all sectors covered by the Regulation.

As a further proof, in order to assess to which extent market surveillance activities are proportionate to the dimension of the national market, **the total number of inspections carried out by MSAs has been compared to the number of enterprises active in the harmonised sectors per Member State**. The correlation between the two variables – though positive – is very low (i.e. 0.15), thus showing that MSAs' activities and efforts are not related to market dimensions. Moreover, its value varies considerably across Member States, as shown in the table below. These results further show the **lack of uniformity of market surveillance activities across Member States**.

Table 4-28 – MSAs' average number of inspections per average number of manufacturing enterprises[173]

MS	Index	MS	Index	MS	Index
IE	824%	FI	67%	HR	16%
LU	447%	EL	56%	SE	13%
EE	208%	RO	56%	SK	10%
AT	148%	PT	39%	PL	9%
HU	104%	BE	35%	CZ	9%
LV	82%	FR	23%	UK	5%
CY	81%	DK	22%	IT	3%
BG	73%	DE	19%	NL	1%
SI	70%				

Source: Author's elaboration of data from national reports and Eurostat SBS

As the table shows, subject to a number of important caveats due to limitations of the methodology used and the comparability of data provided by Member States, Ireland has the highest ratio (842%) whereas the Netherlands have the lowest (1%). The number of market surveillance inspections is remarkable also in Luxembourg, Estonia, Austria and Hungary. On the contrary, market surveillance controls do not seem proportionate with respect to the number of enterprises in the Czech Republic, the United Kingdom and Italy. It is stressed that the methodology only takes into account the number of manufacturing enterprises (excluding retailers) and disregards the number or the value of products available in the different countries. It is to be considered that these wide differences are also due to the differing interpretations of what an inspection is, thus impacting on the way Member States report data. For instance, the Irish, Belgian and Slovenian national reports include 'controls (including checks on the Internet) or other forms of contacts (mail, telephone)' in the number of inspections, which explains the resulting high index. Similarly, Bulgaria, Greece, Portugal, Hungary, Luxembourg and Estonia – the last three having an index greater than 100% - include 'visual inspections' in the definition of inspection. Denmark states that an important element of its market surveillance is inspections at trade fairs, while France lists 'inspections on advertising' among the activities. Italy – which has a very low index – reports only the number of inspections ordered by the Ministry of Health, therefore not including inspections performed by other MSAs on their own initiative. Moreover, as remarked under section 4.3.1, data on market surveillance activities presented in the national reports suffer a number of

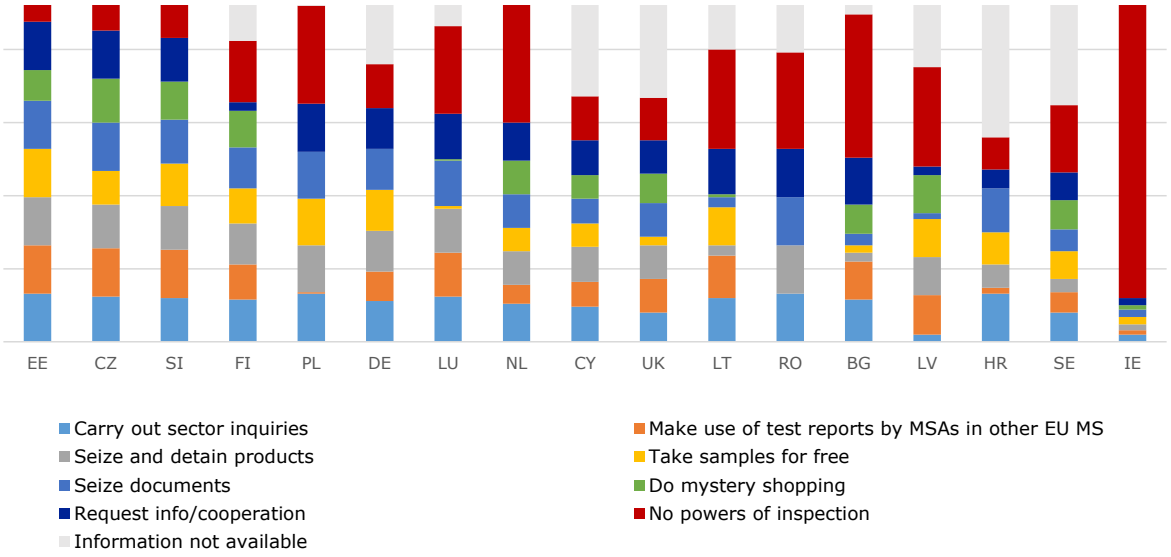
173 More precisely, the average number of inspections carried out at the national level over the period 2010-2013 as provided by the national reports has been compared to the average number of enterprises in the harmonised sectors over the period 2012-2014 as provided by Eurostat SBS. However, as already discussed, it is to be considered that data from national reports have a number of limitations in terms of Member States providing data, sector and timeframe coverage. As a consequence, some Member States (ES, LT, MT) have been excluded from the analysis due to lack of data. Moreover, it is to be considered that market surveillance is performed on products, but the relevant manufacturing enterprises do not necessarily have to be based in the same Member State. In addition, retailers can also be inspected; therefore, the number of enterprises used for the index is smaller than the businesses that could be subject to market surveillance controls and therefore only partly reflect the actual market dimension in the relevant Member State.

limitations, therefore, despite any definition of the term 'inspection', the number of inspections performed shall also be considered with caution.

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

Based on information reported in Table 4-12 - MSAs' powers of inspection and in more detail in Annex, the following figure displays the extent of inspection powers in a sample of Member States for which relevant information was available. The analysis shows that inspection powers are widely and equally distributed across sectors in the Czech Republic, Estonia and Slovenia. On the contrary, MSAs in Bulgaria, Ireland, the Netherlands and Poland lack inspection powers in a number of sectors.

Figure 4-25 – Extent of inspection powers in 17 EU Member States, considering 33 sectors covered by the Regulation[174]



Source: Authors' elaboration on various sources

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

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

Box 4-1 – Market surveillance of online sales

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

- Online sales are characterised by a high number of small consignments, with goods most of the time directly delivered to consumers;
- The number of existing web outlets is huge;
- Even though a web outlet is shut down, it is very easy to create a new web outlet by changing the name and the domain in a short time; as a result, unsafe products withdrawn/banned from the EU market can return on the market through a different website or under a different legal name;
- In many cases, the number of parties and intermediaries determine a complex distribution chain, where especially the role of fulfilment houses[175] and commercial platforms is not clear;
- Economic operators are often located in third countries and Authorities are not informed in advance that products are being imported;
- Online channels can be used to make unsafe, withdrawn products return on the market;
- Consumers are not fully aware of the risks associated with buying products online.

Vis-à-vis these specificities, the majority of stakeholders face specific issues related to online sales[176] and current market surveillance does not seem to be fully effective for online sales for various reasons.

First, specific **powers** of inspections and sanctioning related to online sales are present only in few Member States: most MSAs do not have enough power to deal with products sold online and powers of sanction are generally not extended to those kinds of product (see also Table 4-50 in Annex).

Second, irrespective of the existence of explicit powers, bodies or procedures for online sales, **enforcement activities** are not straightforward: evidence gathered from stakeholders, national programmes and through the case study on online sales (see Annex 8.4) shows that market surveillance on products sold online is particularly challenging for most Member States,[177] due to both the high volumes of products and websites involved (that would require resources that are not available), and the difficulties in inspecting and sanctioning the responsible

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

176 80% (n=67) of respondents to the targeted surveys encountered issues related to online trade with three large consumer associations based in different Member States (BE, DE, IT) encountering difficulties in performing their activities due to online trade.

177 AT, BG, CY, CZ, DE, DK, EE, ES, FI, HR, IS, IT, LT, NL, NO, PL, RO, SE. As reported in both national programmes and in contributions received to the public consultation and targeted surveys.

economic operator given the complex (and sometimes invisible) distribution chain,[178] with products most of the time directly delivered to consumers.

Third, in some cases, in light of the already-mentioned complex distribution chain, the same **identification of the responsible economic operator** is challenging,[179] and even when authorities have the power to shut down websites, this might take several months and the action is ineffective since, as described above, sellers can change name and domain in a short time.

Difficulties are exacerbated in **the case of cross-border online sales**, where action, which should be particularly fast, as some stakeholders underlined,[180] is lengthy and costly due to jurisdictional constraints and becomes basically irrelevant when third countries are involved. Indeed, tackling websites outside of the EU is substantially impossible and would represent a waste of resources: communication (see the section below on 6.1.1.3 Border control of imported products) and response by economic operators, even when clearly identified, are very limited, and cooperation with Authorities from different countries (especially if non EU-countries) is not always fast and effective (see Annex 8.4). Moreover, border controls of goods sold online are particularly difficult since there is no previous information about shipments, Authorities are not informed in advance that products are being imported, and often there are no electronic declarations.[181]

Despite some Member States (e.g. Estonia, the Netherlands, Romania and Slovenia) having tailored strategies to tackle online sold products, **the current market surveillance approach to online sales is still conducted in a fragmented and uncoordinated way.**[182]

As a result, non-compliance of products sold online is a real issue, especially when e-commerce popularity has increased amongst consumers[183] and when 78% of participants to the targeted survey reported that there are non-compliance issues related to online trade. Controls effectively performed are considerably less than those that are necessary, as highlighted by some stakeholders[184] and in the case study on online sales. As a consequence, the incentive for economic operators to be compliant is also low, considering the low risk of being caught and effectively punished.[185]

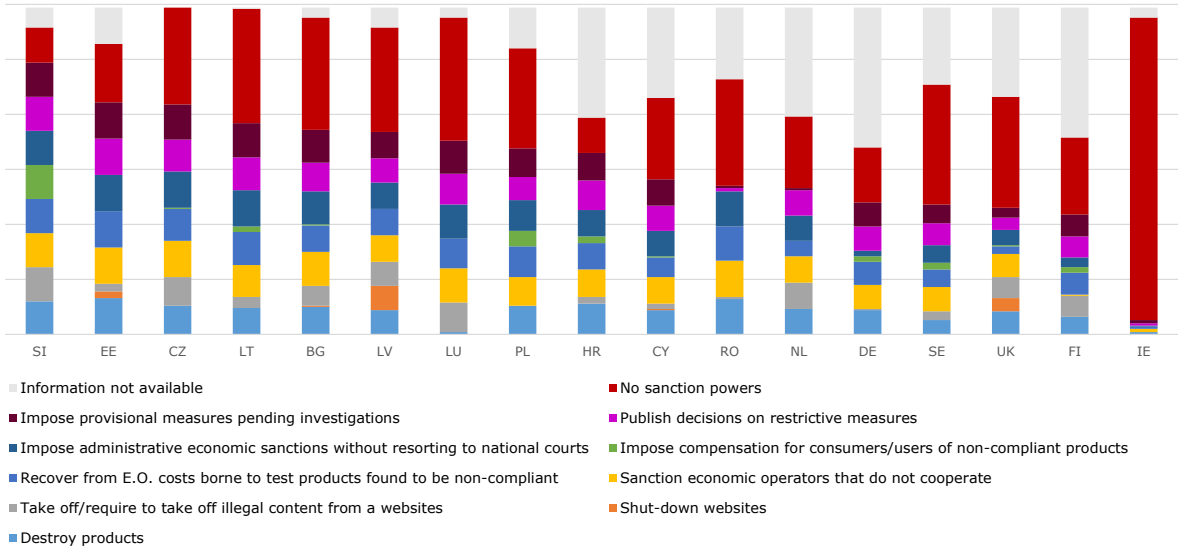
In light of this, the current level of protection and legal support to consumers is lower if compared to that for products marketed through other distribution channels.[186]

Similarly, the figure below – based on information reported in Table 4-23 and detailed in Annex – represents the extent of **sanctioning powers** in 17 EU Member States, considering the 33 sectors covered by the Regulation. The analysis shows again that sanctioning powers

178 As highlighted by an AdCO member (Medical Devices), only a very small share of products sold through fulfilment houses is checked (especially when coming from third countries) as they are delivered directly to consumers.
179 Six MSAs (AT, DK, 3 FI, SE), three AdCO members (measuring instruments, noise, pyrotechnic articles).
180 Five MSAs (2 FI, 2 SE, UK).
181 As stated by an interviewee from the Netherlands Food and Consumer Product Safety Authority.
182 As also underlined in COM(2013)76 final.
183 Source: PANTEIA (2014), *Good practice in market surveillance activities related to non-food consumer products sold online*.
184 Three MSAs (2 FI, NL), one AdCO member (recreational craft).
185 Four MSAs (CY, FI, 2 NO), eight economic operators (ES, 3 FR, 3 NL, UK), 11 industry associations (7 BE, ES, NL, 2 UK), two consumer organisations (BE), one international organisation from the UK, a Belgian trade union, two citizens from Germany and from the UK, three others (2 BE, FR). Source: public consultation.
186 COM(2013) 76 final. Product Safety And Market Surveillance Package – Communication From The Commission To The European Parliament, The Council And The European Economic And Social Committee. 20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0076:FIN:eng:PDF and Panteia and CESS (2014).

are widely distributed across sectors in the Czech Republic, Estonia and Slovenia, though with differences for some powers such as those related to online sales (shut down websites and remove/require to remove illegal content from a website) and impose compensation for consumers/users of non-compliant products. Irish MSAs are, once again, the ones lacking sanctioning powers in the highest number of sectors.

Figure 4-26 - Extent of sanctioning powers in 17 EU Member States, considering 33 sectors covered by the Regulation[187]



Source: Authors' elaboration on various sources

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

Thirdly, a **high level of heterogeneity can also be traced in the level of sanctions and related procedures**, as presented in detail in the specific case study undertaken and in the analysis of the penalty framework presented in the Annex. The mapping performed shows that the level of penalties differs both among Member States and across sectors. Similarly, procedures for imposing sanctions differ. In some Member States, MSAs can directly impose administrative monetary sanctions together with restrictive measures. In other Member States, MSAs are instead obliged to recur to Courts, even to impose administrative monetary sanctions. As result of these differences, **the current system of penalties and sanctioning powers does not provide sufficient deterrence**, as also confirmed by stakeholders.[188] In addition, stakeholders underlined that the existence of different methodologies and core elements to set penalties at the national level represents an issue in the internal market, and their harmonisation a priority.[189] Also, in terms of rigorousness of the system, it is worth underlining that penalties are not sufficiently high to prevent non-compliant behaviour,[190] so that the consequences of placing a non-compliant product on the market are mild if compared

187 AT, BE, DK, EL, ES, FR, HU, IT, MT, PT and SK are not reported due to lack of data. The height of the bars equals the sum of each of the 33 sectors covered by the Regulation where a given power is granted.
188 52% of respondents to the Public consultation state deterrence is not sufficient, while 38% of them think it is sufficient only to a moderate extent.
189 According to 77% of respondents to the public consultation.
190 According to 64% of respondents to the public consultation.

to the costs of respecting compliance rules. Therefore, the probability of being sanctioned is very low and does not ensure the right incentives to sell only compliant goods,[191] given that market surveillance is very fragmented at the national level.

Finally, a **heterogeneity exists in the system of monitoring and reporting** set up by the Regulation, i.e. the national reports. As discussed, the Regulation aims at creating a framework for market surveillance controls and sets up a monitoring system (through Article 18(5)) to supervise how and to what extent these controls are performed. However, as thoroughly discussed under section 4.3.1, national reports are not uniform or comparable across Member States, and present a significant number of gaps and inconsistencies. These issues reflect the existing differences in the organisation models – which make it, for instance, difficult to collect and/or aggregate data on market surveillance activities – but also differences in market surveillance approaches – e.g. the different interpretations of what an inspection is.

The heterogeneity existing across Member States in the implementation of the Regulation allows the conclusion that **the level of market surveillance is certainly not uniform**, given that Member States with more resources and powers have – at least – more tools for a proper enforcement. This lack of uniformity allows the inference that **market surveillance might also be more rigorous** in some Member States than in others. Potential effects are a less effective deterrence power and an unequal level playing field among businesses in some Member States, thus also potentially generating imbalances in the level of product safety across Europe. Some stakeholders, for instance, highlighted the need for a higher level of cooperation among EU MSAs to effectively increase deterrence.[192]

Nonetheless, if stakeholders' input is considered, according to more than half of respondents to the targeted surveys,[193] the current system of market surveillance controls does **not generate serious discrepancies within and across Member States**. However, as presented in the consultation in Annex, the opinion changes according to the stakeholder category considered. The majority of economic operators and civil society (53%) think that discrepancies exist across Member States, while the majority of MSAs and Customs (62%) think they do not exist.[194] But in light of the picture presented above, this opinion could be interpreted as resulting from a lack of full awareness of enforcement authorities of the situation existing in other EU Member States, rather than from real uniformity. This interpretation is also confirmed by the fact that most **MSAs (78%) rarely restrict the marketing of a product following the exchange of information on measures adopted by another EU MSA against the same product**, thus implying a 'lack of confidence' in other Member States' rigorousness on controls. In addition, despite declaring that there are no discrepancies in uniformity and rigorousness of market surveillance controls, MSAs and Customs express opinions on the effects of these discrepancies in terms of product safety reduction, influence on market behaviour and obstacles to free circulation of goods. A further

191 Four MSAs (CY, FI, 2 NO), eight economic operators (ES, 3 FR, 3 NL, UK), 11 industry associations (7 BE, ES, NL, 2 UK), two consumer organisations (BE), one international organisation from the UK, a Belgian trade union, two citizens from Germany and from the UK, three others (2 BE, FR). Source: public consultation.

192 Three MSAs or Customs Authorities (2 DE, CZ), a Swedish economic operator, seven industry associations (4 BE, NL, ES, FR), three consumer organisations (2 BE, DK), a Belgian trade union.

193 58 % declared to be not aware of any discrepancies across EU Member States in terms of uniformity and rigorousness of controls (total number of respondents = 118). A Belgian civil society association reports that only six MS are actively engaged in verifying the energy-efficiency labelling. A Danish MSA makes the example of controls over dangerous hover boards: many MS did not take any action, despite notifications via RAPEX, ICSMS and AdCO.

194 Respectively, 16 economic operators and civil society representatives and 66 MSAs and Customs.

evidence of the perceived low rigour of market surveillance recognised univocally by all stakeholders is the **incapacity of the Regulation to deter rogue traders**.[195]

To conclude, the differences identified in the implementation at the national level allow the inference that **market surveillance is not uniform across Member States**. As for its **rigorousness**, the serious lack of data and inhomogeneity of national reports do not allow for a thorough assessment, except if based on stakeholders' perceptions, on the discrepancies in the penalty framework and in the 'lack of confidence' of enforcement authorities in other MSAs' risk assessments. However, the low usability of data of national reports is already a finding in itself of a drawback of the Regulation in the achievement of its objectives, inasmuch as the major evidence on its functioning (i.e. the effectiveness of market surveillance controls) is hard – if not impossible – to retrieve.

6.1.1.3 Border control of imported products

Overall, stakeholders claim that **powers attributed by the Regulation to Customs are adequate**,[196] and the **procedures** for the control of products entering the EU market foreseen by Articles 27 to 29 of the Regulation are **clear, easy to apply and still relevant**.[197]

However, **checks of imported products** seem to be not sufficient.[198] Border control is indeed one of the most challenging tasks for market surveillance nowadays, in light of the increasing importance of EU trade with third countries and particularly with China. Evidence of this lies in the fact that the large majority of products notified on RAPEX come from China – as presented in Table 4-27. The share of non-compliant products imported from China accounted for an annual average of 54% of total RAPEX notifications over the period previous to 2010, this average even increasing up to 59% in 2010-2015. These data were confirmed by **more than half of respondents to the public consultation experiencing** non-compliance of products imported from non-EU countries. In addition, not only extra-EU, but **also intra-EU trade** deserves attention from a market surveillance perspective, as it represents a large share of overall EU trade. As presented in Table 4-27, 14% of total RAPEX notifications over the period 2010-2015 related to products imported from six EU Member States (DE, ES, FR, IT, PL, UK). In addition, **imported products are often bought online**,[199] this making enforcement even more challenging (for more information on online sales please refer to case study 3 in Annex 8.4).

The main difficulties related to controls of imported products are due to a **lack of jurisdiction** of MSAs outside of their Member State,[200] and to a **lack of direct communication** between MSAs and businesses,[201] particularly – again – in the context of online sales.[202] As a consequence, **businesses are not willing to collaborate** with MSAs' requests for corrective

195 As confirmed by 83% and 89% of economic operator/civil society representatives (n=15, n=16) for checks of MSAs and checks of Customs respectively – and by 75% of MSAs and Customs (n=64).
196 As declared by Customs in BE, BG, CY, CZ, EE, FI, DE, HU, IT, LU, LV, MT, NL, PL, RO, SE and SK. Source: targeted surveys.
197 According to Customs answering the targeted surveys, procedures are clear (95% n=20), easy to apply (76% n=16) and relevant (86% n=18).
198 According to the majority of stakeholders answering to the targeted surveys. When breaking down the results by stakeholder category, all Customs have a positive opinion on the adequacy of performed checks, while MSAs and AdCO members are divided between those stating that checks are adequate and those reporting the contrary. When asked about difficulties in performing market surveillance or controls of imported products in a particular sector, MSAs, Customs and AdCO members most frequently mention the machinery sector, toys, electrical appliances and equipment under LVD, chemicals, biocides, PPE and construction products.
199 Based on the results of the public consultation, 14% of respondents report that most of them are sold online, 56% say that some of them are sold online and 18% think that only a few are supplied online.
200 67% of respondents to the public consultation.
201 79% of respondents to the public consultation.
202 83% of respondents to the public consultation.

actions, for information/documentation or for paying penalties for non-compliance.[203] As discussed in case study 3, other issues specifically inherent to online sales relate to products directly mailed to consumers, to the high number of intermediaries and to the low level of consumers' awareness concerning the risks of buying products online, as described in detail in Box 1. Moreover, **despite the fact that the necessary tools are in place to ensure cross-border market surveillance cooperation** (e.g. RAPEX, ICSMS and the safeguard clause procedure), they are not used effectively, as discussed previously. Moreover, as shown in Table 4-12, only 12 MSAs out of 28 have the power to make use of test reports from other EU countries in more than 14 sectors.

To conclude, the Regulation is effective when looking at the existing coordination and cooperation within and among Member States, though some adjustments are needed particularly in the use of the information tools (i.e. RAPEX, ICSMS). Border controls of imported products present no implementation problems and Customs' powers as provided for by the Regulation are adequate; however, results are not satisfactory (i.e. more than half of notified products are imported). Finally, the uniformity and rigorousness of the market surveillance system definitely needs to be enhanced.

6.1.2 Achievement of the strategic objectives

Overall, the **Regulation provides an effective framework** for ensuring the protection of public interests[204] and a level playing field among businesses in the EU.[205] Nevertheless, its implementation suffers a number of shortcomings that hinder the achievement of these objectives. The assessment of the effectiveness of the Regulation in **achieving its objectives** focused on their expected result, i.e. the reduction of non-compliant products on the market. The existence of non-compliant products indeed poses threats to consumers/users and also points to the existence of rogue traders that benefit from lower compliance costs. Overall, the analysis of the information gathered from both the field and the desk research highlights that **the Regulation has not fully achieved its strategic objectives**.

All sources of information indeed converge on the conclusion that **there are still many products in the EU market that do not comply with legislative requirements**, as highlighted already by the 2007 IA for the Regulation and, later on, by the Proposal for product safety and market surveillance package.[206] Interestingly, despite the problem being identified 10 years ago and then regularly through the following years, nothing has changed, despite the entry into force of a Regulation aiming, *inter alia*, at tackling the issue.

As described, **the average number of RAPEX notifications increased by nearly 60% from 2006-2009 to 2010-2015** (rising from an average of 1,209 to 1,928 notifications per year), **even though the Regulation came into force.** In particular, notifications of products in sectors such as **construction, jewellery and pyrotechnics experienced a remarkable growth**, with a percentage increase greater than 400% over the two periods. If compared over the same period, data from national reports on MSAs' findings of non-compliance (Table 4-25) confirm the trends in RAPEX notifications in the electrical appliances equipment and in

203 According to 72%, 67% and 68% of respondents to the public consultation respectively.
204 'Public interests' include: health and safety in general, health and safety at the workplace, protection of consumers, protection of the environment, supported by respectively: 93%, 80%, 84% and 69% of respondents to the targeted surveys.
205 According to 63 public authorities replying to this question in the targeted surveys (equal to 84%) and according to 12 among businesses and industry associations (equal to 71%).
206 SEC(2007) 173, p.19 and SWD(2013) 33 final.

the machinery sector.[207] Moreover, the correlation between RAPEX notifications and findings of non-compliance is positive, though low (on average 0.44 over the period).[208]

In order to better understand these trends, we have verified whether the average number of RAPEX notifications is correlated with the value of harmonised products traded in the internal market over the two periods considered.[209] The aim was to check whether the increase in notifications was not – or at least not only – due to a mere increase in traded products, but actually to an increase in non-compliance at the EU level. **A positive growth in the number of RAPEX notifications is registered** in five product categories (again construction and pyrotechnics, together with textiles, cosmetics and motor vehicles), **despite a reduction in the value of harmonised traded products**. Moreover, as shown in the table below, the annual average value of trade for all harmonised products is almost constant (+0.1%) over the two periods considered, but, as said, the annual average number of notifications increased (+59%). Yet, this result has to be taken with due care given the impossibility to confirm casual links.

Table 4-29 - Annual average value of harmonised traded products and average number of RAPEX notifications by product category over the periods 2006-2009 and 2010-2015

Product category	2006-2009	2010-2015	Δ% traded products	Δ% RAPEX notifications
Chemicals	1,067,897,632,898	1,106,833,111,374	3.6%	103%
Construction	156,586,485,690	128,882,492,028	-17.7%	1,144%
Textiles	104,626,637,224	104,598,300,839	-0.03%	232%
Cosmetics	17,870,226,314	15,421,496,892	-13.7%	14%
Appliances burning gaseous fuels	2,236,818,858	2,062,761,701	-7.8%	-12%
Machinery	278,111,694,212	271,828,263,683	-2.3%	-10%
Motor vehicles and tractors	338,802,673,379	329,544,444,282	-2.7%	18%
Simple pressure vessels and pressure equip.	243,498,460,356	248,009,349,724	1.9%	-
Personal protective equip.	33,664,105,623	35,624,391,429	5.8%	143%
Pyrotechnics	2,314,375,580	2,302,762,034	-0.5%	2,866%
Recreational craft	6,185,094,424	5,755,650,303	-6.9%	-33%

207 Electrical appliances: finding of non-compliance +2%, RAPEX notifications: +3% over 2010-2013. Machinery: finding of non-compliance +2%, RAPEX notifications: +16% over the 2010-2013 period.

208 Due to lack of data, the following MS are not included: ES, HR, LT, MT, NL and UK. Moreover, only a few sectors are covered, namely: biocides, crystal glass, eco-design & energy efficiency, electrical appliances and equipment under LVD, machinery, measuring instruments, non-automatic weighting instruments and pre-packed products, noise emissions for outdoor equipment, personal protective equipment, pyrotechnics, radio and telecomm equipment under R&TTE, textile & footwear labelling, and toys.

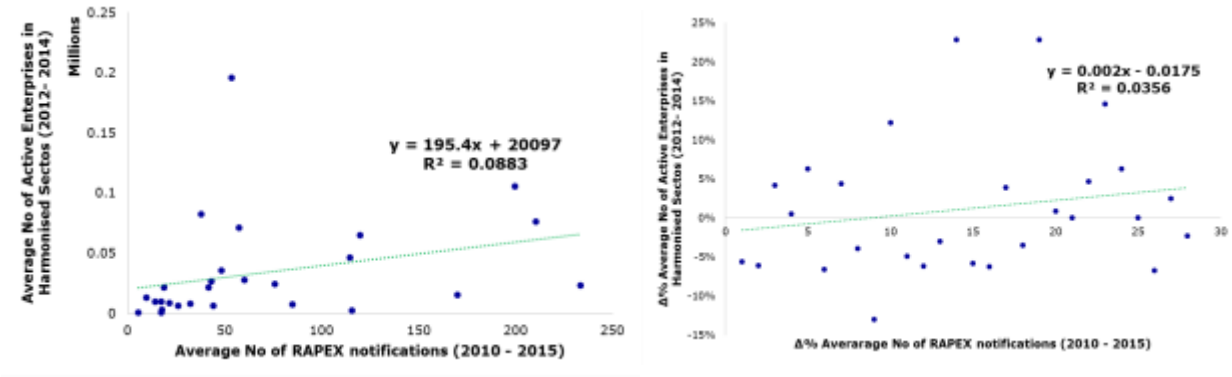
209 Since the product categories included in RAPEX slightly differ from the classifications used for the market analysis, only the product categories for which a reconciliation was possible were examined.

Product category	2006-2009	2010-2015	Δ% traded products	Δ% RAPEX notifications
Toys	9,359,483,585	12,004,549,187	28.3%	16%
Total	**2,261,153,688,142**	**2,262,867,573,475**	**0.1%**	**59%**

Source: Authors' elaboration on PRODCOM (2016) and RAPEX database

As described, **the average number of notifications has increased from one period to another in most Member States**, with very few exceptions. Also in this case, the possible link to the number of enterprises active in the harmonised sectors at the national level has been examined. As previously, the check aimed at assessing whether the increase in notifications was not – or at least not only – due to a mere increase in traded products, but actually to an increase in non-compliance at the national level. Although a positive correlation exists, it seems not to be statistically significant, thus further confirming that the increase in the number of notifications is not related with changes to the market structure.

Figure 4-27 - Correlation between RAPEX notifications and number of active enterprises in harmonised sectors by Member State



Source: Authors' elaboration on PRODCOM (2016) and RAPEX database

As already described, **the average number of notifications has increased from one period to another in most Member States**, with very few exceptions. Also in this case, the possible link to the number of enterprises active in the harmonised sectors at the national level has been examined. Although a positive correlation exists, it seems not to be statistically significant, thus further confirming that the increase in the number of notifications is not related with changes to the market structure.

Similarly, **the number of restrictive measures imposed by MSAs** in reaction to non-compliant products has increased.[210] Interestingly, as shown in Table 4-16, the most significant increases have been registered in the most coercive measures (i.e. seizure, withdrawal, destruction), while other measures such as requests for information or corrective actions have even decreased. This could indicate that not only non-compliance has increased, but that **its seriousness has worsened**, requiring MSAs to take 'decisive' measures. Similar conclusions can be drawn on the measures undertaken by economic operators to correct non-compliance. As shown in Table 4-18, since the entry into force of the Regulation, the most

210 RAPEX database

significant increase has been registered in the average number of notifications relating to product destructions. Moreover, Table 4-20 displays that **non-compliance does not affect all sectors equally, thus differently impacting on the level playing field**. The number of notified restrictive measures has diminished over time for the majority of sectors. However, the overall number of restrictive measures increased over the period. This means that there are some product categories particularly subject to restrictive measures, whose increase largely outweighs the decrease in the number of restrictive measures experienced by the other sectors.[211] It is worth mentioning that **textiles, construction, motor vehicles and pyrotechnics,** as shown in Table 4-29, registered the highest number of RAPEX notifications despite a reduction in their traded values, this further confirming a possible increase in product non-compliance in these sectors. The **toy sector** represents an exception, given that it registered **a lower number of restrictive measures**. This could effectively be an indicator of increased compliance given the large attention devoted to toys in market surveillance activities[212] – in light of the target group involved (i.e. children) – and since it is known to be the sector with the highest number of RAPEX notifications. [213]

Although data provided by national reports are partial in terms of sector, Member State and time coverage, the analysis performed allows the conclusion that, overall, **product non-compliance is increasing in Europe.** This is also in line with the results of the analysis based on RAPEX data. **These data are widely confirmed by stakeholders' perceptions** on trends in non-compliance. Most stakeholders do not perceive a substantial variation in the dimension of product non-compliance considering the period 2010-2015, despite the entry into force of the Regulation.[214]

Moreover, as already discussed, the Regulation has been implemented in different ways across Member States, in terms of powers of sanction/inspection attributed to MSAs, resources and level of penalties. These discrepancies diminish the Regulation's effectiveness in achieving a level playing field, inasmuch as they **influence regulatory/ administrative costs to businesses across Member States** (e.g. preparing documents and information requested by MSAs/Authorities in charge of EU external border controls in implementing surveillance measures).[215] Similarly, these discrepancies **influence market behaviour** (e.g. decision of companies to enter the EU market via certain Member States).[216] For example, according to an EU industry association, the impact of unfair competition due to rogue traders could be equivalent to -10% of the turnover of a lawful manufacturer, depending on product categories and countries. Specifically for engineering products, the drop in market share due to unfair competition could reach as much as -20%.

The above considerations allow to conclude that **the Regulation has not been capable** of fully achieving a high level of protection of public interests and a level playing field for businesses across the EU in light of the significant discrepancies in its implementation and of the dimension of product non-compliance, which did not vary (or even increase) since its

211 The following were particularly subject to restrictive measures: chemicals, clothing, textiles and fashion items, communication and media equipment, construction products, jewellery, laser pointers, motor vehicles, pressure equipment/vessels, protective equipment, pyrotechnic articles.

212 As discussed, Member States are used to prioritise market surveillance strategies focusing on mass products or on products targeting sensitive classes of consumers.

213 As also reported by an interviewee from an EU industry association.

214 26% (n=21) of respondents to the targeted survey state that the level of product non-compliance increased in the last five years whereas 25% (n=20) state it diminished. The remaining 49% state it did not change in the last five years.

215 According to 11 economic operators and industry associations answering to the targeted surveys (equal to 73% of respondents).

216 According to 10 economic operators and industry associations answering to the targeted surveys (equal to 71% of respondents) and to 26 Public Authorities (equal to 63% of respondents).

entry into force. As mentioned, these aspects negatively influence the capacity of the Regulation to achieve its objectives inasmuch as:

- **An unequal implementation of the Regulation creates disparities in the level of enforcement, and thus of protection of public interests across the EU**. Similarly, the increase in the number of non-compliant products signals that the protection of public interests has not improved with respect to the years previous to the entry into force of the Regulation.

- **An unequal implementation also creates disparities in the level of enforcement and thus differences in the burden of controls borne by economic operators**, which in some Member States and in some sectors is higher than in others. In addition, the increase in the number of non-compliant products signals that there are rogue traders that can still benefit from lower compliance costs, this further hindering the achievement of a level-playing field within the internal market.

6.1.3 Enabling factors

EQ of reference

EQ 4. *Are there specific forms of the implementation of the Regulation at Member State level that render certain aspects of the Regulation more or less effective than others, and – if there are – what lessons can be drawn from this?*

EQ 5. *To what extent has the different implementation (i.e. discrepancies in the implementation) of the initiative in Member States impacted on the effectiveness of the measures on the objective?*

As described, **the Regulation has been differently implemented across the EU.**

The first element of differentiation between Member States is their national organisation of **market surveillance structures**. Based on the information provided in Table 4-8, three types of organisational models can be identified:[217]

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

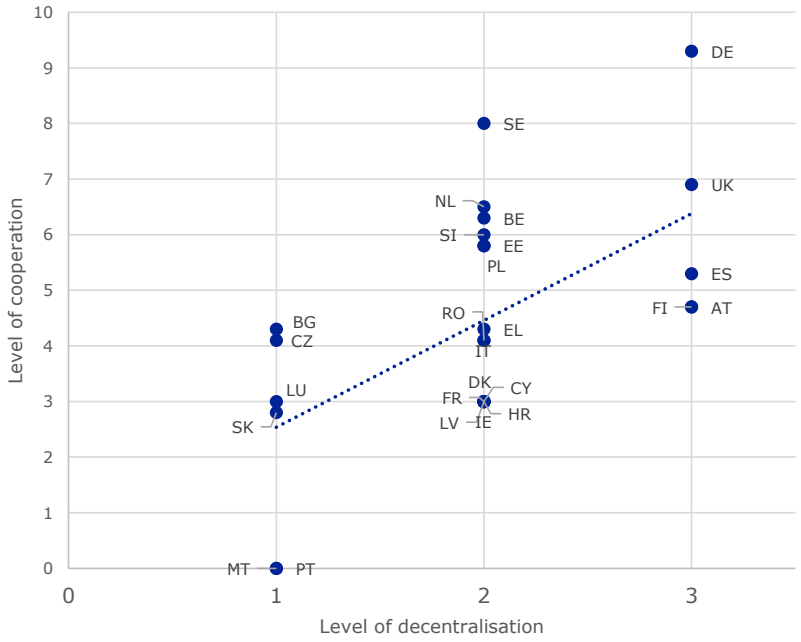
- **Decentralised at the sectoral level**, where several MSAs operate and have different competences, depending on the sector where they perform market surveillance activities. This model is adopted in Belgium, Cyprus, Croatia, Denmark, Estonia, France, Greece, Ireland, Italy, Latvia, Lithuania, Poland,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

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

217 European Parliament (2009), Effectiveness of Market Surveillance in the Member States. Directorate A: Economic and Scientific Policies. IPOL/A/IMCO/ST/2009-04; GROW.B1 (2016). Summary of Member States' assessment and review of the functioning of market surveillance activities according to Article 18(6) of Regulation (EC) No 765/2008; National market surveillance programmes from EU Member States.

Each Member State organises market surveillance in a way that best suits its particular cultural and legal framework or legal system, so that there is no 'one size fits all'. As discussed in 0, the lack of structured data on product non-compliance and on market surveillance activities makes the establishment of a causal link between the national organisation and the effectiveness of enforcement action not straightforward. **Organisational models influence how market surveillance is performed**,[218] resulting in differences across the EU. For instance, as shown in the figure below, Member States with a centralised structure need to rely on fewer and simpler cooperation tools. In contrast, the more a Member State is decentralised, the more it needs to set up numerous and complex cooperation mechanisms.[219]

Figure 4-28 – Existing correlation between the level of decentralisation of market surveillance and the complexity of cooperation tools within a Member State[220]



Source: Author's elaboration of information from national programmes

The results of case studies 1 and 2 allow the inference that **crucial elements for the effectiveness of decentralised models** are a clear attribution of tasks among authorities and to each MSA (i.e. that market surveillance is not just one 'among other tasks' that a MSA has to perform in its daily activities – this also impacting on cost-effectiveness), the existence of a

218 PROSAFE (2013). *Best Practices Techniques in Market Surveillance*, p.16. http://www.prosafe.org/library/knowledgebase/item/best-practices-techniques-in-market-surveillance

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

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

coordination board, the possibility for each MSA to have direct contacts with Customs, the visibility (to the public) of identity and contacts of relevant competent authorities. As far as the **sector-decentralised model** is concerned, formal channels and procedures for coordination are essential to have coherent policy approaches in different sectors. The crucial aspect for the **local-decentralised model** is to have a strong coordination body granting not only coherent policy approaches in different regions, but also coordination of investigations via a common database and a tool for common decision making.

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

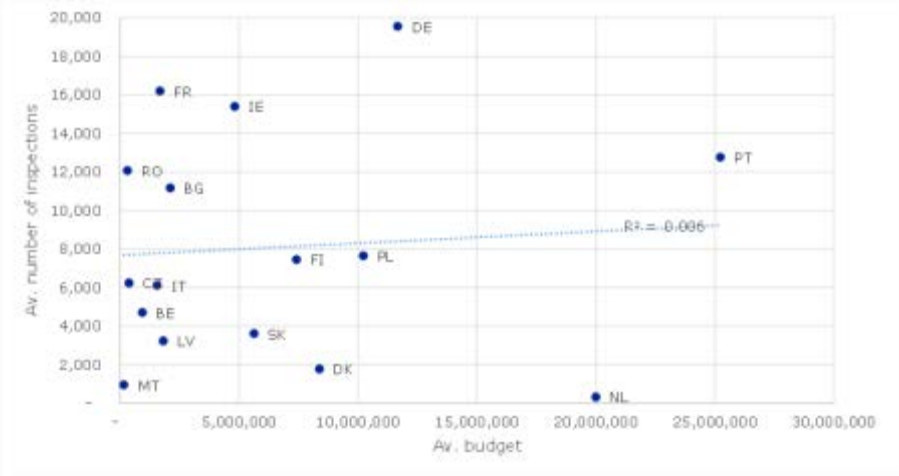
As presented in Figure 4-12, more than 80% of the total **budget available** for market surveillance is concentrated in seven Member States,[221] meaning that there are significant differences in terms of budget availabilities to implement the Regulation's provisions across Member States. Overall, the budget available for market surveillance decreased between 2010 and 2013 (Figure 4-13), though variations at the national level did not follow a common trend. Budget indeed increased in nine Member States,[222] decreased in seven[223] and remained stable only in two.[224] Possibly as a consequence of budget reduction, the number of **inspectors** also decreased (see Figure 4-19) and is very concentrated at the EU level, with 90% of them based in only six Member States[225] (see Figure 4-20) Finally, as presented in Table 4-9, only Germany and Bulgaria have MSAs with their own testing facilities for the majority of sectors covered by the scope of the Regulation (i.e. 27 and 18 sectors respectively).

This picture suggests a diffused lack of resources for MSAs, as also widely confirmed by stakeholders.[226] In general, this is indicated as one of the **main bottlenecks** to market surveillance implementation[227] and effective deterrence.[228]

In this context, we verified whether **MSAs' resources show a small positive correlation to the number of inspections performed** at the national level.[229] As shown in the figure below, the correlation is equal to 0.08, possibly due to the lack of reliability and completeness of data from the national reports. As a consequence, we can only suppose that **differences in the levels of available resources influence the inspections performed at the national level, but it is not possible to conclude on a direct causal relationship.**

221 DE, DK, ES, FI, NL, PL, PT, SE. The following: AT, CY, EE, EL, HR, LU, SI, and UK are excluded due to lack of data.
222 FI, FR, IT, LT, LV, MT, PL, RO, SE.
223 BE, BG, CZ, DE, ES, PT, SK.
224 IE, NL.
225 CZ, IT, PL, PT, RO, SK.
226 Lack of financial resources: 121 respondents to the Public consultation (equal to 70% of those answering the question); lack of human resources: 123 respondents to the Public consultation (equal to 72% of those answering the question); Lack of technical resources: 87 respondents to the Public consultation (equal to 52% of those answering the question). In the context of interviews, 6 interviewees from the Ministry of Health and Social Services (Spain), the Ministry of Economic Development (Italy), ISPRA (Italy), REACH – CLP Unit (Italy), the Ministry of Economy, Development and Tourism (Greece) and a large French economic operator also reported this issue.
227 Data from national reports. BG, CZ, EE, EL, ES, IE, LT, LV, MT, PL, PT, and SI.
228 Three MSAs, three economic operators (FR, PL, UK), two industry associations (BE, FR) and an international organisation. Source: public consultation.
229 Since the total budget as indicated in the national reports refers to the overall resources available to MSAs, it was not possible to provide an estimation of the average cost per inspection at the national level and of the average cost per FTE at the national level, since the allocated budget does not cover only market surveillance-related activities.

Figure 4-29 - Average annual budget available to MSAs in nominal terms vs average number of inspections performed (2010-2013)[230]



Source: Author's elaboration on data from national reports

The different levels of resources, however, have implications on the way MSAs perform their tasks and therefore deserve consideration.[231] For instance, MSAs' **market knowledge in order to target checks is perceived as sufficient only in certain cases,**[232] as some sectors (e.g. chemicals, construction) require specific skills.[233] As discussed in the previous section, **this could result in a higher level of non-compliance**. For instance, chemicals and construction are among the sectors with the highest number of RAPEX notifications (see Table 4-24) and of restrictive measures imposed by MSAs (see Table 4-20), despite a reduction in their traded values (for construction, see Table 4-29). As confirmed by an MSA from Sweden, some Member States cannot afford chemical analyses and therefore they just perform formal checks on chemicals. Moreover, based on the available information, the only MSAs with their own in-house laboratories for product testing are in the construction (3 MSAs) and in the chemical (6 MSAs) sector respectively (see Table 4-10). Testing products is more costly and time consuming than simple documentary checks, since it often involves test laboratories and an officer who is usually able to check only a few products per week (excluding the follow-up activities).[234] **The excessive costs of testing have been reported as the most likely explanation for the low level of surveillance in some sectors** and they are, therefore, another possible explanation for the data gaps in the national reports. As mentioned, national reports do not always include data on market surveillance activities for all sectors. The reasons for these gaps are many, as discussed: some sectors are not relevant for the concerned Member State (e.g. marine equipment in Austria) or in some cases it was impossible to collect data due to the high number of authorities involved. However, the major issue in other sectors excluded from national reports (e.g. lifts, recreational craft and

230 Some MS (i.e. AT, CY, EE, EL, ES, HR, HU, LT, LU, SE, SI, UK) have been excluded from the sample due to lack/unreliability of data from the national reports.

231 PROSAFE (2013). Best Practices Techniques in Market Surveillance. p.19.

232 Data from national reports of BG, CY, DK, HR, EE, IT, LT, PL, SK, and UK. 92% of respondents to the public consultation either agree or strongly agree (55% and 37% respectively) with the following statement: *'MSAs should have more knowledge about the relevant sector'* (total number of respondents: 218, of which 51 MSAs, 10 coordinating authorities, 62 economic operators, 47 industry associations, 4 international organisations, 6 consumer organisations, 3 academic/law firms, 1 trade union, 4 consumers/citizens, 13 others). Data from the targeted surveys do not fully confirm this point, although they might be biased by respondents' identity. The question '*Do you usually perceive to have sufficient market knowledge to target checks to be carried out?*' was only asked to MSAs and Customs, which answered 'yes' in 71% of cases (n=51, 39 MSAs and 12 Customs).

233 Data from targeted surveys, seven MSAs.

234 PROSAFE (2013). Best Practices Techniques in Market Surveillance. p.19.

pressure equipment) is that **inspections and testing of the related products are so costly that MSAs usually perform or consider to perform only documentary checks**, thus further confirming an unequal enforcement of market surveillance across sectors and across Member States.[235] Figure 4-22 and Figure 4-23 presented above support this evidence, showing how **the higher or lower availabilities of laboratories for product testing seems to confirm a tendency to perform more or less laboratory tests at the national level**.

The availability of resources also influences MSAs' criteria for prioritisation of monitoring and enforcement activities.[236] For instance, **MSAs and Customs determine the 'adequate scale'**[237] of controls first on the basis of financial and human resources rationalisation,[238] and then of product risk level.[239] However, the Regulation requires Member States to give MSAs all the resources they need 'for the proper performance of their tasks'.[240] This would imply that first MSAs determine their targets in terms of controls, and sufficient resources would be given as a consequence. This may actually explain the low number of controls. Interestingly, the German Product Safety Act defines the adequate number of products to be tested by means of a 'sample rate' (i.e. 0.5 products per thousand inhabitants per year, as an indicative target for each Federal State).[241] The establishment of a clear benchmark makes it easier to calculate the number of MSA working hours and staff needed to perform such tests. However, the measure of adequate scale also depends on product features (i.e. whether it is a serial or single product). Moreover, in some Member States such as Italy, MSAs' resources are not linked to specific objectives or targets, except for special financial allocations assigned by the MISE (the coordinating authority) to specific projects – as discussed in case study 1. In general, however, each Italian MSA can set its own priorities and is free to allocate resources and to focus on self-established issues, although the MISE organises meetings to provide strategic orientations, European guidelines and general updates every 6 months.

As shown in Figure 4-29 above, differences are traced also in MSAs' **strategies for market surveillance.** In general, proactive market surveillance is more cost-efficient than reactive market surveillance, because the required resources can be defined in advance.[242] However, not all market surveillance activities can be planned ahead. In order to avoid duplication, a MSA should check ICSMS and any other appropriate platforms (e.g. national database) to see if the same product has already been assessed. Once again it can be concluded that **market surveillance is not uniform across the EU,** being also strategically influenced by the level of resources, which is different from one Member State to another.

In addition, **the relationship between the number of inspections and the number of RAPEX notifications** has been considered (see Figure 4-30 below). Interestingly, the correlation between the two is positive and quite significant (i.e. 0.61). These data confirm that the number of inspections performed at the national level is an enabling factor to detect non-compliance, and that human and technical resources available at the national level might play a relevant role in the effective enforcement of market surveillance.

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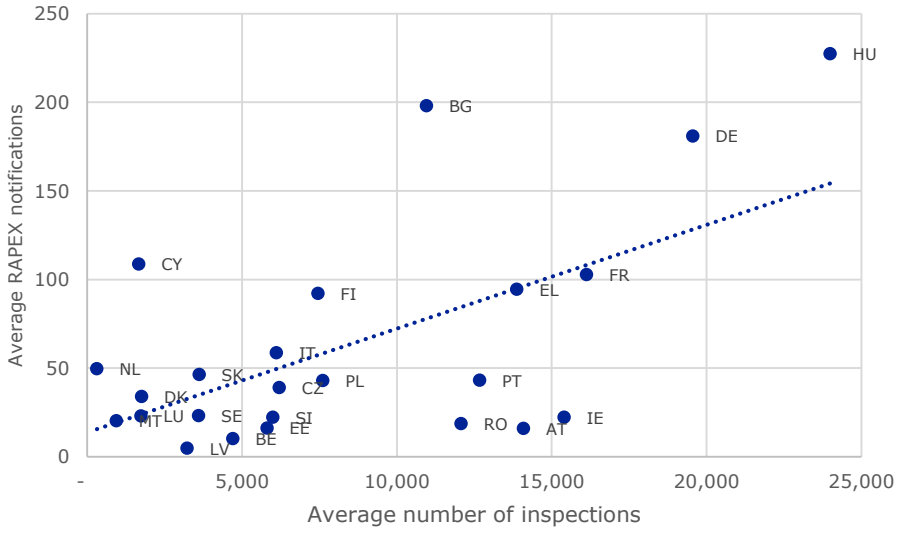
235 Confirmed by the coordinating authorities of EL, FI, IT, NL and a Swedish MSA.
236 Data from national programmes: MT, PL.
237 Based on Article 19 of the Regulation, *'Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples.*'
238 Ten MSAs (AT, CY, DK, 3 FI, LV, 2 SE, UK) and one AdCO member (pyrotechnic articles).
239 Eight MSAs (CY, EE, 4 FI, LT, NL) and three AdCO members (construction products, explosives for civil use and recreational craft).
240 Regulation (EC) No 765/2008, Article 18(3).
241 Article 26 of the Product Safety Act, available at: https://www.gesetze-im-internet.de/englisch_prodsg/englisch_prodsg.html#p0023.
242 European Commission (2017), *Good Practice for Market Surveillance*. p.8. http://ec.europa.eu/DocsRoom/documents/21081

Figure 4-30 – Average number of inspections and average number of RAPEX notifications (2010-2013)[243]



Source: Author's elaboration of data from national reports and RAPEX database

Powers attributed at the national level and the **role of Customs** in enforcing the Regulation influence the effectiveness of border control. For instance, based on the available data, 16 Member States do not have in-house testing laboratories for any (or almost any) sectors.[244] The lack of laboratories, resulting in the impossibility for Customs to perform more in-depth and time-efficient controls, hinders potential improvement in border controls. However, in some Member States where Customs do not have laboratories, this shortcoming is compensated by MSAs having their own laboratories in some sectors.[245] On the one hand, this assures that testing is performed. On the other hand, the intervention of two different authorities (i.e. MSAs and Customs) could make procedures slower. According to data provided in the national reports, over the period 2010-2013, **Customs were particularly proactive** in Luxembourg and Croatia as they prompted on average, respectively, 45% and 37% of the total inspections performed. Similarly, they had a considerable role in triggering controls in Belgium, Poland and Bulgaria (they induced 22%, 17% and 15% of total inspections, respectively).

Furthermore, **controls are expected to be tougher in Member States where Customs act as MSAs**, such as in Finland, France, Latvia and Malta.[246] If Customs have MSA powers, there is a substantial extension of their area of competence and a significant need for in depth expertise.[247] While Customs powers are essential for the control of traded products, the introduction of Regulation 765/2008 highlights the need for cooperation between Customs and MSAs and with other EU Customs[248] as a crucial element for enhancing market

243 ES, HR, LT and UK have been excluded due to lack of data.
244 AT, BE, BG, CY, CZ, DE, DK, ES, FI, LT, LU, LV, MT, NL, PL, SE.
245 Based on the available information, in BG, CZ, DE, LT, NL, PL and SE. For more detailed information, please refer to Annex.
246 This being confirmed by two German and one Swedish MSAs and two Dutch Customs authorities responding to the targeted surveys.
247 Swedish Board for Accreditation and Conformity Assessment.
248 Dutch Customs and Swedish Board for Accreditation and Conformity Assessment.

surveillance on imported products.[249] In this respect, there are notable **differences across Member States**.

Overall, it seems these discrepancies are being allowed by **the general requirements set in the Regulation**,[250] as further discussed below.

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

Article 18(5) and Article (6) require a **periodical update of national programmes and a review of the functionality** of market surveillance activities every four years, but it does not mention any timing for update, neither does it provide any specific methodologies for the review. Article 18(5) therefore does not foresee the provision of **structured information** from Member States to the EC relating to market surveillance activities, which is particularly evident in light of all the data limitations of national programmes and reports described in section 4.3.1. This lack of harmonisation makes the national programmes and reports **not immediately comparable across countries**, which is a missed opportunity for Member States to benchmark and learn from each other's experiences. In practice, as further discussed below in section 6.3, it is a missed opportunity for market surveillance harmonisation.

As discussed below, the Regulation **does not include specific provisions related to the principles of cooperation between Member States**. This clearly impacts on the existing cooperation mechanisms and tools, which, as described in the previous sections, are many and different, but could be improved. Finally, the Regulation is **not specific enough to set a minimum and/or a maximum level of penalties**, or any principles to define them. As discussed, this results in wide differences in the minimum/ maximum amounts within and across Member States, which lower the enforcement deterrence power.

An additional enabling factor has been identified in the (lack of) cooperation with between enforcement authorities and businesses. Among the main reasons for product non-compliance in the internal market, there seems to be **a lack of economic operators' knowledge**[251] on the relevant legislative requirements to be complied with, as well as a **deliberate choice to exploit market opportunities at the lowest cost**,[252] possibly due to low incentives to comply with the existing rules. This issue was particularly emphasised by some stakeholders participating to the public consultation, highlighting how violations are often due to

249 PROSAFE (2013). Best Practices Techniques in Market Surveillance. p.90.

250 44% of respondents to the targeted surveys state there is a need for additional guidance on the Regulation. Total number of respondents to the question *'Is there a need for any additional guidance on any areas of the Regulation?'* = 118. Yes = 52 (35 MSAs, 6 coordinating authorities, 5 Customs, 2 economic operators, 4 industry associations). No = 66 (33 MSAs, 7 coordinating authorities, 14 Customs Authorities, 2 civil society associations, 2 economic operators, 8 industry associations).

251 According to 57% of respondents to the public consultation (n=136). Confirmed by OECD (2000*). Reducing the risk of policy failure: challenges for regulatory compliance.* Also confirmed by an EU industry association.

252 According to 49% of respondents to the public consultation (n=117). Confirmed by OECD (2000*). Reducing the risk of policy failure: challenges for regulatory compliance.* Also confirmed by two EU industry associations.

complexity or complicated interplay among rules,[253] especially for SMEs, which are hardly able to understand bureaucratic requirements.[254] As mentioned in section 6.4.2, an EU industry association claims that the interplay between the GPSD and the Regulation leads to extreme legal uncertainty 'which economic operators and enforcement authorities are increasingly unable to understand and to apply properly in the remit of their respective obligations'. As a further proof, the UK adopts an approach to sanctions that sees prosecution as a 'failure of the enforcement' and that is therefore based on the collaboration between economic operators and MSAs, setting compliance as a common goal and helping economic operators in understanding and correcting non-compliance. Several stakeholders[255] expressed a need for a **higher level of information flow from MSAs to businesses** and more practical guidance for economic operators. In the context of the interviews, an EU industry association suggested giving economic operators that are willing to comply the opportunity to do so before imposing sanctions, while another EU industry association suggested organising educational campaigns targeting economic operators.

6.2 Efficiency

EQ of reference

EQ 6. *What are the regulatory (including administrative) costs for the different stakeholders (businesses, consumers/users, national authorities, European Commission)?*

EQ 7. *What are the main benefits for stakeholders and civil society that derive from the Regulation?*

EQ 8. *To what extent have the market surveillance provisions been cost effective?*

EQ 9. *Are there any significant differences in costs (or benefits) between Member States? If so, what is causing them?*

This section first describes how different stakeholders are directly or indirectly impacted by the Regulation, secondly it provides an overview of the costs for the different stakeholders, and finally it presents a qualitative analysis of the cost-effectiveness of the Regulation, as well as differences across Member States.

6.2.1 Costs of the Regulation

6.2.1.1 Costs for Member States

The EU harmonisation legislation is mainly based on standards adopted by a recognised Standardisation Body in accordance with a request made by the European Commission and cited in the OJEU. Within this framework and in line with Regulation (EC) No 765/2008 Member States have the following obligations:

253 Also stated by the Swedish Board for Accreditation and Conformity Assessment and by an EU industry association.
254 Also confirmed by an interviewee from an EU industry association.
255 An MSA from Norway, seven industry associations (2 BE, ES, DK, FI, NL, UK), two economic operators (IT, SE), a Belgian consumer organisation, one academic/law firm from the UK. Also confirmed by an EU industry association.

- Organisational obligations:
    - Provide the necessary infrastructures, resources and powers to perform market surveillance;
    - Establish market surveillance programmes and communicate them to the European Commission;
    - Establish complaint procedures and monitoring of accidents;
- Information obligations:
    - Inform the European Commission on responsible authorities and their specific areas of competence;
    - Inform the public on responsible authorities and contact possibilities;
- Surveillance obligation:
    - Perform appropriate checks: documentary/physical, and laboratory checks;
    - Request documentation and enter premises;
    - Cooperate with economic operators to eliminate risks;
    - If necessary, destroy/render products inoperable when they pose a serious risk;
- Cooperation obligations:
    - Exchange of information;
    - Mutual assistance;
    - Participation in administrative cooperation;
    - Possibility to develop cooperation with third countries.

However, **unavailability of data about costs incurred by Member State Authorities** for surveillance activities before 2008 did not allow for the assessment of the additional costs deriving from the new obligations introduced by the Regulation.

With respect to organisational, information and cooperation obligations a qualitative analysis can be found in Sections 0 and in the first two case studies presented in the annexes.

To answer to the evaluation questions related to the efficiency, this section focuses on the costs related to surveillance obligations for which data included in the national reports might be considered as the best source of information.

To estimate the regulatory costs for national authorities related to surveillance obligations the following four indicators have been selected:

- Budget available to MSAs in nominal terms;
- Budget available to MSAs in relative terms (% of the total national budget);
- Staff available to MSAs (FTE units);
- Number of inspectors available to MSAs (FTE units).

The main highlights of the analysis show the **costs at Member State level**:

- The budget allocated to Market Surveillance Activities:
  - On average, is €7.5 m per each Member State in nominal terms,[256] representing around 0.1-1.33%[257] of total national budget;
  - Decreased by 7% over the period 2010-2013 (from €7.8 m to €7.5 m);
- Human resources allocated to MSAs
  - More than 280 FTEs[258] were involved on average at Member State level over the period 2010-2013 in inspection activities. The number of inspectors decreased by 4.4% (i.e. reduced from 288 to 275) over the period considered;
  - MAs can count on average on more than 415[259] FTEs in order to perform market surveillance activities each year; however, the number of FTEs available decreased by 2.6% over the period 2010-2013.

However, from the data presented in the national reports a lack of a structured approach clearly emerged:

- Some countries, such as France, **declared in the report only financial resources concerning a specific activity** (i.e. testing capacity on state-owned laboratory);
- Other countries, such as Ireland and Italy, **provided information only related to specific sectors;**
- Some others, such as Estonia, could not indicate separately the financial resources allocated to market surveillance, since market surveillance is only a part of their MSA activities.

Therefore, the figures presented so far, extracted from the national reports, probably represent a lower estimate of costs at national level for market surveillance.

256 Not all EU-28 Member States provided reliable data for this indicator. Therefore, figures do not include AT, CY, EE, EL, HR, HU, LU, SI, UK. The average for Sweden is computed considering only data for 2012 and 2013 because some authorities did not provide any figures for some sectors for 2010 and 2011.
257 The figures refer to 10 MS that provided reliable data, precisely: DK, EE, ES, FI, IT, LV, MT, PL, SE, SK.
258 The figures refer to 16 MS that provided data, precisely: BE, BG, CZ, DK, EE, ES, FI, IE, IT, LT, LU, LV, PL, PT, RO, SK.
259 The figures refer to 18 MS that provided data: BG, CZ, DK, EE, DE, ES, FI, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SK. For Sweden, the average is computed considering only data for 2012 and 2013 because some authorities did not provide any figures for some sectors for 2010 and 2011.

Within this framework, an estimation of the costs related to surveillance obligations is only possible for a limited number of countries (15) that provided completed and reliable data regarding the above mentioned indicators (Table 4-30).

Specifically, the analysis compared the average nominal budget to the number of inspections and the number of tests performed. It emerged that:

- Member States follow different approaches in:
  - Performing market surveillance activities;
  - Reporting data to the EC;
- Each Member State performed each year around 7,500 inspections and 770 tests in laboratories on average over the period 2010-2013;
- Even if the nominal budget for the countries considered remained virtually constant, the yearly number of inspections increased by 21% while the yearly average number of tests in laboratories decreased by 7%.

Table 4-30 – MSAs' average number of inspections per average number

MS	Nominal budget (Av. '10-'13) €	Δ% 2010 - 2013	Number of inspections (Av. '10-'13)	Δ% '10-'13	Average cost of inspections €	Num. of tests performed in laboratories (Av. '10-'13)	Δ% '10-'13	Average cost of tests €
	(a)		(b)		(a)/(b)	(d)		(a)/(d)
BE	946,903	-32%	4,701	94%	201	386	-45%	2,452
BG	2,114,559	-16%	10,953	58%	193	466	21%	4,535
CZ	384,594	-5%	6,200	-4%	62	166	-55%	2,313
DK	8,386,750	0%	1,754	14%	4,782	561	0%	14,950
FI	1,417,861	0%	7,448	0%	996	2924	6%	2,537
FR	1,680,000	1%	16,119	-1%	104	1147	-1%	1,465
IE	4,825,000	0%	15,401	32%	313	193	-58%	25,000
IT	1,561,372	6%	6,110	11%	256	581	153 %	2,690
LV	1,818,645	40%	3,221	-1%	565	361	63%	5,038
MT	163,592	7%	939	-7%	174	:	:	:
PL	10,229,088	16%	7,605	5%	1,345	926	44%	11,047
PT	25,229,517	-16%	12,670	174%	1,991	411	-9%	61,348
RO	320,108	25%	12,071	-14%	27	2716	-35%	118

SE	14,258,602	n/a	3,593	-3%	3,968	367	-14%	38,852
SK	5,634,232	-1%	3,610	-31%	1,561	352	-30%	15,995
Aver.	**5,264,722**	**0.92%**	**7,493**	**21%**	**703**	**770**	**-7%**	**6,837**

Source: Author's elaboration of data from national reports

As shown for inspections and tests, the fact that every Member State defines its own market surveillance approach creates a high variation in the ways the different sectors are controlled and managed. Moreover, fragmentation throughout the Internal Market may interfere with Authorities' early action and produce additional costs for businesses.

Different approaches may also reduce the efficiency of the market surveillance when responsibilities of national authorities are not primarily related to market surveillance of non-food products within the meaning of the Regulation, creating overlapping and duplication of activities. To give an example, the toy sector in Italy is indicated as controlled by the Guardia di Finanza, by Chambers of Commerce, by Customs, and by the Carabinieri NAS. The Ministry of Economic Development (MISE) acts as a 'filter' redirecting – for instance – Customs' requests regarding specific product issues to the relevant Ministry, since the system as it is designed does not grant an immediate contact between the different actors involved, nor does it create synergies across them for overlapping sectors.

6.2.1.2 Costs for economic operators

As stated previously, the Regulation under the scope of the study provides a framework for the market surveillance of products and controls on products from third countries.

Therefore, the only **direct costs** for economic operators **deriving** from the Regulation are related to **information obligations** pursuant Article 19. Specifically, "*Market surveillance authorities may require economic operators to make such documentation and information available as appear to them to be necessary for the purpose of carrying out their activities, and, where it is necessary and justified, enter the premises of economic operators and take the necessary samples of products. They may destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary. Where economic operators present test reports or certificates attesting conformity issued by an accredited conformity assessment body, market surveillance authorities shall take due account of such reports or certificates*."

Concerning the costs incurred by businesses, only two industry associations and one company replied to the targeted survey question on costs for economic operators related to the application of the Regulation. As for public authorities, even if the number of responses is sufficient (around 25 authorities answered the question related to costs for economic operators), their informative power is low: the answers do not appear to be robust since they have a very high variance.

In this context, we integrated results from the survey with **10 targeted interviews** with businesses and business associations in order to understand the nature and magnitude of the costs for businesses deriving from the Regulation.

During the interviews it emerged that costs related to information as established in Article 19 of the Regulation are perceived as not significant.

However, a potential ineffective **market surveillance might lead to additional and more significant costs for economic operators, related to** a lower product compliance, including for those from outside Europe, **to unfair competition**, and to a reduced safety and user trust.

For business associations involved in the study, the internal market constitutes an indispensable, stable and important economic area where companies are asked to comply with health and safety conformity requirements offering a high level of protection.

From stakeholders' perspective, the implementation of the approach introduced with the NLF is a 'learning by doing' process where some **across-the-board inconsistencies** still remain and the current enforcement mechanism is not able to create a level playing field for business that are selling products in the Internal Market. This **is creating additional costs for economic operators**, especially SMEs.

From the discussion with some business associations, it emerged that additional costs are generated by:

- The concept of 'appropriate' applied to checks foreseen by the Regulation (cf. Article 19(1)) leads – in some cases – to discrepancies in market surveillance practices within the EU due to the concomitant-wide leeway for interpretation and transposition; this creates unbalances in costs, especially for SMEs;

- MSAs have limited financial, human and technical resources that limit their capacity to control the entire market and reduce thoroughness of the performed controls; a low enforcement programme and a low risk of detection of infringements can discourage compliant behaviour and increase unfair competition;

- Member States give greater importance to administrative aspects than to technical aspects – in some cases, manufacturers are requested to translate the product-specific documentation in different languages, English not always being accepted as 'lingua franca' and generating additional information obligation and administrative burden;

- Economic operators give greater importance to user safety regulation than other technical aspects (e.g. standard level on noise for machineries). This creates potential opportunities for free riding and increases costs for businesses that are willing to comply with all rules

- Communication among MSAs and manufacturers of the products is not effective when they are not both based in the MSA's country; hence the risk is that MSAs prefer to contact the local distributors that do not always have the right information. Thus, communication between businesses supplying products in the Internal Market and MSAs might be laborious and beset with delays. As product cycles are becoming shorter and shorter, the delay in these procedures for demonstrating and controlling product compliance is reflected in additional burdens (costs) for businesses (especially SMEs). However the use of an IT database collecting all technical product specifications raises issues related to intellectual property protection. Instead, there is a need for more cooperation between industry and authorities. In this way, MSAs can take advantage of manufacturers' technical knowledge and may be in a better position to identify non-compliant products on the market and set appropriate priorities for market surveillance activities.

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

- In some cases product non-compliance is related to a lack of awareness about product legislation based on EU harmonised rules. Knowledge among SMEs and especially micro businesses about harmonised rules applicable to industrial products is not always high;

- As online trade is becoming increasingly relevant, the absence of a specific regulation poses serious compliance challenges for suppliers and manufacturers.

All issues contribute to the framework in which **the level playing field is not completely ensured** and in which ineffective controls and checks lower businesses' willingness to comply with the rules, and discriminate businesses that abide by the rules against those who do not.

6.2.2 Benefits of the Regulation

In terms of **benefits** the following have been considered:

- Direct benefits:
  - Cost savings for business;
  - Improved safety and trust for end-users;
- Indirect benefits:
  - New market opportunities for businesses.

Cost savings result from the simplification of pre-existing regulatory provisions. They relate to lower administrative, operational and external costs in comparison to the situation before 2008.

Benefits for businesses have been investigated through the online survey with individual companies as well as through 10 interviews with businesses associations.

During interviews, business' associations were asked whether their industry had benefited from cost savings since the entry into force of the Regulation. **The majority of the associations did not report cost savings** as a result of the implementation of the Regulation in terms of administrative and operational tasks if compared to the situation prior to 2008.

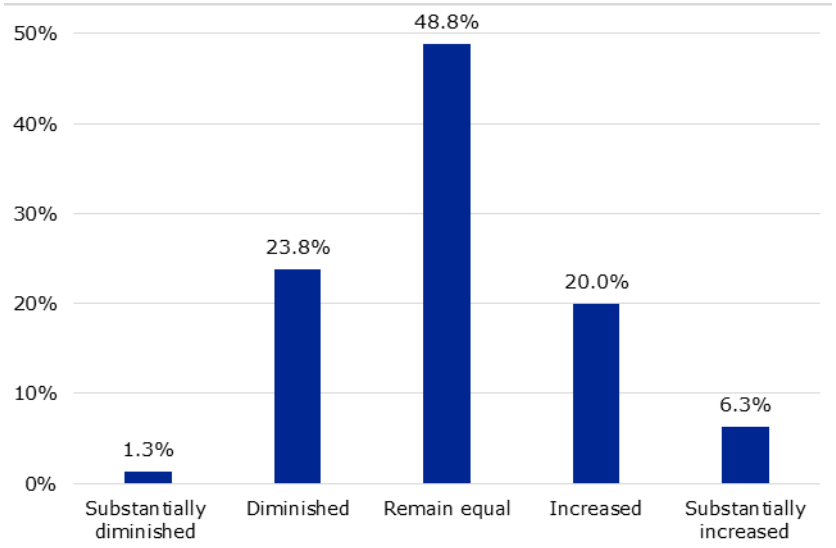
The Regulation is expected to induce benefits also in terms of **improved safety** and provision of information along the value chain. This relates to the obligation of making the information available to public authorities and third parties and to the incentive of complying with the EU's standard product rules. In this case, benefits would translate into improved safety due to better communication on the technical performance of the products and into increased users' trust.

Businesses' association were asked:

- Whether in their opinion the level of product compliance had diminished in the last 5 years;
- Which are the sectors more affected by non-compliance;
- Whether market surveillance activities are sufficient to deter rogue traders in their sector in their Member State.

Most **stakeholders involved did not perceive a substantial variation in product non-compliance** considering the period from 2010 to 2015 (Figure 32); however the number of stakeholders that perceived an increase in product non-compliance is higher than the numbers of the stakeholders that perceived that product non-compliance had reduced. This seems to be also confirmed by the increased number of notifications and corrective measures taken by the MSAs in the last few years.

Figure 4-31 - Perceived level of product non-compliance in the last five years (80 responses)

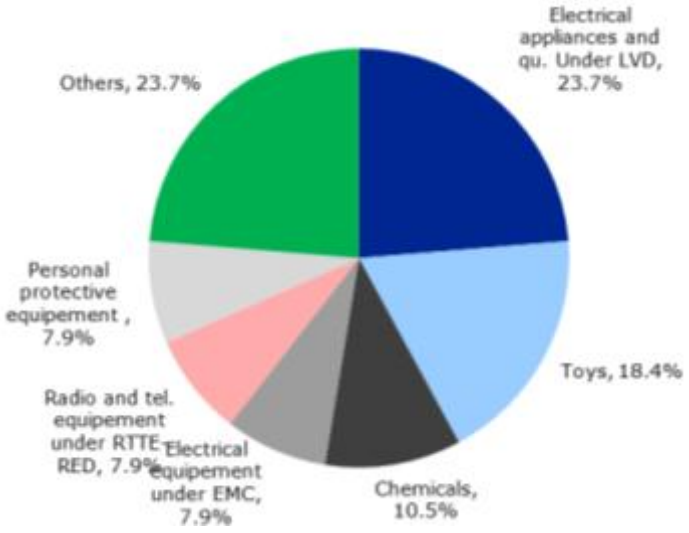


Source: Author's elaboration of data from online targeted survey

The analysis of responses to the survey highlights also that 'Toys', 'Chemicals' and 'Electrical appliances under the Low Voltage Directive' seem to be the sectors were the product non-compliance is more problematic (Figure 4-33).

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

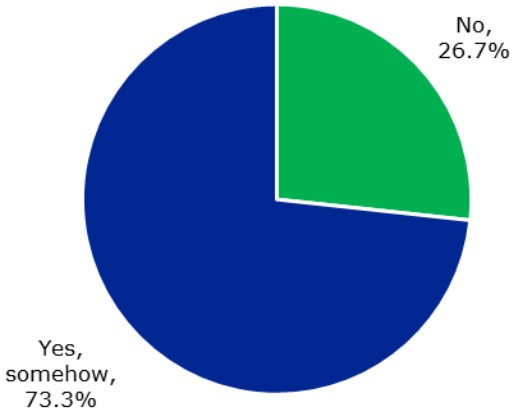
Figure 4-32 - Sectors heavily affected by product non-compliance (34 responses)



Source: Author's elaboration of data from online targeted survey

Market surveillance activities are perceived as not sufficient to deter rogue traders. However these findings are related to a low number of total received answers (Figure 4-33).

Figure 4-33 - Do you think that market surveillance activities are sufficient to deter rogue traders in your sector in your Member State? (15 responses)



Judging from the figures presented above, it might appear that **the Regulation is not producing the envisaged benefits and that the problem related to product non-compliance still remains**. However, it is not possible to measure how this has impacted safety and uniform protection of consumers across the EU. No data are available about injuries caused by product non-compliance. An exception is represented by the IDB but the currently available IDB data are produced voluntarily by Member States and do not clearly mention if notified injuries are caused by product non-compliance or improper use by consumers.

The Regulation aimed at ensuring a level playing field for businesses. This can create benefits in terms of increased turnover, reduced barriers to trade and increased competition for economic operators in the home and EU markets, thus also benefitting end-users.

However, as shown so far, the Regulation demonstrated a reduced capacity to achieve its strategic objectives. Interviewed stakeholders had mixed views with regard to the ability of the Regulation to ensure a level playing field for business. Therefore, the Regulation is perceived to have introduced more costs for manufacturers than benefits.

6.2.3 Cost-effectiveness of the Regulation

The cost- effectiveness of the Regulation is related to the extent to which the **desired results** (i.e. increased product compliance and increased cooperation and exchange of information among the EC, the Member States, the MSAs and Custom authorities) and **impacts** (i.e. increased protection of consumers across the EU and contribution to ensuring a level playing field for businesses) **have been achieved at a reasonable cost** (i.e. resources allocated to market surveillance activities).

Within this framework, it emerged that the Regulation has a limited cost effectiveness due to:

- A partial achievement of both expected results and impacts;
- Resources allocated seems not correlated to the size of surveyed markets.

6.2.3.1 Results and impacts of the Regulation

It has been showed that, after the entry into force of the Regulation, **product non-compliance increased consistently from 2006-2009 to 2010-2015**:

- The use of **restrictive measures** has grown by an impressive 52% (Table 4-16). In addition, the most significant increases have been registered in the most 'coercive' measures (i.e. seizure, withdrawal, destruction);
- **MSAs' restrictive measures** remained broadly unchanged (i.e. -0.33%);
- **Measures and corrective actions undertaken by economic operators** on average have increased. From 2005-2009 to 2010-2015, the most significant increase (by nearly 124%) has been registered in the average number of notifications relating to product destructions (Table 4-18).

In terms of cooperation and exchange of information, there are no uniform working practices across Member States and, as emerged from interviews with business representatives, the cooperation mechanisms in place are not effective in identifying non-compliant products on the market and in ensuring a level playing field for businesses.

Furthermore, section 6.1.1 analysed in detail to which extent the Regulation achieved both its specific and strategic objective that clearly reflect a reduced cost-effectiveness.

6.2.3.2 Cost of market surveillance activities and size of surveyed markets

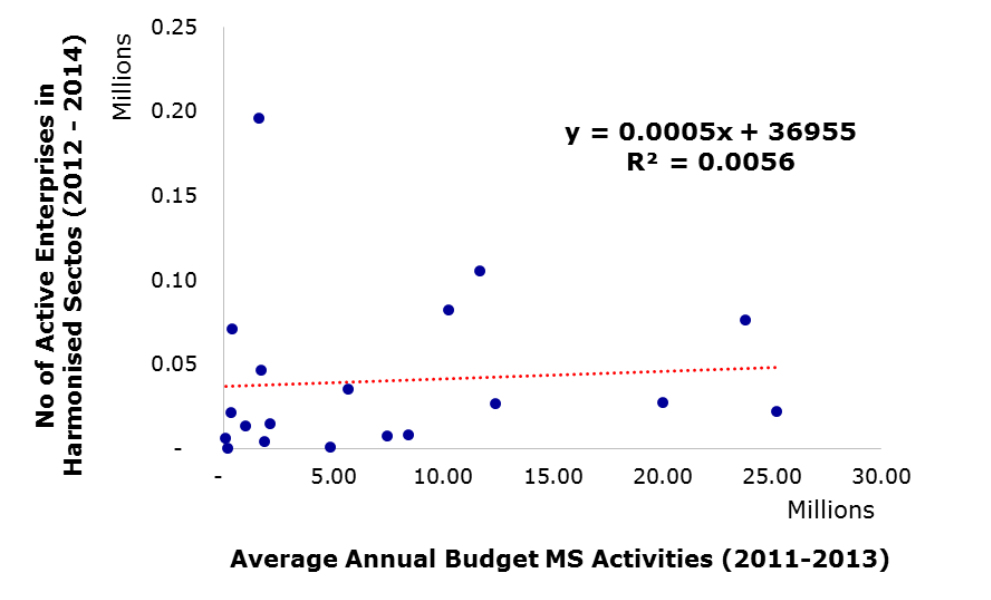
The limited cost-effectiveness of the market surveillance provisions also emerged from the comparison between the **financial resources allocated to surveillance activities at national level and the size of the local market for harmonised products**.

Specifically, the following dimensions have been compared:

- The average annual budget available to MSAs in nominal terms to the average number of enterprises active in the national market;
- The variation of the nominal budget available to MSAs to the variation of the number of enterprises active in the national market.

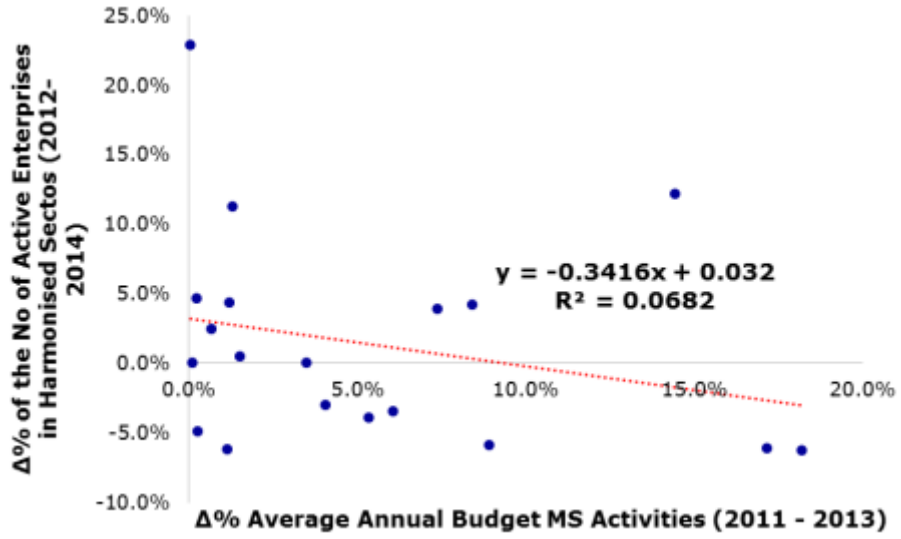
The results of these comparisons show that neither the average annual budgets allocated to MSA activities (Figure 4-34) or their variation over the period 2011-2013 (Figure 4-35) are correlated with the number of enterprises active in the harmonised sectors.

Figure 4-34 - Average annual budget available to MSAs in nominal terms vs average number of enterprises active in harmonised sectors



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

Figure 4-35 - Average annual budget available to MSAs in nominal terms vs average number of enterprises active in harmonised sectors (percentage variation)



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

The **differences** in the budgets allocated to MSA activities might be related to the fact that Member States have different organisational models requiring different levels of financial resources. However, another possible explanation might be sought in the different approaches followed by MSAs in reporting data concerning the used financial resources as well as the performed activities.

6.3 Relevance

EQ of reference

EQ 10. *To what extent are market surveillance provisions of the Regulation still relevant in the light of, for instance, increasing online trade, the increase in imports from third countries, shortening product life, increasing budgetary constraints at national level, etc.?*

EQ 11. *To what extent do the effects of the market surveillance provisions satisfy (or not) stakeholders' needs? How much does the degree of satisfaction differ according to the different stakeholder groups?*

EQ 12. *Is there an issue on the scope (i.e. all EU product harmonisation legislation) of the measure or some of its provisions?*

EQ 13. *Is the concept of lex specialis still a suitable interface between the market surveillance provisions in the Regulation and those in other (notably sector) legislations?*

This section presents the answer to the evaluation questions in two main blocks. First, it looks at the relevance of the Regulation in terms of its general scope and nature; second, it looks at whether the Regulation meets stakeholders' needs, with a focus on needs related to new/emerging issues.

6.3.1 Relevance of the scope of the Regulation

The **scope** of the Regulation is considered clear and adequate by 71% of stakeholders,[260] but **not clear and adequate by 29%**[261] of them. Considering that MSAs are those implementing the Regulation and economic operators are those subject to market surveillance, the latter percentage is to be considered quite relevant and an **indication of a problem in the scope** that should be taken into consideration.

The same fact that some Member States included additional sectors within their national reports, as mentioned,[262] is an indication of some confusion on the scope of application of the Regulation (so that an MSA suggested that the Regulation should mention more clearly the sectors it applies to). Moreover, input gathered from stakeholders confirms that it is not always straightforward for economic operators to understand whether a product is subject to market surveillance and specific requirements or not, thus resulting in a 'good faith' non-compliance. The request from the majority of stakeholders (78%) for MSAs to provide information on product requirements in addition to enforcement, or support to companies through guidance on how to interpret product requirements, and in general terms to increase cooperation with the private sector,[263] has to be interpreted in the light of this picture. In perspective, difficulties in understanding the Regulation's scope might be exacerbated by technological developments, including 3D printing, and new kinds of products, such as apps and intangible products.

Next to this, some stakeholders, while considering the current scope clear, suggest to enlarge it to additional sectors.[264]

Also when looking at the specific items covered by the Regulation through its **definitions**, some points have to be underlined. Even though definitions are considered clear and appropriate,[265] a few stakeholders suggest they are **not complete and up to date**,[266] and might need some **adjustments** to further improve clarity and enhance implementation and enforcement capacity for all stakeholder categories. For instance, the current definitions do not consider the specific needs related to online sales, so that some stakeholders suggest to include specific definitions,[267] such as that of 'fulfilment house',[268] and to revise the definition

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260 Nine coordinating authorities, 37 MSAs, 13 Custom authorities, 3 economic operators (ES, IT, SE), 12 industry associations (AT, 8 BE, DK, EL, ES).

261 Three coordinating authorities (DE, DK, FI), 22 MSAs (BE, CH, 6 DE, DK, ES, 4 FI, IS, LT, 3 LV, NO, PL, SE), 3 Custom authorities (DE, FI, RO), one civil society association and one economic operator from Belgium.

262 Belgium also includes cigarette lighters, leather, products imitating foodstuffs, packaging, electrical equipment, liquid fuels and wheeled tractors. Denmark includes off-shore and food contact materials. Greece includes steel for the reinforcement of concrete and metal scaffolding. Portugal includes plant protection products, packaging waste management and information on the misuse of the CE marking. Sweden includes equipment for TV sets and precious metals. The UK includes end-of-life vehicles, passenger cars and products under the EU Timber Regulation.

263 For instance, 87% of respondents to the public consultation agree that MSAs should provide information on product requirements in addition to enforcement or support to companies through guidance on how to interpret them (78%). Finally, agreements between businesses and authorities are considered effective by 54% of respondents.

264 A Finnish authority suggested end-of-life vehicles; an Austrian MSA, software; a Polish MSA, civil aviation products for recreational use; a Finnish MSA, drones; a German MSA ring transformers and smart meters.

265 Source: targeted surveys. On average, 93% of respondents (51 out of 55) state definitions are appropriate and 93% that definitions are clear (100 out of 107).

266 Source: targeted surveys. On average 82% of respondents (34 out of 41) evaluate definitions as complete and up to date, while 18% of them (7 out of 41) state they are incomplete and outdated.

267 Nine MSAs (DE, DK, 3FI, LT, NL, PL SE), one AdCO member (electromagnetic compatibility), three Member State coordinating authorities (DE, DK, LT) and a Belgian industry association.

268 It is not always clear when fulfilment houses have to be considered as hosts and are thus not liable for product non-compliance - or when they act as proper distributors. According to Article 14 of Directive 2000/31/EC on hosting, *'Where an information society service is provided that consists of the storage of information provided by a recipient of the service, Member States shall ensure that the service provider is not liable for the information stored at the request of a recipient of the service, on condition that: (a) the provider does not have actual knowledge of illegal activity or information and, as regards claims for damages, is not aware of facts*

of 'EU importer'.[269] Similarly, the distinction between the definitions of 'making available on the market' and 'placing on the market' is not completely clear in the context of imported goods and online sales.[270] The interpretation of 'placing on the market' provided in the Guide in this regard is reported by some stakeholders to be unsatisfactory.[271] On the same lines, the Regulation is not completely clear in the definition of 'product' – currently not listed under Article 2 – and does not include the concepts of 'second-hand good', 're-used good' and 'by-products'.[272] As regards 'recall', a Swedish MSA states that the definition should be extended in order to refer also to situations where the manufacturer offers to remedy the fault (rectification), accept return and supply of another product (exchange) or accept return of the product and pay compensation (return). There is also the need to better define the concept of 'risk'.[273]

The concept of *lex specialis* is deemed to be a suitable interface to address sector specificities of market surveillance and it causes no difficulties in implementation according to the vast majority of stakeholders consulted.[274] Despite the generally positive views about the concept of *lex specialis*, some issues have been raised. In more detail, some stakeholders[275] underline that the scope of market surveillance rules in sector-specific legislation is not always clear, as it is not straightforward to assess which provisions of the Regulation apply and which articles of the sector-specific legislation are covered by the *lex specialis* principle. These interpretation problems often result in an excessive administrative burden and in legal uncertainty,[276] so that some MSAs suggest having a uniform market surveillance regulation for non-food sectors,[277] containing all market surveillance provisions at the EU level for all sectors,[278] or anyhow some adjustments. Yet, the idea of a joint Regulation is not shared by all, and some other stakeholders[279] find such merging for non-food products not appropriate.

6.3.2 Relevance of the Regulation to stakeholders' needs

6.3.2.1 Relevance to strategic objectives

Overall, **the Regulation meets stakeholders' needs.[280]** The framework for market surveillance provided is generally appreciated, being considered as useful in defining national market surveillance programmes and policies for controlling imported products.[281] The Regulation is considered relevant to meet the needs related to the free movement of goods and the protection of consumers, and – to a lower extent compared to the first ones – to a level

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or circumstances from which the illegal activity or information is apparent; or (b) the provider, upon obtaining such knowledge or awareness, acts expeditiously to remove or to disable access to the information'.

269 Eight MSAs (DE, DK, FI, LT, 2 NL, SE, UK), a Lithuanian and a Danish coordinating authority, one AdCO member (electromagnetic compatibility), an industry association from Belgium.

270 Five MSAs (AT, DE, DK, FI SE), a Danish, the Turkish and the Romanian coordinating authorities, four Customs Authorities (BE, BG, EE, FR).

271 Five German MSAs.

272 The Finnish coordinating authority, a Swedish MSA, a Swedish Customs. A by-product is something produced in an industrial or biological process in addition to the principal product.

273 As stated by an interviewee from the Swedish Board for Accreditation and Conformity Assessment (SWEDAC).

274 70% (n=48) of respondents replying to the survey.

275 An AdCO member (pyrotechnic articles), seven MSAs (2 BE, 2 DE, 2 FI, NO).

276 Romanian and Slovenian coordinating authorities.

277 Five MSAs (4 DE, LV).

278 Two Danish coordinating Authorities and one Latvian MSA.

279 Three German MSAs and one German coordinating Authority, one Danish MSA (stating that it is useful to keep the sector-specific regulation for construction products).

280 According to 73% of respondents to the targeted survey.

281 49% of stakeholders (23 MSAs, 7 Customs authorities, 5 coordinating authorities and 3 AdCO members -construction products, measuring instruments, recreational craft) think it is useful in defining their national policies to a large extent, 46% consider it to be useful to a small extent (28 MSAs, 5 Customs authorities and 6 coordinating authorities), and only 5% declare it not to be useful (3 MSAs and one Customs authority).

playing field (see Annex). There is a smaller but still very positive consensus that the framework provided by the Regulation contributes to the protection of the environment.[282]

The relevance of the Regulation is also confirmed by **the dimension of the internal market for non-food products**, as presented in section 5.1.[283] In this context, market surveillance is fundamental both to ensure that users are protected from non-compliant (and potentially) dangerous products and to ensure a level playing field for businesses across the EU. Without a Regulation setting out the minimum requirements for market surveillance, some Member States may apply less stringent provisions, allowing the entrance of non-compliant products into the EU market. Alternatively, different market surveillance practices could result in unbalanced surveillance to the detriment of economic operators and to the level playing field.

6.3.2.2 Relevance to specific objectives

The analysis undertaken on the effectiveness of market surveillance highlighted that the main challenges in enforcing market surveillance refer to cooperation and coordination arrangements and to the uniformity and rigorousness of the system and drive to the conclusion that market surveillance could be enhanced through further exchange of information and cooperation.

In light of this, **provisions related to cooperation** (under Articles 24, 25, and 26) together with provisions requesting the use of tools to exchange information (under Articles 22 and 23, as well as 17), are particularly relevant to enhance market surveillance enforcement, yet encountering some implementation issues that might need to be addressed. As discussed in case study 4, RAPEX and ICSMS are not used at their full potential as there are some cross-border cooperation gaps.

Along the same lines, the **provisions on market surveillance programmes and reports** (as per Article 18(5)) are also useful,[284] and represent a tool for cooperation between MSAs. Nonetheless, limitations to this study and feedback from stakeholders highlight room for improvement. Being the main source of information for monitoring market surveillance, the quality and comparability of the information provided is far from being sufficient, thus limiting any proper assessment of the functioning of market surveillance and making their consultation very burdensome,[285] if not useless, as already remarked. Reasons behind their limited informative power can be related to:

- The administrative burden associated to the drafting on a yearly basis *vis-à-vis* market surveillance activities that do not change every year[286] (making the administrative burden sometimes higher than the benefits);

282 70% of respondents to the targeted survey (54 out of 78) stating that the framework is adequate to the protection of the environment.

283 As discussed in section 5.1, over the period 2008-2014, around 1.2 million enterprises were operating within harmonised sectors, representing more than 65% of the total number of active enterprises in the manufacturing economy. The value added produced therein totalled €1,269 billion in 2014. Moreover, approximately 30% of the value of harmonised products (€678 billion) is related to goods imported from non-EU countries.

284 76% of respondents to the targeted surveys. Various benefits have been highlighted by stakeholders. National programmes are considered to be an opportunity to define market surveillance strategies and to inform consumers; they push MSAs to improving the effectiveness and efficiency of market surveillance activities, since they help in verifying and monitoring implemented activities; they are useful to avoid overlapping of market surveillance actions, working as a tool for cooperation between MSAs; they even contribute to ensuring a level playing field in Europe, since they allow Member States to acknowledge the differences in the enforcement actions and possibly to eliminate them.

285 They are separate documents and do not always include relevant information.

286 Four MSAs (3 FI, SE), two Member State coordinating authorities (EE, FI).

- The generality of the requirements, which hinders the harmonisation of programmes across Member States;[287]

- The too lengthy procedure for providing the EC with the programmes and the publishing process of the documents,[288] which makes it difficult for Member States to learn from each other's experiences and to enhance collaboration (since when all the programmes are published – or sent to other Member States – in late autumn, the period they refer to is already over).

As regards the controls of products entering the community market (i.e. Articles 27 to 29), the **powers attributed by the Regulation to Customs are adequate**,[289] and the **procedures** for the control of products entering the EU market foreseen by Articles 27 to 29 of the Regulation are **clear, easy to apply and still relevant**.[290]

6.3.2.3 Relevance to new needs

Some issues emerge when looking at needs related to specific dynamics such as increasing online trade, increasing imports from third countries, shortening product life, and increasing budgetary constraints at national level. These dynamics had been raised in the inception phase of the study and have been then verified with stakeholders, to check whether additional phenomena had to be integrated into the analysis, which was not the case.

The Regulation appears to be **only partially relevant to new dynamics, with specific reference to online trade and increasing budgetary constraints**.

As shown, market surveillance on products sold online is particularly challenging, and the Regulation does not seem to be able to properly address related specificities. Specifically, the Regulation **does neither include specific provisions covering online sales, nor does it provide for definitions that account for its specificities**. As mentioned above, the same definitions of 'making available on the market' and 'placing on the market' do not consider the complex distribution chains of online sales, as also highlighted by some stakeholders when discussing both import from third countries and online sales.[291] Also, when considering the economic operators involved in the online sales supply chain, the Regulation does not reflect the latter complexity, for example leaving a grey area on whether fulfilment houses, which according to various stakeholders represent an increasing concern,[292] should be subject to market surveillance.[293] Moreover, in the case of e-commerce, other parties, such as the commercial platforms where products are sold, **should be punishable** when selling non-compliant products.[294] The overall limited relevance of the Regulation to online sales is also underlined by stakeholders.[295]

287 Five MSAs (BE, 2 DE, FI, SE), one AdCO member (medical devices) and three coordinating authorities (2 DK, SI).
288 Three MSAs (LV, NL, SE), two AdCO members (recreational craft).
289 As declared by Customs in BE, BG, CY, CZ, EE, FI, DE, HU, IT, LU, LV, MT, NL, PL, RO, SE, SK. Source: targeted surveys.
290 According to Customs answering the targeted surveys, procedures are clear (95% n=20), easy to apply (76% n=16) and relevant (86% n=18).
291 Five MSAs (AT, DE, DK, FI SE), a Danish, the Turkish and the Romanian coordinating authorities, 4 Customs Authorities (BE, BG, EE, FR).
292 Four MSAs (3 DE, NL), two AdCO members (electromagnetic compatibility, medical devices), and two EU industry associations.
293 These facilities are often regarded as logistics service providers rather than economic operators as defined in the Regulation, and this makes them difficult to sanction.
294 According to a Finnish MSA.
295 47% of survey respondents stated that the Regulation is not able to address specific issues deriving from the increase in online trade.

Yet, it is worth underlining that problems with market surveillance on products sold online can hardly be addressed by means of legislative measures only. Evidence gathered suggests indeed that the cost-effectiveness of proper rules and procedures would not be achieved unless accompanied by proper information and communication campaigns enhancing consumers' awareness of the risks related to products sold online.

A large share of stakeholders[296] has also challenged the relevance of the Regulation **to the needs related to budgetary constraints at national level**.

As discussed, market surveillance activities are indeed influenced **also by budgetary constraints,** several Member States identifying the **lack of financial and human resources** as one of the main bottlenecks hindering market surveillance implementation and enforcement.[297] Despite the increase in non-compliant products, the total **budget available to MSAs** in nominal terms at EU level[298] decreased during the period 2010-2013, representing around 0.1-1.33%[299] of the total national budget. Furthermore, neither the average annual budget allocated to market surveillance activities nor its variation over the period 2011-2013 are correlated with the number of enterprises active in the harmonised sectors. The lack of resources makes, for example, market surveillance measures lengthy, *vis-à-vis* a market that requires fast reaction, as in the case of online sales, already discussed, and the shortening of the product life cycle. Moreover, as discussed, budgetary constraints hamper the participation of many MSAs to AdCO groups, thus limiting the possibilities for cooperation.

Whereas the organisation of market surveillance is under the responsibility of Member States, the Regulation could both define minimum criteria for deploying resources to market surveillance and further streamline arrangements for the exchange of information and best practices, to further favour cooperation and reduce the burden for national authorities.

6.4 Coherence

EQ of reference

EQ 14. *To what extent are the market surveillance provisions coherent internally?*

EQ 15. *To what extent are the market surveillance provisions above still coherent with other Union legislation on market surveillance on non-food products?*

EQ 16. *To what extent are these provisions coherent with wider EU policy?*

6.4.1 Internal coherence

The objective of this analysis is to assess whether the market surveillance provisions of the Regulation are coherent within themselves.

The scope of Regulation (EC) No 765/2008 covers:

296 48% of survey respondents (all public authorities) stated the Regulation is not able to address specific issued deriving from increase in budgetary constraints.
297 Data from national reports of BG, CZ, EE, EL, ES, IE, LT, LV, MT, PL, PT, and SI.
298 Not all EU-28 Member States provided reliable data for this indicator. Therefore, figures do not include AT, CY, EE, EL, HR, HU, LU, SI, UK.
299 The figures refer to 10 MS that provided reliable data, precisely: DK, EE, ES, FI, IT, LV, MT, PL, SE, SK.

1. The rules for the organisation and accreditation of conformity assessment bodies;
2. The rules for market surveillance of products;
3. The control on products from third countries;
4. The general principles for CE marking.

For this purpose, the Regulation defines, among others:

- *Market surveillance,* consisting of all the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Community harmonisation legislation;
- *Public Authorities,* including **'market surveillance authority(ies)', namely the authorities 'of a Member State responsible for carrying out market surveillance on its territory';**
- *Product*, defined as '**a substance, preparation or good produced through a manufacturing process other than food, feed, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction**'. This definition is restricted to '**products covered by Community harmonisation legislation'**. It is to be noted that this definition is not listed under Article 2 – Definitions, but under Article 15(4) – Scope;
- *Community harmonisation legislation* is defined as 'any Community legislation harmonising the conditions for the marketing of products';
- *Public interests*: although there is no definition for this term, the text of the Regulation indicates that public interests concern health and safety in general, health and safety at the workplace, protection of consumers, protection of the environment and security.

Moreover, the definitions refer to actors – manufacturer, authorised representative, importer and distributor – and processes of 'making available' and 'placing' on the market of products, as well as to restrictive measures such as 'withdrawal' and 'recall'. They are in line with the scope of the Regulation.

Article 16 of the Regulation establishes the obligation of Member States to organise and carry out market surveillance of harmonised products **in accordance with specific requirements**, relating, among others, to the product risk and the obligation to inform the public, the Commission and the other Member States of the measures taken to reduce such risks. Further **obligations of Member States** are, for instance, to designate national MSAs and to inform the Commission thereof; to establish appropriate communication and coordination mechanisms between MSAs; to set up adequate procedures in order to follow up on complaints or reports on issues relating to risks, monitor accidents and harm to health potentially caused by those products; to verify that the corrective action has been taken; to entrust MSAs with the powers, resources and knowledge necessary for the proper performance of their tasks; to notify of dangerous products and related measures in RAPEX and ICSMS system; to establish, implement and *periodically update* their market surveillance programmes. To this purpose, Member States may cooperate with all relevant stakeholders. However, **there is no mention of the timing for updating the programmes**. Moreover, the

Regulation requires Member States to periodically evaluate the functioning of their surveillance activities. The reviews shall be performed every four years and the results shall be communicated to the other Member States and the European Commission and be made available to the public. The Regulation **does not provide any specific methodology** to be followed by the Member States to review and assess the functionality of the surveillance activities, though information about possible technical guidance is included in Article 38.[300]

Requirements for MSAs are set in terms of performing appropriate product checks on an adequate scale; r**equiring** economic operators to make relevant documentation and information available; where necessary and justified, **entering the premises of economic operators** and taking samples of products; **destroying or rendering inoperable products** presenting a serious risk where necessary; **cooperating with economic operators**; **alerting users** to identified hazards relating to products; **informing economic operators** of any measures restricting the free circulation of products.

Article 20 makes reference to products presenting a serious risk, for which Member States shall ensure rapid intervention. To this purpose, the Regulation indicates that **Member States shall perform appropriate risk assessments**, taking into account the nature of the hazard and the likelihood of its occurrence. If a product presenting a serious risk has been made available on the market, Member States shall notify the European Commission of any voluntary measures taken and communicated by an economic operator as per Article 22(2). **However, the Regulation does not make reference to any specific risk assessment methodologies,** but a reference to technical guidelines is made in Article 38.[301]

The limitations under Article 21 refer to restrictive measures, which shall be based on proportionality and necessity. These measures and the remedy actions shall be communicated to the economic operators involved, to the Member State concerned and to the European Commission. This communication shall be done 'without delay' but **there is no indication of a maximum deadline.** The Regulation states that the economic operator shall have the opportunity to be heard within 10 days, unless such consultation is not possible because of the urgency of the measure. **However, the Regulation does not provide the date from which 10 days are to be calculated.**

Article 23 states that the European Commission shall **develop and maintain a general archiving and exchange of information system**, using electronic means, on issues relating to market surveillance activities, programmes and information on non-compliance with Union harmonisation legislation. Member States shall provide the European Commission with information at their disposal (and not already provided under Article 22) regarding, in particular, identification of risks, results of tests carried out, provisional restrictive measures, contacts with the economic operators concerned and justification for action or inaction.

Articles 24 to 26 refer to international cooperation via exchange of information and resources sharing between national MSAs, between Member States and the European Commission and the relevant Community agencies, and with third countries. In this regard, Member States shall ensure efficient cooperation and exchange of information on market surveillance programmes and products presenting risks. Cooperation consists in providing information or documentation, in carrying out investigations or any other appropriate measures and in

300 However, non-binding guidance was elaborated at expert group level.
301 The EC drafted, however, a guidance on risk assessment in collaboration with Member States, which has been published last year. Available at: http://ec.europa.eu/DocsRoom/documents/17107/attachments/1/translations

participating in investigations initiated in other Member States. The Regulation **does not include provisions related to the principles of cooperation between Member States** (i.e. spontaneous and/by request provision of information, fullest availability for cooperation, reciprocity basis, including in the case of negative response/no information). As discussed this is an issue for the consistent implementation of the Regulation, which has impacts on the achievement of its objectives.

Section III covers the control of products entering the Community market. The designated Member States' authorities in charge of this task shall have the powers and resources necessary for the proper performance of their tasks. The **external border control authorities** shall suspend the release of a product for free circulation in the Community market, whenever the case, and shall immediately notify national MSAs of any such suspension. Where MSAs find that the product in question does not present a serious risk to health and safety, that product shall be released. In accordance with Article 28, a suspended product is released if the external border control authorities have not been notified of any actions taken by the MSAs within three working days. Based on Article 29, if products presenting a serious risk are declared for a **Customs procedure** and the MSAs do not object, the endorsements shall also be included in the documents used in connection with that procedure. Inoperable products presenting a serious risk may be destroyed where deemed necessary and proportionate.

Chapter V refers to Community Financing. Among the eligible activities we identified:

- The drawing up and updating of contributions to guidelines in the fields of – among others – market surveillance;

- The making available of technical expertise for the purpose of assisting the European Commission in its implementation of administrative cooperation, including the financing of AdCOs, market surveillance decisions and safeguarding clause cases;

- The performance of preliminary or ancillary work in connection with the implementation of the conformity assessment, metrology, accreditation and market surveillance activities;

- Activities carried out under programmes of technical assistance, cooperation with third countries, market surveillance and accreditation policies and systems among interested parties in the Community and at international level.

Chapter VI – Final Provisions – covers the issuance of technical guidance for the implementation of the Regulation (Article 38) and the application of penalties (Article 41). As mentioned, Member States shall perform **reviews and assessments over the functionality of the surveillance activities**, as well as risk assessments to identify if products present serious risks. The technical guidance shall consider providing a methodology for these two processes. Finally, Member States shall set the **penalties** for economic operators, which may include criminal sanctions, applicable to infringements of the Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement under the Regulation. In this regard, a Finnish MSA indicates that penalties for infringements regarding the CE marking (with reference to

Article 30(6)[302]) shall be 'proportionate to the seriousness of the offence'. However, he states that **since non-compliance with rules on the CE marking concerns only formal requirements and not safety, the Regulation should not name them as 'penalties'.** In addition to this, the Regulation does not provide a minimum and maximum level of penalties. As discussed, this caused discrepancies in the level of sanctions and penalties for infringements of the Regulation across the EU.

Overall, **the Regulations' provisions appear to be coherent within themselves** in that roles and responsibilities of all relevant stakeholders involved, and processes are clearly defined and in the scope of the Regulation.[303] **The issues identified relate to the general character of the Regulation's requirements, which allow for different implementations at the national level.** As discussed in section 6.1.2, this heterogeneity impacts on the Regulation's achievement of its strategic objectives.

6.4.2 External coherence

In order to evaluate the external coherence of the Regulation, we analysed to which extent its provisions are coherent with other Union legislation on market surveillance on specific non-food products (i.e. the GPSD) and with harmonised sectoral legislations.

The **General Product Safety Directive (GPSD)** aims to ensure that only safe products are made available on the market. It applies to all non-food consumer products in the absence of specific provisions with the same objective in EU legislation governing the safety of the products concerned.[304] Thus, it has the effect of a safety net as it covers consumer products not covered by more specific provisions of EU product safety legislation.

The definitions of the GPSD are not always aligned with those of the Regulation. For instance, the definitions of 'distributor', 'withdrawal', 'recall' are different from one piece of legislation to the other, while the definitions of 'serious risk' and 'dangerous products' are set in the GPSD and not in Regulation 765/2008, though the latter widely refers to these concepts. In this regard, clarifications are needed on how to apply these concepts to products that are rarely dangerous but can still have non-conformities that imply a high risk (e.g. lifts).[305] Further, Article 18 of the GPSD states that Member States shall notify the party concerned about restrictive measures and indicate the remedies available. The parties concerned shall, whenever feasible, be given an opportunity to submit their views before the adoption of the measure. However, there is no deadline for hearings, as indicated by Regulation 765/2008.

Moreover, the boundary between the GPSD and the Regulation is not always clear,[306] despite the existing Commission's Guidelines. Therefore, **the two legislations sometimes seem to overlap**, 'leading to extreme legal complexity which economic operators and enforcement

302 Article 30(6) where it states that *'Without prejudice to Article 41, Member States shall ensure the correct implementation of the regime governing the CE marking and take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use'*.

303 As confirmed also by four coordinating authorities (EE, HR, RO, TR), 14 MSAs (BE, CY, DK, IS, IT, 4 LT, NL, PL, 2 SE, UK), 4 Customs (CZ, CY, IT, LV), two EU industry associations, a Swedish company (equal to 62% of respondents to this question in the targeted surveys).

304 Article 1(2) of the General Product Safety Directive.

305 SE MSA.

306 Three coordinating authorities (2 DE, FI), eight MSAs (2 BE, CY, 2 DE, DK, ES, LV), two EU industry associations, one Swedish Customs authority.

authorities are increasingly unable to understand and to apply properly in the remit of their respective obligations, leading to diverging interpretations on both sides and to uncertainty'.[307]

As mentioned, the external coherence has also been assessed with respect to **each sectoral legislation** covered by the scope of the Regulation. **No coherence issues** have been found with the majority of legislations, whose interface with Regulation 765/2008 is clear in light of the *lex specialis* principle. Rather, some **complementarities** have been spotted, although they **do not raise any concerns with respect to overall coherence**.

The following table shows, for the remaining sectoral legislations, the **coherence issues** identified with respect to the definitions and penalties set down in each of them. For instance, in the case of lifts, 'recall' is not feasible, and the definition of 'placing on the market' in the Lifts Directive is different from the definition provided in Regulation 765/2008. Moreover, for sectors such as the lifts sector, the definition of 'putting into service' is fundamental, but – though set out in the relevant legislation – it is currently missing from the Regulation.[308]

Nonetheless, these inconsistencies **mainly regard misalignments in the terminology** provided in different legislative texts and do not seem to hamper the application of the Regulation; issues have also not been reported by stakeholders in this respect. As proof, product non-compliance in the internal market is not due to ambiguity in the rules.[309]

Table 4-31 – Consistency issues between the Regulation and some sectoral legislation

Sectors	*Definitions*	*Issue*	*Penalties*	*Issue*
Medical devices	• Manufacturer • Authorised representative • Placing on the market • Putting into service	Inconsistent	No reference about applicable penalties for substantial non-compliance.	Inconsistent
Personal protective equipment[310]			No reference about applicable penalties for substantial non-compliance.	Inconsistent
Construction products			No reference about applicable penalties	Inconsistent
Transportable pressure equipment			Article 14(7) refers to penalties only in respect to the failure to implement the rules governing the Pi marking.	Inconsistent
Lifts	Placing on the market	Inconsistent		
Cableways	European specification	Inconsistent	No reference about	Inconsistent

307 An EU industry association.
308 AdCO chair contributing to the targeted survey.
309 According to 51% of respondents to the public consultation (n=121).
310 Recently redrafted: Regulation (EU) 2016/425.

	(instead of European harmonised standards)		applicable penalties	
Noise emissions for outdoor equipment	Different definition in respect to 'marking'	Inconsistent	No reference about applicable penalties	Inconsistent
Gas appliances (Directive 2009/142/EC)			No reference about applicable penalties	Inconsistent
Pre-packaged products	No definitions provided	Inconsistent		
Measuring containers	No definitions provided	Inconsistent		
Units of measurement	No definitions provided	Inconsistent		
Motor vehicles, Directive (Directive 2007/46/EC)	Manufacturer	Inconsistent		

6.5 EU added value

EQ of reference

EQ 17. *What is the additional value resulting from the market surveillance provisions at EU level, compared to what could be achieved by Member States at national and/or regional levels?*

EQ 18. *To what extent do these provisions support and usefully supplement market surveillance policies pursued by the Member States? Do the provisions allow some sort of 'control' by the EU on the way national authorities carry out market surveillance?*

As described in the previous sections, there are no issues on the EU added value provided by the Regulation in terms of its objectives. It is clear, indeed, that by its same nature, the Regulation provides EU added value in terms of **harmonisation of market surveillance** if compared to what could be achieved by different pieces of national legislation, and that stakeholders recognise this value.[311]

According to stakeholders, the Regulation has the potential to:

- Contribute to the establishment of a level playing field;[312]
- Improve the free movement of goods;[313]

311 25 MSAs, four coordinating authorities, nine Customs authorities, four industry associations (3 BE, AT). Source: targeted survey.
312 10 MSAs, two coordinating authorities, two EU industry associations, an Italian and a Swedish economic operators. Source: targeted survey.

- Enhance efficiency and effectiveness of market surveillance activities.[314]

Stakeholders also state that the Regulation has stimulated **transparency and unambiguous interpretation of rules**.[315] By setting common requirements, the Regulation **contributed to uniform safety levels across the EU**.[316]

Moreover, the Regulation has **improved cooperation** among actors involved in market surveillance activities.[317] By clarifying the role of Customs, for instance, "*the Regulation has enhanced their channels and opportunities of collaboration with other EU authorities*".[318] In this regard, stakeholders positively assess **the role of the RAPEX and ICSMS system** as valuable tools that increase and enhance the exchange of information and open for possibilities of collaboration between Member States. Moreover, **the framework provided by the Regulation is useful to define national market surveillance and control of imported products policies**.[319] Interestingly, a Finnish MSA declares that the Regulation brought an additional benefit in this sense thanks to its comprehensiveness, *"which could not be achieved by small countries"*.

Nonetheless, it is more interesting to look at to what extent the **specific content** of the Regulation is capable of bringing EU added value. In this respect, the analysis performed enables the identification of some provisions that bring more EU added value than others.

The analysis undertaken for effectiveness, highlights that **cooperation and coordination** among authorities in a Member State and across Member States are fundamental to assure effectiveness of market surveillance measures, even more considering that intra-EU trade represents 66% of the value of the overall imports of manufacturing goods (Figure 11). Therefore, understanding whether provisions of the Regulation related to this objective have provided EU added value is particularly important.

The EU added value of the Regulation mainly stems from provisions envisaging common information systems, **which are managed by the European Commission, favouring administrative cooperation, and enhancing collaboration between Customs and MSAs.**

As for information systems, all Member States make use of RAPEX and most of them utilise ICSMS to exchange information and coordinate market surveillance activities. As shown in previous sections and presented in detail in case study 4, the use of RAPEX has significantly increased over the years, in terms of both the number of notifications and follow-up actions (even though with the limitations described), thus showing the EU added value of such a system that allows for an information sharing that would not be possible otherwise (even though the Regulation in fact extended the use of RAPEX).

As regards ICSMS, the EU added value is more limited, especially considering that a number of MSAs highlight the possible duplication with other pre-existing internal/national databases (see section 6.1.1).

313 Four MSAs. Source: targeted survey.
314 Five MSAs, a Slovakian Custom authority, two industry associations, an Italian economic operator. Source: targeted survey.
315 14 MSAs, a Finnish Custom authority, three coordinating authorities. Source: targeted survey.
316 EU and DK industry association, Swedish company. Source: targeted survey.
317 6 MSAs, Slovak and Swedish Custom authority, to Danish coordinating authorities, an EU industry association. Source: targeted survey.
318 Swedish Customs. Source: interview.
319 According to 95% of answers received to this question, and namely by 11 coordinating authorities, 54 MSAs and 16 Customs.

Provisions related to administrative cooperation are also providing EU added value. The role of **EU level working groups and initiatives** supporting administrative cooperation (i.e. AdCOs) is worth mentioning: the presence of EU-level working groups and related initiatives enables a sharing of information and good practices that would not be possible otherwise, thus responding to a need of an increased exchange between Member States.

Finally, the enhanced collaboration between MSAs and Customs also reflects the EU added value of related provisions that create an incentive to collaborate that would not exist otherwise.

On a different note, the EU added value provided by provisions related to **collaboration between Member States** is not as straightforward. Whereas stakeholders consulted confirm a high level of collaboration, evidence of a non-complete recognition of national practices of market surveillance when dealing with cross-border non-compliance (see again section 6.1.1.) limits their EU added value.

Similarly, and connected, the EU added value linked to provisions dealing with **market surveillance organisation at national level** is limited. In this case, the picture emerging is still one of a highly fragmented and uncoordinated system, largely due to the adaptation of market surveillance organisation at national level to national governance models that are independent from the Regulation. In this respect, it seems that the Regulation has not provided minimum guidance to have a more homogenous market surveillance system but instead rather too general requirements.

Last, but far from being least, it is worth recalling the EU added value of provisions on **national programmes and reports**. In this case, it seems that an important opportunity has been lost. Whereas in principle the existence of a system to gather information from Member States provides EU added value in terms of an EU monitoring of the enforcement of market surveillance, once again the lack of clear guidance on how to draft national documents and interpret their contents makes these documents largely irrelevant when seeking a reliable picture, with all the limitations in terms of follow-up action that have clearly emerged in this study.

7. CONCLUSIONS

7.1 Effectiveness

The evaluation analysed the effectiveness of the Regulation in meeting its specific and strategic objectives, and looked into enabling factors.

As for the effectiveness in meeting specific objectives, the evaluation concluded that the Regulation has been only partly effective in achieving them.

The **problems** related to the achievement of specific objectives are many.

Although **coordination and cooperation mechanisms are significantly developed,** and recognised as useful, they **have not reached a level that can be considered satisfactory, especially considering those existing among Member States.** In particular, despite the necessary tools (i.e. RAPEX and ICSMS) being in place to ensure cross-border market surveillance cooperation, they are not used effectively. This hampers the possibility to avoid duplication of effort, which is the case when the system is properly used. More significantly, MSAs do not fully benefit from the advantages of these systems as they rarely restrict the marketing of a product following the exchange of information on measures adopted by another EU MSA against the same product. Also, the possibility for MSAs and Customs to make use of test reports drafted by MSAs in other EU countries seems to be limited. As for EU level arrangements, although participating in AdCO proves to be essential for coordinating actions and learning from best practices, not all MSAs participate in this form of administrative cooperation, also due to lack of resources.

Based on the analysis undertaken there is still need for higher level and more transparent cooperation and exchange of information.

As the level of **uniformity and rigorousness of market surveillance, the evaluation concluded that the Regulation has not been fully effective.** Uniformity and rigorousness have not been achieved yet, due to the significant differences across Member States in the implementation of the Regulation. These differences are related to the organisation of market surveillance at the national level, the availability of resources (financial, human and technical), the strategies of market surveillance, the powers of inspection and of sanctions, the level of sanctions and the systems of monitoring and reporting, i.e. the national reports. The general character of the Regulation's requirements is likely to have allowed these different implementations.

The heterogeneity existing across Member States in the implementation of the Regulation allows inferring that **the level of market surveillance is certainly not uniform**, given that Member States with more resources and powers have – at least – more tools for a proper enforcement. As for its **rigorousness**, the serious lack of data and inhomogeneity of national reports do not allow for a thorough assessment, except if based on stakeholders' perceptions, on the discrepancies in the penalty framework and in the 'lack of confidence' of enforcement authorities in other MSAs' risk assessments.

As for **border controls**, although **powers attributed by the Regulation to Customs are adequate**, and the **procedures clear, easy to apply and still relevant**, the **checks of imported products** seem to be insufficient.

The main difficulties related to controls of imported products are due to a lack of jurisdiction of MSAs outside their Member State, and to a lack of direct communication between MSAs and businesses, particularly in the context of online sales. Moreover, despite the fact that the necessary tools are in place to ensure cross-border market surveillance cooperation (e.g. RAPEX, ICSMS and the safeguard clause procedure), they are not used effectively, as discussed.

As for its strategic objectives of strengthening the protection of public interests through the reduction of the number of non-compliant products on the Internal Market and of ensuring a level playing field among economic operators providing a framework for market surveillance and controls of products**, the evaluation also concluded that the Regulation is not fully effective**. This conclusion is based, first, on the evidence of an increasing number of non-compliant products covered by harmonisation legislation (as demonstrated by the rising number of RAPEX notifications and of restrictive measures taken by MSAs, see sections 0 and 0). On the one hand, the increasing product non-compliance threatens the achievement of a high level of protection of public interests for as long as these products present risks to consumers and end-users. On the other hand, a level-playing field among businesses trading goods subject to EU harmonisation legislation risks not being achieved as long as there is still the possibility for rogue traders to disregard legal requirements and sell non-compliant products.

Moreover, as already discussed, the Regulation has been implemented in different ways across Member States. These discrepancies diminish the Regulation's effectiveness in achieving a level playing field, inasmuch as they create disparities in the level of enforcement that influence regulatory/administrative costs to businesses across Member States and market behaviour. Ultimately, this impacts a lower protection of public interest – due to increasing non-compliant products – and to the achievement of a level playing field.

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

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

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

Powers attributed at the national level and the role of Customs in enforcing the Regulation influence the effectiveness of border control. Controls are indeed expected to be tougher in Member States where Customs act as MSAs. While Customs powers are essential for the

control of traded products, the introduction of Regulation 765/2008 highlights the need for cooperation between Customs and MSAs and with other EU Customs as a crucial element for enhancing market surveillance on imported products. In this respect, there are notable differences across Member States.

Overall, it seems that these discrepancies are being allowed by the general requirements set in the Regulation. This lack of specificity relates to Member States' obligations as regards organisation, powers, resources and knowledge necessary for MSAs to perform their tasks properly. Article 18(5) on national reports and programmes is also general, as it does not foresee the provision of structured information from Member States to the EC relating to market surveillance activities, which is particularly evident in light of all the data limitations highlighted in the study. Moreover, the Regulation does not include specific provisions related to the principles of cooperation between Member States. This clearly impacts on the existing cooperation mechanisms and tools, which, as described in the previous sections, are many and different, but could be improved. Finally, the Regulation is not specific enough to set a minimum and/or a maximum level of penalties, or any principles to define them. As discussed, this results in wide differences in the minimum/ maximum amounts within and across Member States, which lower the enforcement deterrence power.

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

7.2 Efficiency

The efficiency of the Regulation has been assessed in terms of costs incurred by different stakeholders, benefits produced, and the extent to which the desired effects (results and impacts) have been achieved at a reasonable cost. Furthermore, significant differences between Member States have also been considered.

The Regulation introduces costs for Member States and economic operators. Costs for Members States are related to organisational, information, surveillance and cooperation obligations embedded in the Regulation. Costs for economic operators are related to information obligations as defined in Article 19 of the Regulation.

The unavailability of data on costs incurred by Member States Authorities in charge of market surveillance before 2008 did not allow for the measurement of additional costs deriving from the new obligations introduced by the Regulation.

However, data included in the national reports provide information about costs incurred in performing market surveillance on harmonised products.

The main highlights of the analysis show that at Member State level:

- The budget allocated to Market Surveillance Activities:

- On average, is €7.5 m per Member State in nominal terms,[320] representing around 0.1-1.33%[321] of total national budget;

- Decreased by 7% over the period 2010-2013 (from €7.8 m to €7.5 m);

- Human resources allocated to MSAs:

  - More than 280 FTEs[322] were involved on average at Member State level over the period 2010-2013 in inspection activities. The number of inspectors decreased by 4.4% (i.e. reduced from 288 to 275) over the period considered;

  - MAs can count, on average, on more than 415[323] FTEs in order to perform Market Surveillance activities each year; however the number of FTEs available decreased by 2.6% over the period 2010-2013.

Costs incurred by MSAs **vary considerably from one Member State to another**. These differences might be related to the fact that Member States have different organisational models requiring different levels of both human and financial resources. However, another possible explanation might be sought in the different approaches followed by MSAs in reporting data concerning the used financial resources as well as the performed activities.

The fact that Member States define their own market surveillance approach creates a high variation in the ways the different sectors are controlled and managed. Moreover, fragmentation throughout the Internal Market may interfere with the Authorities' early action and produce additional costs for businesses (for instance, multiple evaluations and validations in order to allow them to place a product in the Market).

With respect to costs for economic operators, **information costs are perceived as not significant but some across-the-board inconsistencies** still remain; also the current enforcement mechanism is not able to create a level playing field for businesses that are selling products in the Internal Market. This might reduce businesses' willingness to comply with the rules and discriminate businesses that abide by the rules against those who do not.

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

Furthermore**, the expected improved safety** is not confirmed by RAPEX notifications and by the statistics on the implemented restrictive measures at national level.

An increase in RAPEX notifications and surveillance measures may also imply that MSAs have become more effective in finding – and thus correcting – non-compliance. However this underlines that the Regulation is still not able to increase businesses' willingness to comply with the rules, thereby discriminating businesses that abide by the rules against those who do not.

320 Not all Member States provided reliable data for this indicator. Therefore figures do not include AT, CY, EE, EL, HR, HU, LU, SI, UK. For SE the average is computed considering only data for 2012 and 2013 because some authorities did not provide any figures for some sectors for 2010 and 2011.

321 The figures refer to 10 MS that provided reliable data, precisely: DK, EE, ES, FI, IT, LV, MT, PL, SE, SK.

322 The figures refer to 16 MS that provided data, precisely: BE, BG, CZ, DK, EE, ES, FI, IE, IT, LT, LU, LV, PL, PT, RO and SK.

323 The figures do not include: AT, BE, CY, EL, FR, HR, HU, SI, UK. For SE the average is computed considering only data for 2012 and 2013 because some authorities did not give any figures for some sectors for 2010 and 2011.

The limited cost-effectiveness of the market surveillance provisions is confirmed by the fact that the average annual budgets allocated to MSA activities nor their variation over the period 2011-2013 are correlated with the size of the market (i.e. number of enterprises active in the harmonised sectors).

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

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

7.3 Relevance

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

The analyses highlighted that the **scope** of the Regulation raises some problems. A quite high percentage of stakeholders (even though not the majority) indeed find the scope of the Regulation not fully clear. Some confusion on the scope of the Regulation has also emerged from the analysis of national reports (adding sectors not in the scope of the Regulation), and considering input from economic operators. The analysis also underlined that difficulties in understanding the Regulation's scope might be exacerbated by technological developments introducing new forms of products.

As for the Regulation's **definitions**, the evaluation highlighted some points to consider. Although these are generally clear and appropriate, they are not fully **complete and up to date,** especially when considering the need to also cover online sales, but also with reference to the definitions of 'making available on the market' *vis-à-vis* 'placing on the market', 'product' in relation to the concepts of 'second hand good', 're-used good' and 'by-products', of 'recall', or the definition of 'risk'.

The assessment of the relevance of the Regulation focused also on the concept of ***lex specialis,*** concluding that the concept results are a suitable interface to address market surveillance in specific sectors, with not specific difficulties in implementation. Some issues though have emerged as regards a lack of clarity in the scope of market surveillance rules in sector-specific legislation.

Looking at the relevance of the Regulation to **stakeholders' needs,** the analysis concluded that the Regulation is relevant to some extent, as it is relevant overall when considering the current needs associated with its general and specific objectives, but it becomes less relevant with looking at the needs related to new/emerging dynamics**.**

Indeed, the framework it provides results in being useful overall in defining national market surveillance programmes and policies, and in meeting the strategic objectives of the Regulation. It also results in meeting the relevant needs of cooperation and exchange of

information. With specific reference to the provisions on market surveillance programmes and reports, though, the quality and comparability of the information provided is far from sufficient, making their consultation very burdensome if not useless. Finally, the results are relevant when referenced to the needs of border controls.

However, when moving to the relevance of **emerging issues**, the Regulation is not as relevant, especially with reference to increasing online trade and budgetary constraints at national level. As for online trade, the Regulation neither includes specific provisions covering online sales, nor does it provide for definitions that account for its specificities, as already mentioned. As for budgetary constraints, the Regulation does not properly account for the relation between the lack of resources and the related lengthy processes to enforce market surveillance, and the dynamics of the market that require a fast reaction.

7.4 Coherence

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

As for **internal coherence**, overall the market surveillance provisions of the Regulation are consistent within themselves and in the scope of the legislation. Furthermore, the roles and tasks of all the different stakeholders concerned by the Regulation are well defined and no duplication of activities has been traced. The analysis – supported by stakeholders' opinions – has not identified any overlaps or contradictions between the Regulation's provisions within the scope of this study. However, some areas for improvement have been identified. In this respect, there are areas where further guidance and clarity would be beneficial. For instance, the Regulation does not provide any specific methodology to be followed by the Member States when reviewing and assessing the functionality of the surveillance activities. Similarly, the Regulation does not include provisions related to the principles of cooperation between the Member States (i.e. spontaneous and/by request provision of information, fullest availability for cooperation, reciprocity basis, including in cases of negative response/no information). At present, provisions about the implementation of market surveillance are too general, thus allowing for significant differences in the implementation of the Regulation in terms – for instance – of communication and collaboration tools existing within/among Member States, endowments of powers and resources, and the 'adequacy' of checks, as already discussed under section 7.1.

As for **the external coherence of the Regulation with the GPSD, some issues have been traced**. More specifically, the definitions provided in the GPSD are not always aligned with those of the Regulation. Moreover, the boundary between the GPSD and the Regulation is not always clear, **the two legislations sometimes seem to overlap**, and the differences between mutual scopes should be further defined. A low number of stakeholders suggested improving the overall coherence of the Regulation by merging it with the GPSD. This would allow significant simplification and increased legislative certainty, as the convergence would solve some inconsistencies in terms of definitions and concepts between the two Regulations. A similar but less radical solution would be to at least clearly exclude all products covered by specific Union legislation from the scope of the GPSD.

Finally, the coherence of the Regulation with sectoral directives is safeguarded to a sufficient extent by the existence of the *lex specialis* provision. Nonetheless, also in this case, there exist discrepancies and shortages in the definitions and terminology provided in the different

legislations. Although not hindering the implementation of the Regulation, they still cause inconsistencies and diminish the overall clarity of the framework for market surveillance.

7.5 EU added value

The EU added value of the Regulation in terms of **harmonisation, transparency and unambiguous interpretation of rules** is widely recognised by stakeholders. Moreover, the framework provided **by the Regulation is useful to define national market surveillance and control of imported products policies.**

However, the analysis focused on assessing the EU added value as per the **specific provisions** of the Regulation. In this respect it appears that some of them achieve a higher EU added value when compared to others.

The EU added value of the Regulation mainly stems from provisions envisaging common **information systems for cooperation and coordination, favouring administrative cooperation, and enhancing collaboration between Customs and MSAs.**

On a different note, the EU added value provided by provisions related to **collaboration between Member States** is not as straightforward, due to an incomplete recognition of national practices of market surveillance when dealing with cross-border non-compliance, despite a general positive opinion expressed by stakeholders. Similarly, and connected, the EU added value linked to provisions dealing with **market surveillance organisations at national level** is limited, mainly because the Regulation does not provide minimum guidance to have a more homogenous market surveillance system. Finally, it is worth recalling provisions in **national programmes and reports**. Although they could provide significant EU added value in terms of monitoring the enforcement of market surveillance, the lack of clear guidance on how they should be drafted and interpreted makes these documents largely irrelevant.

8. ANNEXES

8.1 Stakeholder consultation

In line with the Commission's Better Regulation Guidelines,[324] the first section of this Annex sets out a brief summary of the consultation strategy performed within the context of this Evaluation Study. It provides details on how the consultation was conducted, by presenting each consultation tool. Furthermore, a brief summary explains the actions undertaken to meet the EC minimum standards for stakeholder consultation. The second section presents the results of the main findings of the analysis.

8.1.1 The Consultation strategy

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

- A public consultation;
- Five targeted consultations based on online surveys;
- Interviews.

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

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

8.1.1.1 Public consultation

The public consultation was launched on 28 June and closed on 31 October 2016. It consisted of an online questionnaire available in 23 official languages of the EU. The consultation collected stakeholders' opinion on several issues:

- The relevance, reasons and consequences of the problem of product non-compliance in the Internal Market for goods;
- The options available to tackle the problem;
- The impact of those options;
- The issue of subsidiarity;
- Whether action at EU level would produce clear benefits with respect to those created at the Member State level in terms of scale and effectiveness.

324 European Commission, SWD(2015) 110 final. Better Regulation Guidelines.

The great majority of questions were **closed questions**, in order to avoid an excessive burden for respondents and to ease the comparison of the answers received in the analysis phase. The questionnaire also had a very **general character**, so that potentially anyone willing to contribute could do so.

Overall, **239 stakeholders** contributed to the public consultation, and namely:

- 64 MSAs or Customs authorities, from AT, BE, CH, CY, CZ, DE, DK, EE, ES, FI, HR, IE, IS, IT, LT, NL, NO, PL, PT, SE, SI, UK;
- 74 economic operators from AT, BE, BG, CZ, DE, ES, FI, FR, HU, IE, IT, NL, PL, PT, SK, SE, UK;
- 12 Public Authorities (PA) from AT, DE, DK, ES, IS, LT, PL, RO;
- 53 industry associations from BE, CH, DE, DK, EL, ES, FI, FR, IT, NL, PT, RO, UK;
- 6 consumer organisations from BE, DK, UK;
- 4 International organisations (AT, FI, UK);
- 4 academic/law firms (DE, HU, UK);
- 2 Trade Unions (BE, FR);
- 6 consumers/citizens (AT, DE, ES, UK);
- 14 others (from AT, BE, DE, FR, NL, PL, SE, SK, TR, other third country).

8.1.1.2 Targeted surveys

For the purpose of the study, **five targeted surveys based on online questionnaires** were launched, involving:

- Member State coordinating authorities in charge of the implementation of the Regulation;
- MSAs in charge of the enforcement of the Regulation, including AdCO representatives;
- Customs authorities;
- Economic operators, and industry associations;
- Consumer and user associations.

The targeted surveys were launched on 26 October and closed on 20 December 2016 and ran on the EY online survey tool (eSurvey). The deadline was initially planned to be the beginning of December, but it was postponed following several requests from stakeholders to be given more time to contribute and after formal agreement with the Steering Group.

The questionnaires **were drafted in five EU languages** (DE, EN, FR, IT and RO) and they consisted **mainly of closed questions**, in order to ensure higher response rates, with some open-ended questions to allow participants to contribute with more detailed views, opinions or advice. The survey was organised into sections corresponding to the evaluation criteria.

Questions were customised to differently address each category of stakeholder taking into account their different level of engagement and experience with the Regulation. In detail, they aimed at:

- Gathering quantitative data, especially those related to the market and cost-benefit analysis;
- Providing preliminary information for answering the evaluation questions;
- Identifying the most relevant aspects of the evaluation to be further addressed through interviews.

Overall, **119 stakeholders** were involved in the targeted surveys up to 20 December 2016, in particular:

- 54 MSAs (from AT, BE, CY, DK, ES, FI, DE, IE, IT, LT, LU, LV, NL, PL, SE, UK);
- 13 MS coordinating authorities (FI, DE, DK, EE, HR, FI, LT, RO, SE, SI);
- 19 Customs authorities (AT, BE, BG, CY, DE, EE, FI, FR, DE, HR, HU, IT, LU, LV, MT, NL, PL, RO, SK, SE);
- 4 economic operators (BE, ES, IT, SE);
- 3 civil society associations (BE, HU);
- 12 industry associations (AT, BE, DK, EL, ES);
- 14 AdCO representatives (medical devices, radio equipment, lifts, pressure equipment, electromagnetic compatibility, 2 measuring instruments, 2 noise, recreational craft, gas appliances, construction products, pyrotechnic articles, explosives for civil use).

8.1.1.3 Interviews

The field research also consisted of **interviews**, aimed at:

- Investigating in detail the specific topics and issues that have emerged from the analysis of the targeted consultations as well as from the desk research (e.g. to examine specific problems encountered in the implementation of the Regulation at the national level, or any best practices signalled), by discussing them with involved national and EU stakeholders;
- Gaining a better understanding of the consequences of current practices, or the most important/emerging issues, by involving stakeholders active in the market (e.g. representatives of consumer associations and industry associations);

- Understanding the different perspectives and viewpoints through discussions with different stakeholders;
- Triangulating the information and data collected through the consultations.

Interviews involved **relevant stakeholders** concerned by the Regulation, including MSAs, Customs, selected representatives from organisations of stakeholder categories (e.g. industry and SMEs, consumers) and individual enterprises for the CBA.

39 interviews have been performed.[325] More in detail:

- 9 (out of 10 planned) general interviews to further investigate the most relevant issues emerged from the desk and field research;
- 20 targeted interviews aimed at building up the five case studies;
- 10 for collecting additional data for the CBA.

Overall, the following stakeholders have been involved:

- 18 MSAs (AT, CY, 2 DE, DK, ES, EL, 2 FI, 2 FR, IE, 2 IT, NL, MT, SK, UK);
- Three coordinating authorities (DE, IT, SE);
- Five Customs (BG, DE, FI, IT, NL);
- Ten economic operators (7 BE, DE, IT, UK);
- Three EU-level industry associations.

8.1.2 Minimum standards for stakeholder consultation

While conducting the consultations, the evaluation team ensured to respect the standards listed in the "Better Regulation Guidelines" of the European Commission, which aim to guarantee that all relevant stakeholders have the opportunity to express their opinions. The table below presents the five Minimum Standards and actions to ensure compliance.

Minimum Standards	*Actions for compliance*
Clear content of the consultation process ('Clarity'): All communication and the consultation document itself should be clear, concise and include all necessary information to facilitate responses	• All stakeholders consulted were first informed about the objectives of the evaluation study. Moreover, stakeholders have been always provided with the accreditation letter signed by the EC, detailing the background and the implementation process of the analysis and authorising the evaluation team to request for data; • Targeted surveys and interviews were drafted specifically for each stakeholder category, so as to provide them with relevant questions only; • All stakeholders involved through the interviews received the interview guidelines in advance, in order to have the chance of

325 The number of interviews foreseen was 40, but a relevant interviewee refused to be involved.

Minimum Standards	*Actions for compliance*
	preparing their answers and collect the information needed.
Consultation of target groups ('Targeting'): When defining the target group(s) in a consultation process, the Commission should ensure that all relevant parties have an opportunity to express their opinions	• The stakeholders to be targeted were defined in a joint effort with the EC. This process was aimed at ensuring that the most relevant groups had their say in the consultation process; • Due to the relevance of the study and to the tight schedule, the EC worked very closely in cooperation with the evaluation team to achieve a satisfactory level of stakeholders' involvement. Further, the EC provided the evaluation team with specific contacts (e.g. of AdCO chairs) so as these stakeholders could raise awareness about the study and involve the members of their group in the consultation process, thus triggering a positive "snowball effect"; • In order to ensure a balanced representation of all stakeholders in both terms of geographical and category coverage, targeted interviews were intentionally aimed at involving parties under-represented in the public consultation and targeted surveys, particularly the industry side.
Publication: The Commission should ensure adequate awareness-raising publicity and adapt its communication channels to meet the needs of all target audiences. Without excluding other communication tools, (open public) consultations should be published on the internet and announced at the "single access point"[326]	• Several email reminders were sent to relevant stakeholders in order to remark the importance of their contribution to the study. • In order to ensure the maximum stakeholders involvement, the evaluation team participated to the IMP-MSG Meeting on 21 October 2016 in Brussels, where the objectives of the study and the main contents of the targeted surveys were presented. Further, the evaluation team tried to collect some preliminary feedback from participants. • The evaluation team also participated to the PARS Project Group Meeting on 1 December 2016 in order to raise EU Customs' awareness about the study and to inform them about the ongoing consultation of the project, eventually soliciting them to contribute.
Time limits for participation ('Consultation period'): The Commission should provide sufficient time for planning and responses to invitations and written contributions	• The public consultation ran for almost 14 weeks; • The targeted surveys ran for almost 8 weeks. Following numerous stakeholders' requests and in agreement with the EC, the survey deadline was extended to 20 September 2016. • The interviews were performed over a time frame of 8 weeks. However, they were scheduled well in advance so as to allow stakeholders to find the date and time that best suited their schedules.
Acknowledgement of feedback ('Feedback'): Receipt of contributions should be acknowledged and contributions published. Publication of contributions on the "single access point" replaces a separate acknowledgment if published within 15 working days. Results of (open public) consultations should be published and displayed on websites	• Results of all the consultation tools were thoroughly analysed and included in the report. • The contributions to the public consultation have been published on the EC website if the stakeholders provided their consent to it. • The contributions to the targeted surveys will not be published as the evaluation team guaranteed the confidentiality of information to all stakeholders consulted.

326 "Your Voice in Europe": http://ec.europa.eu/yourvoice/

8.1.3 Report Charts

The following sections presents a summary of the most significant results emerged from the targeted surveys and the public consultation. The charts and percentages do not take into account the "no opinion/I do not know" replies, which would bias data. Absolute numbers taking into account all replies are reported in footnote.

8.1.3.1 Effectiveness

8.1.3.1.1 Enforcement powers

One of the issues on which stakeholders have been consulted via the public consultation was **the need for MSAs to be granted particular enforcement powers.** As shown in the following figure, the preferred options are the power to issue requests for information (93%, n=202) and to take temporary measures in case economic operators refuse to collaborate (91%, n=198). Fewer stakeholders see the need for MSAs to enforce fines on behalf of another EU MSAs upon request, though they still represent 55% (n=108) of total respondents.

Figure 4-36 - Powers MSAs need in order to carry out more effective and deterrent action

Source: public consultation[327]

327 *Issue requests for information*: n = 215. In addition, 10% (n=24) of total respondents chose the "no opinion" option; *Take temporary measures against products when economic operators do not reply*: n = 216. In addition, 10% (n=23) respondents chose the "no opinion" option; *Inspect business premises*: n = 214. In addition, 10% (n=25) respondents chose the "no opinion" option; *Sanction*

If the breakdown per specific enforcement power and per stakeholder category is considered, there is a strong agreement among respondents in relation to the **power to issue requests for information**. Overall 94% of respondents agree on this power, despite 25%% (n=3) of PAs disagree.

Similarly, no major differences appear across the categories in relation to the **power to take temporary measures against products when relevant economic operators do not reply to MSAs' requests**. Overall, 91% of respondents agree on the need of this power for MSAs. Interestingly, half of economic operators and industry associations agree with this option (52%, n=34 and 50%, n=24) and even a small share of them strongly agree (respectively 37%, n=24 and 38%, n=18). Also 98% (n=58) of MSAs/Customs either strongly agree or agree. Namely, the strongest support to this power is expressed by civil society representatives as 69% (n=22) of them strongly agree.

As for the **power to inspect businesses' premises**, respondents align independently from the different categories they belong to. The large majority of them (81%, n=174) agree that MSAs should be granted this power. Nonetheless, 29% (n=19) of economic operators and 21% (n=9) of industry associations responding to the public consultation either disagree or strongly disagree on this.

With respect to the **power to sanction economic operators that do not submit to MSAs' inspections of business premises**, there is substantial agreement among the respondents' categories (overall 84% agree). However, a significant part of economic operators (24%, n=16) and PAs (25%, n=3) disagree. MSAs/Customs express the strongest support to this option (53% strongly agree, n=31), immediately followed by civil society representatives (42% strongly agree, n=14).

Overall, the majority of respondents agree on the need for MSAs to be granted with **the power to take samples for free** (73%), especially if MSAs/Customs and PAs are considered (92%, n=59 and 82%, n=10). However, a significant part of economic operators (33%, n=24), and civil society representatives (31%, n=23) disagree.

A very strong agreement is reached by all the respondents on the power to do **mystery shopping** (87%, n=188). Consequently, no significant divergences appear across the categories.

On the contrary, a certain variability appears in the opinions on the power to **take interim restrictive measures on pending compliance assessment**. Even if the majority of respondents agree on this measure, 40% (n=27 and n=19) of economic operators and industry associations are against, as well as 25% (n=3) of PAs.

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economic operators that do not submit to inspections: n = 211. In addition, 11% (n=28) respondents chose the "no opinion" option; *Take samples for free*: n = 216. In addition, 10% (n=23) respondents chose the "no opinion" option; *Do mystery shopping*: n = 216. In addition, 10% (n=23) respondents chose the "no opinion" option; *Take interim restrictive measures pending compliance assessment*: n = 222. In addition, 7% (n=17) respondents chose the "no opinion" option; *Take restrictive measures to stop infringements*: n = 217. In addition, 2% (n=22) respondents chose the "no opinion" option; Take restrictive measures to prevent future infringements: n = 203. In addition, 15% (n=36) respondents chose the "no opinion" option; *Impose dissuasive fines for non-compliance*: n = 217. In addition, 9% (n=22) respondents chose the "no opinion" option; *Conduct inquiries to gain more specific knowledge of the market*: n = 208. In addition, 13% (n=31) respondents chose the "no opinion" option; *Carry out an inspection on behalf of another EU MSA upon request*: n = 198. In addition, 17% (n=41) respondents chose the "no opinion" option; *Notify acts on behalf of another EU MSA upon request*: n = 186. In addition, 22% (n=53) respondents chose the "no opinion" option; Enforce fines on behalf of another EU MSA upon request: n = 186. In addition, 16% (n=38) respondents chose the "no opinion" option.

A wide and strong agreement is found in the option for **MSAs to take restrictive measures against Economic operators to stop infringements**, where overall 92% of stakeholders agree. Only economic operators slightly differ from the average, though 85% (n=55) of them agree.

There is also a wide consensus among respondents in relation to the power **to take restrictive measures against economic operators to prevent future infringements** (64%, n=130). Among the categories, only a small share of economic operators slightly differ from the average, as 21% (n=13) of them disagree.

No substantial differences are reported in relation to **the power to impose dissuasive fines for non-compliance**. The strongest agreement on this issue is expressed by MSAs/Customs (46% of respondents, n=28).

A strong alignment is reported also in favour of the **power to conduct sector inquiries to gain more specific knowledge of the market** (87%, n=181). There are no diverging views on this issue and the highest share of disagreement, equal to 16% (n=7), is expressed by respondents from industry associations.

For the power to **carry out inspection on behalf of another EU MSA**, PAs seems divided, with 55% (n=5) that disagree. Also a significant part of economic operators disagree (30%, n=19), while an impressive 93% (n=42) of industry associations either agree or strongly agree. Finally, 21% (n=6) of civil society representatives and 22% (n=12) of MSAs are against this possibility.

The power to **notify acts on behalf of another EU Member State's authority upon request** is not fully supported by respondents. Except for Industry associations (only 12% disagree, n=5), a significant part among all categories (from 27% of civil society representatives, n=7 to 38% of PAs, n=3) disagree.

The power to **enforce fines on behalf of another EU Member State's authority upon request** encounters a quite low support with respect to previous options (58% overall, n=108). Especially MSAs seem slight against this power (53% either disagree or strongly disagree, n=26), and the other categories disagree from 32% (n=8) of civil society representatives, 39% of economic operators (n=24) and of industry associations (n=16) and 44%of PAs (n=4).

If the results of the **targeted surveys** are considered, 70% of respondents indeed report there is **no need to grant any additional powers to allow MSAs to enter businesses' premises.**[328] Broken down by category, differences in the expressed opinions appear to be relevant. The largest part of respondents from industry associations and MSAs disagree on the need to grant more powers (82%, n=9 and 68%, n=46 respectively). Instead, respondents from companies are perfectly divided as 50% (n=1) of them support the need to grant MSAs more powers to enter businesses' premises.

In addition, 57% of respondents from different categories report that **MSAs have enough powers to effectively detect non-compliance and obtain corrective actions**. Analysed by category, 64% (n=7) of respondents from industry associations believe that there is no need to

328 In this regard a Spanish and two Belgian industry associations state that additional powers are not necessary if not accompanied by more financial and human resources.

grant Authorities in charge with EU external border controls any additional power. However, respondents from companies show more variability in the collected responses, as 50% (n=1) of them do not align with the previous position.

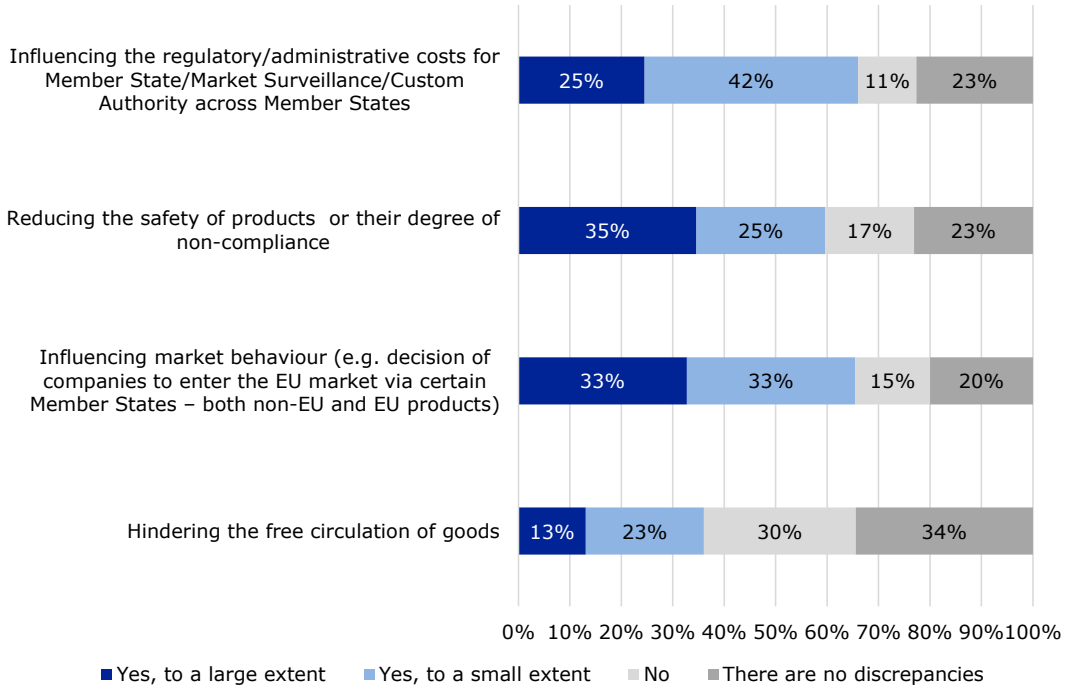
The majority of respondents to the surveys (58%) report not to be aware **of any discrepancies across EU Member States**. Some diverging views appear when responses are analysed by category. The majority of respondents from industry associations (64%, n=7) and from civil society associations (67%, n=2) confirm to be aware of discrepancies across EU Member States. A certain variability also appears in the case of MSAs as 46% (n=31) of them consider to be aware of discrepancies across EU Member States.

8.1.3.1.2 Uniformity and rigorousness of controls

As for the **uniformity and rigorousness of controls by MSAs**, 71% of respondents to the survey report to be not aware of any discrepancies across sectors in their Member State. Analysed by category, the majority of respondents from coordinating authorities (85%, n=11), Custom Authorities (74%, n=14) and MSAs (66%, n=45) share this opinion. However, 67% (n=2) of respondents from civil society associations and 34% (n=23) of respondents from MSAs provide an opposite opinion.

According to respondents to the survey, **discrepancies in market surveillance activities** mainly affect regulatory/administrative costs of businesses across Member States (67%) as well as firms' market behaviour (66%), as shown in the figure below.

Figure 4-37 - Effects of discrepancies in market surveillance activities



Source: targeted surveys[329]

329 *Hindering the free circulation of goods*: n = 61. In addition, 55% (n=76) of respondents chose the "I do not know" option; *Influencing the regulatory/administrative costs of businesses across Member States*: n = 53. In addition, 61% (n=83) of respondents

Opinions provided on possible effects of discrepancies in market surveillance activities vary when responses to the survey are broken down by category.

In relation to the **free circulation of goods**, 75% (n=3) of industry associations consider that such discrepancies do not hinder the free circulation. On the contrary, 42% (n=5) of Custom authorities believe that discrepancies in market surveillance activities affect the circulation of goods from a small to a large extent.

As for **market behaviour**, 75% (n=3) of respondents from industry associations and 70% (n=18) of respondents from MSAs believe that such discrepancies influence market behaviour.

However, the same percentage of respondents from industry associations consider that discrepancies might **reduce the safety of products or their degree of non-compliance** but only to a small extent. Differently, all respondents from civil society associations (n=2) and 45% (n=5) of responding Custom authorities think that the impact is more severe in this sense.

Despite the fact that the majority of respondents consider that discrepancies **influence the regulatory/administrative costs for Market Surveillance/Customs Authorities across Member States**, responses need to be broken down by category to provide a clearer picture. While coordinating authorities and MSAs are in line with this position, 27% (n=3) of Customs Authorities believe that no impact on regulatory/administrative costs is caused by such discrepancies.

8.1.3.1.3 Powers of sanction

52% (n=83) of respondents to the public consultation think that the current framework of market surveillance provides insufficient deterrence, while 48% believe it is sufficient to a significant (10%, n=15) or to a moderate extent (38%, n=59). Interestingly, if compared to other categories, few MSAs or Customs (37%) and PAs (25%) declare that the current framework does not provide sufficient deterrence. Percentage of other categories are higher than 59% in this opinion.

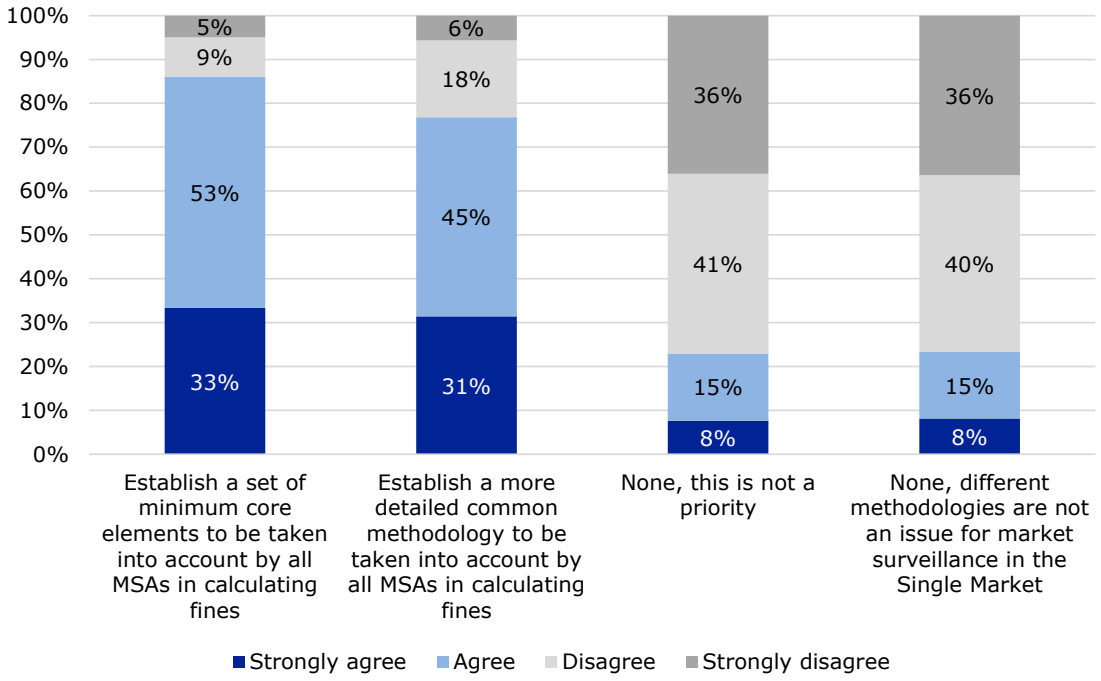
A number of stakeholders indeed state that penalties are not sufficiently high to prevent non-compliant behaviour.[330]

Divergences exist in the methodologies applied by MSAs in different Member States to sanction non-compliant businesses. As shown in the figure below, respondents to the public consultation think it is very important to establish **a set of minimum core elements as well as a more detailed common methodology** to be shared and taken into account by all MSAs in calculating fines. As a proof, only a minority of respondents think this is not a priority and/or that the existence of different methodologies are not an issue in the Internal Market.

chose the "I do not know" option; *Influencing market behaviour*: n = 55. In addition, 60% (n=82) of respondents chose the "I do not know" option; *Reducing the safety of products or their degree of non-compliance*: n = 52. In addition, 62% (n=85) of respondents chose the "I do not know" option.

330 Eight MSAs (CY, 2 DE, 2 FI, LT, NO, PL), two economic operators (AT, FR), five industry associations (2 BE, EL, ES, FR), two consumer organisations (2 BE), a German academic/law firm, a French other.

Figure 4-38 - Measures to be taken to address differences in methodologies to sanction non-compliant businesses



Source: public consultation[331]

If the breakdown per stakeholder category is considered, **a strong agreement on the need to establish a set of minimum core elements** for calculating fines is registered. The only category that significantly disagrees is that of PAs (30%, n=3). Overall 88% stakeholders agree on this matter.

On finding a detailed **common methodology** instead, 'agree' answers drop down to 76%. In this case, 33% (n=17) of MSAs disagree, together with 29% (n=2) of PAs, 24% (n=11) of Industry associations and 18% (n=11) of economic operators.

However the two options of **finding a set of minimum core elements and a more detailed common methodology** are a priority, with only 23% of respondents thinking this is not. PAs stand out with 36% (n=4) of them stating that this is not a priority, followed by 28% (n=12) of Industry associations, 26% (n=13) of MSAs or Customs, 18% (n=10) of economic operators and 14% (n=4) of civil society representatives.

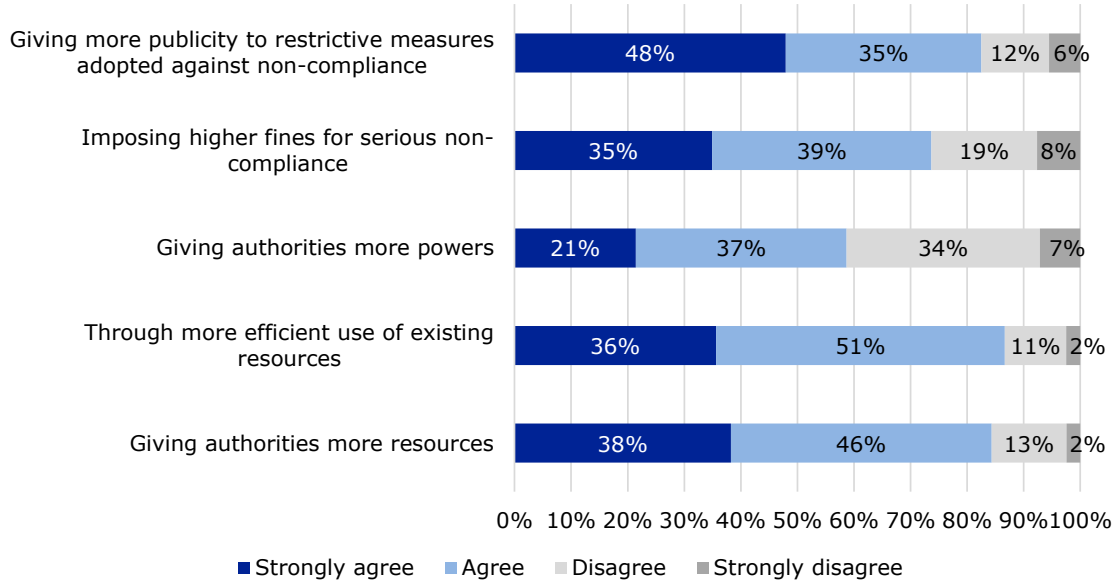
Looking specifically at the **different methodologies existing across Member States for enforcing market surveillance**, it is evident that most of categories consider it is an issue (76% overall). Like in the previous answer, the first category non-aligned with the overall trend is represented by PAs, 40% (n=4) of them considering this not being an issue. Similarly, there is a significant part of MSAs (29%, n=13) and Industry associations (26%, n=11) that do not consider this to be an issue.

331 *Establish a set of minimum core elements to be taken into account by all MSAs in calculating fines*: n = 201. In addition, 16% (n=38) of respondents chose the "No opinion" option; *Establish a more detailed common methodology to be taken into account by all MSAs in calculating fines*: n = 194. In addition, 19% (n=45) of respondents chose the "No opinion" option; *None, this is not a priority*: n = 183. In addition, 23% (n=56) of respondents chose the "No opinion" option; *None, different methodologies are not an issue for market surveillance in the Single Market*: n = 184. In addition, 23% (n=55) of respondents chose the "No opinion" option.

8.1.3.1.4 Solutions to increase the deterrence power of market surveillance

The following figure reports the opinion of stakeholders **on possible solutions to increase the deterrence power of market surveillance**. Giving more publicity to restrictive measures so as to exploit the reputation effect, and a more efficient use of existing resources are the two top options. The least appreciated solution is giving authorities more powers.

Figure 4-39 - Solutions proposed by respondents to the public consultation to increase MSAs' deterrence power



Source: public consultation[332]

If we look at the breakdown per categories, there is a substantial alignment on the **option of giving authorities more resources**, with the overall agreement of 84%. Economic operators represent the category that differs much, considering 29% (n=17) of them disagree. They are closely followed by 29% (n=9) of civil society representatives.

A stronger agreement is registered if the option on **a more efficient use of existing resources** is put forward (87%), with 95% (n=54) of economic operators and 94% (n=44) of Industry associations respectively being in favour of this. On the other hand, the strongest disagreement comes from 36% (n=4) of PAs.

The least appreciated option is definitely to **give authorities more power**, and even if the overall majority of respondents (58%) agree on this option, views change according to the category observed. On the one hand, 70% (n=21) of civil society representatives agree. On the other hand, the majority of Industry associations disagree (56%, n=22), as well as more than 40% of PAs and economic operators (n=4 and n=24).

332 *Giving more publicity to restrictive measures adopted against non-compliance*: n = 217. In addition, 9% (n=22) of respondents chose the "No opinion" option; *Imposing higher fines for serious non-compliance*: n = 209. In addition, 13% (n=30) of respondents chose the "No opinion" option; *Giving authorities more powers*: n = 196. In addition, 18% (n=43) of respondents chose the "No opinion" option; *Through more efficient use of existing resources*: n = 202. In addition, 15% (n=37) of respondents chose the "No opinion" option; *Giving authorities more resources*: n = 204. In addition, 15% (n=35) of respondents chose the "No opinion" option.

About the proposition of **imposing higher fines for serious non-compliance** there is also a substantial agreement (74%) with the only exception of PAs, which are perfectly split on this option (n=6). The other categories anyway for a significant part dislike this option at least in 20% of answers, up to 32% for Industry associations (n=15).

Significant agreement is also registered on the option of **giving more publicity to restrictive measures**, where 83% of four categories out of five agree. The only exception is represented by Industry associations, where only 62% (n=31) of respondents support this option. The highest share of positive answers is from MSAs (90%, n=53) and civil society representatives (94%, n=31).

In order to reduce the level of non-compliant products on the market, stakeholders do not show an overwhelming preference (48% positive, 52% negative) when asked if the responsibility for ensuring product compliance should be left to the businesses. Instead, almost all of respondents (87%) agree that MSAs should provide information on product requirements in addition to enforcement or support to companies through guidance on how to interpret product requirements (78%). Finally, agreements between businesses and authorities are considered effective by 54% of respondents.

When asked if National authorities should focus exclusively on enforcement and leave it entirely up to the businesses to ensure compliance by developing their own approaches, categories are not aligned on considering this measure effective. Only economic operators (59%, n=27) and PAs (70%, n=7) find it effective. The majority of other categories voted for "not effective", for an average of 59.5% (n=around 63).

Overall, the best approach according to stakeholders is that **authorities should also provide support to businesses through guidance on how to interpret product requirements**, justified by 44% of respondents that consider it an effective or very effective (34%) prerogative, with the lowest number of 71% (considering both positive answers) from MSAs.

All the categories also agree that **national authorities should provide information on product requirements**. Every group consider this effective in a range from 80% to 93%, and nearly 30% find it very effective.

National authorities should also allow businesses to enter into agreements with authorities to receive binding advice from them on how to interpret product requirements in specific situations: for only 54% of the sample considered, this measure is effective (of which 19% chose very effective). Numbers are explained by the fact that two categories dislike this measure (75%, n=21 for MSAs and 67%, n=4 for PAs), even if the overall score is positive.

8.1.3.1.5 General description of market surveillance activities and relevant procedures

In light of technological developments and due to the increasing importance of e-commerce, particular attention has to be paid to **online sales and related market surveillance activities**. As a further proof, 80% (n=67) of respondents to the targeted surveys state there are **issues related to online trade,** with three large consumer associations based in different Member States[333] encountering difficulties in performing their activities due to online trade.

333 BE, DE, IT.

More precisely, 88% of MSAs (n=49) and industry associations (n=7) share this opinion. A certain level of opposition is expressed by Custom authorities as 40% (n=6) of them consider that there are no issues/obstacles related to online trade. In opposition with the majority, 75% (n=3) of respondents from companies deny any obstacle/issue related to online trade.

8.1.3.1.6 Customs, controls of imported products

As to specific issues with/obstacles to checks of products imported into the EU carried out by Authorities in charge of EU external border controls, 61% of total respondents to the targeted surveys report none. Broken down by category, the majority of respondents from industry associations and Custom authorities report no obstacles (73%, n=8 and 61%, n=11 respectively). Differently, responses from MSAs on this issue are partially divergent as 50% (n=18) of them consider that there are obstacles to checks of products imported into the EU.

More than half of respondents to the public consultation declare to have experienced non-compliance of products imported from non-EU countries. In particular, 20% of them think that most of these products are non-compliant and 56% think that some of them are non-compliant. In addition, **imported products are often sold online,**[334] this making enforcement even more challenging. Looking at the different categories, 44% (n=4) of PAs believe that most of products imported from non-EU countries are affected by non-compliance, closely followed by 30% (n=13) of respondents among economic operators. Furthermore, 70% (n=31) of industry associations consider that only some of them are affected by non-compliance.

Finally, the majority of respondents to the public consultation from all the categories (70%) consider that **there are non-compliant products in their sector imported from non-EU countries supplied 'online'**. In detail, 21% (n=11) of respondents from MSAs/Customs believe that non-compliance affects most of the imported products from non-EU countries. However, while 18% (n=4) of civil society representatives share this opinion, 23% (n=5) of them totally disagree on this issue. However, also **Intra-EU trade** represents a large share of overall EU trade, inasmuch as 58% of respondents declare that more than 41% of products available in their sector is imported from a different EU Member State.

In general, stakeholders consulted are in favour of the possibility for EU manufacturers or importers to be contacted by MSAs of another EU Member State. The majority of them consider it as a right of MSAs to contact economic operators outside their jurisdiction. Furthermore, most respondents think it would be useful for authorities to discuss non-compliance directly with businesses having the highest level of responsibility and knowledge, thus eventually resulting in the correction of non-compliance in the Single Market. As shown in the figure below, stakeholders outline that the main difficulties faced by MSAs in taking action against non-compliant products traded by businesses located in another EU Member State are represented by online sales (47% agree or strongly agree). Other difficulties to enforcement relate to the lack of businesses' willingness to collaborate with respect to MSAs' requests for corrective actions (57%) or for information/documentation (67%). In addition, 68% of respondents declare that businesses sanctioned do not pay penalties imposed by MSAs.

334 Based on the results of the public consultation, 14% of respondents report that most of them are sold online, 56% say that some of them are sold online and 18% think that only a few are supplied online.

Difficulties in taking actions against non-compliant products traded by businesses located outside the EU are due to different reasons, as presented in the figure below. The main obstacle is represented by sanctioned businesses not paying fines, ignoring requests for corrective actions or not replying to requests for information and/or documentation. Again, online sales are considered an important obstacle to proper enforcement.

Figure 4-40 - Stakeholders' perception of difficulties in taking action against non-compliant imported products

Source: public consultation[335]

About the perception of difficulties in tacking action against non-compliant imported products, the fact that **authorities do not know how to identify and contact businesses located in non-EU countries**, is not felt by stakeholders as a main problem. Every group disagree, although not with significant numbers. Economic operators for example consider this topic irrelevant only in 53% (n=19) of cases.

On the fact that **authorities find it more costly to contact businesses located in non-EU countries**, there is no unique perception. On the one hand, around 70% economic operators and Industry associations agree (n=23 and n=22 respectively), while 58% (n=4) of PAs, 60% (n=9) of Civil society representatives and 73% (n=38) for MSAs disagree.

335 *In particular in the case of goods traded online businesses*: n = 194. In addition, 19% (n=45) of respondents did not reply; *Businesses sanctioned do not pay penalties*: n = 195. In addition, 18% (n=44) of respondents did not reply; *Businesses contacted do not reply to requests for corrective actions*: n = 195. In addition, 18% (n=44) of respondents did not reply; Bu*sinesses contacted do not reply to requests for information/documentation*: 192. In addition, 20% (n=47) of respondents did not reply; *Authorities find it more costly to contact businesses located in non-EU countrie*s: 195195195. In addition, 18% (n=44) of respondents did not reply; *Authorities do not know how to identify and contact businesses located in non-EU countries*: n = 196. In addition, 18% (n=43) of respondents did not reply.

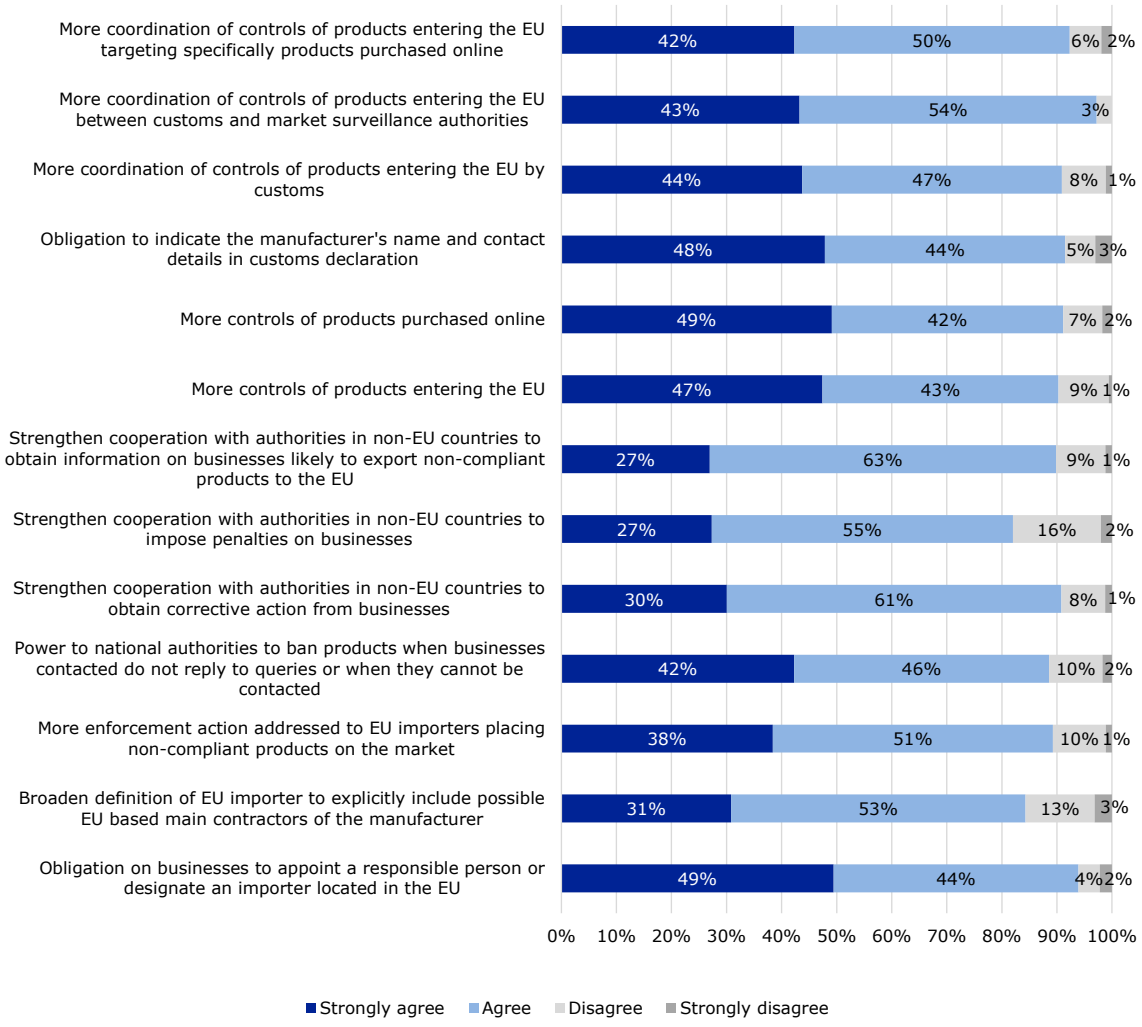
A more clear view can be seen on the perception that **businesses contacted do not reply to requests for information/documentation**. There is agreement on considering it as a problem, according to 65% of stakeholders on average (n= around 77). Similarly, the fact that businesses **do not reply to request for corrective actions**, is perceived as a problem by 72% (n=78) of stakeholders on average with a peak on PAs (100%, n=6).

The perception of difficulties when **businesses sanctioned do not pay penalties** is shared by overall 68% of respondents,[336] with another peak for PAs (100%, n=3) and with the exception of 60% of civil society representatives that disagree, half of them **strongly**. Specifically for difficulties with **businesses trading goods online,** agreement is also shared among stakeholders, but numbers are quite different, starting from the lowest 67% (n=8) of civil society representatives to the highest 100% (n=5) of PAs.

In order to take actions against non-compliant imported products, stakeholders support the idea of a higher level of coordination of controls between Customs authorities and MSAs, the obligation for foreign businesses to appoint a responsible person or importer located in the EU, stronger cooperation between European MSAs and non-EU countries' authorities and more control over specific products purchased online.

Figure 4-41 - Stakeholders' preferences about actions to be taken against non-compliant products traded by businesses located in non-EU countries

336 Number of respondents: Civil society: 10; economic operators: 17; Industry associations: 13; MSAs: 21; PAs: 3.



Source: public consultation[337]

All categories state that an **obligation on businesses to appoint a responsible person or designate an importer located in the EU** is a viable option to help taking action against non-compliant products traded by businesses located in a non-EU country, as 49% strongly agree

337 *More coordination of controls of products entering the EU targeting specifically products purchased online*: n = 156. In addition, 21% (n=37) of respondents chose the "no opinion" option, while 19% (n=46) did not reply; *More coordination of controls of products entering the EU between customs and MSAs*: n = 178. In addition, 11% (n=18) of respondents chose the "no opinion" option, while 18% (n=43) did not reply; *More coordination of controls of products entering the EU by Customs*: n = 176. In addition, 13% (n=21) of respondents chose the "no opinion" option, while 18% (n=42) did not reply; *Obligation to indicate the manufacturer's name and contact details in Customs declaration*: n = 165. In addition, 19% (n=30) of respondents chose the "no opinion" option, while 18% (n=44) did not reply; More controls of products purchased online: n = 169. In addition, 17% (n=27) of respondents chose the "no opinion" option, while 18% (n=43) did not reply; *More controls of products entering the EU*: n = 175. In addition, 14% (n=22) of respondents chose the "no opinion" option, while 18% (n=42) did not reply; *Strengthen cooperation with authorities in non-EU countries to obtain information on businesses likely to export non-compliant products to the EU*: n = 167. In addition, 15% (n=29) of respondents chose the "no opinion" option, while 18% (n=43) did not reply; *Strengthen cooperation with authorities in non-EU countries to impose penalties on businesses*: n = 150. In addition, 23% (n=46) of respondents chose the "no opinion" option, while 18% (n=43) did not reply; *Strengthen cooperation with authorities in non-EU countries to obtain corrective action from businesses*: n = 163. In addition, 17% (n=32) of respondents chose the "no opinion" option, while 18% (n=44) did not reply; *Power to national authorities to ban products when businesses contacted do not reply to queries or when they cannot be contacted*: n = 175. In addition, 13% (n=21) of respondents chose the "no opinion" option, while 18% (n=43) did not reply; *More enforcement action addressed to EU importers placing non-compliant products on the market*: n = 177. In addition, 13% (n=22) of respondents chose the "no opinion" option, while 17% (n=40) did not reply; Broaden definition of EU importer to explicitly include possible EU based main contractors of the manufacturer: n = 159. In addition, 19% (n=36) of respondents chose the "no opinion" option, while 18% (n=44) did not reply; Obligation on businesses to appoint a responsible person or designate an importer located in the EU: n = 180. In addition, 11% (n=17) of respondents chose the "no opinion" option, while 18% (n=36) did not reply.

and 44% agree (n=167 overall). PAs represents the least aligned with 22% (n=2) that disagree.

Broaden definition of EU importer to explicitly include possible EU based main contractors of the manufacturer in the absence of a Civil society representatives responsible person in the EU is also welcomed with no significant deviation from a specific group. Overall 84% agree on this, in range from 78% to 88% considering the single percentage of every category.

In accordance to the previous options, four categories think that more enforcement action addressed to EU importers placing non-compliant products on the market might definitely help, for 89% of respondents, except for PAs (n=6) that are perfectly split.

Strong agreement among all categories also about giving **the power to national authorities to ban products when businesses contacted** do not reply to queries or when they cannot be contacted. From the overall sum of 88% for agree (46%) and strongly agree (42%), groups are allocated between 80% and 92%.

Every category agree on strengthening cooperation with authorities in non-EU countries to perform various activities. In order to obtain corrective action from businesses, four groups are aligned with an overall 91%, except for PAs that agree only in 67% (n=6) of answers. There is substantial agreement also to impose penalties on businesses, but in this case PAs differ significantly from the average –equal to 82%- with a specific percentage of 56% (n=5) on agree and 0% on strongly agree. Finally, there is a strong agreement if the goal is to obtain information on businesses likely to export non-compliant products to the EU, where there is no difference from the overall 90% worthy of note.

All the five categories agree when asked on making **more controls on products entering the EU**, and especially on products purchased online. Overall, 90% of respondents agree on this issue. Analysed by category, 59% (n=32) of MSAs/Customs and 55% (n=22) of civil society representatives express the strongest agreement.

The **obligation to indicate the manufacturer's name and contact details in Customs declaration** is widely accepted by all the sample considered. Considering an overall average of 92%, respondents slightly vary across categories. Only 20% (n=4) of civil society representatives disagree.

On the option of **more coordination of controls of products entering the EU by Customs** (e.g. more exchange of risk information, alignment of measures) all categories are quite aligned on the overall 91%, even if it must be noted of the short distance of Civil society representatives, whose rate of agreement stops at 77% (n=16).

Together with more controls on products, **more coordination of controls on products entering the EU between Customs and MSAs** is broadly needed. Overall, 97% of respondents agree on the need for more coordination especially economic operators as they all (n=45) support this option.

Further coordination of controls is also encouraged in relation **to products purchased online** *(e.g. via a pan-European Task Force of national authorities)*. Also in this case, economic operators widely agree on this opinion (97%, n=35) closely followed by respondents from industry associations (95%, n=39).

Based on respondents' opinion, contacting EU manufacturers or importers located in another EU Member State would be easier through **specific procedures for mutual assistance among authorities of different EU Member States** (91%). Other widely supported options were the possibility to impose stricter obligations on MSAs to respond to requests for mutual assistance (85%) or through granting MSAs the possibility to ask other authorities to sanction businesses located in the latter's country when they refuse to cooperate (85%).

Looking at the **main reasons for product non-compliance**, respondents to the public consultation have provided a ranking (from 1 to 5, 1 being the most important reason) of possible options based on their perception and experience. Above all, there is no a clear distribution of the answers provided, nor significant trends among different groups to be reported.

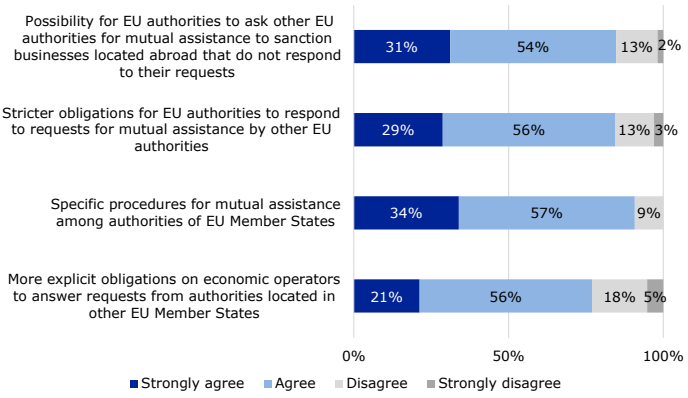
Nearly the majority does not consider non-compliance as a **deliberate choice to exploit market opportunities at the lowest cost**, given the concentration of answers on levels 1 and 2 (48%). A divergent opinion comes from 52% (n=33) of MSAs that chose levels 3 and 4.

A clearer opinion comes when considering the **lack of knowledge**. 57% of respondents chose 1-2, while 43% the remaining, so we can assume that this is perceived as a main reason for non-compliance.

The third option, **a technical or civil society representatives' type of inability to comply with rules**, is seen as a moderate cause: when considering an average of total answers, the result would probably be slightly above level 3. The same conclusion comes from the option **carelessness**, with the only exception of respondents of PAs (n=12), more distributed around level 2.

The last reason, **ambiguity in the rules**, can be considered the first in rank, since 51% of answers are on the two highest levels and 73% from level 3. Also there is a quite similar trends among stakeholders, except for Economic operators.

Figure 4-42 - Possible solutions to ease MSAs' contact with EU manufacturers or importers located in another EU Member State



Source: public consultation[338]

338 *Possibility for EU authorities to ask other EU authorities for mutual assistance to sanction businesses located abroad that do not respond to their requests*: n = 164. In addition, 11% (n=27) of respondents chose the "no opinion" option, while 20% (n=48) did not

8.1.3.1.7 Cooperation with other Member States and third countries

In the targeted surveys, the majority (77%, n=66) of MSAs and Customs state that they cooperate with authorities based in other Member States, while only 23% (n=20) do not. In detail, 85% (n=57) of respondents from MSAs confirm that they usually cooperate while only 47% (n=9) of Custom Authorities act in cooperation with other Customs. Cross-country communication and cooperation is considered useful by nearly all respondents.

According to respondents to the targeted surveys, the **AdCO groups** allow a flexible and efficient form of cooperation between Member States.[339] All (n=13) coordinating authorities confirm that the **MSA in their Member State participates in AdCO activities**. Notably, this opinion is shared by 88% (n=59) of responding MSAs.

As mentioned above, EU MSAs can share information on measures adopted to restrict the marketing of non-compliant products through several means such as RAPEX and ICSMS, the notification procedures, expert groups and AdCOs. However, according to 40% (n=38)[340] of respondents to the public consultation, **MSAs rarely restrict the marketing of a product following the exchange of information about measures adopted by another authority in the EU against the same product**. This occurs "*sometimes*" according to 34%% (n=32)[341] of stakeholders, while a minority declare that it "*very often*" (12%[342], n=11) or "*always*" (6%, n=6[343]) occurs. A minority, 8% (n=8[344]) of respondents thinks that MSAs never exploit information coming from other EU MSAs.

Figure 4-43 - Stakeholders' opinion on the possibility that a national authority uses information on measures adopted to restrict the marketing of non-compliant products by another EU authority to adopt restrictive measures against the same products supplied within its own jurisdiction

reply; *Stricter obligations for EU authorities to respond to requests for mutual assistance by other EU authorities*: n = 167. In addition, 10% (n=23) of respondents chose the "no opinion" option, while 21% (n=49) did not reply; *Specific procedures for mutual assistance among authorities of EU Member States*: n = 174. In addition, 8% (n=18) of respondents chose the "no opinion" option, while 20% (n=47) did not reply; *More explicit obligations on economic operators to answer requests from authorities located in other EU Member States*: n = 174. In addition, 8% (n=18) of respondents chose the "no opinion" option, while 20% (n=47) did not reply.

339 Four MSAs, a Member State coordinating authority.

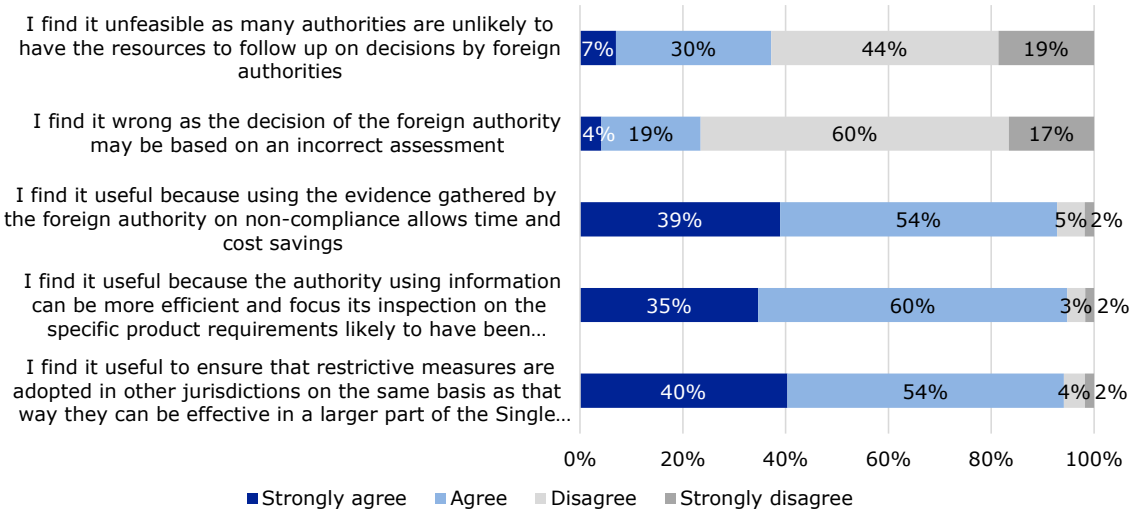
340 Nine MSAs or Custom authorities, four PAs, ten economic operators, ten industry associations, a Belgian trade union, 1 consumer organisation (BE), an English consumer/citizen, two others (BE, SK).

341 13 MSAs or Customs authorities, five economic operators, ten industry associations, an English international organisation, two academic/law firms (DE, UK), a French other.

342 Six MSAs or Customs authorities, two industry associations (BE, PT), a German academic/law firm (DE), two German others.

343 Four MSAs or Customs authorities, a German public authority (DE), an English industry association.

344 A Norwegian MSA, four economic operators (ES, FR, SE, UK), three industry associations (ES, FR, IT).



Source: public consultation[345]

The majority of respondents from the different categories share a positive opinion on the **possibility for a national authority to use information on measures adopted to restrict the marketing of non-compliant products by another EU Member State authority** in order to improve its efficiency and targeted action. Analysed by category, all PAs (n=8) and civil society representatives (n=25) find it useful to ensure that restrictive measures are adopted on the same basis, so as they can be effective in a larger part of the Internal Market. Very few divergent views are provided in the other categories.

Furthermore, the majority of respondents to the public consultation find this possibility as useful because the **MSA using information on measures adopted can be more efficient and focus on the specific product requirements likely to have been infringed**. As in the previous case, all civil society representatives (n=25) and PAs (n=8) responding to this question share this opinion, while few economic operators disagree (12%, n=5).

Almost all the respondents from the different categories also consider that such use of information would be **useful because using the evidence gathered by the foreign authority on non-compliance allows time and cost savings.** Only few economic operators disagree with this opinion (14%, n=6).

Although the majority of respondents disagree with the opinion that **the decision of the foreign authority may be based on an incorrect assessment**, diverging views appear within some categories. More precisely, respondents from the industry associations and economic operators admit the possibility of an incorrect assessment (36% and 37% respectively, n=13 each).

345 *I find it unfeasible as many authorities are unlikely to have the resources to follow up on decisions by foreign authorities*: n = 129. In addition, 26% (n=61) of respondents chose the "no opinion" option, while 21% (n=49) did not reply; *I find it wrong as the decision of the foreign authority may be based on an incorrect assessment*: n = 145. In addition, 18% (n=44) of respondents chose the "no opinion" option, while 21% (n=50) did not reply; *I find it useful because using the evidence gathered by the foreign authority on non-compliance allows time and cost savings*: n = 167. In addition, 10% (n=24) of respondents chose the "no opinion" option, while 20% (n=48) did not reply; *I find it useful because the authority using information can be more efficient and focus its inspection on the specific product requirements likely to have been infringed*: n = 173. In addition, 8% (n=18) of respondents chose the "no opinion" option, while 20% (n=48) did not reply; *I find it useful to ensure that restrictive measures are adopted in other jurisdictions on the same basis as that way they can be effective in a larger part of the Single Marke*t: n = 171. In addition, 8% (n=20) of respondents chose the "no opinion" option, while 20% (n=48) did not reply.

Finally, the majority of respondents think that such a use of information by a national authority would be unfeasible, as **MSAs are unlikely to have the resources to follow up on decisions by foreign authorities**. However, more than half of economic operators (57%, n=20) do not align with the majority along with a relevant share of respondents from industry associations (47%, n=11).

When asked about ways to increase the effectiveness of market surveillance, most of the respondents to **the public consultation** have suggested **more exchange of information and discussion among EU national authorities prior to final assessment on product non-compliance and corrective action so as to prevent diverging conclusions among authorities.** Broken down by category, nearly all the respondents from the industry associations (n=42) and economic operators (n=46) support this option.

The majority of respondents also believe that effectiveness can be increased by adopting **stricter rules on follow up to restrictive measures adopted by EU authorities**. However, 57% (n=4) of respondents from PAs disagree on this.

Furthermore, most of the respondents suggest the introduction of **legal principles to ensure easy replication of measures taken by authorities in other EU Member States** (e.g. portability of test results, presumption that products found to be non-compliant in Member State A are also non-compliant in Member State B). Namely, almost all the respondents from MSAs/Customs (91 agree on this issue, closely followed by industry associations (83%, n=33).

A great consensus is also reached by respondents on a **procedure for the recognition of national decisions in other EU Member States**. Diverging views are expressed by respondents from PAs as 40% (n=2) of them strongly disagree on such procedure.

On the contrary, a high level of disagreement is expressed by respondents from different categories on the **direct applicability of national decisions in other EU Member States**. Results split by category show a high degree of opposition from PAs (88%, n=5). Nearly half of civil society representatives (n=10) and respondents from economic operators (n=20) also disagree with this opinion.

In addition, the majority of respondents agree on the suitability of **decisions against non-compliant products to be taken by authorities of various EU Member States in close coordination and being applicable simultaneously in all relevant jurisdictions**. The strongest opposition in this case comes from respondents of PAs (51%, n=4) along with MSAs/Customs (42%, n=21).

More than half of respondents from the different categories, also support **the appointment of a lead authority to facilitate coordination of national decisions**. Against the other categories, 86% (n=6) of respondents from PAs disagree on the previous opinion.

Diverging opinions are expressed in relation to the possibility of a **lead authority with powers to adopt decisions against non-compliant products applicable in different Member States** (e.g. subject to consultation with relevant national authorities). Among the different categories, 65% (n=34) of MSAs/Customs disapprove this option.

Half of the respondents also disagree on the possibility for the **Commission to take decisions against non-compliant products supplied in various EU Member States**. The largest

opposition is expressed by respondents from industry associations (59%, n=23) and PAs (51%, n=4).

Finally, the majority of respondents agree on providing **powers to the Commission to check the functioning of market surveillance in Member States**. Looking at the categories, 93% (n=37) of respondents from the industry associations and 87% (n=38) of economic operators support this option.

8.1.3.2 Efficiency

Most of the respondents from the different categories **to the public consultation** agree on the fact that a broader use of electronic means to demonstrate compliance would help **reduce the administrative burden for businesses**. Interestingly, respondents from PAs totally agree with this opinion while low percentages of respondents from industry associations and economic operators disagree (27%, n=11 and 18%, n=9 respectively).

Most of the respondents also believe that a broader use of electronic means to demonstrate compliance helps **reduce the administrative costs of enforcement for authorities**. In detail, civil society representatives (91%, n=19) and PAs (86%, n=6) are the categories that support this opinion the most. On the contrary, 32% (n=11) of respondents from industry associations disagree on this issue.

Furthermore, nearly all the respondents from the different categories agree that the use of electronic means would **provide/allow information to be obtained faster**. Only 10% of respondents from industry associations (n=4) and MSA/Customs (n=4) disagree with the majority.

Similarly, the majority of respondents consider that it would help **provide further information to consumers/end users**. Namely, all (n=6) respondents from the PAs share this opinion. However, 30% (n=10) of respondents from industry associations disagree on this issue.

Based on the experience of many respondents, a broader use of electronic means to demonstrate compliance would help **provide up-to-date information to consumers/end users**. PAs and MSAs/Customs positively support this opinion while 33% (n=11) of respondents from industry associations consider that consumers/end users would not receive up-to date information.

Respondents have also been invited to share their views about different options to better exploit the potential of electronic means for demonstrating compliance. First of all, the majority of respondents show disagreement about a **voluntary decentralised 'Digital Compliance' system**, consisting of information available on the websites of economic operators and notified bodies (on a voluntary basis) and responsible for developing and maintaining such information. In particular, all (n=6) PAs show disagreement on this option. However, respondents from industry associations and civil society representatives are highly divided on this issue as approximately half of them are in favour of these system (n=10 and 20 respectively).

Opinions significantly vary in the case of a **compulsory decentralised 'Digital Compliance' system**. On the one hand, 76% of respondents from industry associations disagree on this option as well as 75% of responding civil society representatives. On the other hand, the

majority of PAs respondents (60%, n=3) agree on a compulsory decentralised system instead of a voluntary one.

Diverging opinions also appear in relation to a **voluntary centralised 'Digital Compliance' system**, established in the form of an electronic repository of information owned and maintained by the European Commission but with the possibility for manufacturers, authorised representatives, notified bodies to upload information regarding conformity of products. The strongest opposition comes from industry associations (71%, n=27) and economic operators (59%, n=27) while the other categories are equally divided.

Half of the respondents from all the categories is in favour of a **compulsory centralised 'Digital Compliance' system owned by the Commission**. In particular, this option is supported by 71% (n=27) of MSAs/Customs and by all PAs (n=6).

In addition, many respondents consider that an **e-labelling system containing the address of the electronic repository would be beneficial** for demonstrating compliance. More precisely, civil society representatives and PAs are the categories expressing the highest support (88%, n=15 and 83%, n=5 respectively).

According to the majority of the respondents, an **e-labelling system containing the product identification and/or manufacturer contact details would be beneficial** for the same scope. Also in this case, civil society representatives and PAs express the strongest support. On the contrary, 36% (n=13) of industry associations disagree on this issue.

The majority of respondents **to the public consultation** also find that **resorting to an automatic identification and data capture system to facilitate access to the repository would be beneficial** in the view of demonstrating compliance. Analysed by category, economic operators show diverging views as approximately half of respondents (53%, n=21) disagree with this option.

As for the resources available for market surveillance activities, the majority of respondents from the different categories agree on the fact that **revenues obtained through sanctions should be allocated to market surveillance activities**. Opinions expressed might diverge when respondents are broken down by category. Most of civil society representatives responding to the specific question, for instance, agree with this option (80%, n=25). However, a significant share of them (19%, n=6) express a completely opposite position. This issue is conflictual also among respondents from PAs, as 30% (n=3) of them strongly disagree on allocating revenues from sanctions to market surveillance activities. 25% of both MSAs/Customs (n=14) and industry associations (n=11) also disagree.

Most of the respondents from the different categories state that **MSAs should not levy administrative fees on operators in their sector to finance controls**. The strongest opposition in this sense is expressed by respondents from the industry associations and by economic operators (73%, n=36 and 51%, n=35 respectively). On the contrary, 64% (n=35) of respondents from the MSAs or Customs is in favour of administrative fees imposed on operators. Diverging views are expressed by respondents from civil society, with the majority of them being against (63%, n=21). Interestingly, few respondents from PAs (25%, n=3) seem to approve the possibility for MSAs to impose administrative fees on operators in their sector to finance controls.

When asked about **Programmes at European level**, the overwhelming majority of respondents from all the categories agreed on the fact that those programmes **should finance sufficient laboratory capacity in each Member State**. Looking at the different stakeholders' categories, nearly the totality of respondents from industry associations and PAs share the previous position (91%, n=39 and 90%, n=10 respectively). However, a significant percentage of economic operators (22%, n=14) disagree with the prevailing opinion on programmes at European level.

Respondents to the public consultation have been asked to reflect upon possible ways to **improve the efficiency in the use of resources for market surveillance activities in their sector**. The majority of respondents from all the categories consider that MSAs **should have more knowledge about the relevant sector** in terms of type and number of economic operators, market trends and other key aspects. Namely, all (n=47) the respondents from the industry associations share this opinion, closely followed by civil society representatives (97%, n=31). Some respondents from PAs and MSAs/Customs do not support the need for improved knowledge for MSAs in their sector of competence (16%, n=2 and 15%, n=9 respectively).

In addition, a large part of respondents from the different categories think that **MSAs should have stronger powers in order to ensure that resources for market surveillance activities are used more efficiently**. Diverging views appear when responses are analysed by category. More precisely, a high percentage of industry associations (46%, n=18) and PAs (45%, n=5) disagree with this opinion, together with 38% (n=23) of economic operators and 36% (n=12) of civil society representatives.

There is a strong agreement among the respondents from all the categories on the fact that **MSAs' inspectors should receive better training**. Significantly, 78% (n=45) of respondents from MSAs/Customs express this position. Looking at the other categories, nearly the totality of economic operators (n=64) and industry associations (n=47) responding to the PC, also share this view. A greater variety of opinions is reported by respondents from PAs.

As for the training received by MSAs' inspectors, the majority of respondents from the different categories consider that **MSAs' inspectors should receive more standardised training across the EU**. Namely, all the respondents from PAs (n=10) agree on this option. A strong consensus is also recorded among respondents from industry associations (96%, n=46), economic operators (86%, n=56) and civil society representatives (91%, n=32). Finally, 18% (n=10) of respondents from MSAs/Customs disagree.

According to the vast majority of respondents from the different categories, **MSAs within a Member State should share more intelligence to use resources more efficiently**. The analysis of answers by category does not show significant diverging views. Only a limited number of respondents from MSAs/Customs and PAs express different opinions (respectively 26%, n=15 and 30%, n=3 disagree).

A very large consensus is also reached by respondents on the fact that **MSAs of different Member States should share more intelligence**. Grouped by category, it is possible to notice that all (n=49) industry associations share this opinion. Very few respondents from the other categories disagree.

In order to increase the efficiency in the use of resources for market surveillance, 88% of respondents from the different categories consider that **MSAs within a Member State**

should better coordinate their action. The analysis of the answers broken by category reveals a very large agreement on the need for better coordination among industry associations (98%, n=48), civil society representatives (93%, n=32) and economic operators (94%, n=60). PAs and MSAs/Customs are less in line with the prevailing position.

Nearly the totality of the respondents from all the categories agree on the fact that **MSAs of different Member States** should better coordinate action. Interestingly, all (n=50) industry associations agree on this issue. Similarly, a very strong agreement is expressed by respondents from the civil society (56%, n=19) and by economic operators (55%, n=35). Only few respondents from the PAs disagree on the need for further coordination among Member States (27%, n=3).

Furthermore, the majority of the respondents from the different categories consider that the **MSAs within a Member State should share capacity of testing laboratories to use resources more efficiently**. Considering the responses grouped by category, only MSAs/Customs and PAs report a relatively high percentage of disagreement (above 27%, n=16 overall). More than 93% of respondents from the other categories agree.

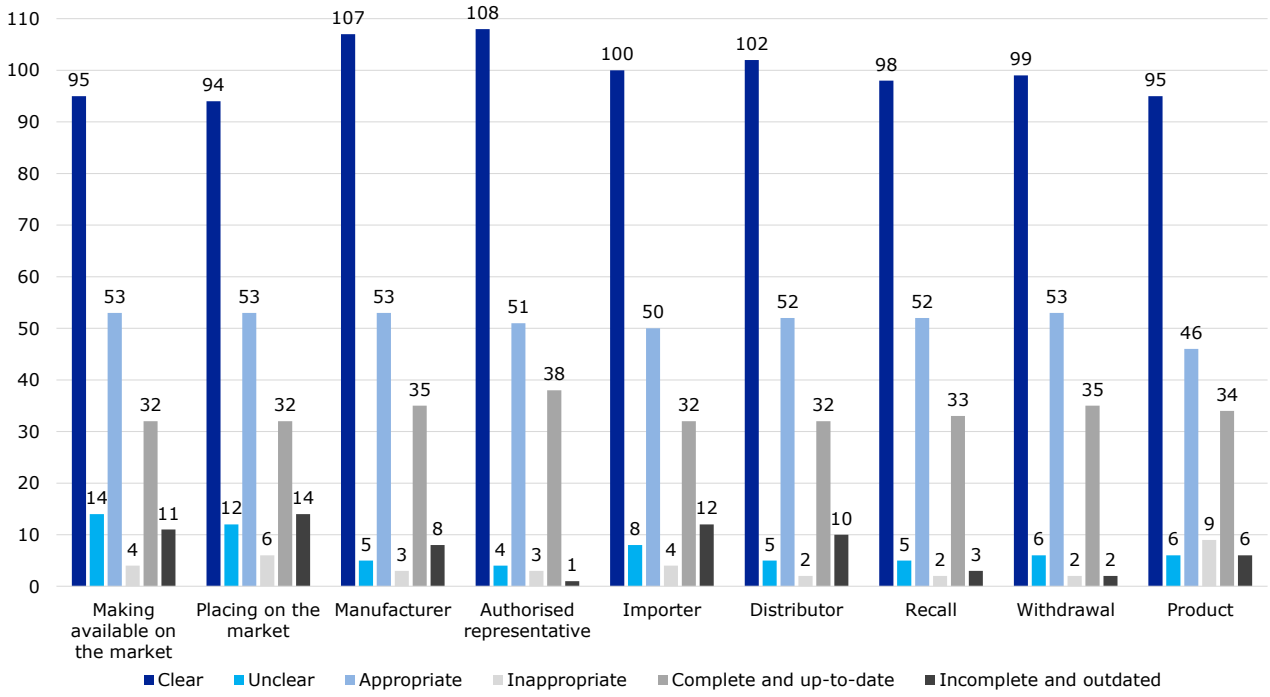
Finally, most respondents from the different categories consider that MSAs **of different Member States** should share capacity of testing laboratories. By comparing the categories, respondents from the industry associations support this position to the largest extent (92%, n=39). Diverging views appeared to be relevant in the case of PAs where half (n=5) of the respondents agrees while the other half disagrees.

8.1.3.3 Relevance

8.1.3.3.1 Definitions

According to the majority of respondents to the targeted surveys, **the definitions** provided in Article 2 of Regulation (EC) No 765/2008 and relevant for market surveillance **are clear**. There is also consensus on the appropriateness of these definitions, whereas **a smaller share of respondents report that they are complete and up-to-date** (as shown in the Figure 4-44 below), this eventually questioning the capacity of the Regulation to answer current stakeholders' needs.

Figure 4-44 - Number of stakeholders' expressing a feedback on the definitions provided in the Regulation[346]



Source: targeted surveys

Responses to the survey may be analysed by definition and respondent category to get a better understanding of the stakeholders' opinions. For instance, the definition of "making available on the market" is considered to be inappropriate, incomplete or unclear by respectively three, eight and seven MSAs out of 94. Conversely, no industry associations express negative opinions on the same concept. The definition "Placing on the market" is considered to be incomplete by 10 MSAs and unclear by two MSAs out of 117 total MSAs responding to this question. As for the concept of "manufacturer", it is generally considered to be clear, except from a notable number of MSAs (27 out of 112) that consider it incomplete and outdated. The definition of "authorised representatives" does not generate any particular concern among stakeholders, given that only three out of 177 consider it as inappropriate (2 MSAs) or incomplete and outdated (1 coordinating authority). Furthermore, nine MSAs indicate the concept of "importer" as incomplete, two of them as inappropriate and three of them as unclear (out of 104 MSAs answering to that point), while all responding industry associations express positive opinions on this definition. As for "distributor", 12 out of 103 MSAs express negative opinions, while the rest of stakeholder categories generally indicated positive views on it. Finally, the definitions of "product", "recall" and "withdrawal" have a uniform very low share of negative opinions across all stakeholders' categories. To conclude with, it is possible to state that there is no significant variability across stakeholder categories regarding definitions, as these are generally perceived as clear.

346 *Making available on the market*: in addition, 6% (n=13) of respondents chose the "I do not know" option. *Placing on the market*: in addition, 6% (n=13) of respondents chose the "I do not know" option. *Manufacturer*: in addition, 5% (n=12) of respondents chose the "I do not know" option. *Authorised representative*: in addition, 5% (n=12) of respondents chose the "I do not know" option. *Importer*: in addition, 5% (n=12) of respondents chose the "I do not know" option. *Distributor*: in addition, 6% (n=14) of respondents chose the "I do not know" option. *Recall*: in addition, 10% (n=21) of respondents chose the "I do not know" option. *Withdrawal*: in addition, 8% (n=18) of respondents chose the "I do not know" option. *Product*: in addition, 8% (n=18) of respondents chose the "I do not know" option.

8.1.3.3.2 Scope of the Regulation

The majority of respondents to the targeted surveys (71%) reported that the current scope of the Regulation is clear. In particular, when analysing the answers per stakeholder category, while all categories are almost aligned on the perception of the scope clarity, only 63% (n=37) of MSAs replying to the question confirm this result.

As for the ***lex specialis*** principle, 70% of respondents to the targeted surveys confirm that it causes **no difficulties of implementation**, though a few stakeholders raised some issues. In opposition to the majority, 31% (n=18) of MSAs consider that the concept of *lex specialis* causes some problems of implementation.

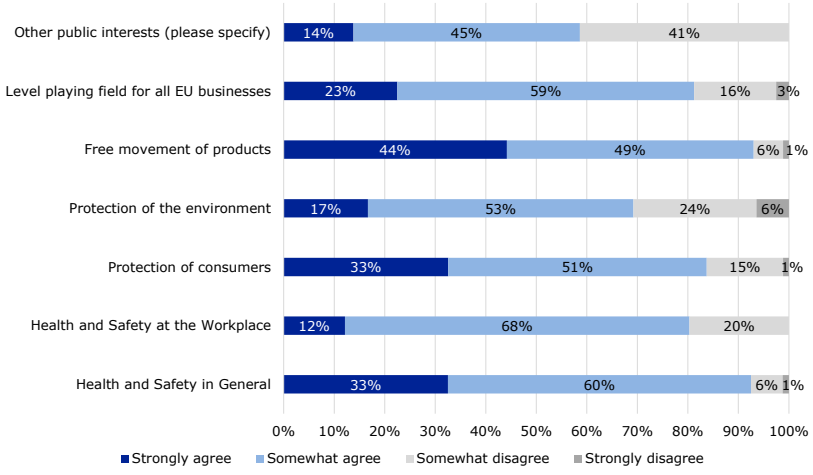
8.1.3.3.3 National reports and programmes on market surveillance

The majority of respondents to the targeted surveys (76%) deem the provisions of Article 18(5) on market surveillance programmes as useful. Broken down by category, both coordinating authorities and MSAs strongly align with this position (89%, n=8 and 74%, n=46 respectively).

8.1.3.3.4 Objectives of the Regulation

When asked about the adequacy of the framework provided by the Regulation in order to achieve its strategic objectives, the great majority of respondents reported that it positively contributes to their achievement, as shown in Figure 4-45 below. In particular, there is a strong consensus that the Regulation promotes the free movements of goods, the health and safety in general and the protection of consumers. Furthermore, according to a Belgian industry association, the compliance checks performed by MSAs contribute to ensure a level playing field in the Internal Market. Interestingly however, a Danish industry association reports that in the case of pyrotechnics articles no free movement of goods exists.

Figure 4-45 - Adequacy of the framework provided by the Regulation to achieve its objectives



Source: targeted surveys[347]

347 *Health and Safety in general*: n = 80; Health and Safety at the Workplace: n = 66; Free movement of products: n = 86. In addition, 19% (n=19) of respondents chose the "I do not know" option; *Health and Safety at the Workplace*: n = 66. In addition, 33% (n=33) of respondents chose the "I do not know" option; *Protection of consumers*: n = 86. In addition, 13% (n=13) of respondents chose the "I do not know" option; *Protection of the environmen*t: n = 78. In addition, 21% (n=21) of respondents chose the "I do not know"

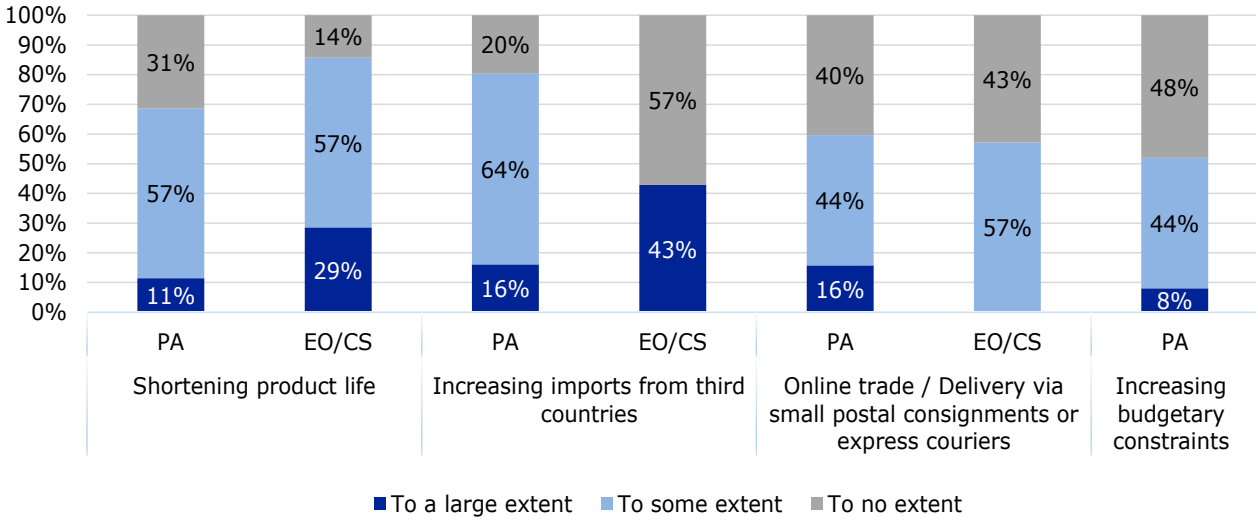
When observing the composition of each listed points in terms of stakeholder category, it is possible to draw some considerations. The totality of industry associations (n=10), companies (n=4) and coordinating authorities (n=11) and the large majority of MSAs (93%, n=49) agree or strongly agree with the idea that the Regulation achieves the objective of protect Health and Safety in general. As for health and safety at the workplace, 23% of MSAs and 20% of coordinating authorities "somewhat disagree" with the statement. As for protection of consumers, no stakeholders' state to strongly disagree, while only 17% (n=2) of coordinating authorities and MSAs (n=10) somewhat disagree, therefore expressing an overall positive perception of the reaching of this goal. In the case of protection of the environment, it is possible to observe an interesting part of MSAs (34%, n=17) and one company out of 4 that disagree or somewhat disagree. No stakeholders disagree with the "free movement of product" point, except from 8% (n=1) of industry associations and 7% (n=4) of MSAs. As for the generation of a level playing field for all EU businesses, the category of industry associations shows 36% (n=4) of disagreement, however no companies (n=4) disagree. Finally, when responding to the "other public interests" option, a higher rate of general disagreement is expressed. In particular, 60% (n=3) of coordinating authorities and 58% (n=11) of MSAs state to disagree or somewhat disagree with the label. Similarly, stakeholders responding to the survey declare that they generally appreciate the framework for market surveillance provided by the Regulation, inasmuch as 49% of stakeholders think it is useful in defining their national market surveillance and control of imported products policies to a large extent, 46% consider it to be useful to a small extent and only 5% declare it not to be useful, for a total of 95% of overall positive answers. Further evidence is provided by **73% of stakeholders reporting that the Regulation currently meets their needs**. In particular, all (n=4) companies and 84% (n=16) of participating Customs and of coordinating authorities (85 n=11) contributed to this figure by answering "yes".

8.1.3.3.5 New dynamics

As for specific issues addressed by the Regulation, **a low share (8%) of public authorities (68%), economic operators and civil society representatives (86%) reported that the Regulation adequately addresses new issues related to increasing general budgetary constraints**, while approximately a half of them (48%) states that it is **not** addressing the issue at all. On the contrary, as shown in Figure 4-46 below, there are different opinions on the role of the Regulation in **addressing the challenges of increasing imported products from third countries**. More in detail, 80% of public authorities report that the Regulation is able to address challenges related to imported products, while only 43% of economic operators share the same opinion and 57% of the last category think that the Regulation does not play any role in this sense. Differently, there is consensus on each respondent category (40% of public authorities and 43% of economic operators and civil society representatives) that the framework provided by the Regulation is **not adequately dealing with issues emerging from online trade**. Finally, 70% of public authorities and 71% of economic operators and civil society representatives confirmed that the Regulation allows authorities to track non-compliant products and ensure corrective action even if the product has a short life.

option; *Free movement of products*: n = 86. In addition, 13% (n=13) of respondents chose the "I do not know" option; *Level playing field for all EU businesses*: n = 19. In addition, 19% (n=13) of respondents chose the "I do not know" option. *Other public interests*: n = 29. In addition, 70% (n=70) of respondents chose the "I do not know" option.

Figure 4-46 - Relevance of the Regulation to new/emerging issues[348]



Source: targeted surveys[349]

As shown in the figure above, the majority of economic operator and civil society associations think that the increasing imports from third countries is an emerging issue that the Regulation is not addressing, while MSAs and Customs mainly think it is addressing it to some extent (64%) and to a large extent (16%), even if 20% of them express a negative opinion concerning the same point. As for online trade, opinions of both public and private stakeholders are similarly in accord in stating that the topic is not addressed by the Regulation or addressed to some extent. Finally, public authorities are particularly concerned when coming to the increase of budgetary constraints.

When asked about **the benefits of having a single European legislation on harmonising market surveillance** instead of several different national legislations, stakeholders report a number of positive achievements of the Regulation. Many respondents to the survey and to the public consultation state that the Regulation contributed to the establishment of a level playing field,[350] while others underline the improvement in the free movement of goods.[351] The simplification of rules[352] is also reported as a benefit, as well as an enhanced efficiency and effectiveness of market surveillance activities.[353] The Regulation is also responsible for

348 Please note that in the figure "PA" stands for "public authorities", "EO" for "economic operators", "CS" for "civil society representatives". Original survey question: *To what extent do you think the Regulation currently addresses specific issues deriving from: Increasing budgetary constraints; Shortening product life impacting the ability of authorities to track non-compliant product and ensure corrective action; increasing imports from third countries; Online trade/Delivery via small postal consignments or express couriers.*

349 *Increasing budgetary constraints*: n = 35; in addition, 47% (n=47) of respondents chose the "I do not know" option. *Shortening product life impacting the ability of authorities to track non-compliant product and ensure corrective action*: n = 46; in addition, 33% (n=18) of respondents chose the "I do not know" option. *Increasing imports from third countries*: n = 56; in addition, 15% (n=18) of respondents chose the "I do not know" option. *Online trade/Delivery via small postal consignments or express couriers*: n = 57; in addition, 15% (n=18) of respondents chose the "I do not know" option.

350 Five MSAs, a Danish and a Finnish coordinating authorities, a Belgian industry association, an Italian and a Swedish economic operators.

351 Four MSAs.

352 Six MSAs, three Custom authorities, three industry associations (3 BE).

353 Five MSAs, a Slovakian Custom authority, two industry associations (BE, DK), an Italian economic operator.

stimulating transparency and unambiguous interpretation of rules,[354] together with cooperation between countries and relevant authorities.[355]

8.1.3.4 Coherence

As for the external coherence, all stakeholders' categories agree on the fact that no serious issues exist. However, few stakeholders report some misalignments between the General Product Safety Directive (GPSD) and the Regulation. More in detail, the boundary between the two are not always clear especially to some MSAs, as they sometimes seem to overlap.[356] Furthermore, few MSAs[357] report that the definitions of the GPSD are not always aligned with those of the Regulation as for instance in the case of "distributor", "withdrawal", "recall".

No other coherence issues have been underlined by any stakeholders' category with regard to sector specific legislation as their interface with the Regulation is clear in the light of the *lex specialis* principle.

8.2 Case study 1: The Italian organisational model of market surveillance: competence sharing among MSAs and among MSAs and Customs

The objective of this case study is to identify critical elements to assess the effectiveness/ efficiency of market surveillance in different types of organisational models. In this respect, Italy can be characterised by a structure that is **decentralised at the sectoral level**, where **competences are shared by various central authorities**. Belgium, Cyprus, Croatia, Denmark, Estonia, France, Greece, Ireland, Latvia, Lithuania, Poland, the Netherlands, Romania, Slovenia and Sweden have similar organisational structures.

The case study assesses, among other issues, the **effectiveness and efficiency of market surveillance**, and the **obstacles** encountered in its enforcement under this type of organisational model.

8.2.1 General organisation

The Italian model of market surveillance is **decentralised at the sectoral level**. The **Ministry of Economic Development (MISE)** is the main national MSA and acts as a coordination body for the different enforcement authorities conducting market surveillance in the field, for relations and negotiations at the EU level, for the use of Rapid Exchange of Information System (RAPEX) and Information and Communication System for Market Surveillance (ICSMS), and for the establishment of *ad hoc* budgets and objectives. The MISE has general responsibilities over all sectors covered by Regulation 765/2008.

8.2.2 Sectoral level

Different ministries are in charge of market surveillance in various sectors within the scope of the Regulation. For instance, the **Ministry of the Interior** is responsible for market surveillance of explosives, while chemicals fall under the responsibility of the **Ministry of Health**. The **Ministry of Infrastructure and Transportation** controls the largest number of

354 14 MSAs, a Custom authority, three coordinating authorities.
355 Seven MSAs, a Custom authority.
356 Three coordinating authorities, eight MSAs, two EU industry associations, a Customs authority.
357 Two MSAs.

product categories. Each ministry organises its own market surveillance enforcement system. For this purpose, ministries can create dedicated units within their organisational structure or rely on external bodies. For example, the Ministry of Health has established the **REACH-CLP Unit**.[358]

Other relevant enforcement bodies are:

- **The Institute for Environmental Protection and Research – ISPRA**, under the Ministry of the Environment. It performs research activities and advises the ministry on environmental issues. It is in charge of enforcing Regulation 765/2008 regarding noise emissions for outdoor equipment.[359] ISPRA autonomously plans its market surveillance activities and carries out controls both on formal and substantial compliance: it checks documents, performs controls on machines during trade fairs and inspects production plants.[360]

- **The Italian Economic and Financial Police – Guardia di Finanza (GdF)**, under the Ministry of Economy and Finance. Its core mission is fighting tax evasion, but it also engages in activities related to IPR (intellectual property rights). Market surveillance activities are undertaken by the Special Unit for the Protection of Markets – Trademarks, Patents and Intellectual Property Group. Its activities are not planned in advance, but mainly based on a reactive approach, depending on the available resources, current needs and suspicions. It exercises its powers on toys, personal protective equipment, low-voltage electronics and electromagnetic compatibility. The Guardia di Finanza operates autonomously within the territory or in collaboration with the Customs Authority. It can also file RAPEX notifications.

- **The Chamber of Commerce, coordinated by Unioncamere**. They manage the action of the individual, regional Chambers and report to the Ministry of Economic Development. Their activities are based on annual bilateral agreements, establishing the number and the sectors of the planned inspections. Inspected sectors vary from year to year and can include toys, textile and footwear labelling, as well as electrical equipment. The Chamber of Commerce can check for the presence of the CE marking and accompanying technical documents and sample tests required by sectoral rules in order to verify that the product conforms to European standards and safety requirements.

- **The Local Health Units (Azienda Sanitaria Locale, ASL)**, under the Ministry of Health. They carry out health and safety inspections in the workplace. Although their core mission is not primarily related to market surveillance, they can sometimes find evidence of non-compliance in plants, machinery, medical devices or personal protective equipment during their inspections.

- **The special unit of the Italian Police Carabinieri, NAS**. It is a law enforcement body under the Ministry of Health, focused on health and safety controls covering several

358 "REACH" stands for 'Registration, Evaluation, Authorisation and Restriction of Chemicals', while "CLP" stands for 'Classification, Labelling and Packaging'.

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

360 ISPRA organises annual meetings with sectoral representatives and Notified Bodies, in order to mutually exchange information, increase the effectiveness of controls and encourage stakeholders to comply. It also provides a checklist to the Customs Authority to facilitate product controls on its product category at the border.

product categories. In particular, this unit of the Carabinieri monitors activities under the General Product Safety Directives (GPSD), toys, medical devices, plant protection products, as well as health products – all within the scope of the Regulation 765/2008.

There are no financial resources dedicated to market surveillance enforcement, as this is only one among the many tasks expected of the ministries and enforcement bodies.

8.2.3 Customs

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

Italian Customs check around 4 million import and 8 million export declarations per year. These checks uncover around 250 product non-compliance cases within the scope of Regulation 765/2008, which are then forwarded to MISE. All of this information is entered into the Customs' information system and the Authority establishes the level of control for each incoming product. In order to speed up the process and facilitate the legal circulation of goods, it is also possible to implement controls after products are placed on the market. This 'post-clearance audit' is implemented by all European Customs. In Italy, this process is called the 'blue channel' and allows Customs to perform more accurate controls based on a risk analysis.

The National Customs Agency's activity is based on three pillars:

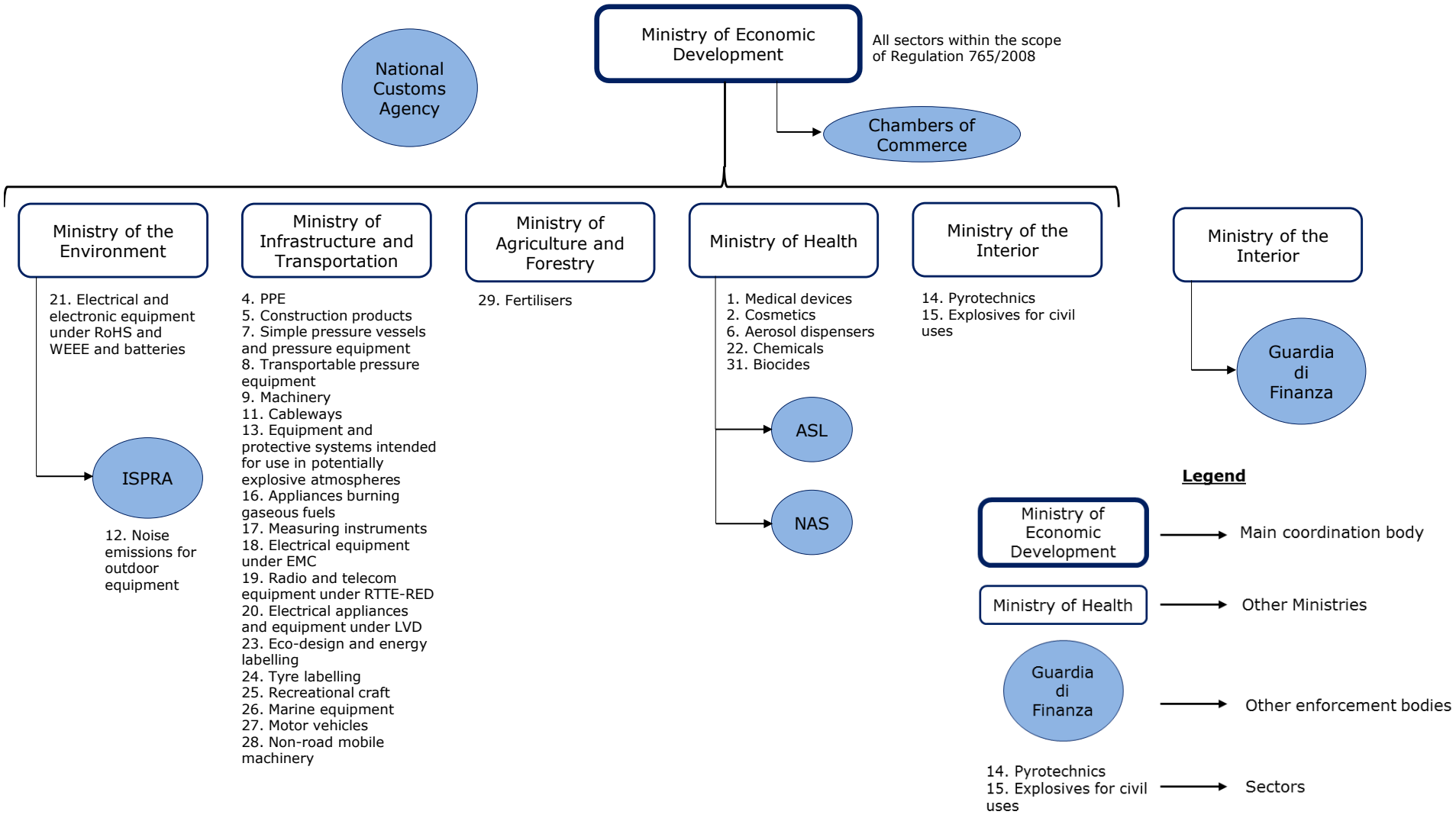
- **Providing information**, through the publication of a Manual on General Product Safety addressing all stakeholder categories. The manual, which dates back to 2005 (revised in 2009), is available[361] on the National Customs Agency website and it can be considered as a best practice in terms of stakeholder information. It addresses not only insiders, but all possible stakeholder categories, ranging from economic operators to citizens, from importers to public officials. It contains operational information, useful links for everyday activities, a glossary and information concerning legislation, technical standards, CE markings, activating procedures, workflow controls and contact points.

- **Conducting training**, which includes the organisation of several workshops open to sectoral associations to enhance cooperation with them. For instance, a collaboration has recently been implemented between the National Customs Authority and Personal Protective Equipment associations to define check lists, training courses and joint projects within the personal protective equipment sector.

- **Engaging in specific actions**, through the implementation of specific projects.

361 Available only in Italian language.

Figure 4-47 - The Italian organisational model of market surveillance[362]



362 **All sectors** within the scope of Regulation 765/2008 are under the responsibility of the MISE. However, surveillance on some specific sectors is implemented by other ministries.

8.2.4 Setting priorities

The **MSA's** resources are normally not linked to specific objectives or targets, except for special financial allocations assigned by the MISE to specific projects. In general, however, each ministry or authority can set its own priorities and is free to allocate resources and focus on self-established issues, although the MISE organises meetings to provide strategic orientations, European guidelines and general updates every six months.

As for **Customs**, specific sectors may be subject to more intensive controls, based on priorities defined by the competent MSAs and/or on risk profiles. Similarly to the situation for MSAs, financial support from the MISE means more laboratory tests can be carried out on imports, such as those leading to the worldwide withdrawal of Mattel's toys from the market in 2007 due the presence of heavy metals in the paints.[363] From that moment on, the MISE continued to finance extra laboratory checks within targeted projects. Risk profiles depend on parameters such as the country of origin, the reliability of the importer or feedback from previous checks.

8.2.5 Internal coordination

The MISE's approach is both proactive and reactive. Proactive surveillance is based on an annual programme establishing priorities and objectives, while reactive surveillance is based on field inspections and notifications from RAPEX and other enforcement bodies.

An example of the autonomy enjoyed by other ministries is the surveillance of chemicals by the Ministry of Health, which has set up a dedicated **REACH-CLP Unit**. Despite its name, the unit aims at covering all product categories relating to chemical substances, such as biocides, plant protection products and electrical equipment – currently under the responsibility of different ministries.[364] The objective is to unify controls within a highly specialised organisational unit working as a single contact point for all chemical products to simplify procedures and controls. Currently, in order to coordinate their activities in the chemical sector, representatives of different ministries, research institutes and regional administrations meet within a technical coordination committee.[365] The committee is organised in working groups dedicated to specific transversal issues, such as training, nanotechnologies or support for enterprises.[366] Furthermore, it is worth pointing out the existence of the Italian **Medical Device Registration database**, implemented by the Ministry of Health in 2007, considered as a best practice in terms of information sharing. All medical devices have to be registered by companies within this database in order to be placed on the Italian market for the first time. It covers more than 500,000 products and allows information sharing between economic operators and public healthcare agencies. The database is available to the public on the Ministry of Health website and contains information both on economic

363 See related article: http://europa.eu/rapid/press-release_IP-07-1234_en.htm?locale=en. Following this case, a number of projects focused on market surveillance in the toy sector have been implemented, such as 'Safe Christmas', "S.T.O.P." (Safe Toys Only Please), 'For a safer market project' and 'Safe Toy'.

364 Biocides and plant protection are managed by the Ministry of Health, electrical products (such as those covered by the ROhS Directive) are under the responsibility of the Ministry of Environment, while fertilisers are assigned to the Ministry of Agriculture.

365 Further relevant information: http://www.reach.gov.it/chi-siamo

366 There is a local REACH-CLP Unit in each Italian Region, mirroring the activity of the central Unit. Every unit appoints its own inspectors, generally two for each Province, with a total of about 400 inspectors in the whole country. They work in a wide range of areas, receiving training from the central unit and having full access to the ECHA (European Chemical Agency) database. There is also a specialised group of 40 inspectors, who receive an intensive and specific training programme in order to be ready to act in case of particularly critical situations (such as urgent notifications from ECHA or in case of toxicological analysis).

operators (i.e. name, fiscal code, and VAT number) and on products (e.g. identification code, type of device, CND classification, and commercial name).

Coordination between the MISE and enforcement authorities, such as the GdF, ASL and Chambers of Commerce, occurs on a case-by-case basis. These authorities are not directly linked to the enforcement of Regulation 765/2008 as they have different core missions. However, while performing their daily activities, such as sanitary inspections for ASL and fiscal checks for the GdF, they can encounter issues related to product non-compliance. Therefore, they perform inspections but cannot take any decisions concerning enforcement measures or penalties for non-compliance. In cases where they identify a suspected non-compliance, they notify the MISE, which will then decide how to react together with the competent ministry.

Coordination between the National Customs Authority and the MISE is based on formal agreements that are published on the Customs Authority's website, as well as on decisions made during meetings, where issues emerging from daily surveillance activities are discussed. The main communication channel between local Customs offices and the MISE is e-mail. When Customs detect a non-compliant product, they refer it to the MISE, which acts as a filter, forwarding the issue to the competent ministry for a decision on whether it is allowed to enter the market or not. At present, databases on product non-compliance are not connected, but the authorities working on particular cases can be granted mutual access to each other's databases. Since the Ministry does not have local offices operating close to Customs facilities, the speed of communication is critical to keep within the three-day limit applied to these decisions.

Another interesting example of collaboration involves Customs and the above-mentioned REACH-CLP Unit within the Ministry of Health. At present, they are involved in implementing the Ticass project, which is focused on gathering information about chemical goods before they enter the country. Product characteristics are registered by the importer in a specific format provided by the Ministry of Health, so that MSAs are rapidly informed about possible critical factors and product traceability is improved. Moreover, the REACH-CLP Unit is planning to extend controls on chemicals at land borders (at the moment chemical checks take place only at airports and harbours), thus increasing law enforcement. In this context, law enforcement bodies at the border, such as the GdF or the Italian Police, will also be required to notify the REACH-CLP Unit about any trucks carrying chemical substances and their destination.

Further, in July 2016, the MISE set up an inter-services conference ('**Conferenza dei Servizi'**), whose objectives are to clarify procedures and legislation underlying controls, to map responsibilities associated with all product categories among different ministries, to define contact points for every possible issue, and to update the Manual on General Product Safety.[367]

367 See earlier in this case. This manual, whose first edition dates back to 2005, is available to the public on the National Customs Agency's website and it could be considered as a best practice in terms of stakeholder information. Indeed, its main feature is the strong informative power as it addresses all possible stakeholder categories, from economic operators to citizens, from importers to public officials. It contains operational information, useful links for everyday activities, a glossary and information concerning legislation, technical standards, CE marking, activation of procedures, workflow of controls and contact points.

8.2.6 Analysis of the effectiveness, efficiency and obstacles

The Italian system is organised in a pyramidal way, with the MISE as the main body responsible for national market surveillance and in charge of coordination. Overall, however, it seems that there are **no formal channels or established standard procedures** through which the different ministries can coordinate their activities. As a consequence, although the MISE may have the formal powers over MSAs' activities, in practice it has no power of control over their budgets and therefore on priority setting. Indeed, it seems that market surveillance, in the context of Regulation 765/2008, is just one of the many tasks that each enforcement body has to deal with on a daily basis. Sectoral decentralisation has led to different product sectors being under the responsibility of the most appropriate ministry or institution, thus providing a **higher level of specific knowledge**. However, this **adds complexity to the management and uniformity of market surveillance** at the national level. In particular, the fact that every ministry internally organises its own market surveillance structure for each product category leads to variation in the ways the different sectors are controlled and managed. Moreover, fragmentation throughout the territory may hinder authorities' response times.

In this context, an overlap of competences may also happen. A critical operational issue is the **integration of Regulation 765/2008 with other sectoral legislation**, given that the primary responsibility for the enforcement of the Regulation is under the MISE, while the enforcement of some sectoral laws is under the responsibility of the relevant ministries. Moreover, some sectors can be controlled by multiple authorities, as in the case of GPSD. Therefore, there may be cases where **products need multiple evaluations and validations** in order to be allowed to enter the market. Overlapping may also occur due the fact that **the core missions of many enforcement bodies** (for instance, GdF, ASL and Chambers of Commerce) **are not primarily related to market surveillance of non-food products within the definition of Regulation 765/2008**. **Further delays may occur as there seems to be no clear division of sectoral responsibilities.** For example, the toy sector is indicated as controlled by the Guardia di Finanza, by Chambers of Commerce, by Customs, and by the Carabinieri NAS. The MISE acts as a 'filter' redirecting queries or cases regarding specific product issues to the relevant ministry because the system, as it is designed, does not factor in direct contact between the different actors involved. This makes it more challenging to create synergies among overlapping sectors.

A joint platform or information system would allow real-time data entry, considerably reduce the duplication of work and speed up responses by the coordination authority to issues encountered by the enforcement bodies in the field. Another related issue is the fact that the MISE has no presence in local Customs' offices, which slows down communication, and makes it harder to respect the established three-day limit for the release of goods. It should be pointed out that central government offices located near or within Customs facilities are rare even within other countries' market surveillance systems.

A further challenge concerns the **disproportionate distribution of the surveillance burden** across EU Member States, which would require more balanced resource allocation at the European level. Italy together with Cyprus, Malta, Greece and Spain handle all border controls along the Mediterranean coast, a considerable cost borne by a handful of countries.

The example shown by projects, such as those previously indicated regarding toys and collaboration with sectoral associations, show that improvements of the current system are possible. This is due to two main reasons: first, they provide the opportunity to improve the

implementation of controls, thanks to better information exchange and availability; second, they provide valuable on-the-job training and boost in-house expertise among Customs officers who are not necessarily specialists in specific product areas.

Despite the above-mentioned drawbacks of sectoral decentralisation, **all interviewees in this case study** deem that **market surveillance enforcement works very well in the country**, also when compared to that of other EU Member States, and **despite a serious lack of resources**. Lack of financial resources is a barrier to in-depth controls over all product categories within the scope of the Regulation. As a consequence, in certain sectors (e.g. construction products) only document and formal compliance checks are performed. As for available human resources, one interviewee underlines the fact that the use of fixed-term contracts within MSAs causes instability from an organisational point of view, and makes it difficult to build on overall expertise gained during employment contracts.

8.2.7 Sources

Interview with the Ministry of Economic Development (MISE)

Interview with ISPRA

Interview with the Ministry of Health, REACH-CLP Unit

Interview with the National Customs Agency

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National Programmes, Italy available at http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/

https://www.agenziadoganemonopoli.gov.it//portale

Carabinieri website: http://www.carabinieri.it/

ECHA website: https://echa.europa.eu/

Guardia di Finanza website: http://www.GdF.gov.it/

ISPRA website: http://www.isprambiente.gov.it/en

Ministry of Health website: http://www.salute.gov.it/

MISE website: http://www.sviluppoeconomico.gov.it/index.php/it/

REACH technical committee website: http://www.reach.gov.it/

Unioncamere website: http://www.unioncamere.gov.it/

8.3 Case study 2: The German organisational model of market surveillance: competence sharing among MSAs and among MSAs and Customs

Germany is characterised by a structure **decentralised at the regional/local level**, where competences are shared among various Land authorities. Austria, Finland, Hungary, Spain and the UK have similar organisational structures.

The case study will assess, among other issues, the **effectiveness and efficiency of market surveillance**, and the **obstacles** encountered in its enforcement under this type of organisational model.

8.3.1 General organisation

Germany is a Federal Republic made up of 16 Länder. **The Länder and related ministries are separate from the Federal Government**, both from a policy and financial point of view, each having their own budgets. The Federal Government and Federal Ministries are responsible for the overall legislation (laws and regulations), while the 16 Länder are in charge of the enforcement of this legislation.

Each Land has a high degree of autonomy over several policy areas, including market surveillance, whose related responsibilities are therefore highly decentralised. Every Land manages its own market surveillance system with dedicated MSAs within their ministries, taking into account specific Land-level features such as market structure and relevant industry sectors.

Resources for market surveillance are therefore provided by the Länder themselves. This configuration implies that the budget for the single product category may vary across the Länder and the Federal Government has no influence over this allocation.

Before the entry into force of Regulation 765/2008, German MSAs were not performing market surveillance in some sectors (e.g. construction products), or they were performing it under a different set of rules. As a consequence, MSAs are still building up their market surveillance approach to these sectors, re-organising themselves and learning from experience in well-performing sectors. In contrast, the sectors that were previously regulated by the 'New Approach' already have a very well-functioning market surveillance structure, with dedicated

Land-based authorities and the Working Committee on Market Surveillance AAMÜ[368] acting as the coordination body.

8.3.2 Federal level

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

- **The Federal Network Agency – BNetzA**, under the Federal Ministry of Economy and Energy, is responsible for market surveillance in two sectors: electrical equipment under the Electro-Magnetic Compatibility Directive[369] and radio and telecommunications equipment under the Radio and Telecommunication Terminal Equipment Directive;[370]

- **The Federal Authority for Maritime Equipment and Hydrography – BSH**, under the Federal Ministry of Transport and Digital Infrastructure, is responsible for the marine equipment sector;

- **The Federal Motor Transport Authority – KBA**, under the Federal Ministry of Transport and Digital Infrastructure, is responsible for motor vehicles.

Three additional Federal agencies are also involved in the context of market surveillance, though they are not responsible for enforcement in individual product sectors, the **Federal Institute for Occupational Safety and Health – BAuA**,[371] the **Federal Institute for Materials Research and Testing – BAM**,[372] and **the Federal Agency for Environment – UBA**.[373]

8.3.3 Land-level

The 16 Länder coordinate their enforcement action through several committees, where representatives from the Land ministries and MSAs regularly meet. Committees are focused on selected sectors. The biggest committee is the **Working Committee on Market Surveillance – AAMÜ**, which covers the largest number of sectors within the scope of

368 Arbeitsausschuss Marktüberwachung.

369 Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast).

370 Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

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

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

373 UBA is the central environmental authority. It plays an important role in the enforcement of national and European environmental law, for example in the field of industrial chemicals, plant protection products, medicinal products, and washing and cleansing agents. If a risk to human health or the environment exists, it recommends conditions of use, use restrictions or bans. UBA's specialists also work to improve scientific knowledge about chemicals and their risks, and formulates science-based recommendations for the improvement of environmental and climate protection instruments. It does not only assess environmental health risks to adults and children, but also develops action programmes designed to reconcile environmental and health protection requirements. Its experts also provide advice to municipalities and the Federal States on environmental health issues.

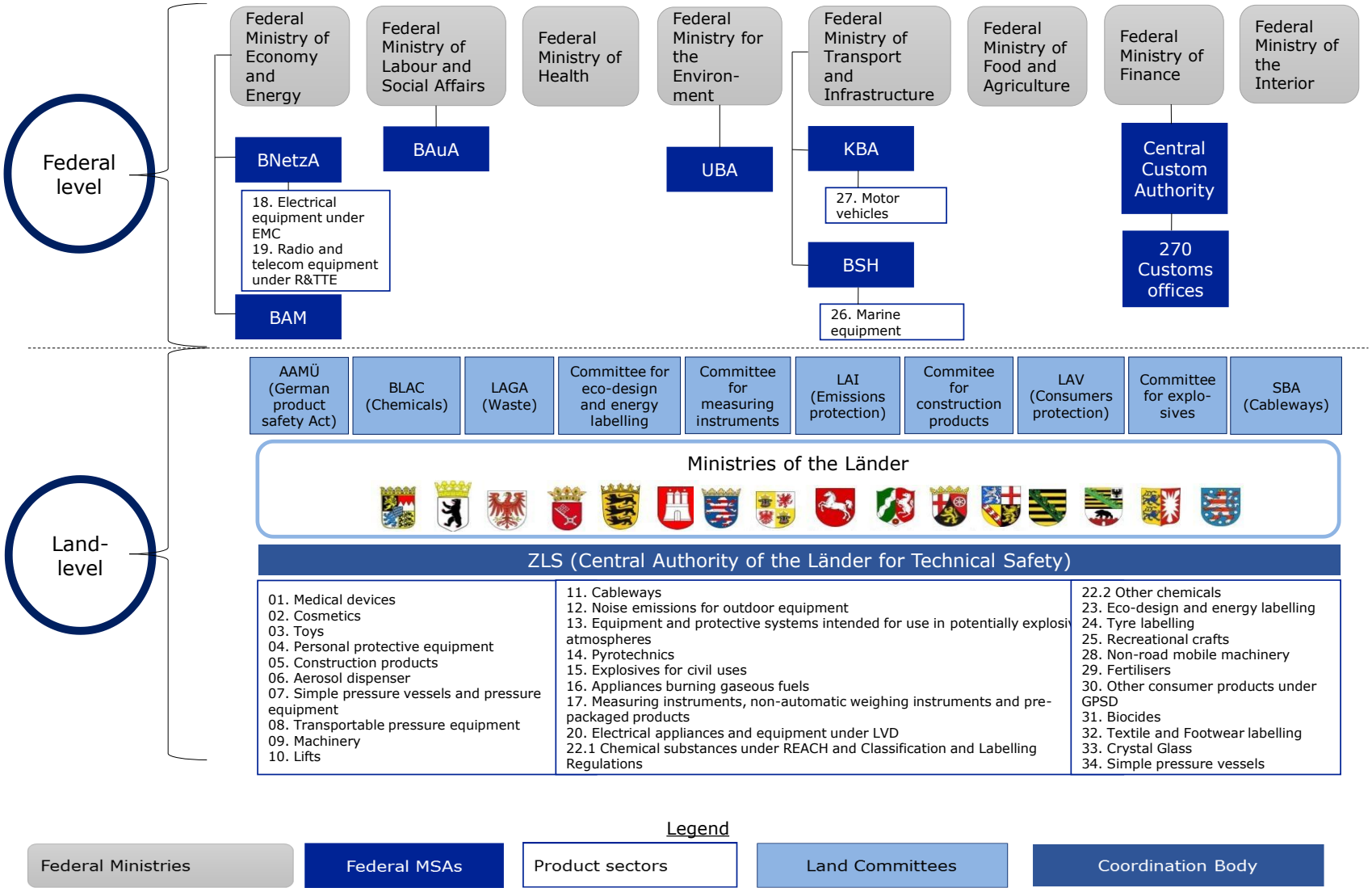
Regulation 765/2008.[374] Other existing committees and related product categories are shown in the figure below.

Another coordination body is the **Central Authority of the Länder for Technical Safety – ZLS.** The ZLS had been set up on behalf of the Länder in order to centralise some market surveillance tasks, such as the creation of product risk profiles and the forwarding of RAPEX notifications, instead of having them repeated for all of the 16 Länder. The ZLS has more operational tasks than the other coordination committees and can even enforce the law under special conditions and following the Länder's requests. For instance, when a market surveillance case involves several Länder or has international relevance, ZLS is allowed to perform market surveillance actions.

The figure below represents the German organisational model of market surveillance.

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

Figure 4-48 - The German organisational model of market surveillance



8.3.4 Customs

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

As for the implementation of Regulation 765/2008, the Central Customs Authority acts as prescribed by Article 27(2)[375] and Article 29(5)[376] on information exchange. It collects information from the ZLS and other coordination bodies or MSAs, in particular with regard to product risk profiles, and distributes this information to local Customs offices. Customs controls are indeed mainly based on risk indicators such as Combined Nomenclature code,[377] product description, consignee, consignor and country of origin/dispatch/export. The Central Customs Authority also provides MSAs and coordination bodies with information extracted from the electronic Customs clearance system (e.g. name and address of importers of certain products).[378]

Relations between Customs and the MSAs are bilateral. On the one hand, if MSAs find high percentages of non-compliant products in some sectors, they inform Customs through land-level coordination committees, asking them to focus on those products. On the other hand, Customs are responsible to inform the MSAs if they have an initial suspicion of a product being non-compliant, although decisions about the non-conformity of a product are ultimately taken by MSAs.

8.3.5 Setting priorities

Although Federal Ministries are responsible for policy-making, they do not set market surveillance priorities, except in those sectors where Federal MSAs are responsible for enforcement (i.e. Electrical equipment under EMC, radio and telecom equipment under R&TTE, motor vehicles and marine equipment). Priorities are set on the basis of information received from the market, by looking at accident data and consumers' complaints, information coming from competitors and press releases on issues related to product safety and, last but not least, information coming from Customs authorities and other Land ministries within coordination committees. Based on this, they identify relevant working fields for the upcoming years. Another important input for setting priorities comes from participation in

375 Article 27(2): 'Where in a Member State more than one authority is responsible for market surveillance or external border controls, those authorities shall cooperate with each other, by sharing information relevant to their functions and otherwise as appropriate.'

376 Article 29(5): 'Market surveillance authorities shall provide authorities in charge of external border controls with information on product categories in which a serious risk or non-compliance within the meaning of paragraphs 1 and 2 has been identified.' Article 29(1): 'Where the market surveillance authorities find that a product presents a serious risk, they shall take measures to prohibit that product from being placed on the market and shall require the authorities in charge of external border controls to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document or, where data processing is carried out electronically, in the data-processing system itself: 'Dangerous product - release for free circulation not authorised - Regulation (EC) No 765/2008'. Article 29(2): 'Where the market surveillance authorities find that a product does not comply with Community harmonisation legislation, they shall take appropriate action, which may, if necessary, include prohibiting the products being placed on the market'.

377 https://ec.europa.eu/taxation_customs/business/calculation-customs-duties/what-is-common-customs-tariff/combined-nomenclature_en

378 All declarations must be electronically filed using the German Customs Administration's ATLAS System (Automatic Rate and Local Customs Clearance System), which makes it easier to check the entered information before submission and to forward it to all the parties involved.

European Joint Actions, which are financed by the European Commission and focused on specific market surveillance topics.

8.3.6 Internal coordination

At the EU level, policy discussions are mainly held by the Federal Government. Nonetheless, collaboration between the Federal and Land level is based on extensive involvement of the Länders' representatives in negotiations at the EU level, so that both the legislative dimension and the enforcement aspects are represented in Brussels within discussion fora that are relevant for market surveillance issues, such as the Consumer Safety Network.[379]

As previously stated, **the 16 Länder coordinate their actions through committees**, each covering specific sectors. Notably, although every Land performs market surveillance in all product sectors covered by Regulation 765/2008, **each of them develops stronger competences in specific product groups** in terms of: higher number of controls and deeper knowledge relating to the specific implementing acts, the relevant standards or test methods.[380] For instance, Baden Württemberg is specialised in electric motors and ventilators, while Hessen is specialised in lights. These decisions on Land 'specialisation' are taken within the committees.

Strong collaboration between Customs and Land MSAs is achieved thanks to the Central Customs Authority having 'permanent guest' status within the coordination committees, thus receiving the minutes of all sessions and participating in meetings in case Customs-related issues are discussed. In contrast, contacts between Customs and Federal MSAs (e.g. BNetzA) are more direct, their units communicating with each other without passing through committees. There are several **formal agreements** between the Central Customs Authority and both Federal and Land MSAs. Moreover, when new EU legislative acts enter into force, it may not be immediately clear to the Customs services which is the appropriate MSA to deal with the new rules. Once 'the right partner' is identified, Customs and the MSA establish and sign a formal agreement to help with market surveillance implementation.

The main platform for information sharing is **ICSMS**.[381] This tool has been developed and adopted at the European level, but it was designed in Germany and it is still used by German MSAs to exchange information and increase the efficiency of market surveillance. Before starting a case, MSAs check to see whether the product has already been filed in the system. This is fundamental in order to prevent duplication of work.

According to all the interviewed stakeholders, **coordination, cooperation and exchange of information work very well** within the German system, also because authorities have been using it since 1993, when Regulation (EEC) No 339/93 – later repealed by Regulation (EC)

379 The Consumer Safety Network is a consultative expert group chaired by the EC and composed of national experts from the administrations of the EU MS, Norway, Iceland and Liechtenstein. Its main areas of discussion are the safety of consumer products, such as lighters and of consumer services, including fire safety in hotels, and the relevant data collection. It meets on average three times a year, usually in cooperation with the General Product Safety Committee meetings. Source: http://ec.europa.eu/consumers/consumers_safety/cooperation_with_stakeholders/index_en.htm

380 As reported by an interviewee from Baden Württemberg Ministry for Environment, Climate Protection and Energy Sector.

381 ICSMS is an information and communication system for the pan-European Market Surveillance. A general information support system set up by the European Commission for the exchange of information between MSAs according to Article 23 of Regulation (EC) No 765/2008. https://webgate.ec.europa.eu/icsms/

No 765/2008 – was applicable. The Regulation became applicable in 2010 and had a wider scope, but cooperation mechanisms were already in place and operating effectively.

A further interesting feature of the German system is represented by the attempt to build an **informal market surveillance network**. Workshops for inspectors are frequently organised, as are events to spread the latest news from Brussels and other relevant information. This helps to keep all inspectors up to date and aligned on how to interpret legislation. It also means inspectors from different institutional levels and sectors have the chance to personally meet and strengthen relations. The people involved tend to know each other and this is very good in developing increased and stronger cooperation among market surveillance actors.

8.3.7 Analysis of effectiveness, efficiency and obstacles[382]

A decentralised market surveillance system requires **highly developed and intense cooperation**, though Germany is used to dealing with decentralisation in several policy areas. Particularly:

- **Substantial resources are likely to be required** to replicate a market surveillance system in 16 Länder. The current allocation of duties at the national level means Länder are responsible for implementing market surveillance as part of their daily tasks using their annual budget.

- **Substantial resources are likely to be required** to ensure the necessary coordination mechanisms (e.g. the establishment of permanent, *ad hoc* coordination bodies such as the ZLS, the organisation of workshops, meetings and events to create an 'informal' network of market surveillance actors). However interviewees stress that **Germany has developed a 'learning economy'** in setting up coordination mechanisms, as decentralisation is based on a well-established 'constitutional principle'.

The German organisational structure establishes a clear division between the 'regulatory' and the enforcement level, mirrored by a respective repartition of resources. An inherent risk of such an approach may be that **high-level policy objectives are not aligned or appropriately shared and implemented in the field**. This misalignment is perhaps compensated by the presence of relevant stakeholders and different authorities in EU-level discussions and committees.

The outcome is a **more tailored response** because market surveillance and enforcement priorities could differ slightly from one Land to another, depending on the regional product portfolio, on the presence of production clusters and on the general market composition (for instance, some Länder may have a strong agricultural tradition, while others are more industrialised). Moreover, although the geographical area where MSAs operate is restricted (i.e. within the Land), they are responsible for a vast array of sectors, thus enhancing their **competences thanks to the role played by the committees**. In any case, all interviewed stakeholders agree that despite this high level of decentralisation, coordination mechanisms in Germany work well, and the level of market surveillance ensures a level playing field for national businesses.

382 Due to lack of data allowing for a proper triangulation, considerations in this section are mainly based on stakeholders' opinions.

Although very complex, **the German organisational structure establishes a responsible authority for each product sector**, which interviewees regard as a strength of the system, because '*tasks are well defined and competences clearly split'*. As proof, **no overlapping occurs** between the Federal and the Land level in terms of market surveillance responsibilities in all sectors covered by the Regulation. Nonetheless, particularly in the case of Customs, **this complexity may make it difficult** for actors internal to the system **to identify the 'right partner'** to deal with market surveillance issues.

Efficiency is further bolstered by a number of coordination tools. The first pillar is represented by the **ZLS**, which is responsible for market surveillance issues with 'cross-Länder' features, such as the development of product risk profiles. In addition, in cases where two Länder make different decisions on similar market surveillance cases, the ZLS is involved in finding a common solution and interpretation. As stated by stakeholders, ZLS ensures a harmonised approach among the 16 Länder. Another pillar of the German coordination strategy is represented by the extensive use of **ICSMS**, which national authorities are very familiar with, as it was first developed in Germany. As already mentioned, ICSMS is crucial to avoiding duplication of work, a possible deficiency of decentralised structures.

Nonetheless, such a thoroughly decentralised system could benefit from some adjustments, particularly in terms of rationalisation of the many different coordination mechanisms in place. Germany is indeed planning to create **a single, general coordination board covering all product categories and ensuring further alignment between the Federal, the Land and the European level**. In order to facilitate this process, ministries have already started to meet on a voluntary basis within this 'Forum for Market Surveillance'. At the moment it still remains a pilot committee, taking place twice a year and organised by the Federal Ministry for Economic Affairs and Energy, though it should be institutionalised by the end of 2017. Moreover, according to one interviewee,[383] '*a centralised system would not be less resource-needing or less time-consuming, as it would in any case need a network of local authorities and an information flow between the two institutional levels'*. Therefore the structures, time and personnel would almost remain the same, and only the responsibilities would be allocated differently.

8.3.8 Sources

Interview with the Federal Ministry for Economic Affairs and Energy

Interview with the Central Customs Authority

Interview with the ZLS

Interview with the Bavarian Ministry for Environment and Consumers Protection

Interview with the Baden Württemberg Ministry for Environment, Climate Protection and Energy Sector

383 ZLS and the Bavarian Ministry for Economic Affairs and Energy.

European Commission, GROW B1 (2016), Summary of Member States assessment and review of the functioning of market surveillance activities according to Article 18(6) of Regulation (EC) No 765/2008.

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

German Product Safety Act

Hessisches Ministerium für Soziales und Integration (2016), Marktüberwachung in Deutschland Strukturen und Verfahren am Beispiel der Produktsicherheit

Market surveillance programme 2014-2017 for the sectors covered by Germany's Product Safety Act (Produktsicherheitsgesetz) available at http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/

UBA (2010), Who we are. What we do. Flyer about the Federal Environmental Agency.

Report on the market surveillance results under the market surveillance programme for 2010 to 2013 for the sectors covered by the German Product Safety Act available at http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/

Review and assessment of the functioning of market surveillance activities pursuant to Article 18(6) of Regulation (EC) No 765/2008 – 2010-2013, available at http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/

BAUA website: http://www.baua.de/en/Homepage.html

BAM website: https://www.bam.de/Navigation/DE/Home/home.html

German Customs website: https://www.zoll.de/EN/Home/home_node.html

UBA website: https://www.umweltbundesamt.de/en/the-uba/about-us

The German Business Portal: https://www.ixpos.de/IXPOS/Navigation/EN/Your-business-in-germany/Market-entry/Tax-and-duty/duties,t=atlas-system-for-electronic-customs-clearance,did=270836.html

CONCLUSIONS of case studies 1 and 2:

In light of case studies 1 and 2, some general conclusions can be drawn:

- **Crucial elements for the effectiveness of both organisational models:** the importance of clear task assignments among authorities and to each MSA (not just performed among the many other daily tasks), the appointment of a coordination board, the need for each MSA to have direct contact with Customs, the identification, visibility (to the public) and access to relevant competent authorities.

- **Crucial elements for the sector-decentralised model**: the importance of formal channels and coordination procedures to ensure a coherent policy approach in different sectors.

- **Crucial elements for local-decentralised model**: the importance of formal channels and coordination procedures to ensure not only a coherent policy approach in different regions, but also coordination of investigations via a common database and tool for common decision-making.

8.4 Case study 3: Difficulties in performing market surveillance of products sold online

The objective of this case study is to identify obstacles (including legislative ones) encountered by market surveillance and, if possible, Customs authorities in controlling products sold online.

The case study makes up a **theoretical case** of a non-compliant cosmetic product made available on an online platform based in a third country. Authorities in Finland, Spain, and the Netherlands were then asked whether they would address the problem and how, for instance, they would carry out the inspection, obtain corrective action, and from which businesses.

In a second section, the case study reviews a **specific case** handled by the Finnish authorities, noting the difficulties encountered, such as the lack/inappropriateness of legal definitions, and the powers/tools needed for the inspection and to obtain corrective action.

8.4.1 Introduction

Why online sales matter in the framework of Regulation 765/2008

E-commerce[384] has grown in popularity thanks to several developments, including improvements in technology and consumer confidence, a wider range of products and services, competitive prices and a better-integrated internal market. The issue of online sales has therefore become relevant for market surveillance enforcement. Furthermore, it deserves particular consideration in light of the results of targeted surveys – 78% of participants reported that there are non-compliance issues related to online trade.

The state of the art of market surveillance enforcement of products sold online

Market surveillance of products sold online is currently fragmented and lacking coordination, resulting in a lower level of protection and legal support to consumers than that afforded to products marketed through classic distribution channels.[385]

Including online sellers and products in market surveillance is an opportunity to gain comprehensive, EU-wide insight into compliance levels of products sold via this ever-growin

384 Source: PANTEIA (2014), Good practice in market surveillance activities related to non-food consumer products sold online.
385 COM (2013) 76.

g channel. A substantial sample of online products can for instance be tested as part of all Joint Actions (JA).[386]

Several issues are linked to e-commerce,[387] and introduce new challenges for MSAs, especially in relation to cross-border online sales where different jurisdictional boundaries exist, and in markets where speed and effective action is a must but resources are limited.

8.4.2 Addressing online sales in Finland, Spain and the Netherlands

The Finnish process

The Finnish Safety and Chemicals Agency (Tukes) is in charge of market surveillance for approximately 30 product Directives, including cosmetics.[388]

Powers. Tukes does not have any special powers related to online sales. For instance, Finnish legislation does not explicitly call for MSAs to engage in 'mystery shopping', although this practice is not forbidden and, in practice, MSAs do carry out random sampling of online products and sellers like this. Similarly, MSAs are not allowed to shut down websites selling non-compliant products, although Tukes reports that it would be an effective tool together with the possibility of imposing monetary fines or criminal sanctions.[389] Possible actions against non-compliant products are recall, withdrawal, sales ban or notification letters, depending on the level of risk.

Customs. Cooperation between Tukes and Tulli (the Finnish Customs Authority) is performed following a mutually agreed, formal process, but with no specific procedures or powers for e-commerce products. Given that the bulk of products sold online are small consignments to individual e-consumers, controlling single products is not realistic nor effective. In any event, checks already take place on incoming packages (whether sold online or not) as part of regular postal and air cargo services.

Decisions on the intensity of controls depend on:

- The package size: small packages are usually considered to be less valuable, therefore controls are focused on larger ones, which also have to be declared;
- The sender's identity, e.g. known or unknown, country of origin;
- The addressee's identity: private persons or companies.

386 Joint Actions are financed by the Commission and focused on specific market surveillance topics and usually involve different Member States and authorities relevant for market surveillance. Further information available at: http://www.prosafe.org/

387 As reported in the existing literature, Member States' national programmes, the public consultation and targeted surveys.

388 Electrical products, lifts, explosives, pressure equipment, chemicals, biocides, plant protection products, cosmetics, measuring instruments, precious metals, rescue service equipment, toys, child care, machinery, PPE, construction products, packages, eco-design and energy labelling.

389 It is theoretically possible that the economic operator is brought to court, in case of serious danger. The court has the power to issue fines or even decide for a prison sentence of maximum of 6 months, but it has never happened.

Communication. Tukes enters information on non-compliant products sold via the internet on its market surveillance register, called Marek, and makes it available to the public through its official website, where market surveillance projects, reports and pictures of non-compliant products are published. It also regularly uses social media networks, such as Facebook and Twitter, to inform the public about recently banned products. Tukes and Tulli cooperate on awareness campaigns concerning online sales. Results of specific projects are often published in newspapers, while RAPEX and ICSMS are used to inform other Member States. Notably, the Finnish campaign '*There is no sheriff in this town'*,[390] aimed to raise public awareness by clarifying the 'buyer beware' principle on the risks of buying products online.

Theoretical case. MSAs find that a cosmetic product made available on an online platform is formally non-compliant. Firstly, Tukes checks the information provided on the website and orders the product to identify the economic operator and verify product compliance.

In this context, three alternative scenarios are possible:

1. Both the web-page and the economic operator are based in Finland → Tukes sends a letter informing the economic operator that the product in question is non-compliant.
    a. The economic operator answers and voluntarily complies → OK
    b. The economic operator does not answer and/or does not comply → Tukes decides on measures to be taken (e.g. sales ban)
2. Both the web-page and the economic operator are based in another EU Member State → Tukes sends a letter informing the economic operator that the product in question is non-compliant.
    a. The economic operator answers and voluntarily complies → OK
    b. The economic operator does not answer and/or does not comply → Tukes notifies the competent MSA in the EU Member State where the business is located, requesting enforcement actions.
3. The web-page is based in another EU Member State and the economic operator is based in a third country or both the web-page and the economic operator are based in a third country → Tukes sends a letter informing the economic operator that the product in question is non-compliant and mentions the European Commission's (non-legally binding) explanatory note on internet sales targeting EU consumers.
    a. The economic operator voluntarily complies → OK
    b. The economic operator does not answer and/or does not comply → Depending on the case, the Finnish MSA contacts the foreign competent MSA and/or the responsible person in the EU/EEA area who can be targeted for enforcement.

390 http://www.tukes.fi/en/Current-and-News/News/Product-safety/Supervision-by-the-authorities-and-consumer-protection-do-not-cover-the-online-stores-of-far-off-countries/

c. If the product presents a high risk in terms of consumer safety and Tukes considers that it would not be fast enough to contact the economic operator outside its jurisdiction, it warns consumers through a press release.

The Spanish process

Market surveillance of consumer products in Spain is under the responsibility of the different Federal Regions, called 'Comunidades Autonomas' (Autonomous Communities). The central Government, particularly the Ministry of Health, is in charge of coordinating their activities in this field, aimed at ensuring uniform action is taken among the different Communities.

The Agencia española de Consumo, Seguridad alimentaria y Nutrición (ECOSAN, Spanish Agency for Consumption and Food Security), operates within the Spanish Ministry of Health. This agency has a special three-person monitoring team for e-commerce. It investigates online suppliers and informs local authorities when issues arise. The Autonomous Communities organise their own responses based on information received from the central Authority.

Powers. There are no powers specifically related to online sales in Spain.

Customs. Collaboration between MSAs and Customs Authorities is regular, but it is not particularly focused on online sales. Customs Authorities act as a filter, labelling products with colours (green, yellow and red) depending on the level of risk. MSAs organise their activities and focus controls based on these indications, regardless of the sales channel.

Communication. Representatives of Communities' Authorities meet once a month in order to coordinate their action and share the main issues they are facing. The Ministry and local authorities manage campaigns via their official websites, especially during particular periods of the year such as Christmas. However, communication is not extensive and it is not usually performed via the main media.

Theoretical case. MSAs find that a cosmetic product made available on an online platform is non-compliant.

The Spanish investigation would start with online research by the Ministry of Health, looking at websites selling cosmetic products. Once they are found, the Ministry performs a formal check, controlling whether all the necessary and mandatory information is provided, such as labelling, the name of the economic operator, ingredients and materials. The follow up actions after this initial formal check of compliance can be summarised as follows:

1. Both the web-page and the economic operator are based in Spain → The Ministry contacts the Autonomous Community where the economic operator is based, urging it to comply. The subsequent action depends on the seriousness of the non-compliance and it ranges from sending a letter asking for an inspection to an obligation to withdraw the product from the market.

2. Both the web-page and the economic operator are based in another EU Member State → The Ministry asks the competent MSA in the other EU Member State for support in contacting the economic operator. In reality, this often turns out to be rather ineffective, because the economic operator does not respond.

3. The web-page is based in another EU Member State and the economic operator is based in a third country or both the web-page and the economic operator are based in a third country → The Ministry writes a letter to the economic operator and MSA of the country informing them about the issue. The rate of effective response is very low.

After a reasonable period the Ministry checks the website again.

a. The economic operator changed behaviour and complies → OK

b. The problem still persists → the Ministry raises the level of action, depending on the specific situation, adopting stronger measures.

The Dutch process

The Netherlands Food and Consumer Product Safety Authority plans its market surveillance activities on the basis of studies on consumer' behaviour, and acts more on the consumer side than on the industry side, thus investing resources in controlling e-shops but especially in educating e-shoppers. Educating consumers is less costly in the long run, and companies will be encouraged to comply – a 'positive leverage' approach.[391]

More specifically, the number of existing web-shops is huge, making it impossible for a single authority to deal with the issue. Therefore, the Food and Consumer Product Safety Authority deliberately decided not to target online platforms, but rather the consumer side. The MSA investigated Dutch e-consumers' shopping behaviour through a dedicated study. This study showed that the large majority of e-shoppers buy from web-shops located in Holland, from well-known and trustworthy economic operators, which already have physical shops. In addition, Dutch e-shoppers generally buy the same brands and the same products that they would buy in normal shops. Given that Dutch MSAs also control shops that have online pages, products sold online bought by Dutch citizens are not considered to represent an added risk in terms of product safety.

Nonetheless, Dutch e-shoppers are increasingly buying products from Chinese web-shops. They mostly buy small items, such as USB devices, chargers, textiles, cheap cosmetics, and jewellery. Dutch authorities have no power against Chinese web-shops. Therefore, the Food and Consumer Product Safety Authority decided to take various samples from the largest Chinese web-shops (such as Deal Extreme, China Buys and Lightinthebox). This led to the discovery that almost 80% of the products were unsafe and non-compliant with EU legislation: for instance, the nickel content of the jewellery was far above the thresholds allowed, while chargers and USB devices entailed a fire risk. These results were not unexpected; despite the fact that these Chinese web-shops operate on a world-wide scale, they do not necessarily target European consumers and their products are therefore not designed specifically for the EU market.

391 The Dutch enforcement action is therefore mostly proactive and based on prevention. Only 25% of activities are complaint-based - and therefore reactive. Priorities are set by looking at a combination of sources such as citizens' complaints, RAPEX notifications, international studies, previous inspection results or the number of consumers potentially impacted. Several criteria are put into the decision model and then assessed through a final validation about the product risk profile and therefore establishing priorities for upcoming inspections.

Also in this case, the Dutch approach considers **consumers as the main drivers** of the process. Therefore, the Dutch MSAs consider themselves responsible for online sellers located in the Netherlands only, since those outside of the EU are impossible to tackle and would represent a waste of resources. As a result, Dutch MSAs try to inform consumers and warn them in the most effective way, so that they are aware of possible risks related to product non-compliance. Most of these products are unbranded, and in these cases the name of the web-shop is published, together with a photo of the product. However, inspecting and testing these products is very costly in terms of money and time, so Dutch authorities are considering whether to stop these product inspections, with the exception of products presenting a serious risk.

Powers. Dutch MSAs can contact web-shops, force them to warn the public by advertising product risks, engage in 'mystery shopping', and impose fines. MSAs can also shut down websites, although it takes several months and it is considered ineffective since sellers can quickly change name and domain. For the same reason, Dutch MSAs do not frequently take actions against economic operators located outside the EU, as it takes weeks to effectively reach the economic operator and in the meantime the web-shop would continue to offer the non-compliant product.

Customs. There are no special Customs procedures related to online sales. MSAs' cooperation with Customs is very close, the information flow works well and they meet every year to discuss specific problems, though not necessarily related to online sales. Recently, Customs informed the Netherlands Food and Consumer Product Safety Authority about a structural stream of small consignments coming from Chinese web sellers that were all sent to the same economic operator's address. This sort of information triggers plans for inspections.

Communication. The main information channel is the relevant authority's website. The Netherlands Food and Consumer Product Safety Authority has registered an increase in consumer interest, as more shoppers are visiting the Authority's website, asking questions about unsafe products. Unfortunately, the number of consumers visiting the page is still relatively low (around 10,000 per month). This low number could be due to continued lack of consumer awareness about product safety issues. Studies indeed show that consumers underestimate the risk of unsafe products, assuming that there are no dangerous products on the market or that the risk to them personally is very low.

Theoretical case. MSAs find that a cosmetic product made available on an online platform is non-compliant.

Based on the Dutch approach to market surveillance of online sales, the process development can be summarised as follows:

1. Both the web-page and the economic operator are based in the Netherlands → Dutch MSAs try to inform and warn consumers in the most effective way on the risks related to product non-compliance. Moreover, when Dutch MSAs have a physical shop of reference, they can contact the seller for inspection or testing and decide on specific measures.

2. Both the web-page and the economic operator are based in another EU Member State → Dutch MSAs try to inform and warn consumers in the most effective way on the risks

related to product non-compliance. In addition, Dutch MSAs rely on other European MSAs' work, deciding whether to contact them on a case-by-case basis.

3. The web-page is based in another EU Member State and the economic operator is based in a third country or both the web-page and the economic operator are based in a third country → Dutch MSAs try to inform and warn consumers in the most effective way on the risks related to product non-compliance.

8.4.3 A concrete case: LED-lamps in Finland

In the context of Joint Action 2014 (WP8 – LED lamps/compact fluorescent lamp),[392] Tukes acquired several LED lamps and compact fluorescent lamps (CFL) from online wholesalers, which were mostly Finnish-based companies selling lighting equipment online.

The case-specific lamp was acquired from a web-shop (e-ville.com)[393] which offers electrical products for Finnish consumers. E-ville is a platform where different economic operators can sell their products, the website owner is Finnish but located in Hong Kong. The page mentioned that distributors were based in China, Hong Kong and Mäntsälä (FI), while behind the seller's name there seemed to be at least two companies, a Finnish-based and a Hong Kong-based company. The web-page indeed displays from which distributor (or company) the product is coming from, and the same product can be acquired at different prices from different distributors. The case-specific lamp was sold by a Hong Kong-based economic operator.

The LED lamp was acquired and tested by Tukes and it turned out to have many defects that could endanger users' safety, leading to it being withdrawn from the market. The Finnish MSA informed the Hong Kong seller about this, asking for a response. In addition, a second letter was sent to the seller in order to clarify the situation and to clearly state that the lamp does not comply with EU safety requirements, and thus cannot be placed on the EU market. The economic operator answered, promising to stop selling the lamp.

Tukes did not contact the competent authority in Hong Kong, due to the difficulties that they may have involved. If the economic operator did not answer, Tukes would have drafted a press release, informing the public about the non-compliant product, with a warning not to buy it and recommendation to return those already purchased to the seller.

8.4.4 Main issues and challenges

To sum up, the main issues with online sales as emerging from the above case study are:

- Unsafe products withdrawn/banned from the EU market can return on the market through a different website or under a different legal name.
- MSAs do not have a legal mandate to enforce the Regulation outside their jurisdictional boundaries and cooperation among authorities from different countries is not always fast and effective.

392 EU-funded Joint Market Surveillance Action on Consumer Products coordinated by Prosafe.
393 https://www.e-ville.com/fi/

- A lot of time is wasted if the economic operator does not reply or cooperate with the foreign authority.

- Difficulties in verifying the compliance of products sold online, because most goods are delivered to consumers directly.

- Scarce resources to check every consumer consignment entering the country, due to the volume of products sold through e-commerce channels and complex distribution chains. Controls carried out are considerably less than those deemed necessary.

- Low level of consumer awareness concerning the risks of buying products online.

8.4.5 Possible solutions

Overall, the described approaches to market surveillance of online sales are similar in the three countries considered. While MSAs are face no particular obstacles if the economic operator and the web-page are located in the relevant country, the process is more complex if they are based in another EU Member State or in a third country.

In light of the limited resources devoted to market surveillance of an impossibly large number of online shops, **mutual learning and greater emphasis on cooperation** among Member States and MSAs is strongly recommended. The use of information-sharing tools, such as RAPEX and ICSMS, needs to be increased, in terms of both the number of notifications and the number of responses. A positive signal in this direction is that, in 2014, for the first time some RAPEX notifications were related to measures taken against products sold online.

In addition, although it is true that the number of online shops and the rapidity through which they can be set up make it impossible to fully control internet sales, it is also true that there are means at hand to tackle the negative effects of online sales of non-compliant products. For instance, carry out **'mystery shopping' tests** to verify product compliance, combined with **the power to shut down websites** in cases of serious infractions, would be a cost-effective approach once the initial investment (software and skills) has been made. Another possibility could be the **designation of a responsible person/entity** (e.g. authorised representative, importer[394]) in the EU that could be held liable for non-compliant products. This could also help address the difficulties MSAs experience obtaining responses from (online) economic operators located in third countries and the limited cooperation MSAs have with authorities in those third countries. Furthermore, **in case of unresponsive economic operators**, authorities could be empowered to stop non-compliant products from entering the internal market, and ultimately destroy them, which may be more cost-efficient than lengthy procedures to trace foreign traders and/or request foreign MSAs to take enforcement measures. The case study shows that online business models evolve quickly and are increasingly complex, with many different parties and intermediaries. The ideal toolbox of the 'digital future' should allow MSAs to identify and act quickly against traders and their intermediaries in complex online supply chains.

394 More controls online overall and designation of a responsible person/importer were rated highly (49% strongly agree) in the public consultation, see interim report page 74)

The case study nonetheless also indicates that coercive enforcement action alone by the MSAs will only be a partial response. Measures are also needed to increase awareness and visibility of product warnings to end-users, including **naming and shaming**.

In this respect, if a more **structured approach** is required, particularly with respect to web-shops based in third countries, the Dutch strategy seems to be a good practice as it significantly reduces costs and is expected to increase compliance in the long run. As also reported in COM (2013) 76 final, **consumer awareness** could be increased and the **roles and responsibilities of the relevant parties** (authorities, economic operators and consumers) further defined by means of '*short, simple and clear public information statements'*.

Similarly, **consumer awareness** could be raised by increasing perception of the importance of the CE marking or by clarifying the 'buyer beware' principle for products bought online. The Finnish public-awareness campaign called '*There is no sheriff in this town'*,[395] is a good example of this.

Some interesting solutions could be based on the management of **relations with e-sellers.** This involves the possibility to punish online platforms when selling non-compliant products and the establishment of cooperation agreements with e-commerce websites in order to ensure additional control over the products offered. Providing accurate information to those wishing to sell online could represent a further path to improvement.[396]

Furthermore, one interviewee[397] underlines that **the market surveillance systems for EU regulations on feed, food and veterinary controls are particularly effective** in keeping out non-compliant products. Fees for inspection and controls are (partially or completely) paid by companies importing these goods. The Dutch Delegation has often referred to this system in discussion with the Commission and Member States, insisting that this system should be replicated for market surveillance and border controls covering non-food products as well. Obviously this system would mean additional burdens for businesses (due to fees and import controls in ports). However, a possible solution could be to introduce a list of products and countries of origin that are constantly notified in RAPEX and agree on mandatory border controls for these products (for instance, by setting a risk-based threshold e.g. 30% of all incoming shipments). Products and countries of origin can then be removed from the list if and when controls show a decline in non-compliance. As stated by the interviewee, experience within the framework for feed, food and veterinary controls shows that the authorities in the country of origin are motivated to get off this list by investing in export controls.

8.4.6 Sources

Interview with the Spanish Ministry of Health and Social Services

Interview with the Finnish Safety and Chemicals Agency (Tukes)

Interview with the Dutch Food and Consumer Product Safety Authority

395 http://www.tukes.fi/en/Current-and-News/News/Product-safety/Supervision-by-the-authorities-and-consumer-protection-do-not-cover-the-online-stores-of-far-off-countries/
396 SEC (2011) 1640 final and PANTEIA (2014).
397 Netherlands Food and Consumer Product Safety Authority.

Interview with the Finnish Customs (Tulli)

COM (2013) 76 final. Product Safety and Market Surveillance Package – Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee. 20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU.

PANTEIA (2014), Good practice in market surveillance activities related to non-food consumer products sold online (+ Annex)

SEC (2011) 1640 final. Commission Staff Working Document. Bringing e-commerce benefits to consumers – available at http://ec.europa.eu/internal_market/e-commerce/docs/communication2012/SEC2011_1640_en.pdf

8.5 Case study 4: Cross-border market surveillance: follow-up given to restrictive measures taken by other Member States

The objective of this case study is to assess the effectiveness of work-sharing arrangements among Member States. In particular, it focuses on two tools: the **RAPEX system** and the **safeguard clause procedure**.[398] It assesses existing issues in the work sharing among both notifying and recipient countries, the type of work carried out by MSAs, issues leading to potential disagreement among Member States, the reasons for not reacting and any other relevant aspects. In order to provide examples of these working mechanisms, a specific RAPEX case and one on a safeguard clause notification is also included.

8.5.1 Communication means among European MSAs: RAPEX system and safeguard clause

Once entering the EU, non-compliant products can freely circulate in all Member States, which makes information sharing among Member States crucial. The RAPEX system and the safeguard clause procedures are tools allowing the exchange of this information.

RAPEX[399] is an information system provided by the European Commission. Whenever Member State authorities find a non-food product posing a serious risk to the health and safety of consumers, they file a notification in the system. Each notification reports information such as the product category, brand, model, a general description, its risk level and details. Moreover, measures taken in relation to this products by the notifying country are also reported. Finally, the system displays other Member States where the product was found and that have taken measures. A list of detected dangerous products is published online – thus accessible to the wider public – by the European Commission every week.

RAPEX is a fundamental tool for the implementation of **reactive** market surveillance in most Member States. Information may also come from producers or distributors who voluntarily organise recalls of their products and want to inform the national competent MSAs. Thanks to RAPEX, data relating to dangerous products found on a national market can quickly circulate all over Europe, thus helping market surveillance efforts within the internal market.

398 The case study has few information on the safeguard clause procedure as interviewees had no experience about it.
399 http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm

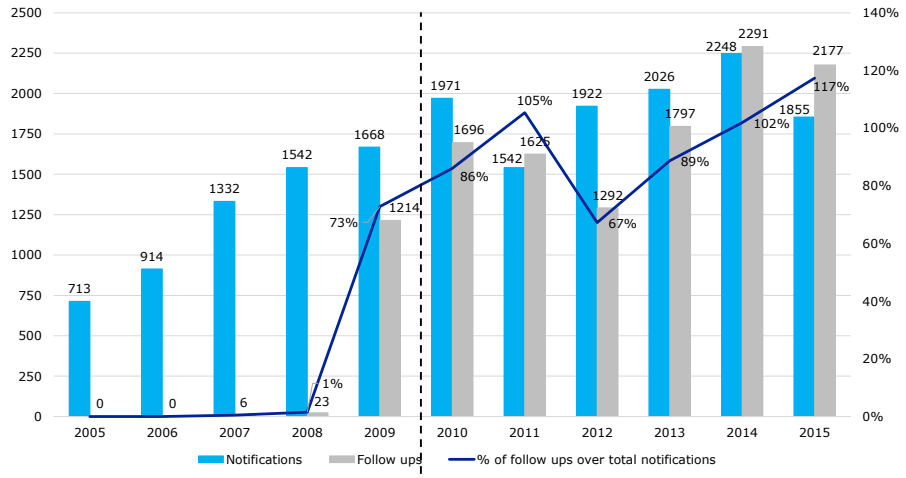
The **safeguard clause** is included in all the New Approach Directives. The safeguard clause procedure requires Member States to take measures against CE-marked products that do not comply with a specific Directive or Regulation and present a risk to the public (health and safety or other), and to inform the Commission and other Member States about these decisions and related reasons. In particular, it has to be used in non-conformity cases, in cases of incorrect application of and/or deficiency in standards. Once notified of a safeguard case, the Commission investigates and decides whether to settle it or not. The safeguard clause is a legal obligation for all Member States and it plays a role in the information exchange among Member States.

Both tools enhance the circulation of information among Member States, thus contributing to the implementation of market surveillance activities.

8.5.2 Use of RAPEX

As shown in the graph below, **the use of RAPEX has significantly increased over the years, both in terms of number of notifications and of follow-up actions**. Figure 4-49 shows that both trends are rising, with a decline only between 2011 and 2012. Overall, 3,228 RAPEX notifications (representing 18.2% of total notifications) from 2005 to 2015 had at least one follow-up reaction. The total number of follow-ups from 2005 to 2015 is 12,182 and the total number of notifications in the same period is 17,736 – the overall proportion of follow-ups to notifications is 68.7%.[400] Interestingly, **the weight of follow-ups over total notifications increased over the period** and from 2014 the number of follow-ups outweighs the number of notifications, this possibly indicating that RAPEX is growing in recognition and use as an information tool for enforcing market surveillance.

Figure 4-49 - Number of RAPEX notifications and follow-up measures per year[401]



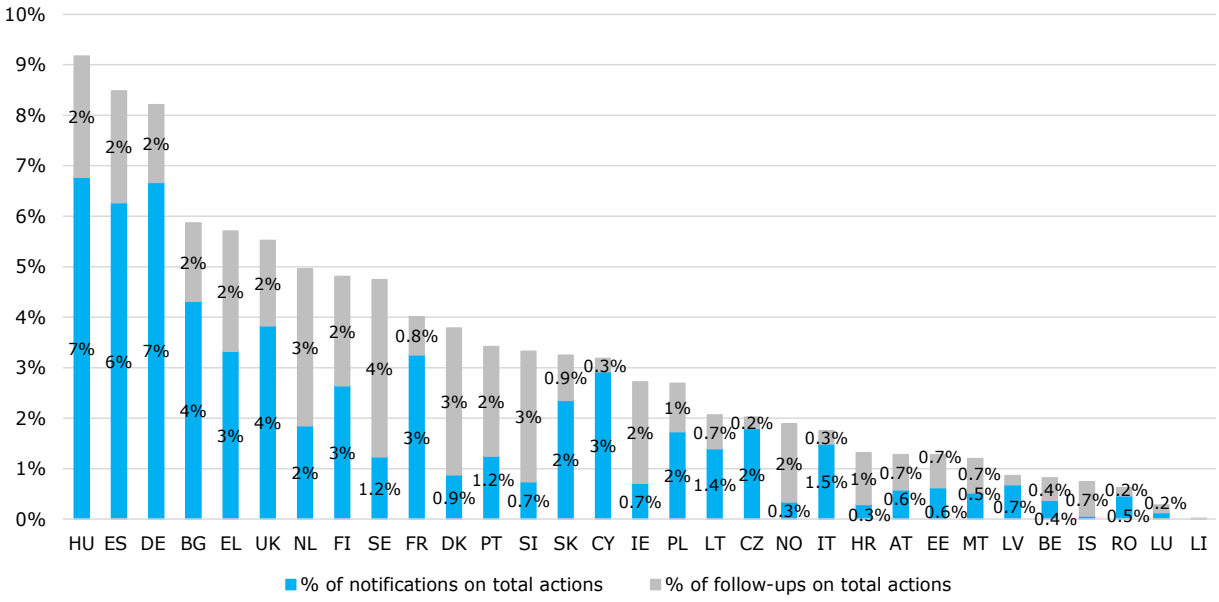
Source: Authors' elaboration on RAPEX database

The use of RAPEX across Member States differs, both as notifying and as recipient countries. As shown in Figure 4-50, overall **Hungary, Spain and Germany are the Member States**

400 The source for these data is RAPEX database.
401 2010 = entry into force of Regulation 765/2008.

reporting the most on RAPEX, while Luxembourg, Romania and Belgium are the least engaged. It is worthwhile observing the distribution of active and reactive measures across countries. **Hungary, Germany and Spain are the most active Member States**, notifying more than 1,500 products each over the last 10 years (i.e. around 33% of total notifications were filed by them). Less active Member States are Luxembourg, Croatia, Belgium and Romania, each filing less than 150 notifications. In terms of follow-up actions, **Sweden, Denmark and the Netherlands are the most reactive Member States** on RAPEX (each with more than 800 notified follow-ups over the last 10 years, representing 23.5% of total follow-ups), while Latvia, Luxembourg and Romania all reported less than 60 follow-ups in 10 years.

Figure 4-50 - Percentage of notifications and follow-ups per Member State on total actions notified on RAPEX over the period 2005 – 2015



Source: Authors' elaboration on RAPEX database

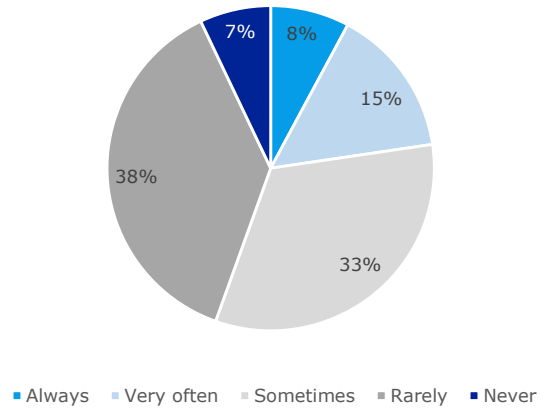
However, low notification numbers do not necessarily mean that Member States are less active against non-compliant products, since RAPEX is a communication tool and it may be that some MSAs are just not sharing all the information. **Member States' behaviour on RAPEX could help in understanding the preferred approach to market surveillance (reactive or proactive)** adopted by different Member States. For instance, it may be possible that Member States that are more active in follow-up than in notifying, such as Croatia, Ireland or Denmark, are adopting mainly a reactive approach. Whereas Member States like Cyprus, the Czech Republic or Germany seem to adopt a more proactive approach.

The answers to the targeted surveys are also useful in describing trends in the use of RAPEX. In particular, 75%[402] of MSAs say they issue a notification when they find a non-compliant

402 41 MSAs (2 AT, 2 BE, BG, 2 CY, DE, 2 DK, ES, 6 FI, 2 IT, 4 LT, LU, 2 LV, 5 NL, PL, 9 SE) and eight AdCO members (electromagnetic compatibility, explosives for civil use, gas appliances, measuring instruments, medical device, noise, pyrotechnic articles, recreational craft).

product, which means 25%[403] do not. However, as shown in the chart below, according to 38%[404] of respondents to the public consultation, MSAs '*rarely'* restrict the marketing of a product following the exchange of information about measures adopted by another MSA in the EU against the same product. This occurs '*sometimes',* according to 33%[405] of stakeholders, while a minority declare that it occurs '*very often'* (15%[406]) or '*always'* (8%[407]). While 7%[408] of respondents think that MSAs '*never'* exploit information received from other EU MSAs.

Figure 4-51 – MSAs' restrictions on the marketing of a product following measures adopted by other European MSAs



Source: public consultation

Nonetheless, stakeholders almost universally recognise the **convenience of using information on restrictive measures adopted by other MSAs to eventually adopt the same approach towards the same products supplied within another Member State's jurisdiction**. The majority of them think this would be useful for saving time and costs, for improving the focus of inspections – thus, again, increasing process efficiency – and for ensuring that restrictive measures are adopted in other jurisdictions on the same basis. That way, they can be effective in a larger part of the internal market.

8.5.3 Focus: use of RAPEX in four Member States

In ***Denmark***, **a RAPEX reaction procedure** starts with the scanning of the weekly report published on the European Commission's website. The Danish RAPEX Contact Point searches for incoming notifications and forwards them to the responsible MSA, to enforce the case. The first step is to **verify the presence** of the product on the national market. If the

403 14 MSAs (2 DE, 3 FI, 2 LT, 3 LV, 3 SE, UK).
404 Nine MSAs or Custom authorities (CY, CZ, FI, 2 NO, 2 PL, 2 SE), four public authorities (DE, ES, 2 LT), ten economic operators (BE, DE, ES, 3 FR, NL, PL, SE, UK), ten industry associations (6 BE, DE, EL, 2 UK), a Belgian trade union, 1 consumer organisation (BE), an English consumer/citizen, two others (BE, SK).
405 13 MSAs or Custom authorities (AT, CZ, 3 DE, DK, EE, ES, FI, IS, LT, NO, PL), five economic operators (DE, ES, FR, HU, NL), ten industry associations (4 BE, CH, ES, FR, NL, 2 UK), an English international organisation, two academic/law firms (DE, UK), a French 'other'.
406 Six MSAs or Custom authorities (CY, HR, NO, 3 SE), two industry associations (BE, PT), a German academic/law firm (DE), two German others.
407 Four MSAs or Custom authorities (DE, HR, IT, LT), a German public authority (DE), an English industry association.
408 A Norwegian MSA, four economic operators (ES, FR, SE, UK), three industry associations (ES, FR, IT).

economic operator indicated by the notification is Danish, the MSA assumes the product is available on the Danish market. In case the country of origin is different, the MSA starts an **online search** to detect the product and collect information about the economic operator. Once found, the MSA usually **approaches the economic operator** with a phone call, asking whether it is selling the product in Denmark. If the economic operator confirms, the MSA sends an official letter to it, explaining the issue and asking for details and information, such as the product name/brand, how many items have been sold, where it was purchased, the name of the importer on the Danish market, the name of the importer at the EU level – if different from the Danish one – and in which other Member States the product is sold. The MSA also provides a copy of the notification and a reply-form, requiring the seller to fill in and return it within a fixed time period (seven days for serious risk and two weeks in normal cases). Finally, the MSA **publishes information** about the product on its website and enters its reaction into RAPEX once a decision is made. Danish MSAs have to close market surveillance cases within 40 days.

The Danish Safety Technology Authority (the competent MSA for the specific case that will be discussed below) typically does not contact the notifying Member States or perform further tests on 'notified' products. It basically trusts the RAPEX notification and tries to solve the case by directly contacting the economic operator, if relevant.

France gives access to RAPEX not only to the National Contact Point – the Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF) – but also to other MSAs so they can check notifications relating to the sectors they are responsible for. When the notified product is manufactured, distributed, or imported into France, and therefore France is explicitly involved in a notification, the case is examined and recorded in the DGCCRF traceability system (the SORA-alert IT application). However, even if France is not directly involved, all notifications are checked daily through the CSCE (Electronic Commerce Monitoring Centre) web inquiry service, aiming to find out whether dangerous products are sold on French-language websites. After a RAPEX notification is recorded in the database, **the DGCCRF performs a risk assessment** and within 24 hours **sends a request for intervention to the MSA of the region** where the economic operator is based, asking them to investigate and take the necessary measures. The local MSA always reports back to the central MSA any information concerning the case and updates it through all phases of the process: from investigations and decisions on measures, through to final controls on whether economic operators' have taken the necessary actions. The relevant MSA takes note of the risk assessment provided by the notifying Member State and, in the event of discrepancies, carries out its own assessment.

The ***Cypriot*** Consumer Protection Service within the Ministry for Energy, Commerce, Industry and Tourism is the National Contact Point for RAPEX. Every week, it forwards the RAPEX weekly report to the other national MSAs, sending the specific notifications they are in charge of. The Consumer Protection Service is responsible for toys and GPSD and is used to translating notifications from English to Greek before forwarding them to the other national MSAs, and making public announcements about the risk and any related measures. As stated by the interviewed Cypriot MSA, Cyprus completely relies on risk assessments provided by other Member States on RAPEX and does not perform its own risk assessments, due to the

fact that it is a small country and economic resources for market surveillance are limited.[409] Once a **RAPEX notification** has been received, if the product is sold on the national market, the Cypriot MSA **immediately proceeds** with a withdrawal notice to the economic operator. Cypriot MSAs clearly **rely on other Member States' notifications**, **and test results**. Due to a lack of resources, it does not test products, even when no test report is provided. At the same time, the economic operator is asked to provide the MSA with information on the product, such as invoices, quantities sold, and number of items in stock, within 10 days. When information is received, the MSA evaluates the case and decides before entering the reaction in RAPEX. It also informs consumers about non-compliant products, asking them to return purchased items to the seller.

In ***Ireland***, the Competition and Consumer Protection Commission (CCPC) is the national contact point for RAPEX, monitoring the system on a continuous basis. The CCPC uses to follow up the notifications related to its areas of competence (i.e. toys, LVD, GPSD, Gas Burning Appliances and PPE (leisure and recreational)) with the relevant economic operators. If the notification relates to a different sector, it forwards it immediately to the relevant MSA, so that it can be processed accordingly. Once a notification relevant for CCPC is received, the MSA firstly gathers all the information available e.g. nature of the risk, details on the number of products circulating in the country, contacts of the relevant Irish economic operator. In this context, **the CCPC relies on the assessment of the notifying Member State**. The CCPC may also contact the notifying country to clarify if the products have been placed on the Irish market and to obtain the contacts details for the relevant economic operator in Ireland. In this process, **the most common issue that could arise is when the notifying country has stated that the product was placed on the Irish market, while this was not the case, or where follow-up questions submitted to the notifying country by the CCPC are not responded to or the requested information is not provided to the CCPC promptly**.

As a second step, the CCPC contacts the economic operator to ask whether the product concerned was actually placed on the Irish market. If this is the case, the MSA ensures that the national economic operator is taking all necessary measures to withdraw the product from the market and to recall it from consumers. Furthermore, it requests information on e.g. how many products they placed on the market, the contact details of any other operators they provided the product to, and details as to how they intend to recall the product. Thirdly, based on the information received, the CCPC may prepare and publish a notice giving the recall information on its own website, which may also be circulated through the CCPC social media platform. Finally, using all the relevant information obtained, the CCPC will prepare and submit the relevant reaction to the RAPEX system.

8.5.4 Focus: use of the safeguard clause in four Member States

As for **safeguard clauses**, the ***Danish*** DSTA enters the product into its internal data collection system and controls whether it is available on the national market. Three scenarios are therefore possible:[410]

409 Interviewee with the Consumer Protection Service, Ministry of Energy, Commerce, Industry and Tourism (Cyprus)

410 The four provided scenarios correspond to the four possible classification codes that DSTA adopts in order to classify safeguard clauses within its internal database.

1. **The product is not on the Danish market**: the DSTA does not need to take any actions;

2. **The product is on the Danish market:** DSTA takes the necessary follow-up actions, approaching the economic operator, providing seven or 14 days to come back with an assessment of product compliance, after which the MSA takes a decision;

3. **The product is on the Danish market and has been notified in RAPEX**: DSTA takes the necessary follow-up actions (as described under point 2);

4. **The DSTA has objections to the notification**: the DSTA provides to the EC all relevant information and documents in order to substantiate its objection.

The ***French*** DGCCRF firstly examines whether the safeguard clause notification concerns a French operator. If this is not the case, they leave it to other authorities responsible to react. If the operator is French, the DGCCRF carries out research in order to find out whether the product is present or not on the national market and assesses the product's safety and conformity levels. Procedures for safeguard clause notifications (including the case-specific notification) are similar to the one already described for RAPEX. However, safeguard clauses may lead to changes in the imposed measures, when the national MSA's opinion concerning measures to be taken diverges from the one suggested by other Member States, due to the related procedures at the European level. In those cases, the DGCCRF communicates its official reaction to the European Commission and explains its reasons, waiting for the Commission's opinion and adjusting the adopted measures in order to fully satisfy the Commission's final decision.

As for the process with **safeguard clause notifications** in ***Cyprus***, the interviewed MSA says it receives very few of them, because it is only responsible for two Directives within the scope of Regulation. Furthermore, it tends to take into consideration notifications on well-known brands and it has so far received only minor, unknown notifications relating to Chinese products that were difficult to detect on the national market. However, the procedure followed would be the same as that for RAPEX notifications.

Finally, the *Irish* CCPC have not received any safeguard alerts to date where the products concerned have been placed or made available on the Irish Market, so no information can be provided in this respect.

8.5.5 The specific case

The table below compares the main information available via RAPEX and safeguard clause notifications, in order to better present the differences and/or similarities between the two.

Table 4-32 – Comparison between a RAPEX and a safeguard clause notification

Information	*RAPEX notification*	*Information*	*Safeguard clause notification*
Year	2015	*Year*	2015
Notification number	A12/1114/15	*Notification number*	SE-15-07

Information	*RAPEX notification*	*Information*	*Safeguard clause notification*
Product	Tablet computer	*Product*	Lightning chain with LED-module
Brand	NVIDIA	*Brand*	Confidential
Name	SHIELD Tablet		
Country of origin	China	*Country of origin*	Sweden
Notifying country	Malta	*Notifying country*	Sweden
Reactions also in	Denmark, France, Ireland	*Other countries in which the equipment is placed on the market*	Belgium, Czech Republic, Denmark, Finland, France, Germany, Latvia, Norway, Russia
Risk level	Serious risk	*Reasons for measures taken*	Non-conformity with Article 2 of the Low Voltage Directive resulting from a faulty application of the applicable standard(s). Standard(s) reference: EN 60598-2-20:2010 and EN 60598-1:2008+A11:2009
Risk type	Fire		
Measures	Recall of the product from end users	*Measures*	Removal from circulation, prohibition of the placing of the equipment on the market

The NVIDIA example was chosen because it is a well-known international brand and both tablets and lighting chains are mass-consumer goods. These features make those products likely to be widespread on the market, and thus circulate in several countries.

As shown in the table above, data provided by safeguard clause notifications relate to specific Directives (Low Voltage Directive in the provided case) and contain information about non-EU countries where the product is likely to be found. It implies that Member States may be particularly encouraged to look for the product on their market and to adopt restrictive measures. A further difference between the two types of notification is the fact that, by using safeguard clauses, MSAs exchange information independently from the product risk level, while RAPEX provides accurate information on product risk. Moreover, RAPEX notifications are public, while safeguard clauses remain more confidential and may also contribute to the modification of the standards set by EC Directives.

The Danish reaction

As shown in the previous table, Denmark is among the countries reacting to the RAPEX notification and warned via the selected safeguard clause. Every time a RAPEX notification appears, the Danish Safety Technology Authority (DSTA) checks whether the case is already under scrutiny by a national authority, in order to avoid any duplication of work. In those cases, they virtually ‘re-open’ the case and insert their action in RAPEX.

With specific regard to the **safeguard clause**, the DSTA decided not to take it into account.[411] As for the **RAPEX notification**, it was already aware of the product and related risk, thanks to a notification received via a business application informing about voluntary measures against this product taken by an economic operator in the UK. So the DSTA was able to act before the publication of the RAPEX notification. Two economic operators were selling the tablet in Denmark and both were contacted by the DSTA one day before the notification appeared on RAPEX. One of the two also received the notification via the business application and voluntarily recalled the product, while the other answered that it was no longer selling the non-compliant tablet. The DSTA therefore accepted the voluntary measures and the explanations provided by the two economic operators and the case was closed. It required the economic operators to inform consumers on their website and also extended the economic operators' responsibility for product non-compliance for a period longer than the usual three months given to economic operators to take voluntary measures.

The French reaction

Contrary to Denmark, the case-specific RAPEX notification was received by the DGCCRF on the day it appeared on RAPEX (i.e. on 4 September 2015). On the same day, the DGCCRF sent a request for intervention to the MSA of the Alpes-Maritimes department, where NVIDIA's French headquarters are based. The MSA was asked to meet the economic operator to verify its legal status, check the technical documentation, establish the traceability of the product (e.g. possible re-sellers, quantities already sold and held in stock), and to inform the notifying Maltese Authority about the existing risk. Moreover, the local MSA had to ensure that the economic operator took appropriate short-term measures and informed consumers about the recall by collecting any documents used for this purpose. In the specific case, NVIDIA sent emails to its customers. On 11 September, the Alpes-Maritimes MSA informed the DGCCRF that the economic operator only had research centres within their territory, while its management was located in the Hauts-de-Seine region. Subsequently, a request for intervention was sent to the local Hauts-de-Seine MSA. On 13 October, implementation of the recall on all French territory was confirmed and a RAPEX reaction was submitted on 15 October. The local MSA in Hauts-de-Seine continued to monitor the effectiveness of the measures, reporting in November that 3,969 requests for replacement products were submitted by consumers in France. An update was provided in February 2016: by that date, the company had received 4,180 exchange requests, which represented a 53% return rate of products sold, of which 4,149 were actually replaced. In addition, they provided evidence of the destruction of 52 tablets that were still in stock. In light of this, the DGCCRF decided to close the case in February 2016.

The Irish reaction

As reported in the CCPC's website,[412] NVIDIA has announced a voluntary recall of its SHIELD™ 8-inch tablets that were sold between July 2014 and July 2015, declaring it will replace them. According to NVIDIA, a total of 89 of these tablets have been placed onto the Irish market.

411 The interviewee was not able to provide additional information.
412 http://www.consumerhelp.ie/index.jsp?p=127&n=391&a=1419

The MSAs informs that the economic operator is asking customers to visit its website for information on how to obtain a replacement device, asking consumers to stop using the recalled tablet.

8.5.6 Main issues and challenges

Several issues related to cross-border cooperation arose during the interviews. Some of them concern the **design of the RAPEX notification procedure**. When filing a notification, many Member States select the option '*ban on the marketing of the product and **any accompanying measure'*** in order to describe the measures taken. Due to its vagueness, this entry may create problems to other Member States in fully understanding the adopted measures, eventually forcing them to start a new investigation with the result of making the communication process less effective. Further information gaps may be due to the **lack of risk assessment data and test reports on RAPEX** and to **possible disagreements on risk assessments** (especially within safeguard clause notifications). In the first case, Member States may find it difficult to rely on other MSAs' decisions, leading to duplication of testing costs. In the second case, disagreements between the Commission and the notifying Member State can result in notifications not being disseminated. Moreover, a barrier for RAPEX users is based on **language –** RAPEX is only available in English.

Issues also arise when the **country of origin of the notified, non-compliant product** is not involved in the process, especially disagreements between notifying and recipient countries. For example, a product whose country of origin is Member State X is notified in RAPEX by Member State Y. If Member State Z's follow-up reaction to this notification is not in line with the measures taken by notifying Member State Y, all the other Member States may find themselves in a difficult position in choosing the best measures to adopt. Finally, according to an interviewee,[413] the **safeguard clause notification procedure is heterogeneously implemented** by Member States and its systematic application is not effective yet. In addition, the existence of two **different notification procedures** for non-compliance (i.e. RAPEX and the safeguard clause) is perceived as redundant by MSAs.[414]

8.5.7 Possible solutions

According to an interviewee there should be proportionality, both between the seriousness of non-compliance and measures adopted by a country, as well as among actions taken by different Member States. **Further details and explanations on the adopted measures** within the single notification could ease MSAs' processes in terms of speed and the proportionality of decisions.[415]

In general, the **more information posted** in a notification, the better it helps MSAs in **prioritising** follow-up actions. An interviewee[416] suggested some measures to speed up the reaction processes. Firstly, the database should be designed in order to **immediately distinguish between already opened notifications and those still to be processed**.

413 Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF).
414 Stated by all interviewees within the framework of this case study.
415 The Danish Safety Technology Authority (DSTA).
416 Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF).

Secondly, the **size of downloadable files** should be increased in order to include heavy files such as photos and colour test reports.

In addition, it may be useful to add to the RAPEX tool a function to **solicit specific Member States to react** regarding cases where an additional opinion is needed, for instance by sending an alert message personally from one Member State to the other, thus creating a sort of 'chat', or forum. As stated by two interviewees,[417] in such cases it could be useful to collect the opinion of the Member State where the good is produced. Moreover, if the supposed non-compliant economic operator is European, the Member State of origin should be aware of investigations carried out by other EU or extra-EU countries using the tool. In addition, voluntary measures taken by foreign retailers should also be notified, so relevant Member States can take adequate measures. This kind of information should be shared by other countries using RAPEX before the final decision is made.

Possible solutions to the language barrier could be to **translate** the RAPEX website into the main languages of the EU, or at least the translation into English of risk assessments attached to RAPEX notifications and a standardised description thereof.[418] Those actions would help as many users as possible to become aware of non-compliant products and to pursue investigations within their countries.

As for the presence of multiple tools for exchanging information among European MSAs, **simplifying and reducing this to one single notification procedure** may reduce administrative burden and speed up the process. In particular, it should be assessed how to improve the IT tool in order to avoid a safeguard clause notification when one has already been filed in RAPEX.

8.5.8 Sources

Interview with the Consumer Protection Service, Ministry of Energy, Commerce, Industry and Tourism (Cyprus)

Interview with the Danish Safety Technology Authority (DSTA)

Interview with the Direction Générale des Finances Publiques (France)

Interview with the Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (France)

Interview with the Swedish Board for Accreditation and Conformity Assessment (SWEDAC)

Interview with the Competition and Consumer Protection Commission (CCPC) (Ireland)

Prosafe (2013), Best practice techniques in market surveillance – available at: http://www.prosafe.org/library/knowledgebase/item/best-practices-techniques-in-market-surveillance

417 The Danish Safety Technology Authority (DSTA) and Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF).

418 Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF).

European Commission website on RAPEX: https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/main/?event=main.listNotifications

Blue Guide 2016 – available at: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=7326

8.6 Case study 5: Penalties available to Member States as incentives to comply

The objective of this case study is twofold.

Firstly, it aims at providing a **quantitative overview** of penalties (administrative and criminal, monetary and non-monetary) available to EU Member States in a specific sector among those covered by Regulation 765/2008, i.e. that of electrical appliances and equipment under the Low Voltage Directive (LVD, 2006/95/CE). For a complete overview on penalties, please also refer to Annex.

Secondly, the case study identifies four Member States where MSAs cannot impose administrative sanctions for product non-compliance without resorting to the courts. This could further hamper the enforcement powers of MSAs inasmuch as **the process for imposing sanctions is, within these models, potentially lengthy and burdensome.**

The ultimate purpose of the case study is to understand whether it is necessary to foresee some **minimum criteria within the regulatory framework** to increase the effectiveness of penalties for product non-compliance.

8.6.1 The case of the low voltage sector

The high variance across Member States in terms of sanctions is particularly evident within a single product category. The following table presents a mapping of sanctions for breaches of the LVD.

Table 4-33 – Comparison of sanctions in LVD sector across Member States[419]

MS	*Administrative penalties*	*Criminal penalties*
AT	Fines up to €25,435	Established dangers to health and fraud and falsifications of documents are the basis for criminal charges
BE	Foreseen	Foreseen
BG	Fines from €125 up to €500 for retailers, from €125 up to €7,500 for importers and manufactures	Not foreseen
CY	First non-compliance: fines up to €6,000.	First non-compliance: fines up to €20,000 and/or up

419 The table is filled on the base of multiple sources. Information mainly comes from the national transposition laws of the Low Voltage Directive 2006/95/EC. Additional sources are targeted surveys, ad-hoc requests sent to IMP-MSG representatives in each Member State and analysis of data received compared with data available in national programmes and other publicly available documents. Where information was not available within the listed sources, cells are filled with 'n.a.'.

MS	*Administrative penalties*	*Criminal penalties*
	Second non-compliance: fines up to €12,000	to two years imprisonment. Second non-compliance: fines up to €40,000 and/or up to four years imprisonment
CZ	Fines up to €1,802,776	n.a.
DE	Fines up to €100,000	n.a.
DK	Not foreseen	Foreseen
EE	Fines up to €3,200	Fines from €300 up to €16,000,000 and/or imprisonment up to three years
EL	Fines up to €1,500	n.a.
ES	Fines from €3,000 up to €601,000	Criminal fines exclude administrative fines
FI	Not foreseen	The penalty for health offence is at minimum a fine, with a maximum six months imprisonment
FR	Foreseen	Foreseen
HR	Foreseen	Fines from €652.91 to €130,582.40
HU	Foreseen	n.a.
IE	Foreseen	Fines up to €500,000 and/or imprisonment up to two years
IT	Fines from €2,000 to €62,000	Established dangers to health and fraud are the basis for criminal charges
LT	Fines for employees and individual enterprises from €50 up to €300 and between €80 and €300 for heads of legal entities. In case of repeated non-compliance: fines for employees and individual enterprises from €80 up to €600 and between €300 and €600 for heads of legal entities	n.a.
LU	Fines up to €15,000	Maximum sanction €1,000,000 and/or up to three years' imprisonment
LV	Fines up to €14,000	Not foreseen
MT	Not foreseen	Fines from €465 up to €11,646 and/or imprisonment (up to three years). If repeated offence: fines from €1,747 to €23,293 and/or imprisonment (up to four years)
NL	Fines up to €900,000	Foreseen
PL	Fines up to €24,000	Not foreseen

MS	*Administrative penalties*	*Criminal penalties*
PT	Fines from 1,500 to 44,750	Foreseen
RO	Fines from €550 up to €2,200	If non-conformities of the products lead to death or acute injuries
SE	Foreseen	Foreseen
SI	Fines from €2,000 to €40,000 for legal entities and from €200 to €4,000 for individuals	Foreseen
SK	Foreseen	n.a.
UK	Administrative fines are not foreseen	Foreseen

Sources: national laws, national reports, interviews and questionnaires sent to stakeholders

The table shows that criminal sanctions and administrative monetary sanctions are not foreseen in all Member States. Moreover, maximum fines vary significantly across countries, as well as minimum ones. For instance, fines in Lithuania go from a minimum of €14 up to a maximum of €600, while in Romania they range from €550 to €2,200, and in Bulgaria they start from a minimum of €125 up to a maximum of €7,500. Those limits are particularly low if compared to minimum fines in Slovenia (€2,000) or Spain (€3,000) and to maximum fines foreseen in Germany, Ireland and Luxembourg, which amount respectively to €100,000, €500,000 and €1,000,000. Imprisonment periods vary greatly and they range from six months in Finland, two years in Ireland, three years in Greece and Luxembourg, and four years in Cyprus and Malta.

8.6.2 The role of the courts in the sanctioning process

The main difference between administrative and criminal procedures is the role of the courts in setting criminal sanctions. They do not usually take part in the administrative process except **in some Member States** (i.e. Austria, Finland, Ireland, Malta and the UK) where the **courts are can be involved in administrative procedures as well**, though playing a different role depending on the national legislative framework.

The sanctioning process in Austria. After a preliminary investigation of suspected non-compliance, the responsible Austrian MSA contacts the economic operator, requesting information and documentation. Depending on the information provided, the MSA decides whether to close the investigation, if compliance is verified, or to impose an administrative sanction. In this case, the economic operator is given two weeks to appeal to the Administrative Court. If the sanction is not contested, the decision will be binding and enforceable. If the economic operator appeals, the case passes from the MSA to the judiciary which examines and decides whether to uphold the MSA's decision or modify it. The court is only responsible for setting the right penalty based on evidence presented, and not for verifying product compliance, which is MSA's task.

The sanctioning process in Malta. MSAs in Malta cannot impose administrative (monetary) sanctions. If a product is found to be non-compliant after an investigation, the economic operator is contacted by the MSA, which imposes a restrictive measure, such as a recall or a

withdrawal. The case is then closed if the economic operator complies. If it does not cooperate, the case is brought to court, which sets the fine and/or period of imprisonment in serious cases. Monetary sanctions in Malta can only be imposed by the court and they may vary case by case, depending on the specific sectoral law and on the seriousness of the infringement.

The sanctioning process in Finland. Finnish MSAs have the power to impose restrictive measures as foreseen by the Regulation, such as the recall, withdrawal or banning of a product from the market. They also have the option to order penalties (payments) if they impose a restrictive measure and the economic operator is not respecting it. In these cases, MSAs can directly impose payments, but only if related to a certain decision. Monetary (administrative) fines and criminal sanctions, such as imprisonment, are matters for the court. If MSAs want to impose fines on non-compliant economic operators, they have to inform the police and refer it to the court, which sets the fine following the provisions of specific sectoral laws and the criminal code.

The sanctioning process in the UK. An interviewee from the UK says that resorting to sanctions and prosecution is viewed as a '*failure of enforcement'*. Helping economic operators to understand what they did wrong and collaborating with them, setting compliance as the common goal, is considered to be more effective in the long run. When an MSA identifies a non-conformity, it generally works with the responsible economic operator and if it proactively collaborates, prosecution and fines can be avoided, unless it is in the public interest to prosecute. However, uncooperative economic operators are prosecuted through a procedure that involves the courts. Assuming the economic operator is judged to have committed an offence, the court determines a fine and considers the MSA's claim for costs, which would normally be granted.

8.6.3 Stakeholders' perception

Based on the results of the public consultation, stakeholders are divided into those stating that the current framework of market surveillance provides '*insufficient'* deterrence (52%),[420] and those thinking it is '*sufficient'* to a '*significant'* (10%)[421] or to a '*moderate'* extent (38%).[422] In particular, **the high degree of heterogeneity** in the penalty framework is indicated as generating low deterrence by some stakeholders.[423] Stakeholders indeed express a need for a **higher level of cooperation** among authorities in different Member States to resolve this

420 22 MSAs or Custom authorities (BE, CY, 6 DE, DK, 2 FI, IE, IS, LT, 3 NO, PL, 3 SE, UK), three public authorities (ES, DE, PL), three international organisations (AT, FI, UK), 21 large economic operators (AT, BE, 7 DE, 6 FR, IE, IT, 2 NL, PL, PT), eight SMEs (2 ES, FI, HU, NL, 2 PL, UK), seven micro- economic operators (BG, CZ, DE, FR, PL, 2 UK), 30 industry associations (14 BE, 2 DE, DK, EL, 2 ES, FI, 3 FR, IT, NL, 4 UK), 2 trade unions (BE, FR), four consumer organisations (3 BE, DK), one consumer/citizen from the UK, a German academic/law firm, seven others (2 BE, 2 FR, SK, TR, 1 other country).

421 Six MSAs or Custom authorities (CH, 2 HR, IS, 2 LT), an Austrian public authority, a Hungarian and a Polish micro- economic operators, a Hungarian large economic operator, a Czech and a Polish SMEs, one 'other' Czech economic operator, six industry associations (BE, CH, 2 ES, FI, FR), two others (2 DE).

422 32 MSAs or Custom authorities (AT, CY, 2 CZ, 6 DE, EE, ES, FI, 2 HR, IE, IS, IT, LT, 2 NL, 2 NO, 2 PL, 2 PT, 5 SE), eight public authorities (AT, DE, DK, IS, 2 LT, PL, RO), eight micro- economic operators (2 BG, 2 DE, HU, 2 PL, UK), six SMEs (FR, HU, 2 PL, SE, SK), five large economic operators (BG, 2 DE, NL, SE), 12 industry associations (6 BE, ES, FI, IT, PT, 2 UK), two consumer organisations (BE, UK), three academic/law firms (DE, HU, UK), an Austrian consumer/citizen, two others (AT, SE).

423 A Danish MSA, a French economic operator, two industry associations (BE, DE), a French trade union.

issue.[424] However, two interviewees[425] underline the importance of **subsidiarity** with respect to Member States' right to set their own public policy within a given European framework.

A couple of interviewees[426] believe such a fragmented framework may even distort the level playing field among EU businesses. Fair companies invest more and incur higher costs in order to comply with legislative requirements. Meanwhile, rogue economic operators avoid these kinds of costs and benefit from an unfair competitive advantage. Furthermore, an interviewee[427] suggests that MSAs prefer to target companies that are more likely to answer when they should focus on more difficult-to-reach players.

8.6.4 Conclusions

Divergences exist in the methodologies applied by MSAs in different Member States to sanction non-compliant businesses and the degree of **involvement by courts in the sanctioning process**. In some countries, the prospect of court intervention acts as a **strong deterrent**. As reported by interviewees, economic operators are used to complying and there are few cases of appeal. In other instances, involving the court in market surveillance processes means additional **administrative burden** in the overall sanctioning process. The challenge is therefore to find a balance between rapid prosecution and protecting economic operators' rights. At the same time, however, some stakeholders state it is important to **establish a set of minimum core elements[428] as well as a more detailed common methodology[429] to be shared and taken into account by all MSAs when imposing penalties**. In particular, the following distinctions need to be taken into account:

- **Formal vs substantial non-compliance**, where sanctioning the former is less burdensome than the latter, in light of the fact that in some cases of formal non-compliance (based on irregular/incomplete documentation or marking) consumer health and safety risk may be lower.

- **First vs repeated infringement**, where economic operators found to be non-compliant for the first time should be encouraged to comply in order not to incur higher sanctions in the future. It also helps in fighting 'serial' non-compliant operators. Cyprus, Denmark, Lithuania, and the Netherlands for instance are applying this distinction. An interesting suggestion also concerns the importance of giving cooperative economic operators the chance to comply. As previously stated, the lack of differentiation between 'rogue' and 'fair' businesses within sanctioning procedures affects the level playing field, in view of the higher costs fair economic operator incur in order to comply.

- **Size of the penalty vs business turnover**, where economic performance is the basis or criteria to calculate fines. Although it may seem fair to adapt fines to the size of a

424 Three MSAs or Custom authorities (2 DE, CZ), a Swedish economic operator, seven industry associations (4 BE, NL, ES, FR), three consumer organisations (2 BE, DK), a Belgian trade union.
425 Malta Standards Authority and Federal Ministry of Science, Research and Economy, Austria.
426 A large French economic operator and an EU industry association.
427 An EU industry association.
428 86% of respondents to the public consultation strongly agree and agree (33% and 53% respectively) with this statement (total number of respondents to this question = 201).
429 76% of respondents to the public consultation strongly agree and agree (31% and 45% respectively) with this statement (total number of respondents to this question = 194).

company's turnover, they should rather be related to the revenues earned as a result of the non-compliant product being on the market.[430]

- **Fixed fine vs fine determined on a case-by-case basis**, where the size of the company is a key determinant, given that bigger enterprises would have less difficulty paying fixed fines than SMEs.

Although the debate relating to the provision of common European criteria for sanctions remains open, the above-mentioned points should provide valuable insight into possible developments.

8.6.5 Sources

Interview with Department for Business, Energy and Industrial Strategy (UK)

Interview with the Federal Ministry of Science, Research and Economy, Austria

Interview with the Finnish Safety and Chemicals Agency (Tukes)

Interview with the Malta Standards Authority

Interviews with two EU industry associations

Interview with a large French economic operator

Businesseurope (2016), Strategy Paper, *Enhancing enforcement and compliance for goods*

National Programmes, Austria and Malta

8.7 Overview tables of penalties set at the national level for product non-compliance

This section is based on information collected through national reports and programmes on market surveillance. Whenever possible, it has been complemented relying on European Commission (2010), "CERTIF 2010–02, *Sanctions foreseen in the national legislation of Member States against infringements of the provisions of Regulation 765/2008/EC"*, and especially on its annex.[431] Additional information (underlined in the table) has also been provided by stakeholders' answers to the targeted surveys. Furthermore, to complement information gaps and following a specific request from the Steering Group, the IMP-MSG representative for each Member State was requested to complete the information for each sector set at the national level.

Whenever possible, the data reported distinguish between:

430 Businesseurope (2016), Strategy Paper, Enhancing enforcement and compliance for goods. Also stated by an interviewee from an EU industry association.

431 Penalties. Overview of the information provided by Member States, http://ec.europa.eu/DocsRoom/documents/6267/attachments/1/translations/en/renditions/native

- Sanctions and penalties based on Article 41 of the Regulation;[432]
- Sanctions and penalties based on Article 30(6) of the Regulation, on infringements of rules on the CE marking;[433]
- Sanctions and penalties set in specific product sectors.

432 Where it states that "*The Member States shall lay down rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement of the provisions of this Regulation. The Member States shall notify the Commission of those provisions by 1 January 2010 and shall notify it without delay of any subsequent amendment affecting them […]*".

433 Where it states that "*Without prejudice to Article 41, Member States shall ensure the correct implementation of the regime governing the CE marking and take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use […]".*

MS	**ADMINISTRATIVE PENALTIES** - Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES** - (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
AT	Fines **Medical devices**: fines up to €25,000 **Electrical appliances and equipment under LVD, eco-design and energy labelling, electrical equipment under EMC, equipment and protective systems intended for use in potentially explosive atmospheres**: fines up to €25,435	Established dangers to health and fraud and falsifications of documents are the basis for criminal charges. **Medical devices:** Established dangers to health as well as fraud and falsifications of documents form the basis of criminal charges, which are heard in a court of law. Imprisonment if a financial fine is not paid in due time.
BE	Fines (doubled in case of recidivism)	Fines up to €100,000 Imprisonment
BG	Information/publication on authorities' websites Fines ranging from €128 up to €511, from €255 up to €7,700 and €51 up to €2,555, respectively, are imposed on traders; manufacturers/importers and natural persons. There exist however sectoral exceptions, detailed below. **Medical devices, cosmetics:** fines from €500 up to €6,100. **Toys, PPE, simple pressure vessels and pressure equipment, transportable pressure equipment, machinery, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment under EMC, radio and telecom equipment under R&TTE-RED, electrical appliances and equipment under LVD, eco-design and energy labelling, recreational craft**: fines from €125 up to €500 for retailers, from €125 up to €7,500 for importers and manufactures **Aerosol dispensers, footwear labelling**: fines from €25 up to €256 **Textile labelling**: fines from €511 up to €1,534 **Lifts, cableways**: fines from €100 up to €7,500 **Electrical and electronic equipment under RoHS and WEEE and batteries:**	**CE marking:** the registration of the CE marking as a Community mark would entail the possibility of imprisonment and the setting of sanctions by the Court. Criminal penalties are not foreseen except for **chemicals**.

MS	**ADMINISTRATIVE PENALTIES -** Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES -** (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	fines from €5,112 up to €25,562 **Chemicals:** fines from €513 up to €51,282. **Fluorinated greenhouse gases and ozone depleting substances:** fines from €1,500 up to 20,000. **Detergents:** fines from €511 up to €20,452. **Paints:** fines from €250 up to €7,500. **Biocides:** fines from €5,113 up to €51,129.97 **Tyre labelling, motor vehicles and tractors:** fines from €2,550 up to €51,130 **Fertilisers:** fines from €500 up to €2,000 **Other consumer products under GPSD**: fines from €2,556 up to €12,782 **Construction products**: no administrative fine is foreseen **CE marking:** fines up to €5,000.	
CY	**Medical devices, toys, PPE, simple pressure vessels and pressure equipment, machinery, lifts, cableways, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment under EMC, electrical appliances and equipment under LVD, tyre labelling, recreational craft**: first non-compliance fines up to €6,000, second non-compliance fines up to €12,000 **Radio and telecom equipment under R&TTE-RED**: fine is €17,100 **Chemicals**: fines up to €20,000 **Eco-design**: fines up to €3,418 **Energy labelling:** fines up to €8,500, doubled if offense is repeated **Other products under GPSD**: fines up to €3,400 **Biocides**: fines up to €5,000 **Cosmetics, aerosol dispensers, transportable pressure equipment**: no administrative sanctions are foreseen. **Toys**: fines up to €12,000	**Medical devices, toys, PPE, simple pressure vessels and pressure equipment, machinery, lifts, cableways, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment under EMC, electrical appliances and equipment under LVD, tyre labelling, recreational craft**: first non-compliance fines up to €20,000 and/or up to 2 years imprisonment, second non-compliance fines up to €40,000 and/or up to 4 years imprisonment **Cosmetics**: fines up to €40,000 and/or up to 2 years imprisonment **Aerosol dispensers**: fines up to €20,000 and/or up to 2 years imprisonment **Transportable pressure equipment**: fines up to €7,000 and/or up to 2 years imprisonment **Radio and telecom equipment under R&TTE-RED**: fine is €2,562 and/or up to 6 months imprisonment **Chemicals**: fines up to €80,000 and/or up to 2 years imprisonment **Eco-design:** imprisonment up to 2 years or a fine up to €8,545, or both. In the event of a second or subsequent conviction, the said offences shall be

MS	**ADMINISTRATIVE PENALTIES -** Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES -** (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
		punished with imprisonment for a period of no more than 4 years or a fine up to €17,090 and/or both. **Other products under GPSD**: fines up to €8,500 and/or up to 2 years imprisonment **Biocides**: fines up to €20,000 and/or up to 2 years imprisonment **Toys**: fines up to €20,000
CZ	**Medical devices, toys, PPE, construction products, aerosol dispensers, simple pressure vessels and pressure equipment, transportable pressure equipment, machinery, lifts, cableways, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment under EMC, radio and telecom equipment under R&TTE-RED, electrical appliances and equipment under LVD, electrical and electronic equipment under RoHS and WEEE and batteries, recreational craft, marine equipment, non-road mobile machinery, other products under GPSD, textile and footwear labelling, crystal glass**: fines up to €1,802,776.28 **Cosmetics**: fines up to €108,166 **Chemicals, fertilisers, biocides, eco-design and energy labelling**: fines up to €180,277.63 **Motor vehicles and tractors**: fines are not foreseen Information/publication on authorities' websites **CE marking**: fines up to €2 million.	**CE marking:** the registration of the CE marking as a Community mark would entail the possibility of imprisonment and the setting of sanctions by the Court.
DE	**CE marking:** fines up to €3,000 **Measuring instruments, eco-design and energy labelling, efficiency**	**Other consumer products under GPSD:** imprisonment for up to one year or a fine.[434]

434 http://germanlawarchive.iuscomp.org/?p=777#s20

MS	**ADMINISTRATIVE PENALTIES -** Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES -** (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	requirements for hot-boilers fired with liquid or gaseous fuels, tyre labelling: fines up to €50,000 **Electrical equipment, radio and telecom equipment, transportable pressure equipment, aerosol dispensers, simple pressure vessels and pressure:** fines up to €100,000	
DK	**Medical devices, toys, appliances burning gaseous fuels, pyrotechnics, measuring instruments, measuring instruments electrical equipment under EMC, radio and telecom equipment under R&TTE-RED, electrical appliances and equipment under LVD:** administrative sanctions are not foreseen. **PPE, aerosol dispensers, simple pressure vessels and pressure equipment, transportable pressure equipment, machinery, lifts, cableways:** fines from €1,333 **CE marking:** fines if infringement is repeated. **Pyrotechnics**: fines up to €750, 000	Imprisonment is foreseen **Medical devices, toys**: criminal monetary sanctions are foreseen (no imprisonment). **Pyrotechnics**: criminal monetary sanctions and imprisonment are foreseen **Electrical equipment under EMC, radio and telecom equipment under R&TTE-RED:** criminal monetary sanctions are foreseen with no given limit (no imprisonment).
EE	Information/publication on authorities' websites **Medical devices, cosmetics, toys, PPE, construction products, aerosol dispensers, simple pressure vessels and pressure equipment, transportable pressure equipment, machinery, lifts, cableways, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment under EMC, radio and telecom equipment under R&TTE-RED, electrical appliances and equipment under LVD, eco-design and energy labelling, recreational craft, marine equipment, motor vehicles and tractors, non-road mobile machinery, fertilisers, other products under GPSD, textile and footwear labelling, crystal glass:** fines up to €3,200 **Electrical and electronic equipment under RoHS and WEEE and batteries, chemicals, biocides**: fines up to €32,000 **Tyre labelling**: fines up to €13,000	**All sectors:** fines from €300 up to €16,000,000 and/or imprisonment up to 3 years.

MS	**ADMINISTRATIVE PENALTIES -** Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES -** (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
EL	Fines up to €1,500	
ES	Fines from €3,000 up to €601,000 Oblige economic operators to inform consumers[435] Suspension of the economic operator's activity for a maximum period of five years.	
FI	Fines Oblige economic operators to inform consumers **Cosmetics, electrical and electronic equipment under RoHS and WEEE and batteries, chemicals:** fines **Recreational craft, electrical equipment, eco-design and energy labelling, equipment and protective systems, efficiency requirements for hot-boilers fired with liquid or gaseous fuels, medical devices**: MSAs have no power to impose fines, as restrictive measures already imply an economic damage. Decisions are taken case by case by a Court. **Medical devices**: fines up to €25,000	**Toys, PPE, machinery, construction products, appliances burning gaseous fuels and consumer products:** the penalty for a consumer safety offence is a fine and/or imprisonment up to 6 months. **Simple pressure vessels, equipment and protective systems intended for use in potentially explosive atmosphere, electrical equipment under EMC, electrical appliances and equipment under LVD, electrical and electronic equipment under RoHS and WEEE and batteries, chemicals, eco-design and energy labelling:** the penalty for a consumer safety offence is a fine. **Pyrotechnics, explosives for civil uses**: the penalty for a consumer safety offence is a fine and/or imprisonment. Cosmetics **Medical devices**: established dangers to health as well as fraud and falsifications of documents are the basis for criminal charges, which are decided by a court of law. Imprisonment if a financial fine is not paid in due time. The penalty for health offence is at minimum a fine and at a maximum a 6-month imprisonment.
FR	Fines **CE marking:** Fines up to €3,000 (depending on sectoral legislation), €37,500 (under	**CE marking:** imprisonment is also possible

435 http://noticias.juridicas.com/base_datos/Admin/rdleg1-2007.l1t4.html#c2

MS	**ADMINISTRATIVE PENALTIES -** Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES -** (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	the Consumer Act) or double the value of the merchandise (Customs Code).	
HR	Fines Administrative fines are foreseen for all sectors. **Pyrotechnics, explosives for civil uses**: fines from around €5,223 up to around €13,058	**Medical devices**: fines from €9,333 to €13,333 on legal and natural persons. The responsible person within the legal person is also fined from €933 to €1,333 **Cosmetics, toys, noise emission for outdoor equipment, chemicals, biocides**: monetary fines are foreseen (no imprisonment). **PPE, aerosol dispensers, simple pressure vessels, transportable pressure equipment, machinery, lifts, appliances burning gaseous fuels, electrical equipment under EMC, electrical appliances under LVD, tyre labelling, textile and footwear labelling, crystal glass:** fines from €652.91 to €130,582.40 **Construction products**: fines from €783.49 to €13,058.24 **Eco-design and energy labelling**: fines from €2,611.65 to €65,291.20 **Other products under GPSD**: fines from €6,529.12 to €32,645.60 **Equipment and protective systems intended for use in potentially explosive atmospheres**: no criminal sanctions are foreseen
HU	Fines	
IE	Fines Information/publication on authorities' websites **Fertilisers:** fines up to €3,000. **Recreational craft:** fines up to €3,000. **Medical devices**: fines up to €1,000 **CE marking**: fines up to €2,000 (in the case of explosives)	**Medical devices:** max 6-month imprisonment **Fertilisers:** max 6-month imprisonment **CE marking:** imprisonment is also possible
IT	Fines	**Recreational craft**: criminal proceedings is also possible

MS	**ADMINISTRATIVE PENALTIES -** Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES -** (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	Recreational craft: fines from €10,329 up to €154,937 **Noise emissions for outdoor equipment**: fines up to €50,000	
LT	**Dangerous products (all sectors):** fines from €144 up to €23,169. **Marking and labelling non-compliance (all sectors)**: fines for employees and individual enterprises from €30 up to €150 and between €150 and €300 for heads of legal entities. In case of repeated non-compliance: fines for employees and individual enterprises from €50 up to €300 and between €300 and €600 for heads of legal entities. **Medical devices**: fines on natural persons from €30 up to €290, fines on officers between €300 and €850. In case of repeated non-compliance: fines on natural persons from €280 up to €600, fines on officers between €820 and €1,500. **Cosmetics:** fines from €100 up to €300. In case of repeated non-compliance: fines between €280 and €600. **Chemicals:** fines from €60 up to €4,300.**C:** fines from €60 up to €4,300. **Toys, PPE, construction products, aerosol dispensers, simple pressure vessels and pressure equipment, transportable pressure equipment, machinery, lifts, cableways**: fines for employees and individual enterprises from €30 up to €140 and between €300 and €560 for heads of legal entities. In case of repeated non-compliance: fines for employees and individual enterprises from €60 up to €140 and between €550 and €1,200 for heads of legal entities. **Noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil use, appliances burning gaseous fuels eco-design and energy labelling, electrical appliances and equipment under LVD, electrical and electronic equipment under RoHS and WEEE and batteries, tyre labelling, marine equipment, motor vehicles and tractors, non-road mobile machinery, fertilisers, textile and footwear labelling, crystal glass:** fines for employees and individual enterprises from €50 up to €300 and between €80 and €300 for heads of legal entities. In case of repeated non-compliance: fines for employees and individual enterprises from €80 up to €600 and between €300 and €600 for heads of legal	**Explosives for civil uses**: criminal monetary penalties and/or imprisonment are foreseen. **Medical devices, pyrotechnics, electrical equipment under EMC, radio and telecom equipment under R&TTE-RED, recreational craft, marine equipment, motor vehicles and tractors, non-road mobile machinery, fertilisers, other products under GPSD, biocides, textile and footwear labelling crystal glass**: no criminal sanctions

MS	**ADMINISTRATIVE PENALTIES -** Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES -** (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	entities. **Electrical equipment under EMC, radio and telecom equipment under RR&TTE — RED:** fines from €750 up to €1,450. In case of repeated non-compliance: fines from €1,400 up to €3,000. Fines of up to 3% of the total annual income from activity relating to electronic communications. **Recreational craft:** fines for employees and individual enterprises from €300 up to €850 and between €600 and €1,450 for heads of legal entities. **Measuring instruments, non-automatic weighing instruments, pre-packaged products and units of measurement:** fines on natural persons from €30 up to €300. Fines on legal persons or managers of foreign company branches in the Republic of Lithuania or persons authorised thereby between €100 and €550. In case of repeated non-compliance: fines on natural persons from €300 up to €560. Fines on legal persons or managers of foreign company branches in the Republic of Lithuania or persons authorised thereby between €550 and €1500. **Biocides**: fines from €340 up to €4,300	
LU	**Medical devices, fertilisers**: fines up to €60 **Cosmetics**: no administrative fines are foreseen **Toys, PPE, construction products, aerosol dispensers, simple pressure vessels, transportable pressure equipment, machinery, lifts, cableways, equipment and protective systems in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment, radio and telecom equipment, eco-design and energy labelling, tyre labelling, textile and footwear labelling**: fines up to €15,000 **Noise emissions for outdoor equipment, electrical and electronic equipment under RoHS and WEEE and batteries, chemicals:** no administrative fine is foreseen.	**Medical devices**: fines up to €25,000 and/or imprisonment up to 1 year **Cosmetics**: no criminal sanctions foreseen **Toys, PPE, construction products, aerosol dispensers, simple pressure vessels, transportable pressure equipment, machinery, lifts, cableways, equipment and protective systems in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment, radio and telecom equipment, eco-design and energy labelling, tyre labelling, textile and footwear labelling**: maximum sanction €1,000,000 + up to 3 year imprisonment **Noise emissions for outdoor equipment:** fines up to €20,000 and/or up to 6 months imprisonment **Electrical and electronic equipment under RoHS and WEEE and batteries**: fines up to €100,000 and/or up to 6 months imprisonment **Chemicals, biocides**: fines up to €500,000 and/or up to 3 years

MS	**ADMINISTRATIVE PENALTIES -** Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES -** (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
		imprisonment **Fertilisers:** fines up to €7,500 and/or up to 6 months imprisonment
LV	Fines **CE marking**: Fines up to €4,200 for legal persons (€350 for natural persons). **Fertilisers, toys, PPE, construction products, aerosol dispensers, simple pressure vessels, transportable pressure equipment, machinery, lifts, cableways, noise emissions for outdoor equipment, appliances burning gaseous fuels, measuring and weighting instruments, electrical equipment, crystal glass, radio and telecom equipment, electrical appliances, eco-design and energy labelling, efficiency requirements for hot boilers, tyre labelling, recreational crafts, marine equipment, motor vehicles and tractors, non-road mobile machinery, textile and footwear, medical devices, cosmetics, chemical substances, biocides**: fines up to €14,000	
MT		Penalties for infringements of the Product Safety Act and/or the Pesticides Control Act only come into force following conviction by the law courts. Both laws mentioned fall under the criminal code and the penalties therein are commensurate with other criminal legal instruments, including fines, increasing in the case of subsequent indictment following the first and prison terms.
NL	Fines that may be: - *Variable*, based, for instance, on a percentage of the company's annual turnover up to €80,000. - *Fixed* for a specific infringement (around €600 for consumer products for a company with less than 50 employees up to €1,200 for larger companies). Where a fixed penalty applies, if it is a second or recurrent offence, the penalty may be doubled or tripled. **CE marking:** fines up to €1,050. **Crystal glass, cosmetics, toys, PPE, toys, machinery, appliances burning gaseous fuels, electrical appliances, eco-design, biocides, textile and footwear labelling:**	MSAs can impose fines under the criminal law, imprisonment, obligation to close down the company. **CE marking:** punishable by imprisonment not exceeding 2 years or a fine up to €74,000. **Crystal glass, cosmetics, toys, PPE, toys, machinery, appliances burning gaseous fuels, electrical appliances, eco-design, biocides, textile and footwear labelling:** imprisonment is also possible.

MS	**ADMINISTRATIVE PENALTIES -** Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES -** (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	fines up to €70,000 **Appliances burning gaseous fuels**: fines up to €810,000 or 1% yearly turnover **Motor vehicles, construction products, transportable pressure equipment, cableways, noise emissions for outdoor equipment, pyrotechnics, explosives for civil uses, electrical and electronic equipment, chemical substances, eco-design, tyre labelling, recreational craft, marine equipment, non-road mobile machinery, biocides, construction products, recreational craft:** no fixed maximum level **Measuring instruments, electrical equipment, radio and telecom equipment:** fines up to €900,000	
PL	**Medical devices, cosmetics, PPE, aerosol dispensers Machinery Cableways Noise emissions for outdoor equipment Appliances burning gaseous fuels, electrical and electronic equipment under RoHS and WEEE and batteries, chemicals, biocides, eco-design and energy labelling, motor vehicles and tractors, non-road mobile machinery, tyre labelling, crystal glass:** no administrative fine is foreseen. **Toys, construction products, simple pressure vessels and pressure equipment, transportable pressure equipment, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, measuring instruments, electrical equipment under EMC, radio and telecom equipment under R&TTE – RED, electrical appliances and equipment under LVD, recreational craft, marine equipment, fertilisers, textile and footwear, other products under GPSD:** fines up to €24,000	**Medical devices**: fines up to €270,000 and/or imprisonment up to 2 years **Toys, construction products, simple pressure vessels and pressure equipment, transportable pressure equipment, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, measuring instruments, electrical equipment under EMC, radio and telecom equipment under R&TTE – RED, electrical appliances and equipment under LVD, recreational craft, marine equipment, fertilisers, other products under GPSD:** no criminal penalties are foreseen. **Cosmetics, chemicals, biocides**: criminal monetary sanctions and/or imprisonment are foreseen **PPE, aerosol dispensers machinery cableways noise emissions for outdoor equipment appliances burning gaseous fuels, electrical and electronic equipment under RoHS and WEEE and batteries, eco-design and energy labelling, tyre labelling, motor vehicles and tractors, non-road mobile machinery, textile and footwear, crystal glass:** criminal monetary sanctions are foreseen (no imprisonment)
PT	Fines **Medical devices and cosmetics:** fines to be applied in accordance with Decree Law	Criminal penalties are foreseen for product non-compliance

MS	**ADMINISTRATIVE PENALTIES -** Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES -** (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	No 145/2009 amounts between €2,000 and €45,000. **CE marking**: Fines up to €37,890; however, major penalties are to be introduced. **Toys, PPE, Aerosol dispensers, simple pressure vessels, machinery, pyrotechnics, appliances burning gaseous fuels, electrical appliances, chemical substances, eco-design, tyre labelling, non-road mobile machinery, textile and footwear labelling, crystal glass**: fines up to €25,000.	
RO	**Medical devices, cosmetics, construction products, electrical equipment under EMC, radio and telecom equipment under R&TTE – RED, chemicals, other products under GPSD, biocides:** administrative fine is foreseen. **Toys, non-road mobile machinery:** fines from €330 up to €2,200 **PPE, aerosol dispensers, machinery, lifts, cableways, noise emissions for outdoor equipment, electrical appliances and equipment under LVD, recreational craft:** fines from €550 up to €2,200 **Transportable pressure equipment, appliances burning gaseous fuels**: fines from €1,100 up to €4,400 **Simple pressure vessels and pressure equipment:** fines from €440 up to €2,200 **Equipment and protective systems intended for use in potentially explosive atmospheres, explosives for civil uses:** fines from €550 up to €2,645 **Pyrotechnics, measuring instruments:** fines from €110 up to €2,200 **Electrical and electronic equipment under RoHS and WEEE and batteries:** Fine from €2,238 up to €111,192 and possible temporary suspension of the activity. **Eco-design and energy labelling**: fines from €2,200 up to €11,000 **Tyre labelling**: fines from €1,985 up to €4,400 **Motor vehicles and tractors**: fines from €110 up to €11,000 **Fertilisers**: fines from €1,100 up to €11,000 **Textile and footwear labelling, crystal glass:** fines from €220 up to €2,200	If the non-conformities of the products lead to death or acute injuries the Criminal Code applies. **CE marking:** there is a general provision stipulating "material, civil and contravention or criminal liability".

MS	**ADMINISTRATIVE PENALTIES -** Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES -** (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	CE marking: fine up to €1,200.	
SE	Fines are foreseen for all sectors. **CE marking:** Fines **Cosmetics**: fines up to €1,000 **Toys, other products under GPSD**: fines from €500 up to €500,000 limited to max 10% of annual sales **PPE, machinery, equipment and protective systems for use in potentially explosive atmospheres:** fines up to €100,000 + a percentage of sales revenues **Construction products**: fixed-amount fine established every year **Lifts, cableways:** fines up to €235,000	Fines and – in serious cases – even imprisonment are foreseen for **all** sectors except for: toys, PPE, eco-design and energy labelling, tyre labelling, other products under GPSD, textile and footwear labelling, crystal glass.
SI	**Medical devices**: fines from €1,000 to €150,000 for legal entities and from €300 to €7,000 for individuals **Cosmetics**: fines from €500 to €40,000 for legal entities and from €200 to €5,000 for individuals **Toys**: fines from €800 to €40,000 for legal entities and from €200 to €3,000 for individuals **PPE, construction products, aerosol dispensers, simple pressure vessels, transportable pressure equipment, machinery, lifts, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, pyrotechnics, explosives for civil uses, appliances burning gaseous fuels, measuring instruments, electrical equipment under EMC, radio and telecom equipment under R&TTE-RED, electrical appliances and equipment under LVD, electrical and electronic equipment under RoHS and WEEE and batteries, chemicals, eco-design and energy labelling, tyre labelling, recreational craft, marine equipment, motor vehicles and tractors, non-road mobile machinery, textile and footwear labelling, crystal glass:** fines from €2,000 to €40,000 for legal entities and from €200 to €4,000 for individuals. **Cableways**: fines from €2,500 to €40,000 for legal entities and from €200 to €1,000	Payment orders, reminders and warnings of an offence committed. Fines and imprisonment are foreseen for **all** sectors. The only exception is represented by textile and footwear labelling and crystal glass, where imprisonment is not foreseen.

MS	**ADMINISTRATIVE PENALTIES -** Imposed in cases of infringements of administrative law	**CRIMINAL PENALTIES -** (such as imprisonment) imposed in cases of serious infringements by means of a judicial procedure
	for individuals **Fertilisers**: fines from €830 to €20,000 for legal entities and from €200 to €2,000 for individuals **Other products under GPSD**: fines from €1,000 to €40,000 for legal entities and from €100 to €2,000 for individuals **CE marking:** Monetary fines up to €15,000.	
SK	Fines **CE marking**: fines up to €167,000; these fines can be doubled if the abuse is repeated.	The registration of the CE marking as a Community mark enables criminal sanctions.
UK	Oblige economic operators to inform consumers The level of the financial penalty imposed is a matter for the Courts. Administrative fines are foreseen for **all** sectors, except from: cosmetics, toys, PPE, noise emissions for outdoor equipment, appliances burning gaseous fuels, electrical equipment under EMC, radio and telecom equipment under R&TTE-RED, electrical appliances and equipment under LVD, recreational craft. **CE marking**: the registration of the CE marking would entail civil sanctions (infringement action as set by the Court).	Fines and imprisonment are foreseen for **all** sectors. Successful prosecutions can result in monetary penalties or, in the most extreme cases, imprisonment. **CE marking**: the registration of the CE marking would entail criminal sanctions (a maximum of 10 years imprisonment and/or a fine on conviction on indictment).

8.8 Overview tables of laboratories and powers of MSAs and Customs

The following tables show the presence ("√") or the lack (blank cell) of laboratories and powers available to MSAs and Customs Authorities (CA) in each Member State. Where information was not available, cells are filled with "-". The column headings report the number of sectors as per the 2016 EC template provided to Member States for filling the national reports,[436] as reported in Table 4-1.

The tables are filled on the base of multiple sources such as the targeted surveys, ad-hoc requests sent to IMP-MSG representatives in each Member State and from the data available in national programmes and other publicly available documents.

Table 4-34 – Laboratories of national MSAs and Customs Authorities[437]

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	MSA		-	-	-	-	-	-	-	-	-		-	-	-	-	-	-		-		-	-		-		-	-	-	-	-	-	-	-
	CA																																	
BE	MSA	-	-						-				-	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	CA																																	
BG	MSA		√					√	√	√	√	√	√	√	√	√	√		√	√	√	√		√		√	-			√				
	CA																																	
CY	MSA		√			-												√				-		-			-	-	-	-		√		
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436 Sectors: 1) Medical devices, 2) Cosmetics, 3) Toys, 4) PPE, 5) Construction products, 6) Aerosol dispensers, 7) Simple pressure vessels and pressure equipment, 8) Transportable pressure equipment, 9) Machinery, 10) Lifts, 11) Cableways, 12) Noise emissions for outdoor equipment, 13) Equipment and protective systems intended for use in potentially explosive atmospheres, 14) Pyrotechnics, 15) Explosives for civil uses, 16) Appliances burning gaseous fuels, 17) Measuring instruments, 18) Electrical equipment under EMC, 19) Radio and telecom equipment under RTTE – RED, 20) Electrical appliances and equipment under LVD, 21) Electrical and electronic equipment under RoHS and WEEE and batteries, 22) Chemicals , 23) Eco-design and energy labelling, 24) Tyre labelling, 25) Recreational craft, 26) Marine equipment, 27) Motor vehicles and tractors, 28) Non-road mobile machinery, 29) Fertilisers, 30) Other consumer products under GPSD, 31) Biocides, 32) Textile and footwear labelling, 33) Crystal glass.

437 No information was available for EL, HU, IT, PT, SK.

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
CZ	MSA		√	√	√		√					-	√		√	√			√		√		√						√	√	√			
	CA																																	
DE	MSA	√	-	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	√	-	√	-	√
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DK	MSA		-										-			-							-	-	-	-	-	-	-	-	-	-	-	-
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EE	MSA	-	√	√																			√			-	-	-	-	√	-	√		-
	CA	-	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	√	-	-	-	-	-	-	√	-	√	√	-
ES	MSA	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	-	-	-	-	√	-
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FR	MSA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	CA		√	√	√	√				√											√	-	-							-	√	-		
HR	MSA		√	√								-	√					√					√					-	-	-		√		√
	CA	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
IE	MSA																																	
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		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
LT	MSA		-	-	√	-	-	-	-	√	√	√	-	-				√	√	√	-	-	-	-	-		-	-	-	-	√	-	-	
	CA																																	
LU	MSA		-	√										√					√	√	√								√				
	CA																																	
LV	MSA													-	-	-	-		-											√	-			
	CA																																	
MT	MSA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	CA																																√	
NL	MSA	-				√		-	√	-		√	√	-	√	√	-	√	√	√		√	√	-	-	√	-			-				
	CA																																	
PL	MSA		√	√												√		√	√	√		√	√								√		√	
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SE	MSA	√	√																			√		√						-				
	CA																																	
SI	MSA																	√																
	CA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
UK	MSA	-							-	√	√	-		√		√											-	-	-	-	-		-	-
	CA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Table 4-35 – MSAs' power of inspection: Carry out sector inquiries[438]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	√	-	√	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	-			√	√	√	√	√
CY	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√
DE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	√	-	√	-	√
DK	-	-	√	√	√	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	-	-
HR	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

438 No information was available for EL, FR, HU, IT, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
IE	√	√															√				√	√											
LT	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	-	√	√	√	√	√
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-
LV	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	√	-	-	-	√	-	-
NL	-	√	√	√	√	√	-	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	√	√	√
PL	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE	√	√	√	√	√	-	√	-	√	-	-	-	√	-	-	-	√	√	√	√	-	√	√	√	√	√	-	-	-	-	√	√	√
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	√	√	√	-	√	√	√	√
UK	-	√	√	√	√	-	√	-	√	√	-	√	√	-	-	√	√	√	√	√	√	√	√	-	√	-	-	-	-	√	√	-	-

Table 4-36 - MSAs' power of inspection: Do mystery shopping[439]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-						-				-	-			-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√		√	√	√		√	√	√	√		√	√	√	√	√	√	√	√	√	√	√		√		√	-						

439 Information was not available for DE, EL, ES, FR, HR, HU, MT, PL, PT, RO, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
CY	√	√	√	√	-	-	√	-	√	√	-	√	√	√	√	-	√	-	√	-	-	-	-	√	√	-	-	-	-	√	-	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	√	-	√	√	√	√	√	√
DK	-	-	-	√	-	√	√	√	√	√	√	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	-	√	√	√	√	-	-	-	-	-	-	-	-	√	-	-	-	√	√	√	√	√	√	√	√	√	√	√	-	√	√	√
FI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	-	-	√	-	√	-	-
IE	√																				√	√											
IT	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-
LT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
LU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-
LV	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	-	√	-	√	√	√	√	√	√	√	√	-	√	√	-	√	√	√
MT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
NL	-	√	√	√	√	√	-	√	√	-	√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	-	-	-	√	√	√
SE	-	√	√	√	√	-	√	-	√	√	√	-	√	-	-	-	√	√	√	√	-	√	√	√	-	-	-	-	-	√	√	√	√
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	-	√	√	√	√	-	-	-	√	√
UK	-	√	√	√	√	-	√	-	√	√	-	√	√	-	-	√	√	√	√	√	√	√	√	-	√	-	-	-	-	√	√	-	-

Table 4-37 - MSAs' power of inspection: Request for information/cooperation by any possible natural or legal person[440]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	√	-	√	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√
CY	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
DE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	√	-	√	-	√
DK	√	-	√	√	√	√	√	√	√	√	√	-	√	√	-	√	√	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	√	√	√	√	-	-	-	-	-	-
HR	√	√	√	-	-	-	-	-	-	-	-	√	√	-	√	-	√	-	√	-	-	√	-	-	√	√	-	-	-	-	√	-	√
IE	√	√															√				√	√											
IT	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
LT	√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	√	√
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-

440 Information was not available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
LV	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	√	-	√	-	√	-	-
NL	-	√	√	√	√	√	-	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	√	√	√
PL	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE	√	√	√	√	√	-	√	-	√	-	-	-	√	-	-	-	√	-	√	-	-	√	√	√	√	√	-	-	-	√	√	√	√
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	√	√	√	-	√	√	√	√
UK	-	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	-	-	-	√	√	-	-

Table 4-38 - MSAs' power of inspection: Seize and detain products[441]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	√	-	√	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG		√								√							√					√				-			√		√		
CY	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	√
DE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	√	-	√	-	√

441 Information was not available for EL, FR, HU, IT, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
DK	-	-	√	√	√	√	√	√	√	√	√	-	√	√	-	√	√	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	-	-
HR	-	-	-	√	√	√	√	√	√	-	-	-	√	-	√	√	-	√	-	√	√	-	√	√	-	-	-	-	-	√	-	√	-
IE	√	√															√					√											
LT	√	-	-	√	-	-	-	-	√	-	-	-	-	-	√	√	-	√	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-
LV	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	-	√	-	√	√	√	√	√	√	√	√	-	√	√	-	√	√	√
NL	-	√	√	√	√	√	-	√	√	-	√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	-	-	-	√	√	√
PL	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE	√	√	-	-	√	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	√	√	√	√	-	-	-	-	-	√		
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	√	√	√	-	√	√	√	√
UK	-	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	-	-	-	√	√	-	-

Table 4-39 - MSAs' power of inspection: Seize documents[442]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	√	-	√	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG						√				√	√						√							√		-				√		√	√
CY	√	-	√	-	-	√	-	√	-	-	√	-	-	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
DE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	√	-	√	-	√
DK	-	-	√	√	√	√	√	√	√	√	√	-	√	-	-	√	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	-	-
HR	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	√	√	√	√	√	√
IE	√	√															√				√	√											
LT	-	-	-	√	-	-	-	-		√	√	√	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-
LV	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	√	-	-

442 No information was available for: EL, FR, HU, IT, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
NL	-	√	√	√	√	√	-	√	√	-	√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	-	-	-	√	√	√
PL	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE	√	√	-	√	√	-	√	-	√	√	√	-	√	-	-	-	√	-	-	-	-	√	√	√	√	-	-	-	-	-	√		
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	√	√	√	-	√	√	√	√
UK	-	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	-	-	-	√	√	-	-

Table 4-40 - MSAs' power of inspection: Take samples for free[443]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	√	-	√	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√	√																				√				-			√		√		
CY	√	-	√	-	-	√	-	√	-	-	√	-	-	√	√	√	√	√	√	√	-	-	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	-	-	-	√	-	√	-	√	√	√	√	√	√	√	√	-	-	-	-	-	√	√	√	√	√
DE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	√	-	√	-	√
DK	-	-	√	√	√	√	√	√	√	√	√	-	√	√	-	√	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

443 No information was available for EL, FR, HU, IT, MT, PT, RO, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	-	-	√	-	√	-	-
HR	√	√	√	√	√	√	√	√	√	-	-	-	-	-	√	√	-	√	√	√	√	√	-	√	-	√	-	-	-	√	√	√	√
IE	√	√															√				√	√											
IT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-
LT	√	√	√	√	√	√	√	√	√	-	-	-	√	√	-	√	√	√	√	√	√	√	√	√	√	-	-	√	-	√	√	√	√
LU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-
LV	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	-	√	-	√	√	√	√	√	√	√	√	-	√	√	-	√	√	√
NL	-	-	-	-	√	-	-	√	-	-	√	√	-	√	√	-	√	√	√	-	√	√	-	√	√	√	√	-	-	-	√	-	-
PL	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE	√	√	√	√	√	-	√	-	√	√	√	-	√	-	-	-	√	√	√	√	-	√	-	-	√	√	-	-	-	√	√	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	√	√	√	√	-	√	√	-	√
UK	-	-	-	-	-	-	-	-	-	√	-			-	√	-	√	-		-	√	√	-	-	-	-	-	-	-	-	√	-	-

Table 4-41 - MSAs' power of inspection: Make use of test reports by MSAs in other EU countries[444]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	-	-	-	-	-	√	√	√	√	√	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-				√	√		
CY	√	√	√	-	-	√	-	√	-	-	√	-	-	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	-	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
DE	√	-	√	√	√	√	√	√	√	√	-	√	√	√	√	√	-	-	-	√	-	√	√	-	√	-	-	-	√	-	√	-	-
DK	-	-	√	√	√	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
FI	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	-	-	√	-	√	-	-
HR	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	√	-	-	-	-	-	√	√	-	-	-	-	-	-	-
IE	√	√															√																
LT	-	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	√	-	√	-	√	√	√	√
LU	-	-	√	√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-
LV	√	√	√	√	√	√	√	√	√	√	√	√	-	-	-	-	√	-	√	√	√	√	√	√	√	√	√	√	√	-	√	√	√
MT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

444 Information was not available for EL, ES, FR, HU, IT, PT, RO, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
NL	-	√	√	√	-	√	-	-	√	-	-	-	-	-	-	√	√	√	√	√	-	-	√	-	-	-	-	-	-	-	-	√	√
PL	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SE	√	√	-	√	√	-	√	-	√	-	-	-	√	-	-	-	√	-	-	-	-	√	√	√	√	√	-	-	-	-	√	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	-	-	-	√	√	-	-

Table 4-42 - MSAs' power of sanction: Destroy products[445]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	-	-	-	√	√	-	-	√	√	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√	√	√	√	√		√	√	√	√		√	√	√	√	√	√	√	√	√	√	√	√		√	-			√	√	√		
CY	√	√	√	√	-		√		√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ			√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√				√		√	√
DE	√		√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	-	√	-	-	√	√	√	-	-	-	√	-	-	-	√
DK		-		√		√	√	√	√	√	√	-	√	√	-	√	√				-	-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-		√	√	-	-	-	-	-	-	-	-	-	-	√	-

445 No information was available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
FI	-	√	√	√		-	√		√	-	-	√	√			√	-	√	-	√	√	√	√	-	√	-	-	-	-	√	√	-	-
HR	√	√	√	√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	-	√	√	√	√	√			√	√	√	√	√	√	√
IE	√	√																				√											
IT	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-
LT		√	√	√	√	√	√	√				√	√	√	√	√				√	√	√	√	√			√	√	√	√	√	√	√
LU		-																			√							√				-
LV			√	√	√	√	√	√	√	√	√	√					√		√	√	√		√	√	√	√	√	√				√	√
NL	-	-	√	√	√	√	-	-	√		√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	√	-		√	√	√
PL		√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√			√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE		√	√	√	√		√		√	√	√		√	-	-	-	√					-			√		√		-		-		
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√
UK	-	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√		√	-	-	-	-	-	√	-	-

Table 4-43 - MSAs' power of sanction: Impose administrative economic sanctions (without resorting to national courts)[446]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√		√	-	-	-	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√		√	√	√	√	√
CY	√		√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
DE	-		-	-		√	√	√	-	-		√	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-
DK		-										-			-						-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-				-	-	-	-	-	-	-	-	-	-	-	-	-				-	-	-	-	-	-	-	-	-	-		-
FI		√			√	-		√		-	-			√	√		-		-		√	√		-	√	-	-	-	-		√	-	-
HR		√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√		√	√	√	-	√			-	-	-	√	√	√	√
IE	√																				√												
IT	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-
LT	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	-

446 No information was available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
LV	√	√	√	√	√	√	√	√	√	√	√	√					√		√	√	√	√	√	√	√	√	√	√			√	√	√
NL	-	-	√	√	√	√	-	-	√		√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	√	-		√	√	√
PL		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	-	√	-	√	√	√	√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE		√	√	√	√		√		√	√	√		√	-	-	-	√				√	-	√	√	√				-	√	-	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-				√	√	√	-	√	√	-		√	√	√	√	√				√	√	√			-	-	-	-	-	√	-	-

Table 4-44 - MSAs' power of sanction: Impose compensation for consumers/users of non-compliant products[447]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		-		-	-		-		-	-	-	-	-	-	-	-
BE	-	-	√	√		√	-	-	-	√	√	-	-	√	√	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG										√																-							
CY					-			√													-		-			-	-	-	-			-	-
CZ																												√					
DE	√		-	-		-	-	-	√	-		√	-	-	-	-			-	√	-	-			√	-	-	-		-	-	-	

447 No information was available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
DK		-										-			-						-	-	-	-	-	-	-	-	-	-	-	-
EE																																	
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-		√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI						-	√			-	-		√		√		-	√	-	√				-		-	-	-	-			-	-
HR		√	√	-	-	-	-	-	-	-	-	√				-	-	-	-	-	-	√	-	-			-	-	-	-	√	-	√
IE	√																																
IT	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
LT									√	√	√						√																√
LU		-																				-											-
LV																																	
NL	-	-			-		-	-			-	-	-	-	-		-	-	-		-	-		-	-	-	-	-	-				
PL			√		√		√			√	-	√	√	√	√	√	√	√	√	√							-		-	√			
RO																																	
SE		-	-	-										-	-	-	-	√	√	√		-							-	√	-	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-							-			-												√			-	-	-	-	-		-	-

Table 4-45 - MSAs' power of sanction: Impose provisional measures pending investigations[448]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√		√	-	-	-	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	-	√		√	√	√	√	√
CY	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√
DE	√		√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	-	√	-	-	√	√	√	-	-	-	√	-	-	-	√
DK		-										-		√	-		√				-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-		√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI	√	√	√	√	√	-	√	√	√	-	-	√	√	√	√	√	-	√	-	√	√	√	√	-	√	-	-	-	-	√	√	-	-
HR	√	√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	-	√			-	-	-	√	√	√	√
IE	√	√															√				√												
IT	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-
LT	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√		√	√	√	√	√	√	√	√
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√		√	√	√	-

448 No information was available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
LV	√	√	√	√	√	√	√	√	√	√	√	√					√		√	√	√	√	√	√	√	√	√	√			√	√	√
NL	-	-			-		-	-			-	-	-	-	-		-	-	-		-	-		-	-	-	-	-	-				
PL	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√			√
RO																																	
SE	√	√	√	√	√		√		√			√	√	-	-	-	√	√	√	√		-					√	√	-	√	-	√	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-				√		√	-			-			√	√		√				√	√	√			-	-	-	-	-	√	-	-

Table 4-46 - MSAs' power of sanction: Publish decisions on restrictive measures[449]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		-		-	-		-		-	-	-	-	-	-	-	-
BE	-	-	√	√		√	-	-	-	√	√	-	-	√	√	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√		√	-	√			√		√	√
CY	√		√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√		√	√		√		√	√	√	√
DE	√		√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	-	√	-	-	√	√	√	-	-	-	√	-	-	-	√
DK		-	√	√	√	√	√	√	√	√	√	-	√	√	-	√				√	-	-	-	-	-	-	-	-	-	-	-	-	-

449 No information was available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
EE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
FI	√	√	√	√	√	-	√	√	√	-	-	√	√	√	√	√	-	√	-	√	√	√	√	-		-	-	-	-	√	√	-	-
HR	√	√	√	√	√	√	√	√	√	√	√	√				√	√	√	√	√	√	√	√	√			√	√	√	√	√	√	√
IE	√	√																			√												
IT	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-
LT	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√			√	√	√	√	√	√	√
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√		√	-
LV			√	√	√	√	√	√	√	√	√	√					√		√	√	√		√	√	√	√	√	√				√	√
NL	-	-	√	√	√	√	-	-	√		√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	√	-		√	√	√
PL	√		√	√	√	√	√		√	√	√	√	√	√	√	√	√	√		√					√	√	-	√	-	√			√
RO																			√														
SE	√	√	√	√	√		√		√	√	√	√	√	-	-	-	√	√	√	√		-			√	√	√	√	-	√	-	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-							-	√	√	-	√	√		√	√		√	√	√			√		√	-	-	-	-	-		-	-

Table 4-47 - MSAs' power of sanction: Recover from economic operators costs borne to test products found to be non-compliant[450]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	-	-	-	√	√	-	-	√	√	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√		√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√		√		√	-			√	√			√
CY		-	√	√	-		√		√	√	√	√	√	√	√	√	√	√	√	√	-		-	√	√	-	-	-	-	√		-	-
CZ	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	√	√		√		√	√
DE	√		√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	-	√	-	-	√	√	√	-	-	-		-	-	-	√
DK		-	√	√	√	√	√	√	√	√	√	-	√	√	-	√					-	-	-	-	-	-	-	-	-	-	-	-	-
EE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-				-	-	-	-	-	-	-	-	-	-	-	-	-				-	-	-	-	-	-	-	-	-	-		-
FI	√	√	√	√	√	-	√	√	√	-	-	√	√	√	√	√	-	√	-	√	√	√	√	-	√	-	-	-	-	√	√	-	-
HR	-	√	√	√	√	√	√	√	√	√	-	√	√			√	√	√	-	√	√	√	-	√			-	-	-	√	√	√	√
IE	√	√																				√											
IT	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-
LT	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√			√	√	√	√	√	√	√
LU		-	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√			√	√	√	√	√	√		√		√	-

450 No information was available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
LV	√	√	√	√	√	√	√	√	√	√	√	√					√		√	√	√	√	√	√	√	√	√	√			√	√	√
NL	-	-			√		-	-			√	√	-	√	√		-	-	-		√	√		√	√	√	√	√	-				
PL	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	√	√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE		-	√	√	-		√		√	√	√		√	-	-	-	√	√	√	√		-			√	√			-	√	-	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-						√	-	√	√	-		√	√							√		√			-	-	-	-	-		-	-

Table 4-48 - MSAs' power of sanction: Sanction economic operators that do not cooperate[451]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	-	√	-	-	√	-	√	-	-	-	-	-	-	-	-
BE	-	-	√	√	√	√	-	-	-	√	√	-	-	√	√	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√		√	√	√	√	√
CY	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√	√	-	-	-	-	√	√	-	-
CZ	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
DE	√		√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	-	√	-	-	√	√	√	-	-	-	√	-	-	-	√
DK	√	-	√		√							-		√	-	√	√	√	√		-	-	-	-	-	-	-	-	-	-	-	-	-

451 No information was available for EL, FR, HU, MT, PT, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
EE	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
ES	-	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-		√	√	-	-	-	-	-	-	-	-	-	-	√	-
FI	√					-				-	-						-		-					-	√	-	-	-	-			-	-
HR	-	√	√	√	√	√	√	√	√	√	-	√	√	√	√	√	√	√	√	√	√	√	-	√			-	-	-	√	√	√	√
IE	√	√															√				√												
IT	-	-	-	-	-	-	-	-	-	-	-	√	-	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-
LT	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	√	√	√		√	√			√	√	√	√	√	√	√
LU	√	-	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	-
LV	√	√	√	√	√	√	√	√	√	√	√	√					√		√	√	√	√	√	√	√	√	√	√			√	√	√
NL	-	-	√	√	√	√	-	-	√		√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	√	-		√	√	√
PL	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	-	√	-	√			√
RO	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
SE	√	√	√	√	√		√		√	√	√	√	√	-	-	-	√	√	√	√		-	√	√	√	√	√	√	-	√	-	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-	√	√	√	√	√	√	-	√	√	-	√	√	√	√	√	√	√	√	√	√	√	√		√	-	-	-	-	-	√	-	-

Table 4-49 - MSAs' power of sanction: Shut-down websites[452]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		-		-	-		-		-	-	-	-	-	-	-	-
BE	-	-			√		-	-	-			-	-			-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG										√																-							
CY	√				-																-		-			-	-	-	-			-	-
CZ																																	
DE			-	-		-	-	-	-	-		-	-						-	-	-	-				-	-	-		-	-	-	
DK		-										-		-	-						-	-	-	-	-	-	-	-	-	-	-	-	-
EE	-	√	√																					-	-	-	-	-	√	√	-	√	√
ES	-	-				-	-	-	-	-	-	-	-	-	-	-	-	-				-	-	-	-	-	-	-	-	-	-		-
FI	-					-				-	-						-		-					-		-	-	-	-			-	-
HR		-	-	-	-	-	-	-	-	-	-	-				-	-	-	-	-	-	-	-	-			-	-	-	-	-	-	-
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LT																																	
LU		-																															-

452 No information was available for EL, FR, HU, MT, PT, RO, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
LV			√	√	√	√	√	√	√	√	√	√					√		√	√	√		√	√	√	√	√	√				√	√
NL	-	-			-		-	-			-	-	-	-	-		-	-	-		-	-		-	-	-	-	-	-				
PL																											-		-				
SE		-												-	-	-	-								-				-	-	-	-	-
SI																																	
UK	-	√	√	√			√	-	√	√	-	√	√			√		√	√	√					√	-	-	-	-	-		-	-

Table 4-50 - MSAs' power of sanction: Take off or require to take off illegal content from a website[453]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
AT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BE	-	-			√		-	-	-			-	-			-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-
BG			√	√	√		√	√	√			√	√	√	√	√	√	√	√	√	√		√		√	-							
CY	√				-											√		√		√	-		-			-	-	-	-		√	-	-
CZ		√	√	√	√	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√				√	√		√	√	√		√	√
DE			-	-		-	-	-	-	-		-	-						-	√	-	-				-	-	-		-	-	-	-
DK	√	-										-		√	-		√	√	√		-	-	-	-	-	-	-	-	-	-	-	-	-
EE	-	√	√	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	√	√	-	√	√

453 No information was available for EL, FR, HU, MT, PT, RO, SK.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
ES	-	-				-	-	-	-	-	-	-	-	-	-	-	-	-				-	-	-	-	-	-	-	-	-	-		-
FI	-	√	√	√	√	-	√	√	√	-	-	√	√	√	√	√	-	√	-	√	√	√	√	-	-	-	-	-	-	√	√	-	-
HR	-	√	√	-	-	-	-	-	-	-	-	-				-	-	-	√	-	-	√	-	-			-	-	-	-	√	-	√
IE	√																																
IT	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
LT	√								√	√	√			√	√		√	√	√														√
LU		-	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√	√	√		√	√	√	√	√	√	√		√	√	√	-
LV			√	√	√	√	√	√	√	√	√	√					√		√	√	√		√	√	√	√	√	√				√	√
NL	-	-	√	√	√	√	-	-	√		√	√	-	√	√	√	-	-	-	√	√	√	√	√	√	√	√	√	-		√	√	√
PL	√	√																									-		-				
SE	√	√	√											-	-	-	-	√	√	√		-	√	√	-				-	-	-	-	-
SI	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
UK	-	√	√	√	√	√	√	-	√	√	-	√	√			√	√	√	√	√	√	√	√		√	-	-	-	-	-	√	-	-

8.9 Mapping of national reports

As already mentioned, we structured the mapping of national market surveillance reports following the EC template provided to Member States, which is reported in the table below. This is a non-exhaustive list of the sectors included in the scope of the Regulation.

Table 4-51 - Reference list of product sectors

Product sectors	*Relevant legislation*
1. Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	Directives 93/42/EEC, 98/79/EC and 90/385/EEC
2. Cosmetics	Regulation (EC) 1223/2009
3. Toys	Directive 2009/48/EC
4. Personal protective equipment	Directive 89/686/EEC
5. Construction products	Regulation (EU) 305/2011
6. Aerosol dispensers	Directive 75/324/EEC
7. Simple pressure vessels and pressure equipment	Directives 2009/105/EC and 97/23/EC, Directives 2014/29/EU and 2014/68/EU
8. Transportable pressure equipment	Directive 2010/35/EU
9. Machinery	Directive 2006/42/EC
10. Lifts	Directive 1995/16/EC - Directive 2014/33/EU
11. Cableways	Directive 2000/9/EC
12. Noise emissions for outdoor equipment	Directive 2000/14/EC
13. Equipment and protective systems intended for use in potentially explosive atmospheres	Directive 1994/9/EC - Directive 2014/34/EU
14. Pyrotechnics	Directive 2007/23/EC - Directive 2013/29/EU
15. Explosives for civil uses	Directive 93/15/EEC - Directive 2014/28/EU
16. Appliances burning gaseous fuels	Directive 2009/142/EC
17. Measuring instruments, non-automatic weighing instruments, pre-packaged products	Directives 2004/22/EC and 2009/23/EC - Directives 2014/32/EU and 2014/31/EU; Directive 2007/45/EC, 75/107/EEC and 76/211/EEC; Directive 80/181/EEC
18. Electrical equipment under EMC	Directive 2004/108/EC - Directive 2014/30/EU
19. Radio and telecom equipment under R&TTE	Directive 1999/5/EC - Directive 2014/53/EU

Product sectors	*Relevant legislation*
– RED	
20. Electrical appliances and equipment under LVD	Directive 2006/95/EC - Directive 2014/35/EU
21. Electrical and electronic equipment under RoHS and WEEE and batteries	Directives 2011/65/EU, 2002/96/EC and 2006/66/EC
22. Chemical (Detergents, paints, persistent organic pollutants, fluorinated greenhouse gases, ozone depleting substances, etc.)	Regulation (EC) 648/2004, Directive 2004/42/EC, Regulation (EC) 850/2004
23. Eco-design and energy labelling	Directives 2009/125/EC and 2010/30/EU
24. Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	Directive 1992/42/EEC
25. Recreational craft	Directive 1994/25/EC - Directive 2013/53/EU
26. Marine equipment	Directive 96/98/EC -Directive 2014/90/EU
27. Motor vehicles and tyres	Directive 2002/24/EC, Directive 2007/46/EC, Regulation (EC) 1222/2009
28. Non-road mobile machinery	Directive 97/68/EC
29. Fertilisers	Regulation (EC) 2003/2003
30. Other consumer products under GPSD (optional)	Directive 2001/95/EC

We organised the data collection by using an excel file where each sheet corresponded to one of the 30 product sectors specified in the EC template. Each sheet has then been divided to collect:

1) **Information relating to the resources available to MSAs** over the period 2010-2013 for each Member State, and namely:

- Budget available to MSAs in nominal terms (€);
- Budget available to MSAs in relative terms (% of total national budget);
- Staff available to MSAs (FTE units);
- Number of inspectors available to MSAs (FTE units).

2) **Information relating to the market surveillance activities** performed over the period 2010-2013 in each Member State, and namely:

- Number of product related accidents / users' complaints;

- Number of substantiated complaints by industry concerning unfair competition;
- Number of inspections (total number);
- Number of reactive inspections;
- Number of self-initiated inspections;
- Number of inspections prompted by Customs;
- Number of inspections based on:
  - Tests performed in laboratories;
  - Physical checks of products;
- Number of inspections resulting in:
  - Finding of non-compliance;
  - Corrective actions taken by economic operators ("voluntary measures");
  - Restrictive measures taken by MSA;
  - Application of sanctions/penalties;
- Number of inspections where other Member States were invited to collaborate.

However, in light of all the limitations reported, the available information is so scattered and rare that these data are not comparable across countries or across sectors.

The table below presents in detail the sectoral coverage provided by the national reports. An "N" indicates sectors excluded from a national report. DE and LT are not included as they did not follow the EC template when providing information on market surveillance activities.

Table 4-52 - List of sectors covered by each national report

MS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
AT													N								N			N				N	N	
BE	N	N						N			N			N	N		N								N	N				
BG		N																						N		N				
CY		N										N					N				N	N		N	N	N		N	N	N
CZ																										N	N	N		
DK															N									N						N
EE						N						N											N	N				N		
EL	N	N										N	N													N	N	N		
ES	N	N	N	N	N	N		N			N	N	N	N	N	N	N	N	N		N	N	N	N	N	N		N	N	N
FI																												N		
FR																								N				N		
HR	N					N	N	N		N	N	N	N	N	N	N		N			N		N	N	N	N	N	N		
HU						N					N														N					
IE					N	N					N	N						N	N						N	N	N	N		
IT					N	N	N	N		N	N		N			N		N			N	N		N	N		N	N	N	
LU	N	N			N							N		N	N						N	N		N	N	N	N	N	N	

LV																													
MT																							N				N		N
NL								N			N	N											N		N		N		N
PL																							N			N	N		N
PT								N		N												N	N	N			N		
RO	N	N																											
SE																													
SI																							N						N
SK						N	N	N	N	N		N	N					N	N		N			N		N		N		N
UK											N						N					N		N	N	N			N	

Data on market surveillance activities implemented for each sector are not always available in the national reports. This makes unreliable any comparisons between countries and sectors over the period 2010-2013. The table below shows examples of the extent of gaps in data availability by providing the number of Member States reporting data on some indicators of market surveillance activities.

Table 4-53 - Number of Member States reporting data on accidents, sanctions and restrictive measures

	Number of Member States reporting data on:		
Product sectors	*Accidents*	*Application of sanctions/ penalties*	*Restrictive measures*
Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	16	12	14
Cosmetics	12	12	14
Toys	15	18	20
Personal protective equipment	13	16	16
Construction products	14	15	1
Aerosol dispensers	10	9	11
Simple pressure vessels and pressure equipment	10	11	12
Transportable pressure equipment	7	11	13
Machinery	15	15	0
Lifts	8	9	7
Cableways	7	9	7
Noise emissions for outdoor equipment	7	10	12
Equipment and protective systems intended for use in potentially explosive atmospheres	9	9	10
Pyrotechnics	13	15	16
Explosives for civil uses	11	12	14
Appliances burning gaseous fuels	12	15	16
Measuring instruments, non-automatic weighing instruments, pre-packaged products and units of measurement	12	17	15
Electrical equipment under EMC	7	13	14

Radio and telecom equipment under R&TTE RED	14	17	18
Electrical appliances and equipment under LVD	16	17	19
Electrical and electronic equipment under RoHS and WEEE and batteries	8	10	12
Chemical substances under REACH and Classification and Labelling Regulations and other chemicals (detergents, paints, persistent organic pollutants, fluorinated greenhouse gases, ozone depleting substances, etc.)	0	14	15
Eco-design and energy labelling; efficiency requirements for hot boilers fired with liquid or gaseous fuels	11	17	19
Tyre labelling	0	3	3
Recreational craft	6	11	9
Marine equipment	8	9	9
Motor vehicles and tractors	3	3	4
Non-road mobile machinery	2	4	4
Fertilisers	11	14	12
Other consumer products under GPSD (optional)	13	12	15

8.10 Mapping of national programmes

As already mentioned, we followed the EC template for the mapping of national market surveillance programmes. More in detail, we organised the data collection process by using an excel file, in which columns reported information corresponding to the sections of the EC template and rows related to Member States. This allowed us a cross-country comparison of market surveillance implementation. An example of the final output is provided at the end of this section.

The first part of the national programmes provides information on the **organisation and structure** of market surveillance at national level, and namely on:

- **National MSAs**, their competences/responsibilities (either sector-specific or horizontal) and the available resources in terms of budgets, staff, and technical means.
- **Coordination and cooperation mechanisms between MSAs**: evidence of permanent ad-hoc bodies for coordinating MSAs, with details on the bodies' composition, members, decision-making mechanisms, working practices, responsibilities and core tasks; mechanisms in place to ensure cooperation among MSAs such as bilateral agreements, for a, joint actions and procedures for information sharing.

- **Cooperation between national MSAs and Customs**: identification of the existing mechanisms (e.g. regular dialogue, joint actions, communication on an ad-hoc basis); other existing cooperation mechanisms such as working groups, ad-hoc permanent bodies and bilateral agreements;

- **RAPEX**: information on the authorities responsible for managing the system; details on how and for which product sectors MSAs use the RAPEX notification system.

- **ICSMS**: information on the authorities responsible for managing the system; details on how and for which product sectors MSAs use the ICSMS notification system.

- **General description of market surveillance activities and relevant procedures**: approach (reactive vs proactive) and criteria at the basis of these approaches (e.g. risk assessment, users' complaints, notifications from other authorities or Customs, press releases, specific strategies); information on the forms of surveillance (e.g. documentary checks, inspections, laboratory testing); evidence of procedures for dealing with complaints, for monitoring accidents, for warning users of dangerous products; description of any monetary, administrative and criminal penalties available to national MSAs; mechanisms for ensuring the involvement of businesses and consumers in activities related to market surveillance.

- **General framework of cooperation with other Member States and non-Member States**: description of any international partnerships for market surveillance that MSAs engage in with other EU Member States or third countries;

- **Evaluation of market surveillance actions and reporting**: description of the evaluation and monitoring of market surveillance by MSAs at the national level, including timing, objectives and criteria of the evaluation.

- **Horizontal activities planned for the relevant period**: description of any changes in the national market surveillance structure; identification of EU projects for market surveillance; description of any update of the risk assessment methodology for market surveillance.

The second section of the EC template for national programmes aims to provide information about the market surveillance activities carried out in the specific product areas covered by the Regulation. More in detail, Member States are asked to report on the relevant MSAs for the sector, on their specific procedures, activities, and strategies, and on their reporting practices.

Finally, we analysed the sectoral programmes only when information about the general market surveillance frame was not available, to draw a general overview of its implementation at national level.

8.11 Evaluation grids

The study methodology is based on the so-called "evaluation grids".

The evaluation grids present all the elements of our methodology, and namely:

- The evaluation questions;
- The judgement criteria used to specify the focus of the evaluation questions;
- The analytical approach indicating the type of analysis performed in order to answer the evaluation questions, based on the judgement criteria;
- The indicators used to evaluate the achieved results as well as to signal potential shortfalls;
- The sources of information, including both primary sources (i.e. stakeholders) that directly provide data and information on the specific issue, and secondary sources that are based on documents, publications, reports or tools that analyse or comment on existing data or information.

Moreover, they include specific reference to the questions (Q) of the targeted surveys (TS),[454] the interviews (I) and the public consultation (PC)[455] that fed the answers to the evaluation questions.

The evaluation grids are presented below.

454 "TS1" stands for the targeted surveys designed for Public Authorities (i.e. MS coordinating authorities, MSAs and Customs). "TS2" stands for the targeted surveys designed for economic operators, industry associations, consumer and user associations.

455 When referring to the public consultation, we refer to the Public consultation launched by the Commission under the initiative "Internal Market for Goods – Enforcement and Compliance".

Criterion	*Effectiveness*			
Evaluation questions	EQ1. How effective was the measure as a mechanism and means to achieve a high level of protection of public interests, such as health and safety in general, health and safety at workplace, the protection of consumers, protection of the environment and security? What have been the quantitative and qualitative effects of the measure on its objectives? EQ2. How effective was the measure as a mechanism and means to achieve a level playing field among businesses trading in goods subject to EU harmonisation legislation? What have been the quantitative and qualitative effects of the measure on its objectives? EQ3. Are the results in line with what foreseen in the impact assessment for the Regulation, notably as to the specific objectives of (i) enhanced cooperation among Member States/within Member States, (ii) uniform and sufficiently rigorous level of market surveillance, (iii) border controls of imported products? EQ4. Are there specific forms of the implementation of the Regulation at Member State level that render certain aspects of the Regulation more or less effective than others , and – if there are – what lessons can be drawn from this? EQ5. To what extent the different implementation (i.e. discrepancies in the implementation) of the initiative in Member States impacted the effectiveness of the measures on the objective?			
Understanding the questions	Questions under this criterion are focused on the following aspects: - Evaluating how far the provisions under the scope of the evaluation and namely those under Ch. III (market surveillance and controls) and under Ch. V (financing) contributed to achieve the **overarching objectives** of the Regulation (Q1 and Q2) - Identifying whether the Regulation is performing in line with expectations (as defined in its IA) especially as regards **cross-border controls** (Q3) - Identifying relevant aspects in the **national implementation** of the Regulation that impact its effectiveness (Q4 and Q5)			
Focus of the question	*Judgement criteria*	*Analytical approach*	*Indicators and descriptors*	*Sources*
Q1. a) Effectiveness towards achieving the objective of protection of public interests b) Quantitative and qualitative effects on this objective	Increased protection of public interests	a) Desk and field research to provide an analysis on: • Trends in accidents; • Emerging safety, health and environmental risks; • Scale and perception of stakeholders of non-compliant non-food products circulating in the EU. b) Correspondence matrix between the Regulation, the main issues/risks in the market of non-food products and the results of the Regulation in preventing/solving those issues.	• Trends in the number of accidents related to non-food products before and after the implementation of the Regulation as reported by stakeholders and quantitatively/qualitatively assessed in the literature; • Number of non-food products covered by Regulation (EC) No 765/2008 recalled/withdrawn from the market or subject to corrective measures due to safety issues; • Number of and trends in RAPEX notifications related to non-food products covered by Regulation (EC) No 765/2008; • Stakeholders' perception of the extent of non-compliant products existing in the internal market.	Primary: • PC: section B1: Q1, Q2, Q3; section B2: Q4 • TS1: Q47, 48, 60-63, 65, 66; TS2: Q18, 19, 24-27, 42, 43. • I: Q7, Q9, Q17. Secondary: • RAPEX database; • EU IDB; • National market surveillance reports and programmes; • IA for Regulation (EC) No 765/2008.
Q2.	Increased level	a) Desk and field research to provide	• Trends in the EU non-food product market;	Primary:

Criterion	*Effectiveness*			
a)Effectiveness towards achieving the objective of a level playing field among businesses b)Quantitative and qualitative effects on this objective	playing field among businesses	an analysis of non-food product market trends, with specific focus on disproportionate obstacles to the free movement due to the way market surveillance is carried out and the relevance of unfair competition of non-compliant goods in the area of non-food products covered by Regulation (EC) No 765/2008. b) Correspondence matrix between the Regulation, the main obstacles or threats to compliant businesses in the market of non-food products and the results of the Regulation in preventing/ solving those issues.	• Trends in competitiveness of EU businesses as reported by stakeholders during interviews and in targeted consultations; • Qualitative evidence of the effects of the Regulation on competitiveness unbalances between EU and Extra-EU; • Competitiveness indicators: comparison before and after 2010; • Perception of economic operators on the creation of a level playing field by means of the Regulation.	• PC: section B1: Q4, Q5; section B2: Q4; section B4: Q6, Q7 ; section B5: Q5, Q6, Q7, Q8; • TS1: Q47, 48, 64, 65, 66; TS2: Q18-23, 28, 29, 42, 43; • I: Q7, Q10-12, Q14, Q15. Secondary: • Eurostat database on international trade; • IA for Regulation (EC) No 765/2008.
Q3. Comparison between expected and actual results as for (i) enhanced cooperation among/within MS, (ii) uniform and sufficiently rigorous level of market surveillance, (iii) border controls of imported products	• Enhanced cooperation among/within Member States • Uniform and sufficiently rigorous level of market surveillance • Increased border controls of imported products	a) Desk and field research to provide an analysis of trends in product safety and other public interest, with specific focus on: • Existing cooperation mechanisms among/ within MS, possibly in a comparison with those existing before the Regulation was implemented; • Differences in national strategies of market surveillance; • Scale of imported non-compliant non-food products circulating in the EU. • Mapping of national approaches to sanctions and powers granted to authorities (e.g. procedures) b) Correspondence matrix between the Regulation, the IA and the current situation.	• Number of AdCO groups before/ after the implementation of the Regulation; • Number of meetings of AdCO groups before/after the implementation of the Regulation; • Number of and trends in measures taken against non-compliant products (at the EU and MS level); • Number of authorities; • Type and level of sanctions at MS level – if possible, information disaggregated by sector will be extracted based on the answers to the targeted surveys; • Perception of involved stakeholders of the uniformity and rigorousness of market surveillance and border controls.	Primary: • PC: section B1: Q14, Q15, Q16, Q17, Q18; section B4: Q6, Q7; section B5: Q8 • TS1: Q17-31, 34, 39-42, 49-55. TS2: Q9-17, 30, 31, 48, 49. • I: Q2-5, Q8, Q10-12, Q14, Q16-20. Secondary: • RAPEX database; • National market surveillance reports and programmes; • IA for Regulation (EC) No 765/2008.

Criterion	*Effectiveness*			
Q4. a) How MS have implemented specific aspects of the Regulation b) Lessons learned	Effectiveness of different implementation mechanisms set at Member State level impacting on certain aspects of the Regulation	Desk and field research to provide an analysis of the implementation of the Regulation, with specific focus on: • Distribution of surveillance competences; • Resources and tasks; • National procedures and powers for inspections; • National procedures for sanctions; • National arrangements and practices for the controls of imports from third countries; • Practices of cross-border cooperation. Issues related to failures in the correct implementation of the Regulation. Identification of national good practices in the implementation of the Regulation.	• Tools for coordination among national authorities; • Authorities product specialisation vs horizontal cross-sectoral competencies; • Resources allocated; • Clear distinction between market surveillance tasks/budget and other attributions of a given authority; • Light vs heavy-handed procedures to impose sanctions on businesses; • Possible additional powers granted by national legislation; • Active use by specific authorities of tools for exchanging information with other MS; • Mapping of criteria for selection of sectors as market surveillance priorities; • Perception of MS on the usefulness of market surveillance reports and programmes.	Primary: • PC: section B1: Q7, Q8, Q9, Q10; section B4: Q4, Q5; • TS1: Q17, 18, 19, 32, 33, 41, 42, 49-55. Ts2: Q16, 17, 30, 31, 48, 49; • I: Q6, Q8, Q13, Q16. Secondary: • National market surveillance reports and programmes; • IA for Regulation (EC) No 765/2008 ; • Evaluation reports of sectoral legislation.
Q5. Extent to which differences in the implementation of the Regulation at national level have an impact on its effective functioning	MS differences in the Regulation's implementation induce different levels of product safety and of other public interest at national level	• Conclusions of Q1, Q2 and Q4, to understand whether and to what extent national differences in the implementation of the Regulation have an impact on its effectiveness. • Analysis of the correlation between national differences in the implementation and the effectiveness of the Regulation at the national level.	Same indicators as Q1, Q2, Q4	Same sources as Q1, Q2, Q3, Q4

Criterion	*Efficiency*
Evaluation questions	EQ6. What are the regulatory (including administrative) costs for the different stakeholders (businesses, consumers/users, national authorities, Commission)? EQ7. What are the main benefits for stakeholders and civil society that derive from the Regulation? EQ8. To what extent have the market surveillance provisions been cost effective? EQ9. Are there any significant differences in costs (or benefits) between Member States? If so, what is causing them?
Understanding the questions	Questions under this criterion are focused on the following aspects: - **Identification and quantification** of the costs and benefits - Assessment of the **proportionality** of costs and benefits - Identification of the reasons for **differences** among countries

Focus of the questions	*Judgement criteria*	*Analytical approach*	*Indicators and descriptors*	*Sources*
Q6. Identification and quantification of regulatory (including administrative) costs for stakeholders	MS authorities incur several costs related to the enforcement of the Regulation, especially for market surveillance activities, and other activities such as administrative cooperation with other MS. The market surveillance measures implemented by MSA create administrative	For the **cost of the enforcement** of the Regulation the following approach will be followed**:** • Definition of activities required to implement and enforce the Regulation; • Estimation of frequency of activities - f (e.g. 1=once a year); • Estimation of the cost of activities; • Estimation of the business-as-usual (BAU) factor; • Sum up and extrapolate costs at EU level.	Enforcement Costs for MSAs and Customs: • Budget allocated to market surveillance (including costs of the enforcement activities, costs for sharing information among authorities) • Difference in the enforcement costs by MS • Difference in the enforcement costs by sectors Costs for economic operators for: • Preparing the documentation and information requested by MSAs in implementing surveillance measures as	Primary: • TS1: Q43, 44, 50, 51, 56, 57 ; TS2: Q39; • I: Q21, Q22 Secondary: • Enforcement indicators; • Enterprise Europe Network;

Criterion	*Effectiveness*			
	costs for economic operators.	For the **administrative costs** for economic operators the following approach will be followed: • Definition of activities required to comply with the administrative costs; • Estimation of frequency of activities - f (e.g. 1=once a year); • Estimation of the cost of the activities; • Estimation of the business-as-usual (BAU) factor; • Sum up and extrapolate costs at EU level. • For the **administrative costs** for MS: estimation of the costs to draft national market surveillance reports and programmes.	required from art. 19 of Reg. 765/2008	• National market surveillance reports.
Q7. Identification and quantification of benefits for stakeholders	**The Regulation creates the following benefits:** • Increased level of protection of safety or other public interest; • Increased clarity and certainty; • Increased effectiveness and efficiency of market surveillance; • Reduction of unfair competition in non-food markets	**Qualitative measurement** of the benefits of the EU Regulation based on stakeholder consultation. Particular aspects that will be investigated are if**:** • The costs of the measures taken by MSAs to prohibit or restrict products being made available on the market, to withdraw them from the market or to recall them, are proportionate to the expected benefits; • The Regulation provides the framework to ensure a level playing field and a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security.	• Trends of internal market trade and exports • Number of notifications on products covered by Regulation (EC) No 765/2008 sent through RAPEX per type (i.e. for information, serious risks and other risk levels) • Number of measures taken against non-compliant products per category of product • Number of measures taken against non-compliant products per type of risk • Perceived level of protection of public interests • Level of satisfaction of economic operators on the procedures put in place (e.g. possibility to be consulted in case of adoption of restrictive measures by MS as per Art. 21 of Regulation (EC) No 765/2008) • Level of satisfaction of economic operators	Primary: • TS1: Q72; TS2: Q55. • I: Q26, Q30 Secondary: • RAPEX; • Eurostat international trade database; • National market surveillance reports.

Criterion	*Effectiveness*			
			on the benefits in terms of fair competition/creation of a level playing field	
Q8. Cost effectiveness of the market surveillance provisions	The implementation of a market surveillance mechanism at European level increases the cost effectiveness of the Regulation	**Analysis of the practical implementation of the Regulation,** in terms of: • Resources used (inputs); • Actions and measures taken (outputs).	• Total budget allocated to law enforcement • Budget allocated in proportion to the number of retailers on the national market and their turnover • Number and budget for inspectors • Number of inspections • Number of products tested • Number of products withdrawn from the market • Number of products recalled from consumers • Number of decisions to reject products at the border • Number of notifications per MS • Number and type of measures adopted at MS level	Primary: • PC: section B1: Q7, Q8, Q9, Q10, Q11, Q12, Q13, Q18, Q19; section B3: Q2; • TS1: Q45, 46; • I: Q21, Q24, Q25; Secondary: • RAPEX; • National market surveillance reports and programmes.
Q9. a) identification of differences in costs/ benefits between Member States b) related causes	Cost and benefits from the implementation differ from MS	The estimation of costs and benefits will take into consideration differences among MS in order to identify possible best practices	• Quantification of differences at MS level of indicators computed for Q6, Q7 and Q8	Primary: • TS1: Q58, 59, 67; TS2: Q36, 40 • I: Q23. Secondary: • See Q6, Q7 and Q8.

Criterion	*Relevance*
Evaluation questions	EQ10. To what extent are market surveillance provisions of the Regulation still relevant in the light for instance of increasing online trade, the increase in imports from third countries, shortening product life, increasing budgetary constraints at national level, etc.? EQ11. To what extent do the effects of the market surveillance provisions satisfy (or not) stakeholders' needs? How much does the degree of satisfaction differ according to the different stakeholder groups? EQ12. Is the concept of *lex specialis* still a suitable interface between the market surveillance provisions in the Regulation and those in other (notably sector) legislation? EQ13. Is there an issue on the scope (i.e. all EU product harmonisation legislation) of the measure or some of its provisions?
Understanding the questions	Questions under this criterion are focused on the following aspects: - Whether market surveillance provisions of the Regulation are relevant and aligned with **market dynamics** (Q10, Q12, Q13) - Whether market surveillance provisions of the Regulation satisfy **stakeholders' needs** (Q11, Q12, Q13)

Focus of the questions	*Judgement criteria*	*Analytical approach*	*Indicators and descriptors*	*Sources*
Q10. Relevance vis-à-vis online trade, the increase in imports from third countries, shortening product life, increasing budgetary constraints at national level, etc.	The Market surveillance provisions of the Regulation are aligned with current market dynamics	a) Desk and field research with a specific focus on • Main changes and developments in manufacturing, marketing and distribution of non-food products in the EU • Main trends in international trade of non-food products directed towards the EU • Emerging risks at EU and global level; • Main trends in budgetary constraints at national level	• EU market of non-food products in terms of volumes and values; • Number of health and safety issues related to market developments not addressed by market surveillance provisions of the Regulation; • Correspondence between emerging market and safety issues with results from IA for the Product Safety and Market Surveillance Package including proposals for a revision of the Regulation; • Sector-specific cases and practices	Primary: • PC: section B4: Q1, Q3; section B5: Q1, Q2, Q3, Q4; • TS1: Q35-38, 69, 70; TS2: Q32-35, 45, 46 • I: Q1, Q7, Q28. Secondary: • National market surveillance reports and programmes; • EU IDB; • Results of the market analysis;

Criterion	*Effectiveness*			
		b)Correspondence matrix between Regulation (EC) No 765/2008 and the main market developments occurred	that are not fully covered by market surveillance provisions of the Regulation.	• IA for the Product Safety and Market Surveillance Package (SWD(2013) 33).
Q11. a) Satisfaction of stakeholders' needs b) Differences in the degree of satisfaction among stakeholder groups	Stakeholder groups are satisfied with the effects of market surveillance provisions, presenting different degree of satisfaction according to their belonging to different groups	Desk and field research with a specific focus on • Main trends in market surveillance measures of non-food products (release, recall or withdrawal of products, cost incurred by economic operators) • Emerging risks at EU and global level • Trends in stakeholder information and engagement with regard to market surveillance of non-food products	• Trends in market surveillance measures taken in the EU in different sectors and addressing different stakeholders • Current and emerging problems regarding health, safety and other public interest related to marketing of non-food products • Qualitative perception of different stakeholders, including national MSAs, border control authorities, SMEs, main economic operators and selected categories of consumers (sample), on market surveillance of non-food products	Primary: • PC: section B4: Q1, Q2; • TS1: Q8, 9, 68; TS2: Q44. • I: Q1, Q27, Q29, Q30. Secondary: • RAPEX; • EU IDB; • National market surveillance reports and programmes; • DG GROW report on the application of the Regulation; • IA for the Product Safety and Market Surveillance Package (SWD(2013) 33).
Q12. Relevance of the concept of lex specialis	The concept of *lex specialis* functions as a suitable interface between market surveillance provisions included in the Regulation and in other sector-specific legislation	a)Desk and field research with a specific focus on • Overview of sector-specific legislations including market surveillance provisions vis-à-vis the whole domain where the Regulation applies • Trends in the implementation at the national level of market surveillance provisions included in the Regulation and in sector-specific legislations • Risk analysis of market surveillance	• Number of sector-specific legislations including market surveillance provisions • Trends in the implementation of market surveillance provisions in different sectors linked to Regulation and other sector-specific legislations • Perception of stakeholders on possible risks deriving from the concept of lex specialis in the framework for market surveillance	Primary: • TS1: Q6, 7, 14; • I: Q32, Q33. Secondary: • Sector-specific legislations including market surveillance provisions; • National market surveillance reports and programmes; • DG GROW report on the application of the Regulation;

Criterion	*Effectiveness*			
		provisions included in the Regulation and in other sector-specific legislation • Cluster analysis of sectors/ domains where market surveillance provisions are defined by sector-specific legislation b)Correspondence matrix between market surveillance provisions included in sector-specific legislations and those included in the Regulation in terms of protection of health, safety and other public interest		• IA for the Product Safety and Market Surveillance Package (SWD(2013) 33); • IA accompanying legislative proposals listed in section 5 of ToR.
Q13. Presence of issues on the scope of the measure or some of its provisions	The scope of market surveillance provisions of the Regulation (i.e. all EU product harmonisation legislation) is still relevant and does not present particular issues	Desk and field research with a specific focus on potential misalignments between market surveillance provisions included in the Regulation and their implementation	Stakeholders' perception on the need to modify the Regulation's scope in light of emerging issues in terms of internal market and public interest	Primary: • TS1: Q4, 5, 70, 71; TS2: Q37, 38, 46, 47 • I: Q1, Q31. • Secondary: • RAPEX; • National market surveillance reports and programmes; • DG GROW report on the application of the Regulation; • IA for the Product Safety and Market Surveillance Package (SWD(2013) 33).

Criterion	*Coherence*			
Evaluation questions	*EQ14. To what extent are the market surveillance provisions above still coherent with other Union legislation on market surveillance on non-food products?* *EQ15. To what extent are the market surveillance provisions coherent internally?* *EQ16. To what extent are these provisions coherent with wider EU policy?*			
Understanding the questions	*Questions under this criterion are focused on the following aspects:* - *Whether market surveillance provisions in the Regulation are coherent with other Union legislation on market surveillance on non-food products and internally with the Regulation itself (Q14 and Q15)* - *Whether market surveillance provisions in the Regulation are coherent with the EU policy framework (Q16)*			
Focus of the questions	**Judgement criteria**	**Analytical approach**	**Indicators and descriptors**	**Sources**
Q14. Coherence with other Union legislation	Market surveillance provisions of the Regulation are coherent with other Union legislation on market surveillance on non-food products	Desk and field research on other Union legislation on market surveillance of non-food products in order to identify potential overlapping / contradictions with the Regulation	Number of provisions of the Regulation not coherent with other pieces of Union legislation or where overlapping or contradictions are recorded, extent of incoherence and related consequences	Primary: • TS1: Q11, 12, 15, 16; TS2: 51, 52, 54 • I: Q34. Secondary: • Directive 2001/95/EC on General Product Safety • Market surveillance provisions of sector-specific legislations covered by Regulation 765/2008; • IA for the Product Safety and Market Surveillance Package (SWD(2013) 33).
Q15. Internal coherence	Market surveillance provisions of the Regulation are coherent with	Desk and field research on market surveillance provisions on non-food products included in the Regulation	Number of provisions of the Regulation not coherent with other provisions included in the same legislation or where	Primary: • TS1: Q13, 15, 16; TS2: Q53.

Criterion	*Coherence*			
Evaluation questions	*EQ14. To what extent are the market surveillance provisions above still coherent with other Union legislation on market surveillance on non-food products?* *EQ15. To what extent are the market surveillance provisions coherent internally?* *EQ16. To what extent are these provisions coherent with wider EU policy?*			
Understanding the questions	*Questions under this criterion are focused on the following aspects:* - *Whether market surveillance provisions in the Regulation are coherent with other Union legislation on market surveillance on non-food products and internally with the Regulation itself (Q14 and Q15)* - *Whether market surveillance provisions in the Regulation are coherent with the EU policy framework (Q16)*			
Focus of the questions	**Judgement criteria**	**Analytical approach**	**Indicators and descriptors**	**Sources**
	themselves and the scope of the legislation		overlapping or contradictions are recorded, extent of incoherence and related consequences	• I: Q35. Secondary: • Market surveillance provisions of Regulation (EC) No 765/2008; • IA for the Product Safety and Market Surveillance Package (SWD(2013) 33).
Q16. Coherence with wider EU policy	Market surveillance provisions of the Regulation are coherent with EU policies (e.g. in the field of market surveillance, protection of public interests, internal market and	Desk and field research on EU policy documents (e.g. in the field of market surveillance, protection of public interests, internal market and controls of products on the internal market) in order to identify potential overlapping / contradictions with market surveillance	Number of market surveillance provisions of the Regulation not coherent with other EU policy documents (e.g. in the field of market surveillance, protection of public interests, internal market and controls of products on the internal market), extent of incoherence and related	Primary: • TS1: Q11, 12, 15, 16. TS2: Q51, 52, 54. • I: Q36. Secondary: • COM(2013) 76 final – multiannual action plan on market surveillance; • SEC(2011) 1640 final – Bringing e-commerce to

Criterion	*Coherence*			
Evaluation questions	*EQ14. To what extent are the market surveillance provisions above still coherent with other Union legislation on market surveillance on non-food products?* *EQ15. To what extent are the market surveillance provisions coherent internally?* *EQ16. To what extent are these provisions coherent with wider EU policy?*			
Understanding the questions	*Questions under this criterion are focused on the following aspects:* - *Whether market surveillance provisions in the Regulation are coherent with other Union legislation on market surveillance on non-food products and internally with the Regulation itself (Q14 and Q15)* - *Whether market surveillance provisions in the Regulation are coherent with the EU policy framework (Q16)*			
Focus of the questions	**Judgement criteria**	**Analytical approach**	**Indicators and descriptors**	**Sources**
	controls of products on the internal market)	provisions of the Regulation	consequences	consumers; • IA for the Product Safety and Market Surveillance Package (SWD(2013) 33).

Criterion	*EU added value*
Evaluation questions	*EQ17. What is the additional value resulting from the market surveillance provisions at EU level, compared to what could be achieved by Member States at national and/or regional levels?* *EQ18. To what extent do these provisions support and usefully supplement market surveillance policies pursued by the Member States? Do the provisions allow some sort of 'control' by the EU on the way national authorities carry out market surveillance?*
Understanding the questions	*Assessing to what extent the results of the EU action are additional to the value that would have resulted from action at Member State level.*

Criterion	*Coherence*			
Evaluation questions	*EQ14. To what extent are the market surveillance provisions above still coherent with other Union legislation on market surveillance on non-food products?* *EQ15. To what extent are the market surveillance provisions coherent internally?* *EQ16. To what extent are these provisions coherent with wider EU policy?*			
Understanding the questions	*Questions under this criterion are focused on the following aspects:* - *Whether market surveillance provisions in the Regulation are coherent with other Union legislation on market surveillance on non-food products and internally with the Regulation itself (Q14 and Q15)* - *Whether market surveillance provisions in the Regulation are coherent with the EU policy framework (Q16)*			
Focus of the questions	**Judgement criteria**	**Analytical approach**	**Indicators and descriptors**	**Sources**
Focus of the question	*Judgement criteria*	*Analytical approach*	*Indicators and descriptors*	*Sources*
Q17. Added value as compared to national/regional measures	• Simplification of the circulation of non-food products across MS. • Improved safety and other public interests due to harmonisation of market surveillance practice and setting of minimum standards.	Desk and field research aimed at: • Analysis of internal market trade of non-food products; • Analysis of convergence between Member States legislative framework concerning market surveillance; • Stakeholders' perception of the uniformity of market surveillance across the EU; • Analysis of data on accidents due to non-compliant food-products.	• Stakeholders' perception on the benefits resulting from a common Regulation.	Primary: • TS1: Q72; TS2: Q55 • I: Q37, Q38. Secondary: • RAPEX database; • EU IDB; • DG GROW report on cross-border cooperation; • Results of the market analysis; • IA for Regulation (EC) No

Criterion	*Coherence*
Evaluation questions	*EQ14. To what extent are the market surveillance provisions above still coherent with other Union legislation on market surveillance on non-food products?* *EQ15. To what extent are the market surveillance provisions coherent internally?* *EQ16. To what extent are these provisions coherent with wider EU policy?*
Understanding the questions	*Questions under this criterion are focused on the following aspects:* - *Whether market surveillance provisions in the Regulation are coherent with other Union legislation on market surveillance on non-food products and internally with the Regulation itself (Q14 and Q15)* - *Whether market surveillance provisions in the Regulation are coherent with the EU policy framework (Q16)*

Focus of the questions	**Judgement criteria**	**Analytical approach**	**Indicators and descriptors**	**Sources**
				765/2008.
Q18. a) Contribution of the Regulation to national policies b) Contribution of the Regulation to the EU control on Member States	• Increased market surveillance effectiveness and efficiency at MS level; • Increased level of safety and other public interest at the EU level.	Desk and field research aimed at: • Analysis of convergence between Member States legislative framework concerning market surveillance; • Stakeholders' perception of the uniformity of market surveillance across the EU; • Analysis of the amendments introduced in the national legislation for compliance with the Regulation.	• Increased cooperation among authorities involved in market surveillance at national level; • Number of positive achievements of the Regulation for the different stakeholder groups; • Increased intra-EU trade and competitiveness; • Stakeholders' perception on the supportive role of Regulation 765/2008 to national policies.	Primary: • TS1: Q73, 74, 75; TS2: Q56, 57. • I: Q39, Q40. Secondary: • Eurostat international trade database; • National market surveillance reports and programmes; • IA for Regulation (EC) No 765/2008.

8.12 Targeted survey questionnaires

The survey was circulated via the EY eSurvey tool. The questionnaires were also provided in French, Italian, German and Romanian. "MS" indicates the Member State authority in charge of coordinating market surveillance activities at the national level. "CA" tands for "Custom Authority".

8.12.1 Questionnaire for Public Authorities

N	Question	MS	MSA	CA
About you				
1.	**Authority name**	X	X	X
2.	**Please qualify the role of your Authority with respect to Regulation (EC) No 765/2008**	X	X	X
	a. Implementing authority (focused on coordination and implementation of the Regulation)			
	b. Market surveillance authority (focused on the enforcement of the Regulation)			
	c. Both a and b			
	d. Custom Authority			
3.	Localisation of the Authority you work for	X	X	X
4.	Please select your relevant sectors *(reference list of sectors in scope of the Regulation, multiple choice)*	X	X	X
About the content of Regulation (EC) No 765/2008				
5.	Are the following definitions clear, appropriate, complete and up-to-date?[456] *(a pop-up appears for each definition)*	X	X	X

456 *Clear*: the definitions are easy to understand or interpret; *Appropriate*: the definitions are suitable for the situations when they are used; *Complete*: the definitions cover all relevant aspects; *Up-to-date*: the definitions incorporate the latest developments and trends.

N	Question	MS	MSA	CA

Definition	Clear			Appropriate			Complete and up to date		
	Yes	No	I do not know	Yes	No	I do not know	Yes	No	I do not know
Making available on the market									
Placing on the market									
Manufacturer									
Authorised representative									
Importer									
Distributor									
Recall									
Withdrawal									
Product									

6.	Please add here any comments relating the existing definitions, or on concept/ definitions that according to you are missing in Regulation (EC) 765/2008.	X	X	X
7.	Does the concept of *lex specialis*[457] cause any problem of implementation? (*yes/no/I do not know)*	X	X	

457 In accordance with the principle of *lex specialis*, the Regulation should apply only as far as there are no specific provisions with the same objective, nature or effect in other existing or future rules of the EU harmonisation legislation.

N	Question	MS	MSA	CA
8.	Please specify	X	X	
9.	Do you deem the provisions of Article 18(5)[458] on market surveillance programmes as useful? (yes/no/I do not know)	X	X	
10.	If not, what should be changed? If yes, why?	X	X	
11.	Is there a need for any additional guidance on any areas of the Regulation? *(y/n)*	X	X	X
12	Could you please highlight any inconsistencies (if any) between the Regulation and any other pieces of EU legislation (e.g. with the General Product Safety Directive,[459] with sector-specific product legislation)?	X	X	X
13	Could you please highlight any contradictions (if any) between the provisions of the Regulation?	X	X	X
14.	Can you indicate any misalignments between the market surveillance provisions included in the Regulation and their implementation in different non-food product sectors?	X	X	
15.	Are there conflicts of jurisdictions of authorities? *(y/n)*	X	X	X
16.	Please explain	X	X	X
About the implementation of Regulation (EC) No 765/2008				
17.	Do MSAs in your Member State have/does your authority have the following powers	X	X	
	□ To carry out sector inquiries *(y/n)*			
	□ Take samples for free *(y/n)*			

458 According to Article 18(5) of Regulation (EC) No 765/2008: "*Member States shall establish, implement and periodically update their market surveillance programmes. Member States shall draw up either a general market surveillance programme or sector specific programmes, covering the sectors in which they conduct market surveillance, communicate those programmes to the other Member States and the Commission and make them available to the public, by way of electronic communication and, where appropriate, by other means*."

459 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0095&from=EN

N	Question	MS	MSA	CA
	□ Recover from economic operators costs borne to test products found to be non-compliant *(y/n)*			
	□ Do mystery shopping *(y/n)*			
	□ Seize and detain products *(y/n)*			
	□ Destroy products *(y/n)*			
	□ Recover from economic operators costs borne to store or destroy products *(y/n)*			
	□ Seize documents *(y/n)*			
	□ Impose provisional measures pending investigations *(y/n)*			
	□ Sanction economic operators that do not cooperate *(y/n)*			
	□ Request information/cooperation by any possible natural or legal person when this is necessary to take corrective action *(y/n)*			
	□ Take off or require to take off illegal content from a websites *(y/n)*			
	□ Shut-down websites *(y/n)*			
	□ Impose administrative economic sanctions (without resorting to national courts) *(y/n)*			
	□ Publish decisions on restrictive measures *(y/n)*			
	□ Impose compensation for consumers/users of non-compliant products *(y/n)*			
18.	Is there any need to grant MSAs more powers to enter businesses' premises? *(y/n)*		X	
19.	Please specify		X	
20.	Do you usually perceive to have sufficient market knowledge (i.e. on products made available and their suppliers) to target checks to be carried out?		X	X

N	Question	MS	MSA	CA
21.	Do MSAs and Customs in your Member State have in-house laboratories for testing?		X	
	□ No, only Customs have in-house laboratories for testing			
	□ Yes, both MSAs and Customs have in-house laboratories for testing			
	□ Neither MSAs nor Customs have in-house laboratories for testing			
	□ I do not know			
22.	Do MSAs and Customs in your Member State make use of test reports by MSAs in other EU countries? *(y/n/I do not know)*		X	X
23.	If not, why?		X	X
24.	Does Regulation (EC) No 765/2008 attribute adequate powers to Custom Authorities? *(y/n)*			X
25.	If not, what should be changed?			X
26.	Are the guarantees provided sufficient to cover possible costs linked to market surveillance checks? *(yes/no/ "no guarantees exist", + "I do not know")*			X
27.	Do authorities in your Member State have/does your authority have the following powers:			X
	□ Request business to provide information and exhibit documents on products presented for release for free circulation (y/n)			
	□ Recover from economic operators costs borne to test products found to be non-compliant *(y/n)*			
	□ Destroy products *(y/n)*			
	□ Recover from economic operators costs borne to store or destroy products *(y/n)*			

N	Question	MS	MSA	CA
Focus on powers of control				
28.	In terms of uniformity[460] and rigorousness of controls by Market Surveillance/ Authorities in charge with EU external border controls, are you aware of any discrepancies **across EU Member States**? *(y/n)*	X	X	X
29.	Could you please provide some examples?	X	X	X
30.	In terms of uniformity and rigorousness of controls of Market Surveillance/ Authorities in charge with EU external border controls, are you aware of any discrepancies **across sectors in your Member State**? (y/n)	X	X	X
31.	Please specify	X	X	X
32.	If any, are they:	X	X	X

	To a large extent	To a small extent	Not at all	I do not know
Hindering the free circulation of goods				
Influencing market behaviour (e.g. decision of companies to enter the EU market via certain Member States – both non-EU and EU products)				
Reducing the safety of products or their degree of non-compliance				
Influencing the regulatory/administrative costs for Member State/Market Surveillance/Custom Authority across Member States? (please answer this question according to the category you belong to)				

460 *Uniformity*: all products and all economic operators are equally targeted by controls across all EU Member States. *Rigorousness*: The types of controls and the criteria for imposing sanctions are equal across the EU Member States.

N	Question	MS	MSA	CA
33.	What are the criteria Market Surveillance/Customs Authorities in your Member State use to select a particular sector as a priority for controls?		X	X
34.	Could you briefly describe the criteria your Market Surveillance/Customs Authorities apply to determine the "*adequate scale*"[461] of product controls?		X	X
35.	Do you consider the procedures for the control of products entering the EU market as described in articles 27 to 29 of the Regulation as:			X
	□ Clear? *(y/n/I do not know)*			
	□ Easy to apply? *(y/n/I do not know)*			
	□ Still relevant to the need of Authorities in charge of external border control? *(y/n/I do not know)*			
36.	Are there issues with/obstacles to checks of products imported into the EU carried out by Authorities in charge with EU external border controls? *(y/n/I do not know)*		X	X
37.	Are there issues with/obstacles to performing market surveillance or controls of imported products in any sector in particular?		X	X
38.	Are there issues /obstacles related to the increasing importance of online trade? *(y/n/I do not know)*		X	X
39.	Could you please provide some examples?		X	X
Focus on powers of sanction				
40.	How did your Member State (for MS) /your authority (for MSAs) implement article 41[462] of Regulation (EC) No 765/2008?	X	X	

461 According to Article 19(1) of the Regulation, "Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples." Article 27 (1) of the Regulation refers to the same principle for Authorities in charge of border controls.

462 According to Article 41 of the Regulation, "*The Member States shall lay down rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement of the provisions of this Regulation. The Member States shall notify the Commission of those provisions by 1 January 2010 and shall notify it without delay of any subsequent amendment affecting them*".

N	Question	MS	MSA	CA
41.	Are you aware of any discrepancies across EU Member States **in the level of sanctions** for non-compliant products? *(y/n)*	X	X	
42.	Could you please provide some examples?	X	X	
43.	In your Member State and in your sector, what is the highest possible economic sanction applicable in case of serious infringements of product requirements that can be applied by MSAs without resorting to courts?	X	X	
	□ Total value (€): _____			
	□ As percentage of turnover: _____			
	□ Other: _____			
	□ I do not know			
44.	In addition to economic fines, could you specify the maximum sanction MSAs are entitled to ask for by law in your sector in your Member State?	X	X	
45.	To what extent is the procedure to impose economic sanctions burdensome?		X	
	□ To a large extent			
	□ To a small extent			
	□ To no extent			
	□ I do not know			
46.	Can you please specify in what respect?		X	
47.	Do you see any scope for efficiency gains, in the following stages of the investigative and sanctioning process?		X	
	□ Targeting of enforcement action *(y/n/I do not know)*			

N	Question	MS	MSA	CA
	□ Inspection *(y/n/I do not know)*			
	□ Dialogue with businesses to obtain cooperative corrective action *(y/n/I do not know)*			
	□ Adoption of the enforcement decision *(y/n/I do not know)*			
	□ Appeal against the enforcement decision/litigation *(y/n/I do not know)*			
	□ Other (please specify) *(y/n/I do not know)*			
48.	Could you please provide evidence for your previous answer?		X	
49.	Do you see any scope for efficiency gains, in the following stages of the process for control of imported products?			X
	□ Targeting of controls (y/n/ *I do not know*)			
	□ Inspection of products and suspension of release for free circulation *(y/n/ I do not know)*			
	□ Transmission of information to competent Market Surveillance Authority *(y/n/ I do not know)*			
	□ Reception of information from competent Market Surveillance Authority *(y/n/ I do not know)*			
	□ Authorisation of release for free circulation following corrective measures *(y/n/ I do not know)*			
	□ Refusal of release for free circulation *(y/n/ I do not know)*			
	□ Other (please specify) *(y/n)*			
50.	Could you specify what could be improved there?			X
51.	Which type of restrictive measure[463] had been the most frequent in your Member State and in your sector over the period 2010-2015?		X	X

463 A "restrictive measure" prohibits or restrict a product's being made available on the market, withdraws it from the market or recalls.

N	Question	MS	MSA	CA
	□ Product withdrawal			
	□ Product recall			
	□ I do not know			
	□ Other, please specify			
52.	Which sector had been the most affected by restrictive measures due to product non-compliance over the period 2010-2015?		X	X
Communication and collaboration activities				
53.	Do you usually cooperate with other MSAs/Customs in other Member States? (y/n)		X	X
54.	Is your communication and collaboration with other Member State Authorities in other Member States useful? Could it be improved and, if so, how?	X	X	X
55.	In case of a non-compliant product, do you usually notify to MSAs in other Member States the restrictive measures you impose (if any)? (y/n)		X	
56.	Have you ever used the ICSMS[464] system until now? (y/n)	X	X	
57.	What are the challenges and difficulties (if any) in the use of ICSMS?	X	X	
58.	Does your Market Surveillance Authority (or do Market Surveillance Authorities in your Member State) participate in AdCO[465] activities? (y/n)	X	X	
59.	How do you consider participation in AdCO work? *(multiple choice)*		X	
	□ Essential to coordinate action			

464 ICSMS is the internet-supported information and communication system for the pan-European market surveillance. https://webgate.ec.europa.eu/icsms/

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

N	Question	MS	MSA	CA
	□ Useful to keep an eye on what Market Surveillance Authority in other Member States do and/or to learn from each other			
	□ Of little practical relevance for my authority work / not a priority			
	□ Other (please specify)			
Costs related to Regulation (EC) No 765/2008				
60.	What is the average annual salary (€) of an employee to perform general market surveillance activities (e.g. inspection, testing, product withdrawal, investigation)?		X	X
61.	Could you please provide an estimate (€) of the annual cost for economic operators related to the application of the Regulation (e.g. preparing documents and information requested by MSAs/ Authorities in charge with EU external border controls in implementing surveillance measures) on top of compliance costs to ensure and demonstrate conformity to EU legislation applicable to your products in your sector/ country?		X	X
62.	Are you aware of any differences in costs for enforcing the Regulation across Member States? *(y/n)*	X	X	X
63.	Please specify	X	X	X
Impact of Regulation (EC) No 765/2008				
64.	According to you experience, in the last 5 years overall product non-compliance in your sector has:		X	X
	□ Substantially diminished			
	□ Diminished			
	□ Remained equal			
	□ Increased			
	□ Substantially increased			

N	Question	MS	MSA	CA
	□ I do not know			
65.	**Which sector** had been heavily affected by product non-compliance **in your country** over the period 2010-2015?		X	X
66.	**Which country** has been heavily affected by product non-compliance **in your sector** over the period 2010-2015?		X	X
67.	Could you explain why?		X	X
68.	Do you think that checks of products imported into the EU carried out by Authorities in charge with EU external border controls are sufficient to deter rogue traders in your sector in your Member State?		X	X
	□ Yes, definitely			
	□ Yes, somehow			
	□ No			
	□ I do not know			
69.	To what extent do you agree or disagree with the following statements? *The regulation effectively provides the right framework to support*:	X	X	X

	Strongly agree	**Somewhat agree**	**Neither agree nor disagree**	**Somewhat disagree**	**Strongly disagree**	**I do not know**
Health and Safety in General						
Health and Safety at the Workplace						
Protection of consumers						
Protection of the environment						

N	Question						MS	MSA	CA
	Free movement of products								
	Level playing field for all EU businesses								
	Other public interests (please specify)								
70.	Could you please provide evidence for your previous answers?						X	X	X
71.	Are you aware of any best practices[466] in market surveillance and controls of imported products in place in EU Member States or in major trading partners (i.e.: Iceland, Norway, Liechtenstein, Turkey, Switzerland, USA, China, Korea, and Japan)?						X	X	X
Relevance of the Regulation for current needs									
72.	In general, does the Regulation currently meet your needs? *(y/n)*						X	X	X
73.	To what extent do you think the Regulation currently addresses specific issues deriving from: *(to no extent, to some extent, to a large extent, I do not know)*						X	X	X
	□ Online trade/Delivery via small postal consignments or express couriers								
	□ Increasing imports from third countries								
	□ Shortening product life impacting the ability of authorities to track non-complaint product and ensure corrective action								
	□ Increasing budgetary constraints								
74.	In addition to those reported in the previous question, could you please indicate additional issues affecting non-compliance with EU harmonisation legislation for the marketing of non-food products (e.g. related to health, safety and other public interest) that the Regulation is not properly addressing?						X	X	X

466 A "best practice" is a commercial or professional procedure recognised as being more effective or efficient as compared with other procedures having the same objective.

N	Question	MS	MSA	CA
75.	The Regulation applies to a number of products: do you find the current scope of application of the Regulation clear? *(y/n/I do not know*)	X	X	X
76.	Could you indicate if there is any additional products that the Regulation should cover or any products that should be excluded from the Regulation's scope?	X	X	X
Added value of the Regulation				
77.	Could you please highlight the benefits linked to having a European legislation on harmonising market surveillance and control of imported products instead of 28 national legislations?	X	X	X
78.	Is the framework provided by the Regulation useful to define your national market surveillance and control of imported products policies?	X	X	X
	□ Yes, to a large extent			
	□ Yes, to a small extent			
	□ To no extent			
	□ I do not know			
Concluding remarks				
79.	Is there any other issue you would like to bring to the European Commission's attention?	X	X	X

8.12.2 Questionnaire for economic operators and civil society

N	Question	EO	CS
About you			
1.	**Legal entity name**	X	X
2.	Please select who you are:	X	X

N	Question	EO	CS
	□ Company		
	□ Industry association		
	□ Consumer association		
3.	Type of economic operator you are or represent	X	
	□ Product Importers / Distributors		
	□ Product Manufacturers / Authorised Representative		
	□ Online intermediaries		
	□ Other		
4.	Please select the size of the firm you are or represent	X	
	□ Less than 10 employees		
	□ from 10 to 49 employees		
	□ from 50 to 249 employees		
	□ more than 249 employees		
5.	Localisation of the establishment you work in *(closed list of EU28 Member States + EEA countries+ Switzerland +Turkey + 'Other third country')*	X	X
6.	Geographical coverage of your association *(multiple choice: list of EU28 Member States + EEA countries + Switzerland + Turkey + 'Other third country' + EU level + International (beyond EU level)*	X	X
7.	Please select your relevant sectors (*multiple choice: list of sectors covered by Regulation (EC) No 765/2008 + possibility of selecting "Other", multiple choices possible)*	X	X

N	Question	EO	CS
Focus on controls			
8.	In terms of uniformity[467] and rigorousness of controls by Market Surveillance Authorities/ Authorities in charge with EU external border controls, are you aware of any discrepancies **across EU Member States**? *(y/n)*	X	X
9.	Could you please provide some examples?	X	X
10.	In terms of uniformity and rigorousness of controls of Market Surveillance Authorities/ Authorities in charge with EU external border controls, are you aware of any discrepancies **across sectors** (e.g. lifts/machinery, electrical equipment under EMC/electrical appliances and equipment under LVD) in your Member State? *(y/n)*	X	X
11.	Could you please provide some examples?	X	X
12.	If any, are they:	X	X

467 *Uniformity*: all products and all economic operators are equally targeted by controls across the EU Member States. *Rigorousness*: The types of controls and the criteria for imposing sanctions are equal across the EU Member States.

N	Question	EO	CS

	To a large extent	To a small extent	Not at all	I do not know
Hindering the free circulation of goods				
Influencing market behaviour (e.g. decision of companies to enter the EU market via certain Member States – both non-EU and EU products)				
Reducing the safety of products				
Influencing the regulatory/administrative costs of businesses across Member States (e.g. preparing documents and information requested by Market Surveillance Authorities/ Authorities in charge with EU external border controls in implementing surveillance measures)? (only for economic operators and industry associations)				

Focus on sanctions			
13.	Are you aware of any discrepancies across EU Member States **in the level of sanctions** for non-compliant products?	X	X
14.	Could you please provide some examples for instance of having being subject to different sanctions for the same problem?	X	
15.	Could you please provide some examples?		X
16.	In your Member State and in your sector, what is the highest possible economic sanction applicable in case of serious infringements of product requirements[468] that can be applied by market surveillance authority without resorting to courts?	X	
	□ Total value (€): _____		

468 The EU technical harmonisation directives specify essential requirements to which products must conform. These requirements are designed to ensure a high level of product safety.

N	Question	EO	CS
	□ As percentage of turnover: _____		
	□ Other: _____		
	□ I do not know		
17.	In addition to economic fines, could you specify the maximum sanction Market Surveillance Authorities are entitled to ask for by law in your sector in your Member State?	X	
Focus on restrictive measures			
18.	**Which sector** had been heavily affected by restrictive measures due to product non-compliance over the period 2010-2015?		X
19.	**Which type of restrictive measure**[469] had been the most frequent in your Member State and in your sector over the period 2010-2015? *(single choice: list of restrictive measures + "I do not know")*		X
	□ Product withdrawal		
	□ Product recall		
	□ I do not know		
	□ Other, please specify		
20.	Have you ever been subject to any of the following restrictive measures? *(list of restrictive measures + "I have never been subject to a restrictive measure")*	X	
	□ I have never been subject to a restrictive measure		
	□ Product withdrawal		

469 A "restrictive measure" prohibits or restrict a product's being made available on the market, withdraws it from the market or recalls.

N	Question	EO	CS
	□ Product recall		
	□ I do not know		
	□ Other, please specify		
21.	If yes, did you have been given the opportunity to be heard within an appropriate period of not less than 10 days (as per art. 21 of Regulation 765/2008)?[470] *(y/n/n.a.)*	X	
22.	Have you found this consultation process appropriate?[471]	X	
	□ Yes, to a large extent		
	□ Yes, to a medium extent		
	□ Yes, to a low extent		
	□ No		
	□ Not applicable		
23.	Could you please provide evidence for your previous answer?	X	
Focus on the impact of Regulation (EC) No 765/2008			
24.	**Which country** had been the most affected by product non-compliance in your sector over the period 2010-2015? *(list of Member States + EEA countries+ Switzerland +Turkey + "I do not know")*		X

470 According to Article 21(3) of the Regulation, prior to the adoption of restrictive measures, "*the economic operator concerned shall be given the opportunity to be heard within an appropriate period of not less than 10 days, unless such consultation is not possible because of the urgency of the measure to be taken, as justified by health or safety requirements or other grounds relating to the public interests covered by the relevant Community harmonisation legislation. If action has been taken without the operator's being heard, the operator shall be given the opportunity to be heard as soon as possible and the action taken shall be reviewed promptly thereafter*".

471 Appropriateness: the process has not been too time-consuming nor too difficult to understand (i.e. transparent) and your level of involvement and the information shared has been satisfactory.

N	Question	EO	CS
25.	Could you explain why?		X
26.	According to you experience, in the last 5 years overall product non-compliance in your sector has:	X	X
	□ Substantially diminished		
	□ Diminished		
	□ Remained equal		
	□ Increased		
	□ Substantially increased		
	□ I do not know		
27.	Do you think that market surveillance activities are sufficient to deter rogue traders in your sector in your Member State?	X	X
	□ Yes, definitely		
	□ Yes, somehow		
	□ No		
	□ I do not know		
28.	**Which sector** had been the most affected by product non-compliance over the period 2010-2015? *(list of sectors + "I do not know")*		X
29.	Do you think that checks of products imported into the EU carried out by Authorities in charge with EU external border controls are sufficient to deter rogue traders in your sector in your Member State?	X	X
	□ Yes, definitely		
	□ Yes, somehow		

N	Question	EO	CS
	□ No		
	□ I do not know		
30.	Is there any need to grant Market Surveillance Authorities more powers to enter businesses' premises? *(y/n/I do not know)*	X	
31.	Please specify	X	
32	Is there any need to grant Market Surveillance Authorities any other additional powers to effectively detect non-compliance and obtain corrective action *(y/n/I do not know)*	X	X
33.	Please specify	X	X
34.	Is there any need to grant Authorities in charge with EU external border controls any additional powers to effectively detect non-compliant products? *(y/n/I do not know)*	X	X
35.	Please specify	X	X
36.	Are you aware of any issue with/obstacles to checks of products imported into the EU carried out by Authorities in charge with EU external border controls? *(y/n)*	X	X
37.	Are you aware of any issue with/obstacles to market surveillance in any sector in particular? *(list of sectors + "No, there are not issues")*	X	X
38.	Are there issues for your activity related to the increasing importance of online trade? *(y/n/I do not know)*	X	X
39.	Please explain	X	X
40.	Are you aware of any best practices[472] in market surveillance and controls of imported products in place in EU Member States or in major trading partners (i.e.: Iceland, Norway, Liechtenstein, Turkey, Switzerland, USA, China, Korea, and Japan)?	X	X
About the content of Regulation (EC) No 765/2008			

472 Appropriateness: the process has not been too time-consuming nor too difficult to understand (i.e. transparent) and your level of involvement and the information shared has been satisfactory.

<table>
<tr><th>N</th><th>Question</th><th>EO</th><th>CS</th></tr>
<tr><td>41.</td><td>Are the following definitions clear, appropriate, complete and up-to-date?[473] (a pop-up will appear displaying each definition)</td><td>X</td><td></td></tr>
<tr><td></td><td colspan="3">
<table>
<tr><th rowspan="2">Definition</th><th colspan="3">Clear</th><th colspan="3">Appropriate</th><th colspan="3">Complete and up to date</th></tr>
<tr><th>Yes</th><th>No</th><th>I do not know</th><th>Yes</th><th>No</th><th>I do not know</th><th>Yes</th><th>No</th><th>I do not know</th></tr>
<tr><td>Making available on the market</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Placing on the market</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Manufacturer</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Authorised representative</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Importer</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Distributor</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Recall</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Withdrawal</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Product</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table>
</td><td></td><td></td></tr>
<tr><td>42.</td><td>Please add here any comments relating the existing definitions, or on concept/ definitions that according to you are missing in Regulation (EC) 765/2008.</td><td>X</td><td></td></tr>
</table>

473 *Clear*: the definitions are easy to understand or interpret; *Appropriate*: the definitions are suitable for the situations when they are used; *Complete*: the definitions cover all relevant aspects; *Up-to-date*: the definitions incorporate the latest developments and trends.

<table>
<tr><th>N</th><th>Question</th><th>EO</th><th>CS</th></tr>
<tr><td>43.</td><td>Could you please provide an estimate (€) of the annual cost for economic operators related to the application of the Regulation (e.g. preparing documents and information requested by Market Surveillance Authorities/ Authorities in charge with EU external border controls in implementing surveillance measures) on top of compliance costs to ensure and demonstrate conformity to EU legislation applicable to your products in your sector/ country?</td><td>X</td><td></td></tr>
<tr><td>44.</td><td>To what extent do you agree or disagree with the following statements? The Regulation effectively provides the right framework to support:</td><td>X</td><td>X</td></tr>
<tr><td></td><td>
<table>
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<tr><td>Protection of consumers</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Protection of the environment</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Free movement of products</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Level playing field for all EU businesses</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Other public interests (please specify)</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table>
</td><td></td><td></td></tr>
<tr><td>45.</td><td>Could you please provide evidence for your previous answers?</td><td>X</td><td>X</td></tr>
<tr><td>46.</td><td>In general, does the Regulation currently meet your needs in terms of (e.g.) harmonisation of market surveillance practices? (y/n)</td><td>X</td><td>X</td></tr>
<tr><td>47.</td><td>To what extent do you think the Regulation currently addresses specific issues deriving from: (to no extent, to some extent, to a large extent)</td><td>X</td><td>X</td></tr>
</table>

N	Question	EO	CS
	□ Online trade/Delivery via small parcel consignments or express couriers		
	□ Increasing imports from third countries		
	□ Shortening product life impacting the ability of authorities to track non-complaint product and ensure corrective action		
48.	In addition to those reported in the previous question, could you please indicate additional issues affecting non-compliance with EU harmonisation legislation for the marketing of non-food products (e.g. related to health, safety and other public interest) that the Regulation is not properly addressing?	X	X
49.	The Regulation applies to a number of products: do you find the current scope of application of the Regulation clear? (*y/n/I do not know*)	X	X
50.	Have you ever used the section of ICSMS[474] system publicly accessible? (y/n)	X	X
51.	Do you find the information in the publicly accessible part of the ICSMS system relevant? (y/n) Please explain	X	X
52.	Is there a need for any additional guidance on any areas of the Regulation? *(y/n)*	X	X
53.	Could you please highlight any inconsistencies (if any) between the Regulation and any other pieces of EU legislation (e.g. with the General Product Safety Directive,[475] sector-specific product legislation)?	X	X
54.	Could you please highlight any contradictions (if any) between the provisions of the Regulation?	X	X
Added value of Regulation (EC) No 765/2008			
55.	Could you please highlight the benefits linked to having a European legislation harmonising market surveillance and controls of imported products instead of 28 national legislations?	X	X

474 ICSMS is the internet-supported information and communication system for the pan-European market surveillance. https://webgate.ec.europa.eu/icsms/

475 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0095&from=EN

N	Question	EO	CS
Concluding Remarks			
56.	Is there any other issue you would like to bring to the European Commission's attention?	X	X

8.13 Interview grids

The following table presents the list of questions used in semi-structured interviews (i.e. those interviews not related to the data collection for case studies or for the CBA).

These interviews served to further investigate, clarify or triangulate data collected through the desk research, targeted surveys and public consultation. Given they were based on open discussion, these questions should be consider as non-exhaustive.

N	*Question*
Effectiveness	
1.	Are there any implementation issues and open points that need to be addressed at national/EU level?
2.	Are you aware of any discrepancies between EU Member States in the level of market surveillance in terms of uniformity and rigorousness of controls?
3.	Are you aware of any discrepancies between EU Member States in the level of sanctions?
4.	Are you aware of any discrepancies between sectors in your Member State in terms of uniformity and rigorousness of controls of MSAs? If yes, could you explain why?
5.	If any, are these discrepancies impacting the safety of products or the level playing field for businesses?
6.	Is there a need for any additional guidance on any areas of the Regulation?
7.	According to your experience, what is the main reason for product non-compliance in the Single Market?
8.	Do you have experience/knowledge of instances where an MSA lacks/lacked sufficient financial/human/ technical resources to carry out specific tasks in your sector?
9.	According to your experience, has the Regulation impacted on product non-compliance over the last 5 years? Could you explain why and how?
10.	Are MSAs in your Member State usually granted resources targeted to specific sectors/objectives?
11.	Overall, do you perceive that the introduction of the Regulation ensured the establishment of a level playing field among businesses? Why?
12.	Could you estimate which proportion of non-compliant products is eventually targeted with sanctions or restrictive measures by MSAs? Can you identify any trends before/after 2010?
13.	Do you perceive sanctions/penalties as effective and proportionate deterrence mechanisms to prevent product non-compliance in your Member State and rogue traders?
14.	Are you aware of any best practices in market surveillance in place in other EU Member States or in major trading partners (i.e.: Iceland, Norway, Liechtenstein, Turkey, Switzerland, USA, China, Korea, and Japan) in terms of national organisation of market surveillance, of particularly effective/efficient mechanisms to perform checks and controls, to ensure communication among MSAs and Customs?

N	*Question*
Efficiency	
15.	Did the Regulation introduce any type of costs on consumers/end-users (e.g. derived from Art. 19 stating that the MSAs may require economic operators to make documentation and information regarding the products available, to present test reports or certificates attesting conformity)?
16.	Do you think these costs affect disproportionately a particular category of stakeholders?
17.	Are you aware of any differences in costs for implementing the Regulation across Member States?
18.	Are the measures taken by MSAs proportionate to their objectives?
19.	Is the regulation able to provide the framework to ensure a higher level of protection of public interests?
20.	Do you think the level of compliance with the Regulation is increased/decreased? How the level of fair competition has been affected?
Relevance	
21.	In general, do you think that the Regulation meets the needs of stakeholders (e.g. in terms of scope)?
22.	To what extent do you think the Regulation currently meets new safety issues deriving from online trade, increasing imports from third countries, shortening product life, increasing budgetary constraints?
23.	Since the entry into force of Regulation (EC) No 765/2008, what have been the main emerging issues regarding health, safety and competitiveness related to marketing of non-food products?
24.	How does non-compliance affect consumers and other end-users? How does it affect competitiveness?
25.	Does the concept of *lex specialis* cause any problems of implementation or any risks in the framework for market surveillance?
26.	Are there any misalignments between the market surveillance provisions included in the Regulation and their implementation in different non-food product sectors?
Coherence	
27.	Are there overlapping or contradictions between the Regulation and any other pieces of EU legislation (e.g. GPSD and sectoral provisions on market surveillance)?
28.	Are there contradictions between the provisions of the Regulation?
Added value	
29.	What is additional value resulting from Regulation (EC) No 765/2008, as compared to what could be achieved through single Member State action?
30.	Do you think that the introduction of common market surveillance requirements strengthened the protection of public interest through the reduction of non-compliant products on the EU Single Market?
31.	To what extent do the Regulation provisions support and usefully supplement market surveillance

N	*Question*
	policies pursued by the Member States?
32.	Do the provisions allow some sort of 'control' by the EU on the way national authorities carry out market surveillance?
Concluding remarks	
33.	Is there any other issue you would like to bring to the European Commission's attention?

8.14 Correspondence tables and data for the market analysis

As stressed, there is not full correspondence between the EC template and NACE/PRODCOM classifications, due to the different nature of issues under analysis (i.e. legislation vs statistical classifications). Therefore, in order to obtain reliable sources of data for the analysis at product and sector level, some hypotheses have been made, and results shall be interpreted having this caveat in mind.

The following tables present the assumed correspondence between the EC list of harmonised sectors and the sectors included in the market analysis at both sectoral and product level.

Correspondence between the EC list of harmonised sectors and economic sectors included in the market analysis (sectoral level)

Harmonised sectors	NACE	Description
1. Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	21	Manufacture of basic pharmaceutical products and pharmaceutical preparations
	26	Manufacture of computer, electronic and optical products
	32	Other manufacturing
2. Cosmetics	20	Manufacture of chemicals and chemical products
3. Toys	32	Other manufacturing
4. Personal protective equipment	14	Manufacture of wearing apparel
	15	Manufacture of leather and related products
	32	Other manufacturing
5. Construction products	23	Manufacture of other non-metallic mineral products
6. Aerosol dispensers	20	Manufacture of chemicals and chemical products
	25	Manufacture of fabricated metal products, except machinery and equipment

Harmonised sectors	NACE	Description
	28	Manufacture of machinery and equipment not elsewhere classified (n.e.c.)
	32	Other manufacturing
7. Simple pressure vessels and pressure equipment	22	Manufacture of rubber and plastic products
	24	Manufacture of basic metals
	25	Manufacture of fabricated metal products, except machinery and equipment
	23	Manufacture of other non-metallic mineral products
	28	Manufacture of machinery and equipment n.e.c.
8. Transportable pressure equipment	22	Manufacture of rubber and plastic products
	25	Manufacture of fabricated metal products, except machinery and equipment
	28	Manufacture of machinery and equipment n.e.c.
9. Machinery	27	Manufacture of electrical equipment
	28	Manufacture of machinery and equipment n.e.c.
	30	Manufacture of other transport equipment
10. Lifts	28	Manufacture of machinery and equipment n.e.c.
11. Cableways	28	Manufacture of machinery and equipment n.e.c.
12. Noise emissions for outdoor equipment	28	Manufacture of machinery and equipment n.e.c.
13. Equipment and protective systems intended for use in	26	Manufacture of computer, electronic and optical products

Harmonised sectors	NACE	Description
potentially explosive atmospheres	26	Manufacture of computer, electronic and optical products
	32	Other manufacturing
	25	Manufacture of fabricated metal products, except machinery and equipment
14. Pyrotechnics	20	Manufacture of chemicals and chemical products
15. Explosives for civil uses	20	Manufacture of chemicals and chemical products
16. Appliances burning gaseous fuels	28	Manufacture of machinery and equipment n.e.c.
17. Measuring instruments, non- automatic weighing instruments, pre-packaged products and units of measurement	26	Manufacture of computer, electronic and optical products
	28	Manufacture of machinery and equipment n.e.c.
18. Electrical equipment under EMC	27	Manufacture of electrical equipment
19. Radio and telecom equipment under RTTE - RED	26	Manufacture of computer, electronic and optical products
20. Electrical appliances and equipment under LVD	27	Manufacture of electrical equipment
	28	Manufacture of machinery and equipment n.e.c.
21. Electrical and electronic equipment under RoHS and WEEE and batteries	26	Manufacture of computer, electronic and optical products
	27	Manufacture of electrical equipment
	28	Manufacture of machinery and equipment n.e.c.
	32	Other manufacturing

Harmonised sectors	NACE	Description
	32	Other manufacturing
22. Chemical substances under REACH and Classification and Labelling Regulations (22A) and other chemicals (22B: Other chemicals: detergents, paints, persistent organic pollutants, fluorinated greenhouse gases, ozone depleting substances, etc.)	20	Manufacture of chemicals and chemical products
	25	Manufacture of fabricated metal products, except machinery and equipment
	26	Manufacture of computer, electronic and optical products
	27	Manufacture of electrical equipment
	36	Water collection, treatment and supply
	38	Waste collection, treatment and disposal activities; materials recovery
	45	Wholesale and retail trade and repair of motor vehicles and motorcycles
	71	Architectural and engineering activities; technical testing and analysis
	72	Scientific research and development
23. Eco-design and energy labelling; efficiency requirements for hot-boilers fired with liquid or gaseous fuels	25	Manufacture of fabricated metal products, except machinery and equipment
24. Tyre labelling	22	Manufacture of rubber and plastic products
25. Recreational craft	30	Manufacture of other transport equipment
26. Marine equipment	13	Manufacture of textiles
	25	Manufacture of fabricated metal products, except machinery and equipment
	26	Manufacture of computer, electronic and optical products

Harmonised sectors	NACE	Description
	27	Manufacture of electrical equipment
	28	Manufacture of machinery and equipment n.e.c.
	29	Manufacture of motor vehicles, trailers and semi-trailers
	30	Manufacture of other transport equipment
27. Motor vehicles and tractors 28. Non-road mobile machinery	28	Manufacture of machinery and equipment n.e.c.
	29	Manufacture of motor vehicles, trailers and semi-trailers
29. Fertilisers	20	Manufacture of chemicals and chemical products
30. Other consumer products under the GPSD	n.a.	n.a.
31. Biocides	20	Manufacture of chemicals and chemical products
32. Textile and footwear labelling	14	Manufacture of wearing apparel
	15	Manufacture of leather and related products
33. Crystal glass	23	Manufacture of other non-metallic mineral products

Correspondence between the EC list of harmonised sectors and manufacturing products included in the market analysis (product level)[476]

Harmonised sectors	NACE	Description
1. Medical devices (including in vitro diagnostic medical	21.2	Manufacture of pharmaceutical preparations

476 We included all PRODCOM codes under the level 4 (four-digit code) NACE hierarchy included in the table.

Harmonised sectors	NACE	Description
devices and active implantable medical devices)	26.6	Manufacture of irradiation, electrometrical and electrotherapeutic equipment
	32.5	Manufacture of medical and dental instruments and supplies
2. Cosmetics	20.42	Manufacture of perfumes and toilet preparations
3. Toys	32.4	Manufacture of games and toys
4. Personal protective equipment	14.12	Manufacture of workwear
	15.2	Manufacture of footwear
	32.99	Other manufacturing n.e.c.
5. Construction products	23.32	Manufacture of bricks, tiles and construction products, in baked clay
	23.51	Manufacture of cement
	23.52	Manufacture of lime and plaster
	23.61	Manufacture of concrete products for construction purposes
	23.62	Manufacture of plaster products for construction purposes
	23.63	Manufacture of ready-mixed concrete
	23.64	Manufacture of mortars
	23.65	Manufacture of fibre cement
	25.11	Manufacture of metal structures and parts of structures
6. Aerosol dispensers	20.3	Manufacture of paints, varnishes and similar coatings, printing ink and mastics

Harmonised sectors	NACE	Description
	20.41	Manufacture of soap and detergents, cleaning and polishing preparations
	20.42	Manufacture of perfumes and toilet preparations
	25.29	Manufacture of other tanks, reservoirs and containers of metal
	28.13	Manufacture of other pumps and compressors
	28.29	Manufacture of other general-purpose machinery n.e.c.
	32.99	Other manufacturing n.e.c.
7. Simple pressure vessels and pressure equipment	22.21	Manufacture of plastic plates, sheets, tubes and profiles
	24.2	Manufacture of tubes, pipes, hollow profiles and related fittings, of steel
	24.51	Casting of iron
	25.21	Manufacture of central heating radiators and boilers
	25.29	Manufacture of other tanks, reservoirs and containers of metal
	25.3	Manufacture of steam generators, except central heating hot water boilers
	23.32	Manufacture of bricks, tiles and construction products, in baked clay
	28.11	Manufacture of engines and turbines, except aircraft, vehicle and cycle engines
	28.12	Manufacture of fluid power equipment
	28.13	Manufacture of other pumps and compressors
	28.14	Manufacture of other taps and valves

Harmonised sectors	NACE	Description
	28.15	Manufacture of bearings, gears, gearing and driving elements
	28.25	Manufacture of non-domestic cooling and ventilation equipment
	28.29	Manufacture of other general-purpose machinery n.e.c.
8. Transportable pressure equipment	22.23	Manufacture of builders' ware of plastic
	25.21	Manufacture of central heating radiators and boilers
	25.29	Manufacture of other tanks, reservoirs and containers of metal
	25.91	Manufacture of steel drums and similar containers
	28.14	Manufacture of other taps and valves
9. Machinery	27.11	Manufacture of electric motors, generators and transformers
	28.11	Manufacture of engines and turbines, except aircraft, vehicle and cycle engines
	28.12	Manufacture of fluid power equipment
	28.13	Manufacture of other pumps and compressors
	28.22	Manufacture of lifting and handling equipment
	28.25	Manufacture of non-domestic cooling and ventilation equipment
	28.29	Manufacture of other general-purpose machinery n.e.c.
	28.41	Manufacture of metal forming machinery
	28.49	Manufacture of other machine tools

Harmonised sectors	NACE	Description
	28.92	Manufacture of machinery for mining, quarrying and construction
	28.99	Manufacture of other special-purpose machinery n.e.c.
	30.11	Building of ships and floating structures
	30.2	Manufacture of railway locomotives and rolling stock
10. Lifts	28.22	Manufacture of lifting and handling equipment
11. Cableways	28.22	Manufacture of lifting and handling equipment
12. Noise emissions for outdoor equipment	28.11	Manufacture of engines and turbines, except aircraft, vehicle and cycle engines
	28.12	Manufacture of fluid power equipment
	28.13	Manufacture of other pumps and compressors
	28.22	Manufacture of lifting and handling equipment
	28.25	Manufacture of non-domestic cooling and ventilation equipment
	28.29	Manufacture of other general-purpose machinery n.e.c.
	28.3	Manufacture of agricultural and forestry machinery
	28.41	Manufacture of metal forming machinery
	28.49	Manufacture of other machine tools
	28.91	Manufacture of machinery for metallurgy
	28.92	Manufacture of machinery for mining, quarrying and construction

Harmonised sectors	NACE	Description
	28.93	Manufacture of machinery for food, beverage and tobacco processing
	28.94	Manufacture of machinery for textile, apparel and leather production
	28.95	Manufacture of machinery for paper and paperboard production
	28.96	Manufacture of plastics and rubber machinery
	28.99	Manufacture of other special-purpose machinery n.e.c.
13. Equipment and protective systems intended for use in potentially explosive atmospheres	26.3	Manufacture of communication equipment
	26.51	Manufacture of instruments and appliances for measuring, testing and navigation
	32.99	Other manufacturing n.e.c.
14. Pyrotechnics	20.51	Manufacture of explosives
15. Explosives for civil uses	20.51	Manufacture of explosives
16. Appliances burning gaseous fuels	28.21	Manufacture of ovens, furnaces and furnace burners
17. Measuring instruments, non- automatic weighing instruments, pre-packaged products and units of measurement	26.51	Manufacture of instruments and appliances for measuring, testing and navigation
	28.29	Manufacture of other general-purpose machinery n.e.c.
18. Electrical equipment under EMC	27.12	Manufacture of electricity distribution and control apparatus
19. Radio and telecom equipment under RTTE - RED	26.3	Manufacture of communication equipment
20. Electrical appliances and equipment under LVD	27.4	Manufacture of electric lighting equipment
	27.51	Manufacture of electric domestic appliances

Harmonised sectors	NACE	Description
	27.9	Manufacture of other electrical equipment
	28.24	Manufacture of power-driven hand tools
21. Electrical and electronic equipment under RoHS and WEEE and batteries	26.11	Manufacture of electronic components
	26.12	Manufacture of loaded electronic boards
	26.2	Manufacture of computers and peripheral equipment
	26.4	Manufacture of consumer electronics
	26.51	Manufacture of instruments and appliances for measuring, testing and navigation
	26.6	Manufacture of irradiation, electromedical and electrotherapeutic equipment
	27.4	Manufacture of electric lighting equipment
	27.51	Manufacture of electric domestic appliances
	27.9	Manufacture of other electrical equipment
	28.23	Manufacture of office machinery and equipment (except computers and peripheral equipment)
	28.29	Manufacture of other general-purpose machinery n.e.c.
	32.3	Manufacture of sports goods
	32.4	Manufacture of games and toys
	32.5	Manufacture of medical and dental instruments and supplies
22. Chemical substances under REACH and Classification	20.13	Manufacture of other inorganic basic chemicals

Harmonised sectors	NACE	Description
and Labelling Regulations (22A) and other chemicals (22B: detergents, paints, persistent organic pollutants, fluorinated greenhouse gases, ozone depleting substances, etc.)	20.14	Manufacture of other organic basic chemicals
	20.41	Manufacture of soap and detergents, cleaning and polishing preparations
	25.61	Treatment and coating of metals
	25.62	Machining
	25.91	Manufacture of steel drums and similar containers
	25.92	Manufacture of light metal packaging
	25.93	Manufacture of wire products, chain and springs
	25.94	Manufacture of fasteners and screw machine products
	25.99	Manufacture of other fabricated metal products n.e.c.
	26.11	Manufacture of electronic components
	26.12	Manufacture of loaded electronic boards
	27.2	Manufacture of batteries and accumulators
	27.31	Manufacture of fibre optic cables
	27.32	Manufacture of other electronic and electric wires and cables
	27.33	Manufacture of wiring devices
	27.4	Manufacture of electric lighting equipment
	36	Water collection, treatment and supply

Harmonised sectors	NACE	Description
	38.21	Treatment and disposal of non-hazardous waste
	38.22	Treatment and disposal of hazardous waste
	38.31	Dismantling of wrecks
	38.32	Recovery of sorted materials
	45.2	Maintenance and repair of motor vehicles
	71.2	Technical testing and analysis
	72.11	Research and experimental development on biotechnology
	72.19	Other research and experimental development on natural sciences and engineering
	72.2	Research and experimental development on social sciences and humanities
	72.2	Research and experimental development on social sciences and humanities
23. Eco-design and energy labelling; efficiency requirements for hot-boilers fired with liquid or gaseous fuels	25.21	Manufacture of central heating radiators and boilers
	25.3	Manufacture of steam generators, except central heating hot water boilers
24. Tyre labelling	22.11	Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres
25. Recreational craft	30.12	Building of pleasure and sporting boats
26. Marine equipment	13.92	Manufacture of made-up textile articles, except apparel
	25.99	Manufacture of other fabricated metal products n.e.c.
	26.51	Manufacture of instruments and appliances for measuring, testing and navigation

Harmonised sectors	NACE	Description
	27.4	Manufacture of electric lighting equipment
	28.11	Manufacture of engines and turbines, except aircraft, vehicle and cycle engines
	29.1	Manufacture of motor vehicles
	30.11	Building of ships and floating structures
	30.12	Building of pleasure and sporting boats
27. Motor vehicles and tractors 28. Non-road mobile machinery	28.3	Manufacture of agricultural and forestry machinery
	28.3	Manufacture of agricultural and forestry machinery
	28.92	Manufacture of machinery for mining, quarrying and construction
	28.92	Manufacture of machinery for mining, quarrying and construction
	29.1	Manufacture of motor vehicles
29. Fertilisers	20.15	Manufacture of fertilisers and nitrogen compounds
30. Other consumer products under GPSD	n.a.	n.a.
31. Biocides	20.2	Manufacture of pesticides and other agrochemical products
32. Textile and footwear labelling	14.12	Manufacture of workwear
	14.13	Manufacture of other outerwear
	14.14	Manufacture of underwear
	14.19	Manufacture of other wearing apparel and accessories

Harmonised sectors	NACE	Description
	14.31	Manufacture of knitted and crocheted hosiery
	14.39	Manufacture of other knitted and crocheted apparel
	15.2	Manufacture of footwear
33. Crystal glass	23.13	Manufacture of hollow glass

Number of active enterprises in harmonised sectors by MS (NACE Digit-3)

MS	2012	2013	2014
AT	9,217	9,600	9,794
BE	13,363	12,757	13,691
BG	15,022	15,058	15,093
CY	2,097	2,078	1,959
CZ	73,402	70,183	69,813
DE	103,922	104,765	108,282
DK	8,138	7,866	7,854
EE	2,573	2,841	2,949
EL	27,132	22,979	23,604
ES	78,929	75,908	74,079
FI	11,323	:	10,878

MS	2012	2013	2014
FR	68,041	71,010	:
HR	9,947	9,594	9,275
HU	23,911	22,742	22,568
IE	1,870	:	:
IT	202,747	195,102	190,216
LT	5,443	5,983	6,687
LU	389	396	380
LV	3,718	3,944	4,136
MT	:	:	:
NL	25,533	28,423	28,646
PL	81,362	80,548	84,522
PT	33,670	:	31,558
RO	21,052	21,350	22,033
SE	27,560	26,969	25,942
SI	8,493	8,527	8,565
SK	36,318	34,679	35,232
UK	63,358	63,731	67,330

MS	2012	2013	2014
Total	1,801,221	1,704,093	1,625,106

Source: Authors' elaboration on SBS (2016)

Value of intra EU imports of harmonised products at MS level, €bn

MS	2008	2009	2010	2011	2012	2013	2014
AT	44	37	42	46	46	47	48
BE	102	89	98	102	103	99	100
BG	7	5	5	6	7	7	8
CY	2	2	2	2	1	1	1
CZ	37	30	37	41	42	43	47
DE	218	185	217	242	240	240	250
DK	26	20	21	23	25	25	26
EE	4	2	3	5	5	5	5
ES	77	60	64	67	63	64	69
FI	18	14	15	17	17	17	17
FR	147	126	142	154	154	154	155
HE	18	16	14	13	12	12	12
HR	6	5	4	4	5	5	6

MS	2008	2009	2010	2011	2012	2013	2014
HU	24	18	22	25	26	27	29
IE	17	13	13	14	14	16	17
IT	96	80	99	104	98	99	100
LT	6	4	5	6	7	7	8
LU	5	5	5	6	6	6	6
LV	4	2	3	4	4	4	4
MT	1	1	1	1	1	1	1
NL	73	61	69	77	81	78	79
PO	53	41	50	55	55	57	61
PT	22	19	20	20	19	19	20
RO	21	15	18	21	21	22	23
SE	35	27	34	40	39	38	39
SI	8	7	7	8	8	8	8
SK	17	14	17	20	21	22	23
UK	101	85	97	104	113	115	118
Total	**1,189**	**983**	**1,123**	**1,229**	**1,235**	**1,239**	**1,281**

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

8.15 Information sources

EU legislative documents

Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers.

Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (Text with EEA relevance).

Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.

Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.

Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC.

Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles.

Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC.

Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses.

Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.

Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments.

Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments.

Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts.

Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres.

Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.

Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment.

Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC.

Directive 2015/13/EU of 31 October 2014 amending Annex III to Directive 2014/32/EU of the European Parliament and of the Council, as regards the flowrate range of water meters.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

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.

Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC.

Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

Impact assessments and other policy documents

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