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PART 1/3

COMMISSION STAFF WORKING DOCUMENT

REFIT EVALUATION

Accompanying the document

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

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

{COM(2017) 795 final} - {SWD(2017) 466 final} - {SWD(2017) 467 final} -
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Glossary

Product	A substance, product or good produced through a manufacturing process other than food, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction (Article 15(4) of Regulation (EC) No 765/2008 or 'the Regulation').
Market surveillance provisions	Articles 15 to 29, Article 38 and Article 41 of Regulation (EC) No 765/2008 and the corresponding definitions and financing provisions,
Market surveillance	The activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection (Article 2(17) of the Regulation).
Market surveillance authority or MSA	An authority of a Member State responsible for carrying out market surveillance on its territory.
Union harmonisation legislation	Any Union legislation harmonising the conditions for the marketing of products (Article 2(21) of the Regulation).
Sector legislation	Legislation that is part of the Union harmonisation legislation.
GPSD	General Product Safety Directive - Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety
Manufacturer	Any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark (Article 2(3) of the Regulation).
Authorised representative	Any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under the relevant Union legislation (Article 2(4) of the Regulation).
Importer	Any natural or legal person established within the Union who places a product from a third country on the Union market (Article 2(5) of the Regulation).
Distributor	Any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market (Article 2(6) of the Regulation)
Economic operators	The manufacturer, the authorised representative, the importer and the distributor (Article 2(7) of the Regulation).
AdCo	The Administrative Coordination group of the authorities responsible for market surveillance with respect to one or more instruments of Union harmonisation legislation.
Recall	Any measure aimed at achieving the return of a product that has already been made available to the end user (Article 2(14) of the Regulation).
Withdrawal	Any measure aimed at preventing a product in the supply chain from being made available on the market (Article 2(15 of the Regulation)).
Making available on the market	Any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge (Article 2(1) of the Regulation)
Placing on the market	The initial making available of a product on the Union market (Article 2(2) of the Regulation).
RAPEX	Rapid alert system for the transmission among all competent market surveillance authorities in the EU of information on measures taken against products presenting a serious risk – e*c.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm* (system referred to in Article 22 of the Regulation).
ICSMS	Internet-supported information and communication system for market surveillance authorities in the EU - *https://webgate.ec.europa.eu/icsms/ (*system referred to in Article 23 of the Regulation).

1. INTRODUCTION

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

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

The Regulation has four main elements:

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

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

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

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

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

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

1 According to Article 15(4), the market surveillance provisions apply to substances, preparations or goods produced through a manufacturing process other than food, feed, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction.
2 The other elements will be subject to another evaluation at a later stage.
3 Commission Communication COM(2015)550 'Upgrading the Single Market: more opportunities for people and business'.

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

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

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

2. BACKGROUND TO THE INITIATIVE

2.1. Description of the initiative and its objectives

2.1.1. Objectives and roles of the market surveillance provisions

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

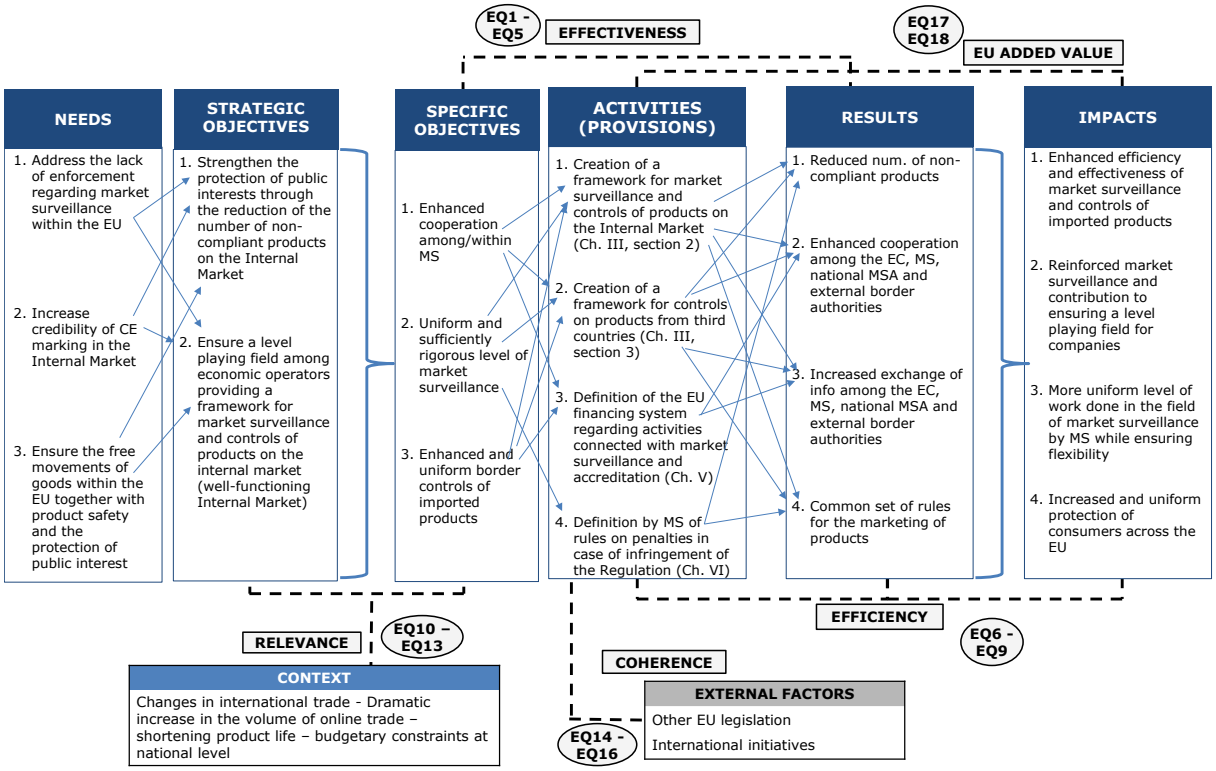
The figure below outlines the Regulation's intervention logic in relation to the evaluation criteria and questions that guided the study and that will be further described in the following

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

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

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

Figure 1: Intervention logic



2.1.2. Scope of the evaluation

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

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

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

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

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

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

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

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

2.1.3. Complementary nature of the market surveillance provisions

Some **market surveillance rules** are laid down **in sector specific Union legislation.** They set out in detail how and when a market surveillance authority should intervene when a non-compliant product is found. Market surveillance authorities should check the compliance of the product with the legal requirements applicable at the moment of the placing of the market or, if relevant, putting into service. The first level of control are usually documentary and visual checks, for example regarding the CE marking and its affixing, the availability of the

EU declaration of conformity, the information accompanying the product and the correct choice of conformity assessment procedures. More profound checks may be however necessary to verify the conformity of the product, for example regarding the correct application of the conformity assessment procedure, the compliance with the applicable essential requirements, and the contents of the EU declaration of conformity.

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

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

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

Table 1: Market surveillance provisions in Regulation (EC) No 765/2008 and new sector legislation		
MARKET SURVEILLANCE MEASURES AND STRUCTURES	**REGULA-TION (EC) No 765/2008**	***NEW SECTOR LEGISLATION*[11]**
MARKET SURVEILLANCE PROCEDURES		
Obligations of economic operators vis-à-vis market surveillance authorities *(information and cooperation)*	**No**	**Yes**
Identification of economic operators *(obligation for economic operators to identify the economic operators who supplied the product and the economic operator to whom the product was supplied)*	**No**	**Yes**
Definition of formal non-compliance *(e.g. markings wrongly or not affixed, declaration of conformity missing, technical documentation not available or incomplete etc.)*	**No**	**Yes**
Procedures for dealing with non-compliant products *(i.e. corrective actions, information obligations, restrictive measures, recalls etc.)*	**No**	**Yes**
Market surveillance measures (i.e. role of market surveillance authorities)	**Yes**	**No but legislation refers to Regulation (EC)**
Products presenting a serious risk (i.e. Member States must ensure		

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

that products which present a serious risk requiring rapid intervention, are recalled, withdrawn or that their being made available on their market is prohibited)		**No 765/2008**
Restrictive measures (i.e. procedural safeguards, statement of reasons, right to be heard, remedies etc.)		
Exchange of information — Rapid Information System for products presenting a serious risk		
General information support system (ICSMS) on issues relating to market surveillance activities, programmes and related information on non-compliance with Union harmonisation legislation, including identification of risks, results of testing carried out, provisional restrictive measures taken, contacts with the economic operators concerned and justification for action or inaction		
Union safeguard procedure	**No**	**Yes**
Procedure for compliant products which present a risk to health and safety	**No**	**Yes**
MARKET SURVEILLANCE STRUCTURES		
General requirements for market surveillance	**Yes**	**No but legislation refers to Regulation (EC) No 765/2008**
Information obligations about market surveillance authorities		
Obligations of the Member States as regards organisation of market surveillance		
Principles of cooperation between the Member States and the Commission		
Sharing of resources		
Cooperation with the competent authorities of third countries		
Controls of products entering the Union market		
Release of products		
National measures on products entering the Union market		
Financing provisions for market surveillance	**Yes**	**No**
Penalties	**Penalties for economic operators applicable to infringe-ments of the provisions of the Regulation**	**Penalties for economic operators applicable to infringements of the provisions of sector legislation**

2.2. Consumer Safety and Market Surveillance Package (2013)

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

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

However, the negotiations between the European Parliament, the Council and the Commission have stalled for a long time. In its session of 26-27 May 2016, the *'Council took note of a request made by eleven member states to renew efforts with a view to moving forward negotiations on the Consumer Safety/Market Surveillance package (8985/16). The package is currently blocked in the Council because of a proposed provision on the introduction of a mandatory marking of origin on industrial products, known as the "Made in" provision (article 7 of the Consumer Safety draft regulation[13]). In March, eleven member states in favour of maintaining the "Made in" provision, presented a compromise proposal based on the deletion of article 7 and the introduction of mandatory marking of origin in a limited amount of sectorial legislation, combined with a revision clause. The presidency verified that positions within the Council remain unchanged*[14].' The discussions on this proposal were not resumed and it is reasonable to assume that any progress on this proposal in view of its adoption by the co-legislator is highly unlikely.

2.3. Baseline

2.3.1. Regulatory aspects

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

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

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

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

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

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

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

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

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

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

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

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

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

2.3.2. Level of non-compliance in 2008

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

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

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

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

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

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

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

Year	0 - No defects identified	1 - Low risk	2 - Medium risk	3 - High risk	4 - Serious risk
2008	574	1.034	1.153	927	0
2009	476	1.094	1.069	888	0

3. EVALUATION QUESTIONS

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

Effectiveness

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

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

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

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

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

Efficiency

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

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

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

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

Relevance

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

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

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

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

Coherence

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

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

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

EU added value

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

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

4. METHOD

4.1. Sources

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

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

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

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

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18 See section 4 of Annex 4.

19 Commission report COM(2013)77 on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

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

21 Directive 2009/48/EC on the safety of toys; Directive 2010/35/EU on transportable pressure equipment; Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products; Directive 2013/29/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles; Directive 2013/53/EU on recreational craft and personal watercraft and repealing Directive 94/25/EC; Directive 2014/28/EU on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses; Directive 2014/29/EU on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels; Directive 2014/30/EU on the harmonisation of the laws of the Member States relating to electromagnetic compatibility; Directive 2014/31/EU on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments; Directive 2014/32/EU on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments; Directive 2014/33/EU on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts; Directive 2014/34/EU on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres; Directive 2014/35/EU on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits; Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC; Directive 2014/68/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment; Directive 2014/90/EU on marine equipment and repealing Council Directive 96/98/EC; Regulation (EU) 2016/424 on cableway installations and repealing Directive 2000/9/EC; Regulation (EU) 2016/425 on personal protective equipment and repealing Council Directive 89/686/EEC; Regulation (EU) 2016/426 on appliances burning gaseous fuels and repealing Directive 2009/142/EC.

4.2. Limitations – robustness of findings

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

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

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

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

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

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

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

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

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

5. IMPLEMENTATION STATE OF PLAY (RESULTS)

5.1. Market surveillance structures and measures

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

- **Centralised,** where activities are carried out by one or few Market surveillance authorities. This model is applied in Bulgaria, the Czech Republic, Luxembourg, Malta, Portugal, and Slovakia.
- **Decentralised at the sectoral level**, where several Market surveillance authorities operate and have different competences, depending on the sector where they perform market surveillance activities. This model is adopted in Belgium, Cyprus, Croatia, Denmark, Estonia, France, Greece, Ireland, Italy, Latvia, Lithuania, Poland, the Netherlands, Romania, Slovenia and Sweden.
- **Decentralised at the regional/local level**, where numerous Market surveillance authorities have enforcement responsibilities on specific geographical areas of competence. Austria, Finland, Germany, Hungary, Spain and the United Kingdom follow this organisational structure.

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

Box 1: The Italian organisational model of market surveillance

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

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

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

Other relevant enforcement bodies are:

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

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

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

Box 2: The German organisational model of market surveillance

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

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

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

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

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

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

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

30 Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast).

31 Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

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

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

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

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

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

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

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

Figure 2: The Italian organisational model of market surveillance

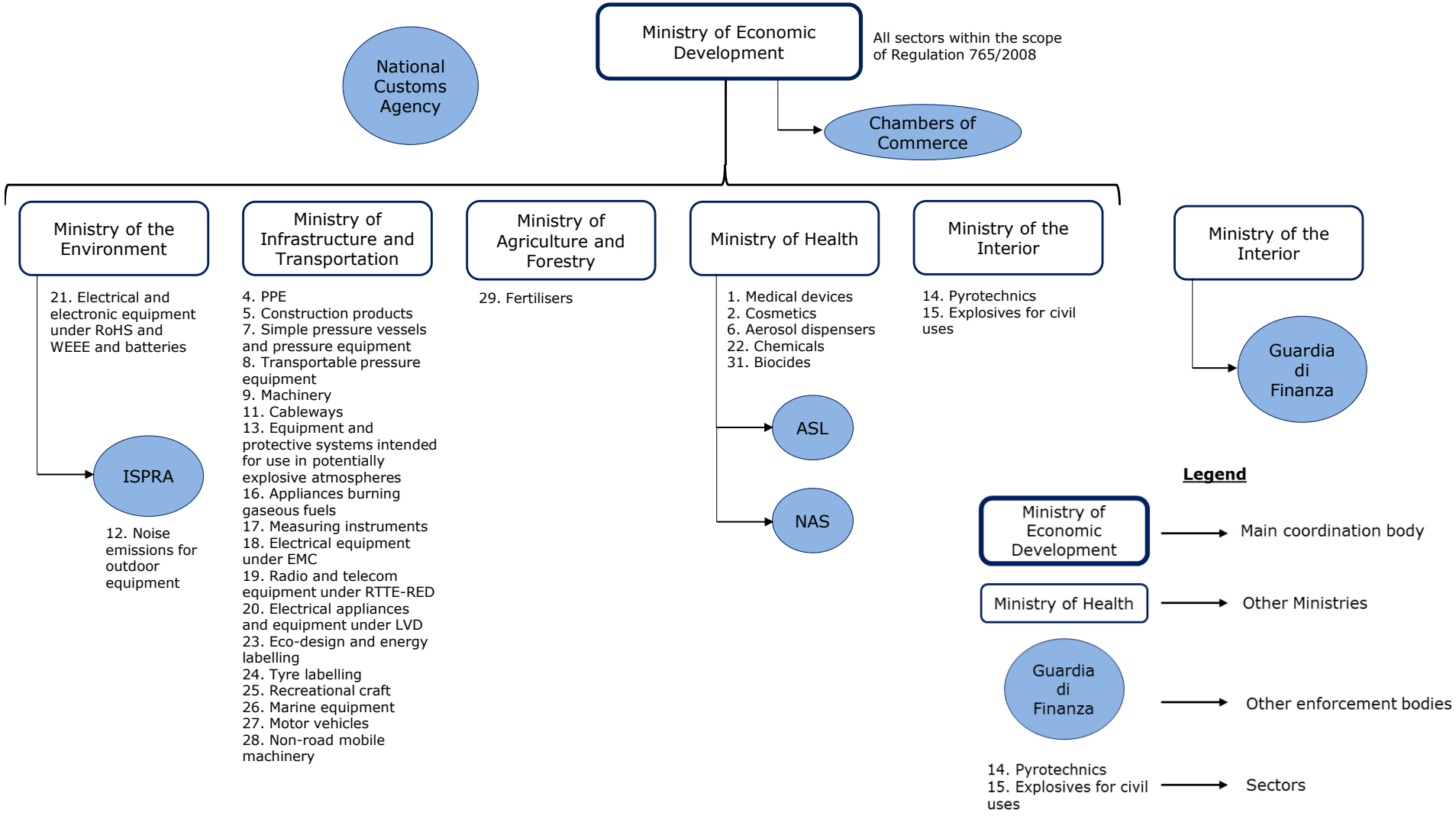
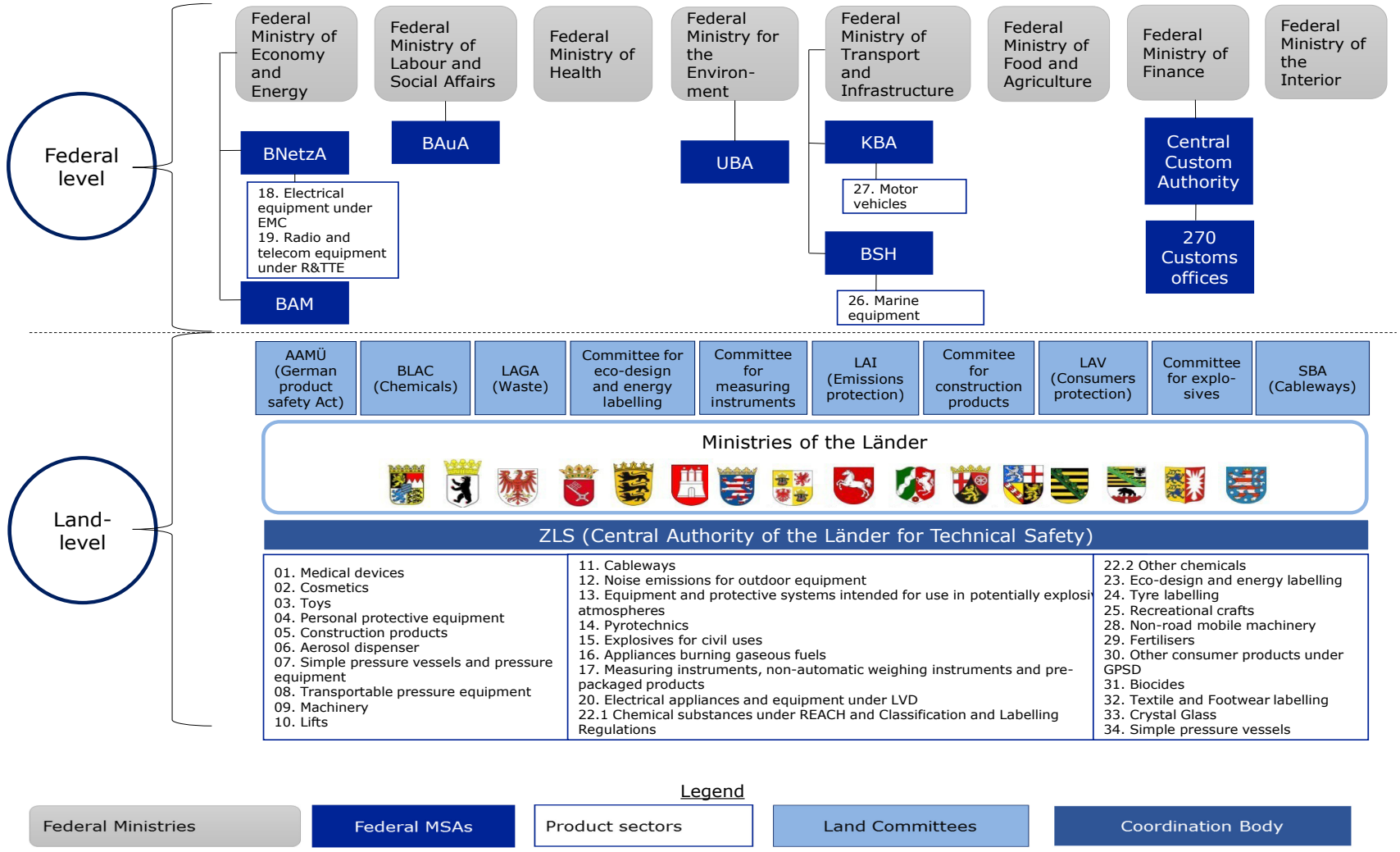


Figure 3: The German organisational model of market surveillance



5.2. Additional information

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

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

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

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

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

Almost all Member States now use ICSMS, after a slow take-up[39]. More than 7,000 products are encoded in the system every year. In 2015 the database contained information on around 70,000 products and more than 250,000 files stored (i.e.: test lab reports, declarations of conformity, pictures, etc.). However, Member States use the system to different degrees, as illustrated in the diagram below which shows the numbers of product information put into the ICSMS system during 2016. Clearly the system is not used very well by many market surveillance authorities and some are not using the system at all. Even within Member States, such as the UK and Germany, there is a great variation between different market surveillance authorities on their use of the system.

35 See section 1 of Annex 8.

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

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

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

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

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

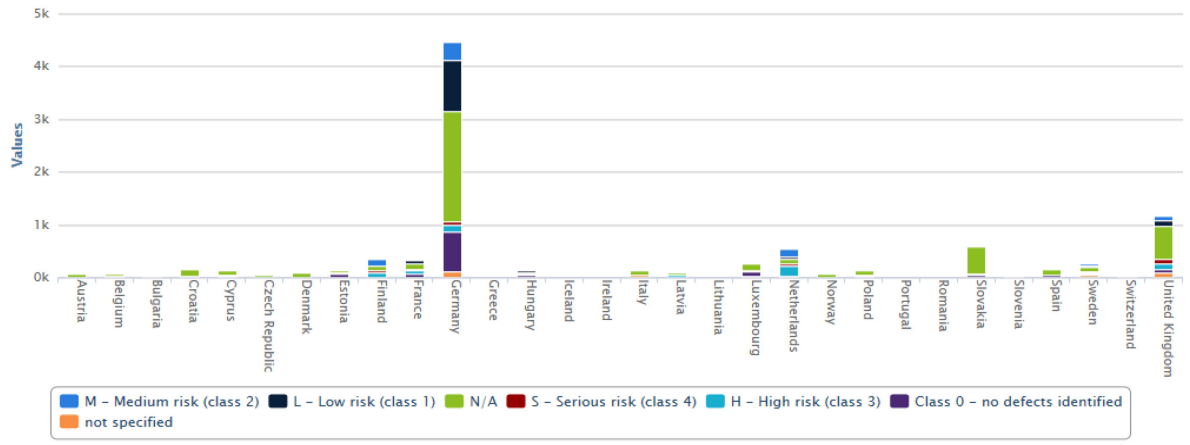
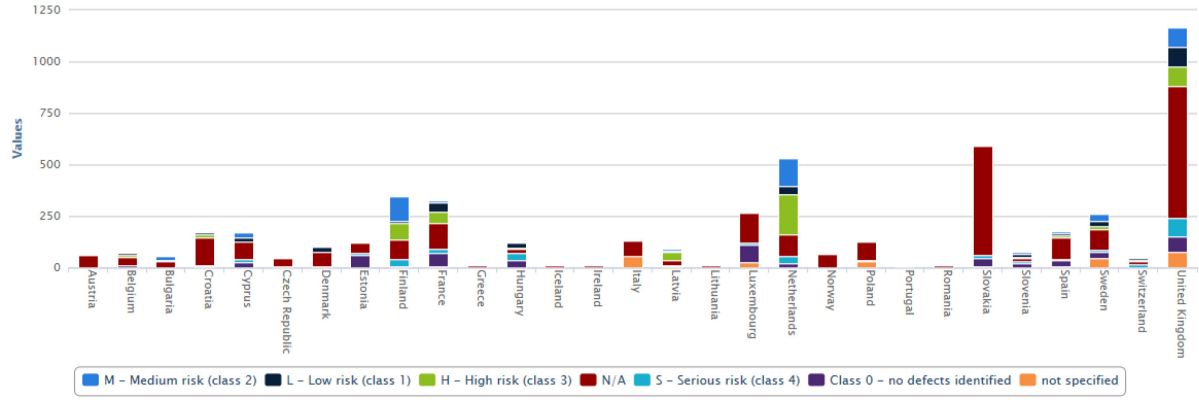


Figure 5: Use of ICSMS by EU/EEA Member States excluding Germany in 2016:



In addition to this, it is worth mentioning that sector specific Union legislation also sets out an obligation for Member States' competent authorities to communicate to the other Member States restrictive measures taken against non-compliant products. This procedure is often referred to as the 'safeguard clause procedure'. Furthermore, receiving Member States then have an obligation to 'follow up' on those notifications, i.e. adopt in turn appropriate measures in respect of their national territory. In many cases they also have the possibility to object to the measures notified and in this case the Commission will assess whether it was justified[41]. Recent guidance discussed at expert's working group level clarifies principles for cooperation based on the existing legal framework and the link between these obligations and the use of the RAPEX and ICSMS tools[42]. However, with the exception of few sectors (notably low voltage equipment) only few notifications of restrictive measures are actually officially sent by national market surveillance authorities. Furthermore, even in these 'best case scenarios'

40 No entries are recorded for Malta and Liechtenstein.

41 The possibility of objections is set out in sector-specific legislation aligned to the reference provisions of Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.

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

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

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

5.2.2. Cooperation

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

Table 5: Participation in AdCo meetings

AdCo[47]	2014				2015				2016 (1st semester)			
	Partici-pants	Represented countries			Partici-pants	Represented countries			Partici-pants	Represented countries		
		MSs	Other	Total		MSs	Other	Total		MSs	Other	Total
ATEX	35	15	3	18	33	17	3	20	33	21	2	23
	33	17	3	20	33	17	2	19	33	14	2	16
CABLE	23	12	3	15	21	10	2	12	26	12	3	15
CIVEX	no data for 2014				30	20	1	21	October/November			
COEN	no data for 2014				no data for 2015				no data for 2016			
CPR	31	20	2	22	43	21	4	25	36	15	4	19
	46	23	3	26	44	25	2	27				
EMC	38	20	4	24	37	21	5	26	40	18	4	27
	36	19	4	23	34	22	4	26				
ENERLAB / ECOD	no data for 2014				32	22	1	23	43	21	1	22
					34	18	3	21				
GAD	18	14	0	14	15	8	2	10	19	12	2	14
	14	11	0	11	16	11	2	13				
LIFT	25	12	3	15	24	14	3	17	25	17	2	19
	21	14	2	16								

43 See section 1.2 in Annex 8.

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

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

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

47 Measuring instruments and non–automatic weighing instruments (WELMEC), low voltage equipment (LVD ADCO), Eco-Design ADCO Group, electromagnetic compatibility (EMC administrative cooperation), civil explosives (CIVEX), machinery, noise emissions by outdoor equipment (NOISE), medical devices (Vigilance Working Group and COEN – Compliance and Enforcement Group), construction products (CPR), PEMSAC (The Platform of European Market Surveillance Authorities for Cosmetics), Toy-ADCO (The Administrative Cooperation Group of toys), recreational craft (RCD), personal protective equipment (PPE), equipment for use in explosive atmospheres (ATEX), Radio and Telecommunications Terminal Equipment (RED), Cableways (CABLE), Energy Labelling and Eco-design (ENERLAB/ECOD), Gas Appliances (GAD), Lifts (LIFT), Marine Equipment (MED), Pressure equipment sector (PED/SVPD), Pyrotechnics (PYROTEC), Chemicals (REACH), Restriction of the use of certain hazardous substances (ROHS), Transportable Pressure Equipment (TPED), Labelling of tyres.

LVD	31	15	4	19	32	20	4	24	36	17	4	21
	33	19	3	22	34	22	3	25				
	31	18	4	22								
MACHINE	32	17	3	20	33	20	3	23	38	20	4	24
	33	15	3	18	30	19	3	22				
NOISE	22	10	2	12	23	9	2	11	Meeting October 2016			
PED/SVPD	22	13	3	16	25	15	4	19	24	15	4	19
	25	18	3	21	15	11	1	12				
PPE	44	21	4	25	39	19	4	23	39	20	5	25
	37	19	4	23	40	21	4	25				
PYROTEC	30	14	0	14	34	17	0	17	32	19	1	20
	30	15	0	15	34	19	0	19				
RCD	35	17	2	19	22	15	2	17	31	19	2	21
	33	16	3	19	30	19	1	20				
RED	23	12	2	14	41	25	4	28	41	23	2	25
	40	24	2	26	41	22	4	26	40	25	2	27
	39	19	4	23								
	44	22	3	25								
TOYS	no data for 2014				37	18	5	23	32	15	4	19
					40	25	3	28				
TPED	12	9	0	9	23	12	1	13	21	8	3	11
	13	5	1	6								
WELMEC	no data for 2014				31	21	1	22	33	19	4	23
					36	19	4	23				

As regards the development of common market surveillance projects, the following table summarises the joint actions carried out or launched within different AdCos during the 2013-2016 period and number of countries participating in the action:

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

AdCo	2013	2014	2015	2016
ATEX				
CABLE				
CIVEX				
COEN			Information and instructions on reprocessable products (12 MS)	Clinical data (7-8) Harmonising inspections (7-8 MS)
CPR	2012-2013: EPS (10 MS)	Smoke alarms (10 MS)	Windows (7 MS)	
ECOD / ENERLAB / ROHS	ECOD: Lighting and chain lighting (10 MS) ROHS: Toys (8 MS) and Kitchen appliances (10 MS)	ROHS: Cheap products (10 MS)	ROHS: Cables/USB/others (6 MS)	ECOD: Defeat devices (4 MS) ENERLAB: Collecting inspection data methodologies (6 MS)
EMC	Switching power supplies (19 MS)	Solar inverters (14 MS)		
GAD				Gas appliances (8 MS)
LIFT				
LVD			LED Floodlights* (13 MS)	
MACHINE[49]	2012-2013: Log Splitters (about 8 MS) 2012-2015:	Boom saws (3 MS)		Portable chain-saws and vehicle servicing lifts* (9-10 MS)

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

49 Joint actions organised in previous periods were: NOMAD Survey of machinery instructions on noise information and noise declarations (original survey work 2007-2012) about 10 Member States participating; Pinspotters/Pinsetters (machines in 10 pin bowling alleys), mostly between 2008 and 2012, about 5 Member States participating; Skid-steer Loaders, 2010-2012, 2-3 Member States; Scissor Lifts, 2010-2012, 5-6 Member States; Wind Turbine access (provision of lifts in towers), 2010-2012, about 4-5 Member States.

	Firewood Processors (about 7-8 MS) (1) 2011-2015: Impact Post Drivers (3-4 MS)			
NOISE				
PED		Air receivers for compressors (2 MS)		
PPE				
PYROTEC				
REACH	1 big action/year involving all Member States. Additional pilot actions on a smaller scale			
RED		Mobile phone repeaters (14 MS)	Drones (18 MS)	
RCD			Small inflatable crafts (6 MS)	
TOYS				
TPED				
WELMEC WG5		Electric energy meters* (11)	Heat meters* (10)	

* project co-financed by the European Commission.

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

- In 2013 the Commission launched the first call for proposals for joint enforcement actions under the multi-annual plan for market surveillance of products in the EU. The grant was awarded to a project focussed specifically on active electrical energy meters and heat meters. The grant took the form of a 70% reimbursement by the Commission of the eligible costs of the action (amount approximately allocated 350 000 EUR) and was fully managed by Member States. The action was carried out by a consortium of authorities under the coordination of a Spanish authority.

- In 2014 a new call for proposals for joint enforcement actions was launched and led to funding by the Commission of two proposed actions respectively in the field of machinery safety and LED floodlights. The grants that have been awarded are in the form of an 80% reimbursement by the Commission of the eligible costs of the actions (total amount allocated is approximately 1000 000 EUR). One of the actions was coordinated by a Finnish authority, while the other was coordinated by the "Prosafe" foundation[50].

- In July 2015 a call for proposals was launched with a maximum budget foreseen for EU financing of 500 000 EUR. One proposal was received by the deadline of 1 October 2015 but did not lead to the award of any grant since the proposal received did not address the objectives as stipulated in the call.

- In March 2016 two calls for proposals were launched with a higher maximum budget foreseen for EU financing of 750 000 EUR and 540 000 EUR respectively, but no proposals were received.

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

5.2.3. Infringement proceedings

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

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

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

6. ANSWERS TO THE EVALUATION QUESTIONS

6.1. Effectiveness

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

6.1.1. Enhanced cooperation among Member States

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

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

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

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

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

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

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

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

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

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

6.1.1.2. Cooperation

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

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

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

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

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

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

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

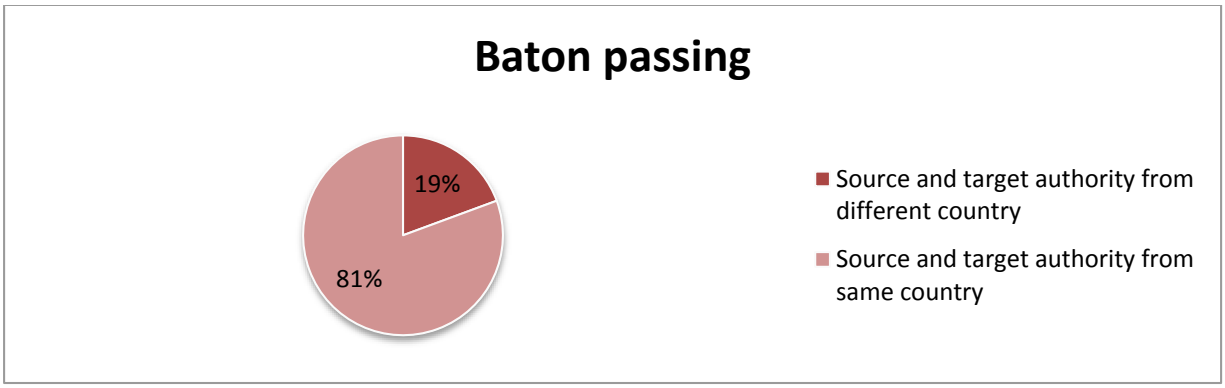
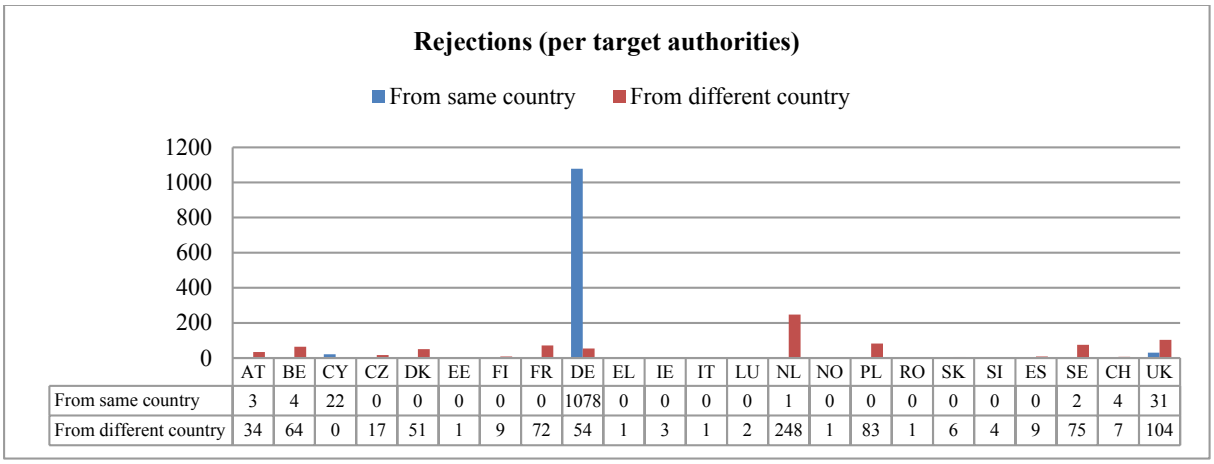
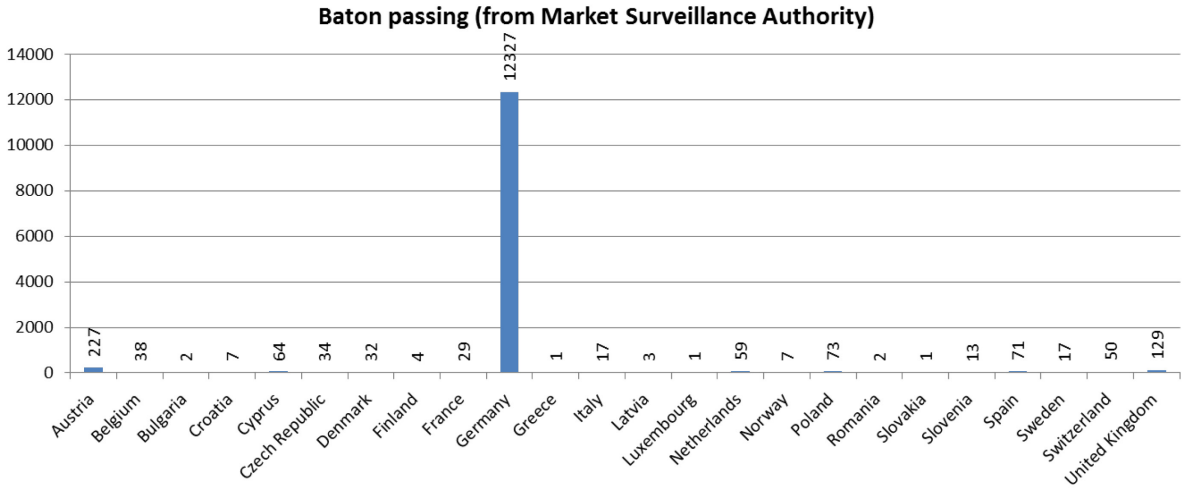


Figure 7: Rejections of baton passing in ICSMS (December 2016):



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

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



6.1.1.3. AdCos

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

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

However, not all Market surveillance authorities participate in this form of administrative cooperation. Figures presented in section 5 show that during the 2014-2016 period for most AdCos (ATEX, CPR, EMC, LVD, MACHINE, PPE, PYROTECH, RCD, TOYS, WELMEC) about two thirds of Member States did take part in meetings (with a peak of 80% participation rate for the radio equipment group); however in others (GAD, LIFT, PED) only about 50% Member States participated in the meetings and in the case of CABLE, NOISE and TPED only about 30-40% of Member States were involved. Furthermore, according to the feedback received from AdCo Chairs, many Member States representatives participating in the meetings do not get actively involved in common discussions and activities. In light of this, the Commission has increased its support for these groups, underlining that the chairpersons bear a remarkable burden when organising meetings and that many Market surveillance authorities cannot attend due to budgetary constraints.

6.1.1.4. EU financing

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

6.1.1.5. Provisional conclusion

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

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

6.1.2. Uniform and sufficiently rigorous level of market surveillance

The 2007 impact assessment of the Regulation was not very explicit on this point but foresaw that the preferred option would allow a more effective and efficient market surveillance. Furthermore, the relevant provisions in the Regulation are drafted in such general terms that it is impossible to measure precisely the progress that was made since 2010. For example, the market surveillance provisions oblige Member States to *'entrust market surveillance authorities with the powers, resources and knowledge necessary for the proper performance of their tasks'* while market surveillance authorities must *'perform appropriate checks on the characteristics of products on an adequate scale*'.

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

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

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

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

- Available figures show that resources allocated to market surveillance amount on average to a few euros per thousand inhabitants (with the exception in particular of medical devices, cosmetics and toys) and from 0 to maximum 0.5 inspectors per million inhabitants[67].

- The total budget available to all Member States' authorities having reported the information, in nominal terms[68] decreased during 2010-2013 period (from €133.4m to €123.8m); also it is concentrated in a limited number of countries and large differences could be noted in terms of budget available to each country during the four year-period[69].

66 See previous section 5, section 5.2 of Annex 4 and section 2 of Annex 7.
67 The analysis in Annex 8 section 3 shows the number of Member States having indicated at least some information on resources available for market surveillance for selected sectors and the simple average of resources reported.
68 Not all EU28 Member States provided reliable data for this indicator. Therefore, figures do not include Austria, Cyprus, Estonia, Greece, Croatia, Luxembourg, Slovenia, the United Kingdom and Hungary.
69 See section 5.2.1 of Annex 4.

- A similar trend was noted for human resources: over the period 2010-2013, a reduction of staff available to MSAs can be observed together with a concentration of staff in a small number of Member States[70]. Furthermore, at least 12 Member States complain about the resources being limited[71].

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

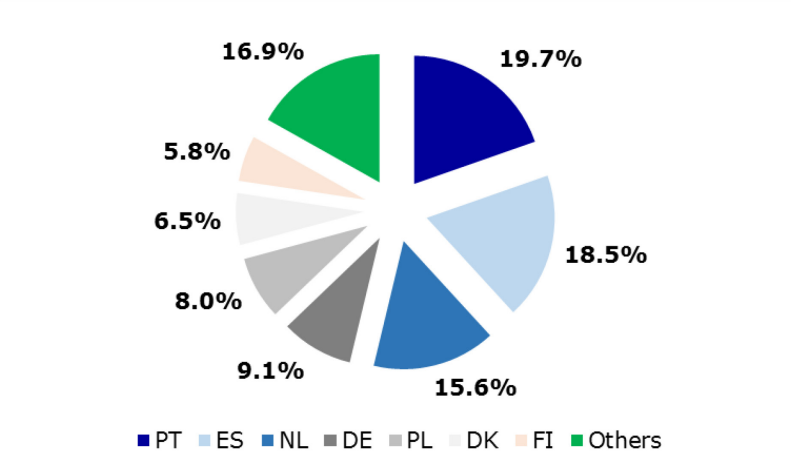
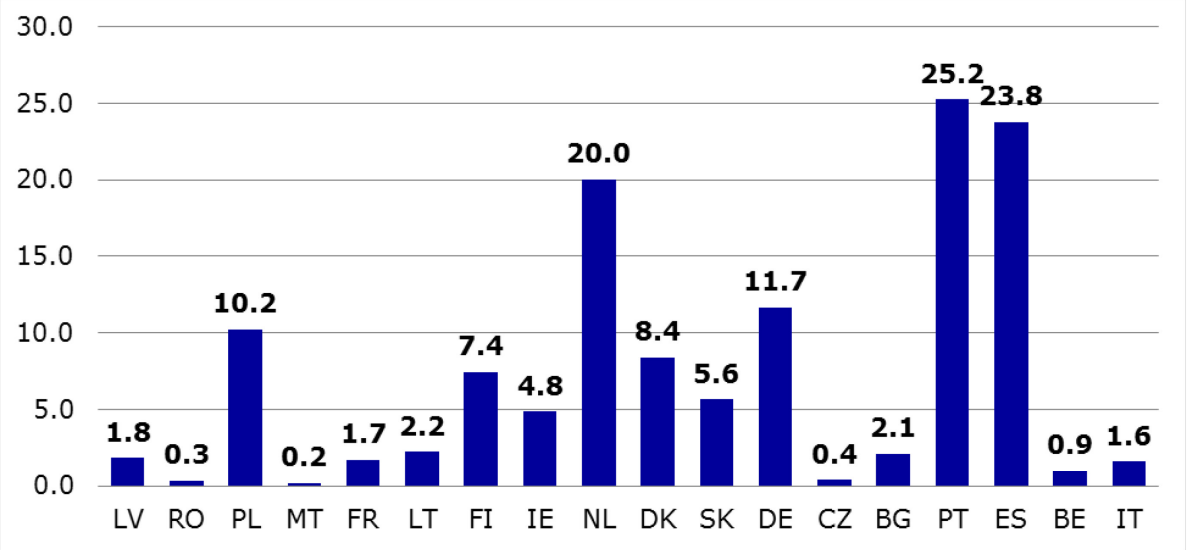


Figure 10: Annual budget available to MSAs in nominal terms, average 2010-2013, € M[73]



70 See section 5.2.1 of Annex 4.

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

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

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

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

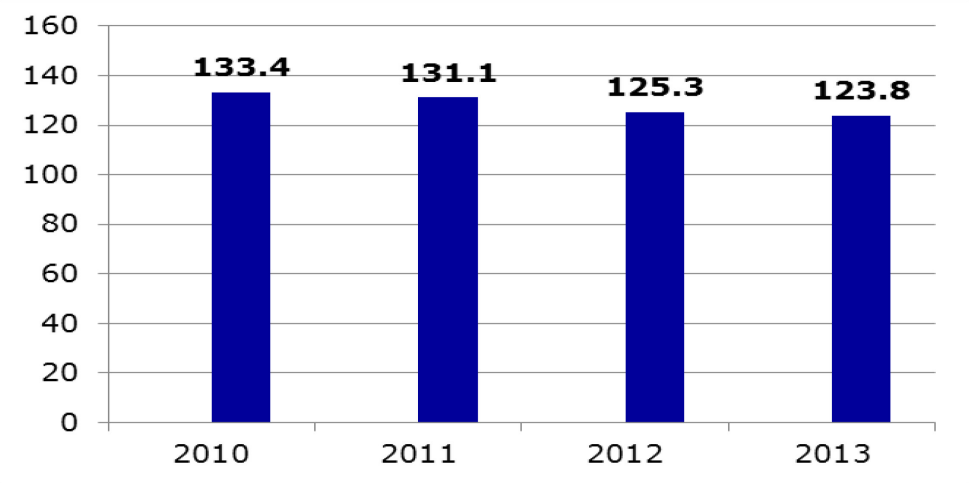
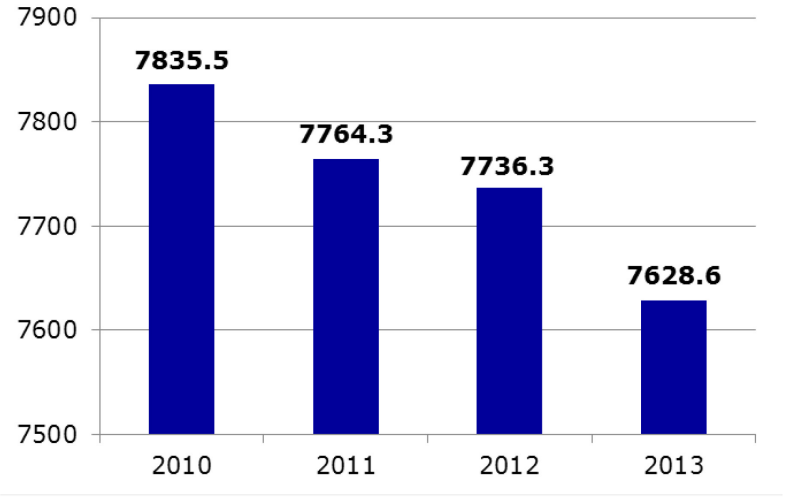


Figure 12: Total staff resources available to MSAs (FTE units) during 2010-2013[74]

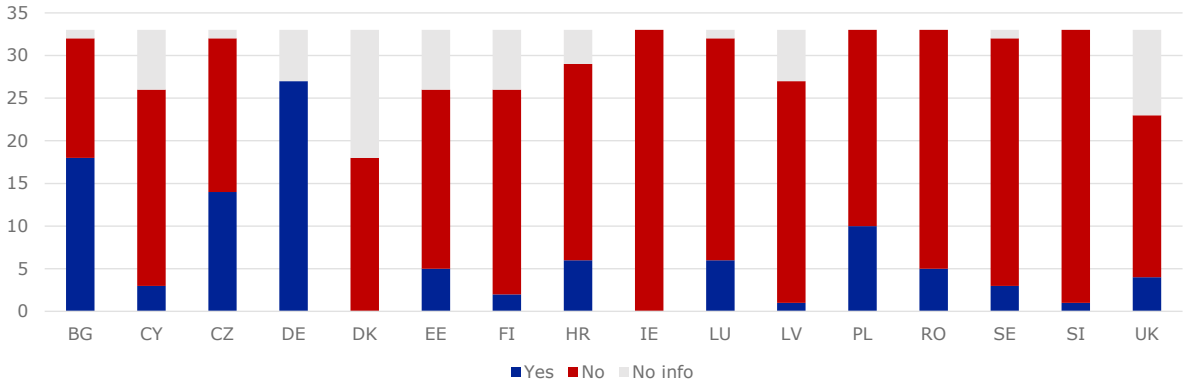


Furthermore, the availabilities of laboratories for product testing widely very across Member States, though a widespread lack of testing capacity can be identified[75].

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

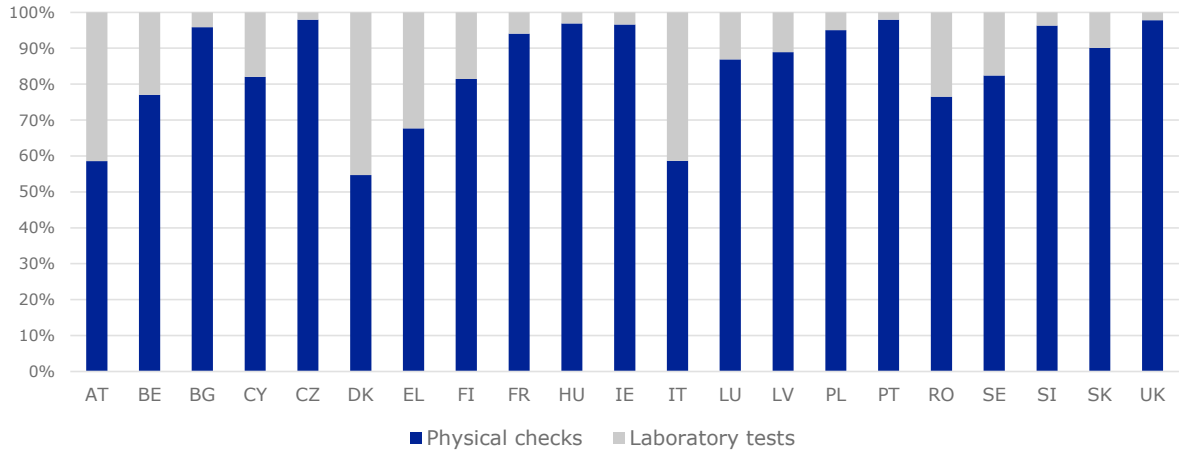
75 For further details, see section 6.1.1 of Annex 4.

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



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

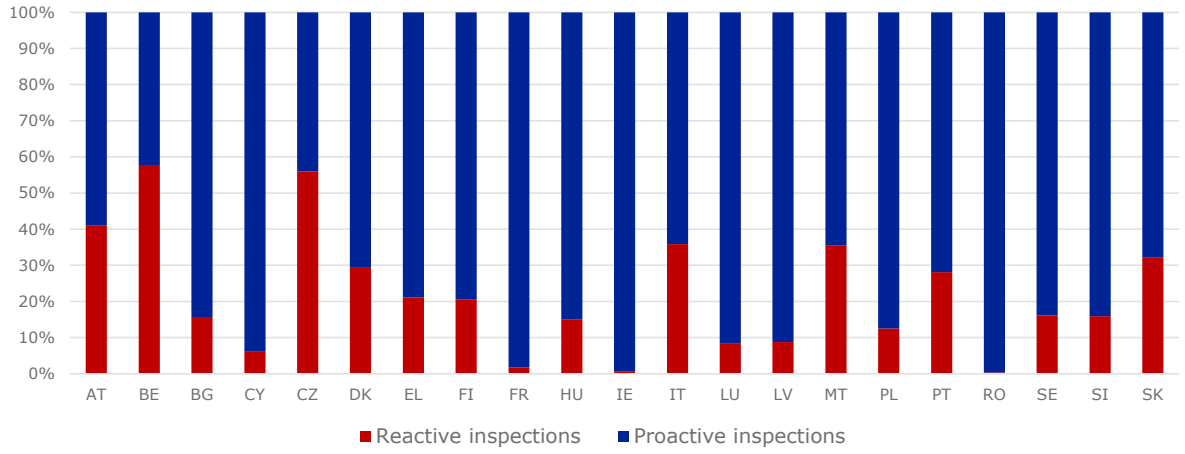
Figure 14: Share of physical checks and of laboratory tests performed on total inspections, average 2010-2013[77]



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

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

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



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

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

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

78 See section 6.1.1 of Annex 4.

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

80 See sections 3.1 and 5 of Annex 7.

81 See section 6.1.1 of Annex 4.

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

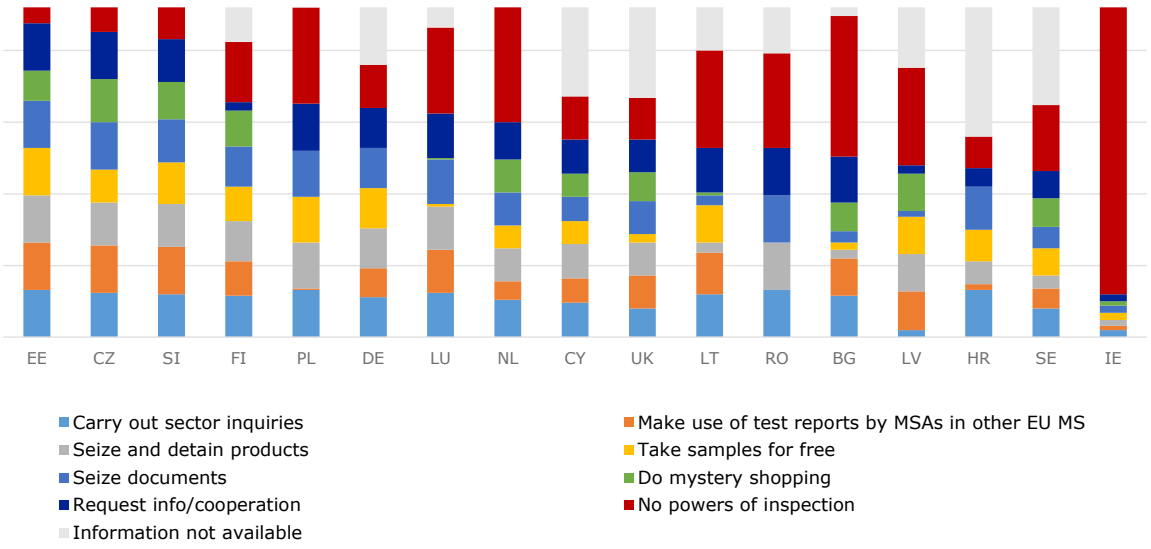
Finally, heterogeneity exists in the system of monitoring and reporting set up by the Regulation, i.e. the national reports. As discussed, the Regulation aims to create a framework for market surveillance controls and sets up a monitoring system (through Article 18(6)) to supervise how and to what extent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

6.1.2.2. Powers of national authorities

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

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

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



83 See section 6.1.1 of Annex 4.

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

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

Box 3 – Market surveillance of online sales[85]

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

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

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

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

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

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

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

85 See section 6.1.1 of Annex 4.

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

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

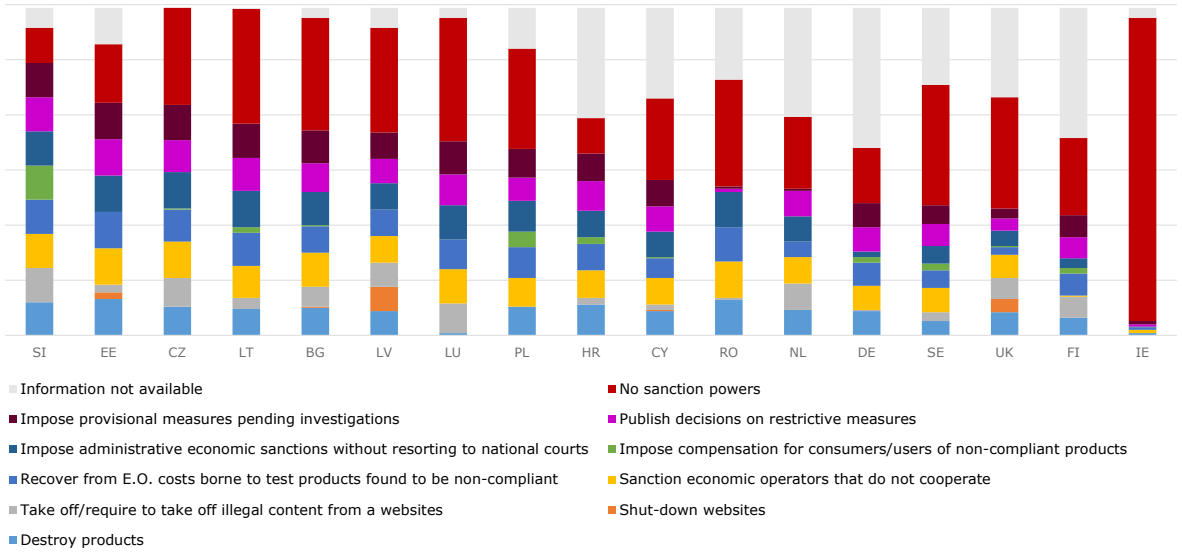
Despite some Member States having tailored strategies to tackle online sold products, **the current market surveillance approach to online sales is still conducted in a fragmented and uncoordinated way.**

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

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

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

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



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

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

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

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

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

6.1.2.3. Provisional conclusion

The heterogeneity existing across Member States in the implementation of the Regulation allows the conclusion to be drawn that the level of market surveillance is certainly not uniform, given that Member States with more resources and powers have - at least - more tools for proper enforcement.

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

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

6.1.3. Border controls of imported products

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

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

88 See section 4 of Annex 9.

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

consultation found it difficult to indicate the proportion of products imported from third countries in their sector[90]; however the general perception among stakeholders is that imports are affected by non-compliance[91]. The analysis of Rapex notifications supports the findings that the non-compliance of imports from extra EU is a relevant issue: from 2010 to 2016 notifications concerning imported products were around 75% of yearly published notifications and the percentage remained overall stable over the period. On average, 59% of total yearly notifications concern products from China.

However, it is often difficult to trace and intercept non-compliant products imported from outside the EU and entering through numerous entry points[92]. The main difficulties relating to controls of imported products are due to a lack of jurisdiction of Market surveillance authorities outside of their Member State, and to a lack of direct communication between Market surveillance authorities and businesses, particularly – again - in the context of online sales. As a consequence, businesses are not willing to collaborate with Market surveillance authorities' requests for corrective actions, for information/documentation or for paying penalties for non-compliance. 65% of authorities participating in the public consultation confirm authorities do not know how to identify and contact businesses located in third countries and 59% confirm that businesses contacted do not reply to requests for information/documentation and for corrective action. Despite some existing informal international cooperation arrangements the number of non-compliant products that can effectively be traced backed to the economic operator and sanctioned at the source in 3rd countries remains limited[93].

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

Table 8: RAPEX notifications by country of origin

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

90 49% consider they were unable to provide estimates or did not reply to the question; however 17%of respondents consider the proportion of imported products to be up to 20%, 15% of them between 21 and 50% and 18% of them beyond 50%.

91 15% of respondents believe non-compliance affects most of imported products, 43% some of them, 16% few of them. Only 2% consider imports not affected by non-compliance. 23% did not know or did not reply.

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

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

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

Source: RAPEX database

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

6.1.4. Conclusion as regards EQ1

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

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

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

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

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

94 DGTAXUD - Customs and MSA limited Report on customs controls in the field of product safety and compliance in 2015, July 2016 providing partial information on import controls from a selection of Member States. See also Annex 7: in absolute numbers controls are low compared to import volumes and on average 8% of controls are prompted by customs as reported by Member States for the period 2010-2013. Controls are concentrated in 6 product sectors (of 30). Moreover inspection coverage is low in the main entry points to the EU, the sea ports and Rotterdam in particular (Public consultation Position papers; Dutch Court of Auditors, Producten op de Europese markt: CE-markering ontrafeld, January 2017)).

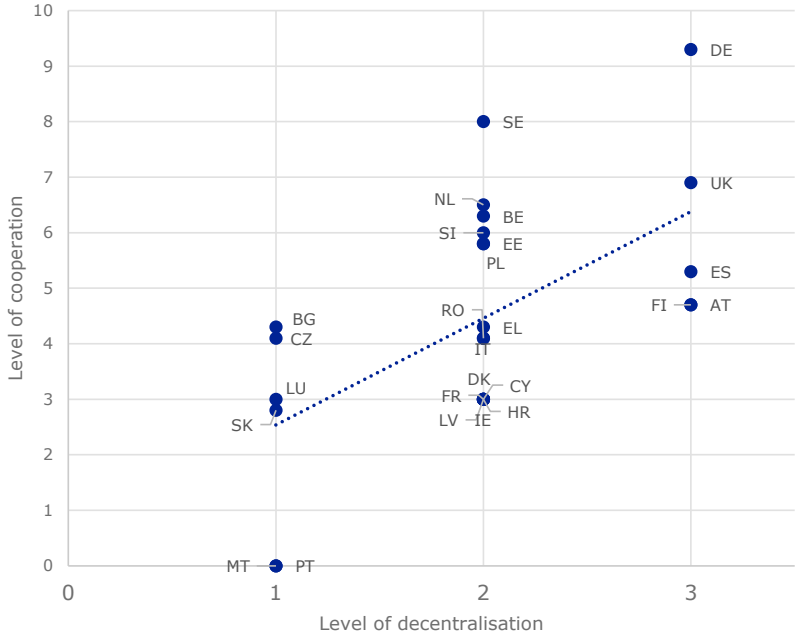
95 For further details, see section 6.1 of Annex 4.

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

97 See section 5.1 of this report

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Table 9: Annual average of RAPEX notifications by product category over the periods 2006-2009 and 2010-2015

Product category	*2006-2009*	*2010-2015*	*Average Δ%*
Chemical products	24.5	49.83	103%
Childcare articles and children's equipment	72	62.17	-14%
Clothing, textiles and fashion items	1,54.5	512.67	232%
Communication and media equipment	7.25	13.50	86%
Construction products	0.75	9.33	1,144%
Cosmetics	66.75	75.83	14%
Decorative articles	18.5	15.17	-18%
Electrical appliances and equipment	158.5	181.33	14%
Food-imitating products	30.25	22.33	-26%
Furniture	12.5	13.00	4%
Gadgets	4.25	2.00	-53%
Gas appliances and components	9.5	8.33	-12%
Hand tools	3.5	0.83	-76%
Hobby/sports equipment	29.75	32.67	10%
Jewellery	6.5	32.67	403%
Kitchen/cooking accessories	10.25	10.17	-1%
Laser pointers	9.25	16.67	80%
Lighters	27	23.17	-14%
Lighting chains	31.75	31.83	0%
Lighting equipment	77	56.50	-27%
Machinery	22.5	20.17	-10%
Motor vehicles	154.75	183.17	18%
Other	10.75	41.83	289%
PPEPPE	13.25	32.17	143%
Pyrotechnic articles	0.5	14.83	2,866%
Recreational crafts	6.5	4.33	-33%
Stationery	7.5	2.17	-71%
Toys	393.75	458	16%
Total	**1209.25**	**1927.5**	**59%**

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

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

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

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

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

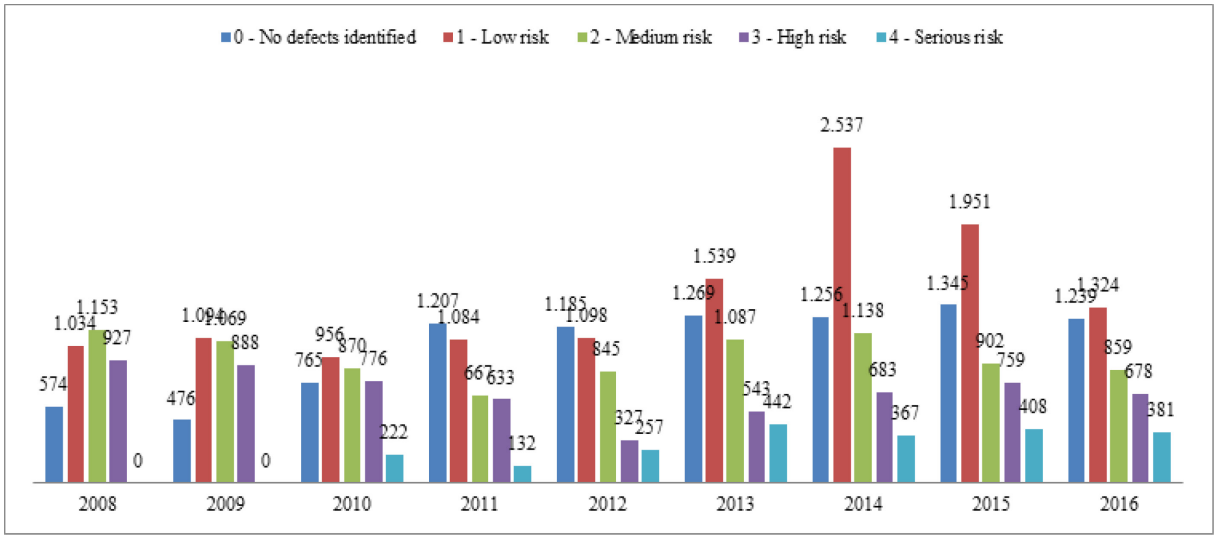
100 See section 5.3 of Annex 4.
101 See section 6.1.2 of Annex 4.

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

These findings are confirmed by data from ICSMS:

Table 11: Data from ICSMS

	0 - No defects identified	1 - Low risk	2 - Medium risk	3 - High risk	4 - Serious risk
2008	574	1.034	1.153	927	0
2009	476	1.094	1.069	888	0
2010	765	956	870	776	222
2011	1.207	1.084	667	633	132
2012	1.185	1.098	845	327	257
2013	1.269	1.539	1.087	543	442
2014	1.256	2.537	1.138	683	367
2015	1.345	1.951	902	759	408
2016	1.239	1.324	859	678	381
	9.316	**12.617**	**8.590**	**6.214**	**2.209**



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

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

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

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

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

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

Source: RAPEX database

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

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

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

102 See section 6.1.2 of Annex 4.

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

Source: RAPEX database

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

6.2. Efficiency

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

The efficiency of the Regulation has been assessed in terms of costs incurred by different stakeholders, benefits produced, and the extent to which desired effects (results and impacts) have been achieved at a reasonable cost.

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

No regulatory costs have been identified for consumers/users.

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

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

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

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

MS	Nominal budget (Av. '10-'13) €	Δ% 2010 - 2013	Number of inspections (Av. '10-'13)	Δ% 2010 - 2013	Average cost of inspections €	Number of tests performed in laboratories (Av. '10-'13)	Δ% 2010 - 2013	Average cost of tests €
	(a)		(b)		(a)/(c)	(d)		(a)/(d)
BE	946,903	-32%	4,701	94%	201	386	-45%	2,452
BG	2,114,559	-16%	10,953	58%	193	466	21%	4,535
CZ	384,594	-5%	6,200	-4%	62	166	-55%	2,313
DK	8,386,750	0%	1,754	14%	4,782	561	0%	14,950
FI	1,417,861	0%	7,448	0%	996	2924	6%	2,537
FR	1,680,000	1%	16,119	-1%	104	1147	-1%	1,465
IE	4,825,000	0%	15,401	32%	313	193	-58%	25,000
IT	1,561,372	6%	6,110	11%	256	581	153%	2,690
LV	1,818,645	40%	3,221	-1%	565	361	63%	5,038
MT	163,592	7%	939	-7%	174	:	:	:
PL	10,229,088	16%	7,605	5%	1,345	926	44%	11,047
PT	25,229,517	-16%	12,670	174%	1,991	411	-9%	61,348
RO	320,108	25%	12,071	-14%	27	2716	-35%	118
SE	14,258,602	n/a	3,593	-3%	3,968	367	-14%	38,852
SK	5,634,232	-1%	3,610	-31%	1,561	352	-30%	15,995
Av.	5,264,722	0.92%	7,493	21%	703	770	-7%	6,837

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

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

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

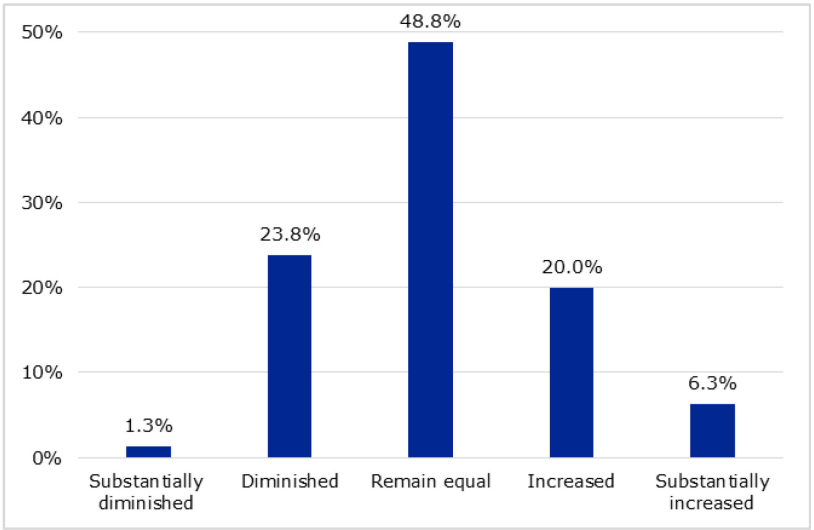
Streamlining the procedures for the notification of non-compliant products, which is currently carried out thorough two separate systems (Rapex and ICSMS), could further reduce administrative burden for authorities[106].

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

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

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

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

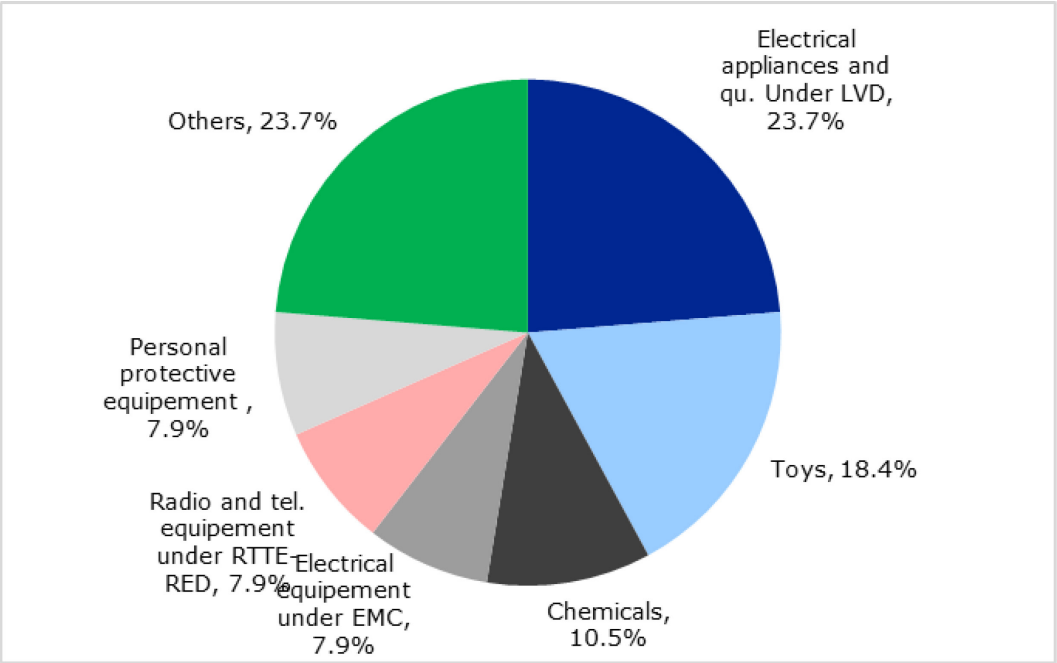


The analysis of responses to the survey highlights also that 'Toys', 'Chemicals' and 'Electrical appliances under the Low Voltage Directive' seem to be the sectors were the

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

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

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



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

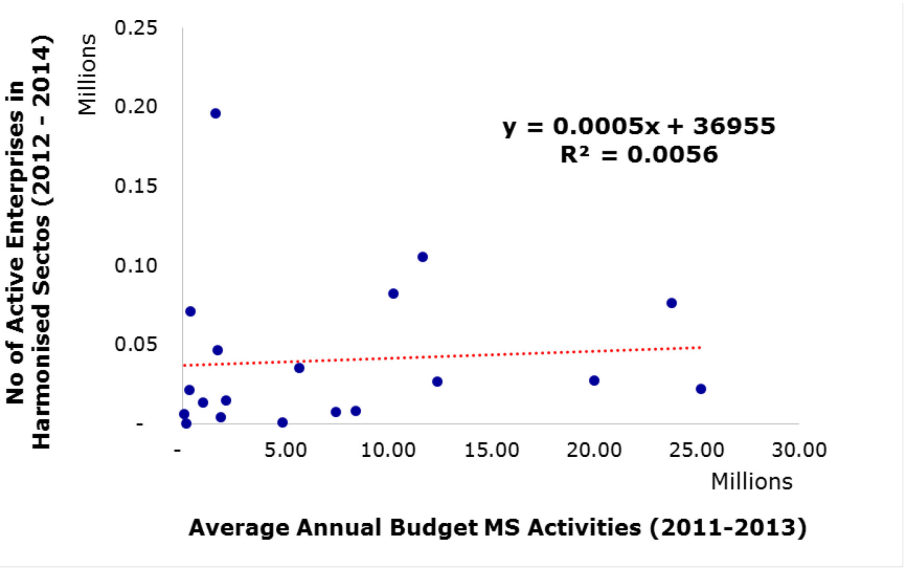
EQ8. To what extent have the market surveillance provisions been cost effective?[108]

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

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

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

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



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

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

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

6.3. Relevance

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

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

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

110 See section 6.3 of Annex 4.

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

Box 4 – Fulfilment service providers[113]

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

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

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

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

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

111 For further details, see the section on coherence.
112 See points 3.4 and 3.5 of 'Commission Notice — The 'Blue Guide' on the implementation of EU products rules 2016', OJ C 272, 26.7.2016, p. 1.
113 See also section 4.2.6, 6.3.1 and 6.3.2 of Annex 4, and box 1 above.

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

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

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

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

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

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

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

(2) There is a need to reinforce customs controls. Furthermore, to make it harder for non-European manufacturers, whose non-compliant products have been rejected by a customs authority, to switch to other customs clearance locations, improved cooperation between the customs authorities of the EU Member States also seems necessary. For some Member States there exists a mismatch between the customs product classification

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

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

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

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

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

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

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

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

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

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

120 See section 6.3.1 of Annex 4.

121 Directive 2009/48/EC on the safety of toys; Directive 2010/35/EU on transportable pressure equipment; Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products; Directive 2013/29/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles; Directive 2013/53/EU on recreational craft and personal watercraft and repealing Directive 94/25/EC; Directive 2014/28/EU on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses; Directive 2014/29/EU on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels; Directive 2014/30/EU on the harmonisation of the laws of the Member States relating to electromagnetic compatibility; Directive 2014/31/EU on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments; Directive 2014/32/EU on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments; Directive 2014/33/EU on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts; Directive 2014/34/EU on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres; Directive 2014/35/EU on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits; Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC; Directive 2014/68/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment; Directive 2014/90/EU on marine equipment and repealing Council Directive 96/98/EC; Regulation (EU) 2016/424 on cableway installations and repealing Directive 2000/9/EC; Regulation (EU) 2016/425 on personal protective equipment and repealing Council Directive 89/686/EEC; Regulation (EU) 2016/426 on appliances burning gaseous fuels and repealing Directive 2009/142/EC.

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

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

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

122 Article 12 of Regulation (EC) No 1222/2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters obliges Member State to ensure, in accordance with Regulation (EC) No 765/2008, that the authorities responsible for market surveillance verify compliance with Articles 4, 5 and 6 of the Regulation, relating to the responsibilities of tyre suppliers, tyre distributors, vehicle suppliers and vehicle distributors ; Article 18 of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment obliges Member States to carry out market surveillance in accordance with Articles 15 to 29 of Regulation (EC) No 765/2008; Recital (14) of Regulation (EU) No 1007/2011 on textile fibre names and related labelling and marking of the fibre composition of textile products and repealing Council Directive 73/44/EEC and Directives 96/73/EC and 2008/121/EC indicates that the market surveillance in Member States of products covered by this Regulation is subject to Regulation (EC) No 765/2008 and Directive 2001/95/EC ; Article 65 of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products lays down that Member States have to make the necessary arrangements for the monitoring of biocidal products and treated articles which have been placed on the market to establish whether they comply with the requirements of the Regulation, and that Regulation (EC) No 765/2008 applies accordingly ; Article 5(4) of Regulation (EU) No 167/2013 on the approval and market surveillance of agricultural and forestry vehicles and Article 6(4) of Regulation (EU) No 168/2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles specify that Member States should organise and carry out market surveillance and controls of vehicles, systems, components or separate technical units entering the market in accordance with Chapter III of Regulation (EC) No 765/2008. Other provisions of the Regulation oblige economic operators to cooperate with national authorities in accordance with Article 20 of Regulation (EC) No 765/2008; According to recital (12) of Regulation (EU) No 540/2014 of the European Parliament and of the Council of 16 April 2014 on the sound level of motor vehicles and of replacement silencing systems, and amending Directive 2007/46/EC and repealing Directive 70/157/EEC, Chapter III of Regulation (EC) No 765/2008, in accordance with which Member States are required to carry out market surveillance and control products entering the Union market, applies to the products covered by this Regulation.

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

124 Articles 27 to 29 refer to Union legislation

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

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

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

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

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

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

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

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

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

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

129 See section 6.3.1 of Annex 4.

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

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

132 Section 5.3 of Annex 4.

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

6.4. Coherence

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

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

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

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

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

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

134 Section See section 6.3 of Annex 4.

135 See section 6.4.1 of Annex 4.

136 See section 6.4.2 of Annex 4.

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

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

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

a) Economic operator[137]

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

137 See also section 6.3.1 of Annex 4.

138 Regulation (EC) No 273/2004 on drug precursors applies to two categories of businesses, namely *'operators'* (i.e. any natural or legal person engaged in the placing on the market of scheduled substances) and *'users'* (i.e. any natural or legal person other than an operator who possesses a scheduled substance and is engaged in the processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, transformation or any other utilisation of scheduled substances); Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) distinguishes the manufacturer, the importer, the distributor, the producer of an article (i.e. any natural or legal person who makes or assembles within the EU an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition) and the downstream user (i.e. any natural or legal person established within the Union, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities); Similarly, Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures provides also contains obligations for the producers of an article and downstream users; Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators defines economic operators as '*any producer, distributor, collector, recycler or other treatment operator'*; Directive 2013/53/EU on recreational craft and personal watercraft introduced specific obligations for the '*personal importer*' vis-à-vis the market surveillance authorities; Directive 2014/33/EU on lifts extended the market surveillance obligations to the 'installers' of lifts; Directive 2010/30/EU on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products applies to two categories of traders, namely the *'dealer'* (i.e. a retailer or other person who sells, hires, offers for hire-purchase or displays products to end-users) and the *'supplier'* (i.e. the manufacturer or its authorised representative in the Union or the importer who places or puts into service the product on the Union market. In their absence, any natural or legal person who places on the market or puts into service products covered by this Directive is considered a supplier); Directive 2010/35/EU on transportable pressure equipment defines the '*economic operator'* not only as the manufacturer, the authorised representative, the importer and the distributor but also includes *'the owner or the operator acting in the course of a commercial or public service activity, whether in return for payment or free of charge'*. The latter are also subject to the market surveillance obligations laid down in the Directive.

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

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

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

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

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

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

c) The GPSD

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

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

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

- In the area of food and feed, Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products[141] will increase Member States' ability to prevent, eliminate or reduce health risks to humans, animals and plants. The new Regulation provides a package of measures that will strengthen the enforcement of health and safety standards for the whole agri-food chain. The new rules will gradually become applicable with the main application date being 14 December 2019.

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

139 See section 6.4.2 of Annex 4.

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

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

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

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

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

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

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

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

6.5. EU added value

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

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

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

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

145 See section 6.5 of Annex 4.

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

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

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

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

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

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

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

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

146 See annexes 2, 6 and 7.

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

7. CONCLUSIONS

7.1. Effectiveness

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7.2. Efficiency

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

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

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

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

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

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

7.3. Relevance

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

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

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

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

7.4. Coherence

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

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

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

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

7.5. EU added value

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

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

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

7.6. REFIT potential

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

- The scope of the market surveillance provisions could become much clearer; a few discrepancies in the definitions and terminology provided in the different sector specific legislations could be addressed when the sector legislation in question is reviewed;[147]

- The relation between RAPEX, ICSMS and the safeguard procedures should be improved in order to reduce inconsistencies and confusion, to avoid duplication of work and useless administrative burden[148]. In February 2017 the Commission released the first version of an interconnection between RAPEX and ICSMS. In 2016 safeguard notifications were implemented in ICSMS, with a second release due by end 2017;

- Inconsistencies in the approach followed by Member States authorities while carrying out market surveillance (e.g. interpretation of the concept of appropriate scale of

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

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

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

- Checks of imported products are still considered insufficient in light of the increasing import from third countries and online sales, especially due to the limited available resources and fragmentation between authorities in different Member States; exchange of information and coordination among the authorities involved could be improved[151].

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