



Council of the
European Union

Brussels, 21 December 2017
(OR. en)

Interinstitutional File:
2017/0353 (COD)

15950/17
ADD 2

ENT 276
MI 987
CONSOM 410
COMPET 895
UD 309
CHIMIE 110
COMER 132
CODEC 2130
IA 225

PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	20 December 2017
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2017) 466 final PART 1/4
Subject:	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council

Delegations will find attached document SWD(2017) 466 final PART 1/4.

Encl.: SWD(2017) 466 final PART 1/4

Brussels, 19.12.2017
SWD(2017) 466 final

PART 1/4

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

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

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

{COM(2017) 795 final} - {SWD(2017) 467 final} - {SWD(2017) 468 final} -
{SWD(2017) 469 final} - {SWD(2017) 470 final}

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

1.1 Introduction

This initiative is announced in the **Single Market Strategy**, *Upgrading the Single Market: more opportunities for people and business*, adopted by the Commission on 28 October 2015¹ and constitutes one of the main initiatives of the 2017 Commission Work Programme.² It is part of the "Goods Package". It should be set in the context of the fourth priority policy area to be tackled under President Juncker's Agenda for Jobs, Growth, Fairness and Democratic Change, i.e. a **deeper and fairer internal market** with a strengthened industrial base.

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

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

1.2 Context

1.2.1 Regulatory context

The Single Market has been a frontrunner in EU economic integration. The most important legislative obstacles have been eliminated through EU harmonisation legislation³. The objective of this legislation is twofold, first ensuring that industrial products placed on the European market guarantee high levels of protection for health and safety and the environment and secondly, ensuring the free movement of industrial products by replacing national rules with a single harmonised set of conditions for placing these products on the market.

The basic product rules are set out in **Union harmonised legislation, which covers the great majority of industrial products** such as toys, machinery, radio equipment, electrical and electronic devices, cosmetics, gas appliances, measuring instruments, pressure equipment, chemical substances that could be found in products belonging to a wide range of sectors, energy using products and many others⁴. The rules are applicable to both consumer products and products used in the context of professional activities, regardless of whether traded in physical 'brick- and mortar' shops or online and regardless of whether produced domestically or imported from third countries, as long as they are offered on EU markets. On the other

1 Communication from Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Upgrading the Single Market: more opportunities for people and business*, COM(2015)550/2.

2 COM(2016) 710 final: http://ec.europa.eu/atwork/key-documents/index_en.htm

3 For a glossary of terms and abbreviations see Annex, page 85.

4 Annex 7 Section 1 contains a non-exhaustive list of product sectors covered by Union harmonisation legislation potentially affected by this initiative.

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

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

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

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

- Regulation (EC) 765/2008 setting out the requirements for accreditation and the market surveillance of products to be fulfilled by Member States,
- Decision 768/2008/EC on a common framework for the marketing of products, which includes reference provisions to be incorporated whenever product legislation is revised. In effect, it is a template for future product harmonisation legislation.

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

are respected in the EU and, in particular, to prevent the making available on the market and use of non-compliant and/or unsafe products⁵. For that purpose Member States must:

- Correctly implement the provisions of the relevant legislation and allow for sanctions proportional to any infringements;
- Control the products (whatever their origin) introduced on their market in order to ensure that they have been subjected to the necessary procedures, that the marking and documentation requirements have been respected and that they have been designed and manufactured in accordance with the Union harmonisation legislation requirements. In the case of products imported from third countries, customs authorities should be closely involved in the market surveillance activities.
- Organise market surveillance according to minimum common requirements (appointment of competent authorities, resources, market surveillance programmes, reviews and assessment of market surveillance, etc.).
- Cooperate with authorities in other member states by sharing information on products controlled and activities carried out, in particular by making use of the common database (ICSMS) and taking part in the Rapex Rapid Alert mechanism (RAPEX) for products presenting a serious risk.

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

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

- definitions of relevant economic operators (i.e. manufacturer, importer, distributor) and corresponding responsibilities concerning product compliance and traceability depending on their role in the supply chain, and
- provisions on specific market surveillance procedures (so-called 'safeguard procedures') to be applied when authorities have reasons to believe that a product does not comply with common rules.

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

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

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

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

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

- 1) For products subject to Union harmonisation legislation aligned to Decision 768/2008/EC:
 - definitions and **obligations of relevant economic operators** depending on their role in the supply chain
 - procedures to determine the **steps to be followed by market surveillance** notably **when they have reasons to believe that a product presents a risk**, i.e.: assessing conformity of the product and level of risk, requesting businesses to take corrective action, communicating relevant measures to other Member States and the Commission, follow-up by authorities in other Member States, in case of objection by another authority Commission decision confirming the measure notified by the initiating Member State was justified or, to contrary, considering it unjustified.
- 2) For all products subject to Union harmonisation legislation (Regulation (EC) 765/2008):
 - obligation for Member States to **appoint market surveillance authorities** (MSAs) and entrust them with the powers, resources and knowledge necessary for the proper performance of their tasks
 - obligation to draw up either a general **market surveillance programme** or sector-specific programmes covering the sectors in which they conduct market surveillance, communicate those programmes to the other Member States and the Commission and make them available to the public
 - obligation to **periodically review and assess the functioning of their surveillance activities** (at least every four year) and communicate the results to the EC, other Member States and to the public
 - obligation for MSAs to **perform appropriate checks** on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples
 - **power of MSAs** to require economic operators to make documentation and information available for the purpose of carrying out their activities, and, where it is necessary and justified, enter the premises of economic operators and take the necessary samples of products. MSA may destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary.
 - obligation to ensure that **products which present a serious risk** requiring rapid intervention, including a serious risk the effects of which are not immediate, are **recalled, withdrawn** or that their being made available on their market is prohibited, and that the Commission is informed without delay and that relative **measures are notified in the Rapex Rapid alert system**
 - obligation to share information on non-compliances via an EU general database (**ICSMS**)
 - obligation for customs (or other authorities in charge of controls at the border) to **check imported products** and to refuse their release for free circulation if found to be non-compliant.

In 2013, the European Commission adopted proposals for new rules improving the safety of consumer products and market surveillance for all non-food products, in the so-called Consumer Product Safety and Market Surveillance Package⁷. The proposals intended to address the need to streamline, simplify and improve market surveillance rules and procedures to make it easier for national authorities and economic operators to apply and follow them. Specifically, at that time the Commission stressed that market surveillance rules

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

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

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

Meanwhile, the Commission evaluated Union harmonisation legislation in 2014⁹. One of its main outcomes was that market surveillance is considered to be the weakest part of the implementation system, partly due to the inherently difficult nature of the task and in part due to varying levels of resources and technical expertise available in different countries¹⁰.

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

The initiative has the ambition to step up enforcement of product requirements set out in a very broad range of Union legislation¹¹ by setting up horizontal rules applying across the board on top of sector-specific rules.

This impact assessment examines options to improve the legal framework for market surveillance of harmonised products and constitutes an ex-ante assessment in the meaning of article 30 of the Financial Regulation to the extent that funding and resourcing of market surveillance by the EU budget could be significantly affected¹².

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

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

10 SWD(2014)23, section 4.8.

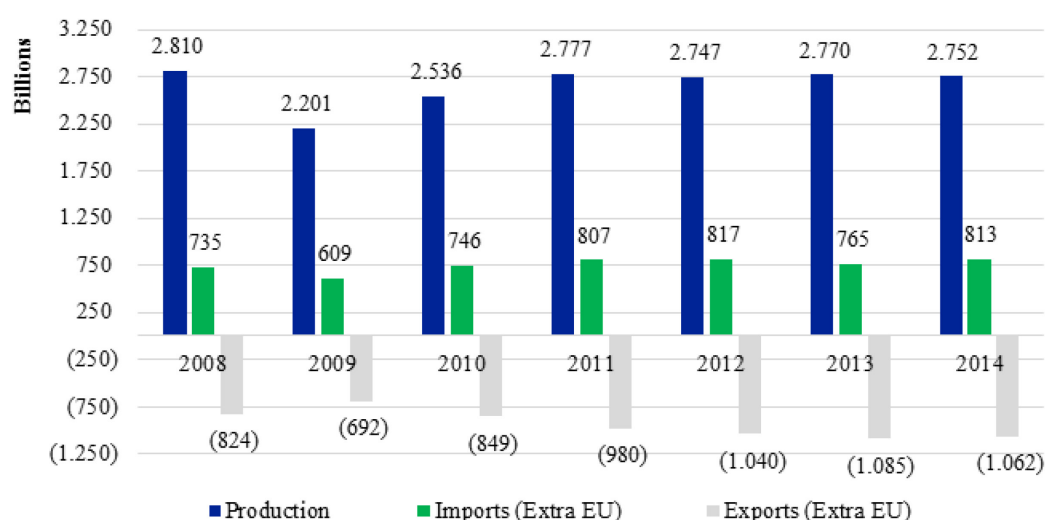
11 More than 60 pieces of legislation are listed in Annex 7 Section 1.

12 Chapter V of Regulation (EC) N° 765/2008 sets out funding provisions for all aspects of the Regulation, including market surveillance.

1.2.2 Economic context

The **value of EU harmonised products** amounted on average to more than 2 400 billion euro per year during the period 2008-2014, and corresponds to about 69% of the overall value of manufacturing products in the EU¹³. Around 1.2 million businesses are involved in the manufacturing of industrial products (65% of all businesses active in the EU manufacturing sector). Furthermore, the value added of wholesale and retail traders whose sales are likely to include harmonised products during the 2008-2015 period is estimated around 850 billion euro per year. The number of enterprises active in the distribution of products in these sectors is estimated around 4 million and the number of their employees over 22.5 million people¹⁴.

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



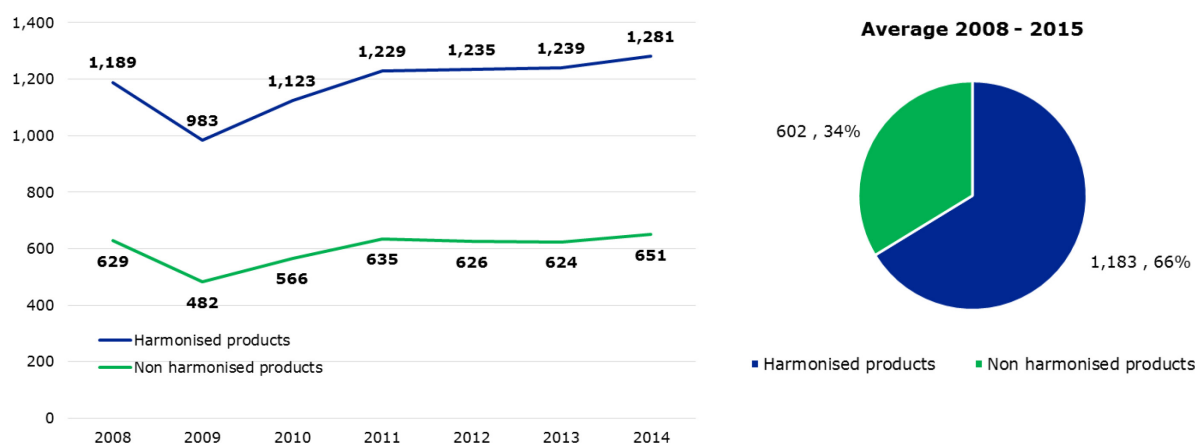
Source: Prodcom – statistics by product, EUROSTAT (2016)

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

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

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

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



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

1.3 What is the problem?

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

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

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

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

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

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

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

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

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

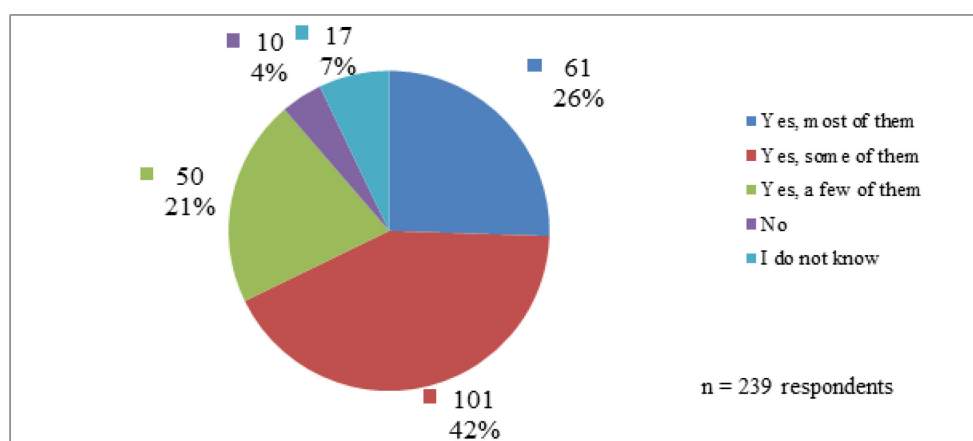
16 "Non-compliant products destroy industrial jobs!", <http://www.industrial-europe.eu/Committees/IP/PolBrief/PB2016-08-MarketSurveillance-EN.pdf>

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

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

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

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



Source: public consultation

The levels of non-compliance vary by Member State and by product sector. Estimates at sector level are hardly available. However, for instance, in the case of the Ecodesign Directive dealing with products such as electric equipment, air-conditioning systems, machines tools etc., a 2009 study estimated non-compliance to be 10% - 20%¹⁹; as concerns the Energy Labelling Directive a stakeholder mentions non-compliance rates of 20 to 50%²⁰. In the area of gas appliances existing studies indicate non-compliance levels of 5% - 10%²¹. In a consultation conducted by the European Commission in 2010 in ten sectors²², 92% of businesses considered that their sector is affected by non-compliance.

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

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

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

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

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

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

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

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

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

Source: national reports and Commission elaboration.

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

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

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

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

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

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

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

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

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

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

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

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

Toys intended for children under 3 years ³²						
Period	Participating authorities	Total of products checked	Non-compliance on warnings, markings and instructions for use	Non-compliance as to physical and mechanical requirements	Non-compliance as to migration of certain elements	Non-compliance as to phthalate content
2014-2016	10	1850	40% of approx. 608 samples tested	46.4% of 265 samples tested	1.5% of 200 samples tested	13.2% of 228 samples tested
LED lighting equipment ³³						
Period	Participating authorities	Total of products checked	Fully compliant	Non-Compliance with CE marking requirements ³⁴	Non-Compliance with the Declaration of Conformity requirements ³⁵	
2011	18	168	17.3%	76.8%	39.9%	
Active electric energy meters ³⁶						
Period	Participating authorities	Total of products checked	Fully compliant	Non-compliance		
2015-2016	11	22	< 60%	Non-compliant products: > 40% (Formal aspects: 27.3%; Software aspects: 27.3%; Sealing aspects: 9.1%)		
Heating meters ³⁷						
Period	Participating authorities	Total of products checked	Fully compliant	Non-compliance		
2015-2016	10	18	39%	Non-compliant products: 61% (Formal aspects: 5.5%; Software aspects: 27.8%; Sealing aspects: 5.5%; Functional aspects: 38.9%; Other aspects: 5.5%)		
Electromagnetic Compatibility						
2013	Switching power supplies for laptop computers (September 2012 - March 2013) ³⁸					
2014	Solar panel inverters (January 2014 - June 2014) ³⁹					

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

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

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

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

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

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

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

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

Period	Participating authorities	Total of products checked	Fully compliant	Formal non-compliance	Technical non-compliance
2013	19	136	23%	69%	44%
2014	14	55	9%	62%	67%
Radio and Telecommunications Equipment					
2013	5 GHz WLAN (November 2012 - March 2013) ⁴⁰				
2014	Repeater for mobile telephones (January 2014 - May 2015) ⁴¹				
2015	Drones (January 2015 - June 2015) ⁴²				
Period	Participating authorities	Total of products checked	Fully compliant	Formal non-compliance	Technical non-compliance
2013	21	101	28%		
2014	14	47	6%	90%	68%
2015	18	79	8%	82%	51%
REACH and CLP⁴³					
2011	REF1. Registration, pre-registration and safety data sheets				
2013	REF2. Obligation of downstream users - formulators of mixtures				
2015	REF3. Inspection and enforcement of compliance with registration obligations by manufacturers, importers and only representatives in close cooperation with customs				
Period	Participating authorities	Total of companies checked *	Fully compliant	Non-compliance	
2011	26	2400	78%	22%	
2013	29	1200	33%	67%	
2015	28	1169	66%	34%	

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

Source: mostly reports from joint actions

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

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

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

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

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

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

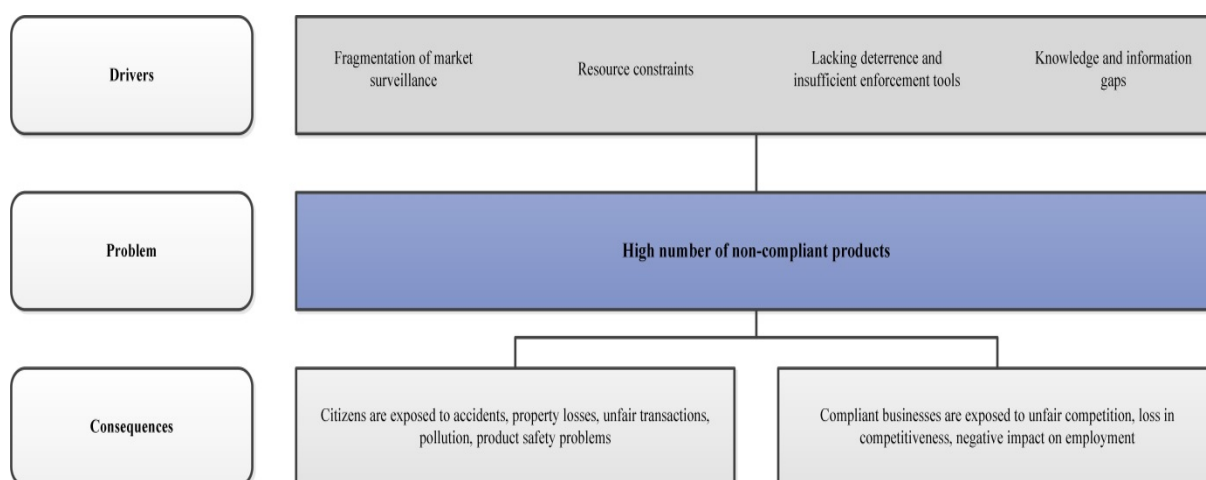
Furthermore, it is a fact that despite the broad scope of this initiative that aims at rules applicable horizontally to several product areas, evidence available focuses on only a sub-set of products for which national authorities were able to report information on the outcomes of their controls carried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

1.4 Problem drivers

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

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

Figure 4: Problem tree



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

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

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

Overall, more than 500 market surveillance authorities exist in the EU⁴⁵. Each authority is competent exclusively for products made available in the part of the single market that corresponds to the national territory of a Member State or a smaller part within the Member State. Furthermore, controls of products entering the EU requires the involvement of customs authorities, i.e. yet a further set of actors. Conversely, businesses often supply products from outside the jurisdiction of the market surveillance authority where the end customer is located. Overall, harmonised products represent about 65% of intra-EU trade in goods⁴⁶, although the percentage depends on the specific sector⁴⁷. Furthermore, recent developments in the online market show an increasing proportion of retail sales with a cross-border dimension⁴⁸.

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

44 See section 5.1 of the evaluation .

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

46 See Annex 5.

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

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

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

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

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

In order to address these issues the current regulatory framework includes a number of legal, administrative and financial tools (e.g. common database ICSMS⁵² for exchange of information on results of inspections, notifications of restrictive measures based respectively on RAPEX and safeguard clause procedures⁵³, mutual assistance⁵⁴, administrative cooperation groups called 'AdCos'⁵⁵, joint actions⁵⁶ and Customs Union principles⁵⁷) allow coordination among market surveillance authorities in different Member States.

However, the findings of the evaluation of Regulation (EC) No 765/2008 show that despite the clearly positive role played by these different cross-border cooperation tools, they are not exploited to an extent sufficient to trigger effective coordination and efficient work sharing among surveillance authorities in the Single Market⁵⁸. For instance: the ICSMS database is only used and to different degrees by a subset of Member States (see Annex 11.1.1); the systems for notifying restrictive measures are not systematically used by national authorities and the response provided by recipient authorities is fairly weak both in terms of official 'reactions' and follow-up measures taken (Annex 11.1.2); mutual assistance among authorities willing to contact economic operators located in another Member States only takes place occasionally (Annex 11.1.3); the degree of active participation in administrative cooperation groups is still unsatisfactory (Annex 11.1.4); joint market surveillance actions are carried out only in some sectors and on an-hoc basis and, in most cases, are triggered by EU funding; yet, even EU funding is not sufficient if authorities cannot rely on some administrative framework for the management of the joint projects (Annex 11.1.4-1.6), customs risk management systems are still managed to a large extent nationally. As a result the overall degree of **cross-border cooperation remains fairly weak and so it is not sufficient to address the limitations of jurisdiction** described above. Market surveillance is still seen to a large extent as a 'national matter' and authorities continue to focus mainly on domestic priorities. Due to national organisation of market surveillance and pressures on staff resources, cross-border cooperation projects may seem more burdensome and their benefits more diffuse and not delivered in the short term.

Furthermore, the evaluation of Regulation (EC) No 765/2008 notes that the relevant EU provisions are drafted in such general terms⁵⁹ that Member States have implemented the Regulation in many different, specific forms. Differences emerge not only in terms of distribution of competences, but also in terms of internal coordination mechanisms, level of deployed resources (financial, human and technical), market surveillance strategies and approaches, powers of inspection and sanctions (including for border controls) and penalties for product non-compliance.⁶⁰ The heterogeneity existing across Member States in the implementation of the Regulation allows concluding that the **level of market surveillance is certainly not uniform**, given that Member States with more resources and powers have - at least - more tools for a proper enforcement. This lack of uniformity allows inferring that market surveillance might also be more rigorous in some Member States than in others. Potential effects are a less effective deterrence power, an unequal playing field among

52 Annex 11.1.1 and 11.1.6.

53 Annex 11.1.2 and 11.1.6.

54 Annex 11.1.3 and 11.1.6.

55 Annex 11.1.4 and 11.1.6.

56 Annex 11.1.4-6.

57 Annex 11.2.

58 See section 6.1.1 in the Evaluation SWD.

59 For example, the market surveillance provisions oblige Member States to '*entrust market surveillance authorities with the powers, resources and knowledge necessary for the proper performance of their tasks*' while market surveillance authorities must '*perform appropriate checks on the characteristics of products on an adequate scale*'.

60 See section 6.1.2 of the Evaluation SWD.

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

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

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

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

- Resources allocated to market surveillance amount on average to a few euros per thousand inhabitants (with the exception in particular of medical devices, cosmetics and toys) and from 0 to maximum 0.5 inspectors per million inhabitants⁶².
- The total budget available to all Member States' authorities having reported the information, in nominal terms⁶³ 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-period⁶⁴.
- 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 States⁶⁵.

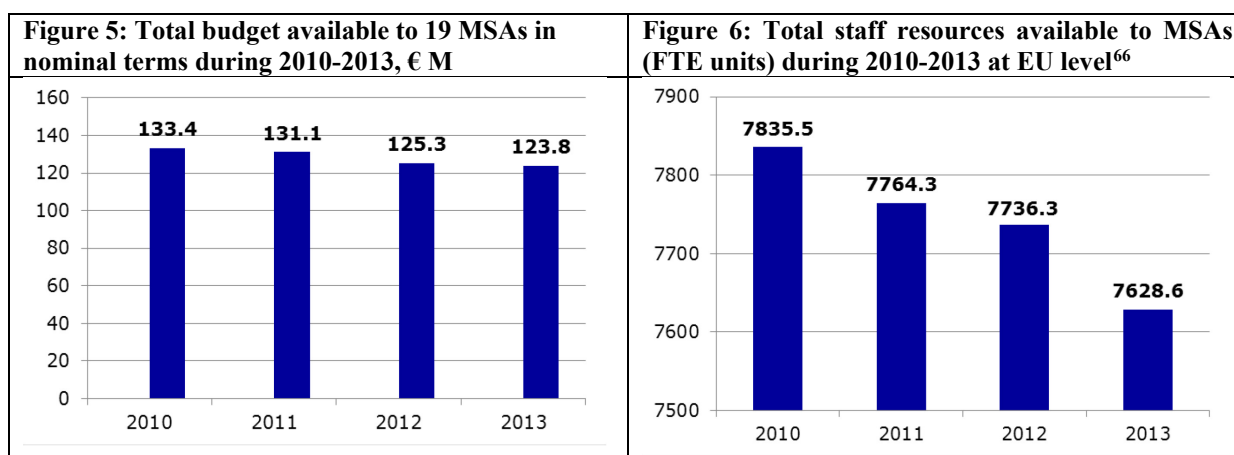
61 See Annex 12 ; Chapters 6.1 and 6.2 of the evaluation and sections 6.1 and 6.2 of Annex 4 of the evaluation.

62 See sections 5, 6.1 and 6.2 of Annex 4 of the evaluation

63 Not all EU28 Member States provided reliable data for this indicator. Therefore, figures do not include Austria, Cyprus, Estonia, Greece, Croatia, Luxembourg, Slovenia, the United Kingdom and Hungary.

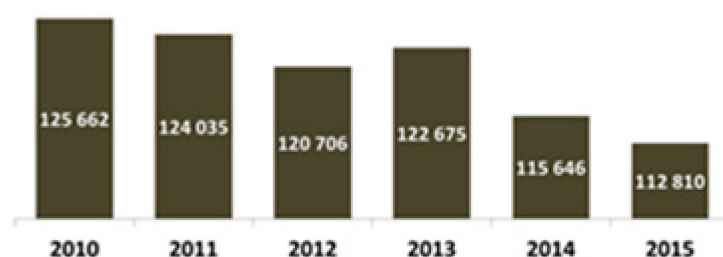
64 See section 5.2.1 of Annex 4.

65 See section 5.2.1 of Annex 4.



Similarly also the number of customs officials has seen a continuing downward trend of about 10% since 2010⁶⁷. This explains at least partially the fact that product compliance checks by customs remains fairly limited in relation to the number of imports^{68 69}. Stakeholders often report that the order of magnitude of controls in one of one of the biggest harbours is only 0.1%.

Figure 7: Total staff resources available to customs during 2010-2015 at EU level⁷⁰



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

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

⁶⁷ See also Annex 11 section 2.2.

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

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

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

authorities to perform appropriate checks on the characteristics of the products on an "adequate scale". Besides risk profiles of products, market surveillance authorities and customs confirm that in first instance they determine the "adequate scale" of controls mainly on the basis of financial and human resources available. Data available show that in many Member States the number of inspections is rather low in comparison with total population and that the average correlation with the number of enterprises in every country is very low⁷¹.

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

Lack of willingness to comply with applicable requirements for products marketed in the EU constitutes another explanation for non-compliance⁷². This was confirmed by the public consultation where 78% of participants considered that the lack of willingness to comply was among the top three reasons for non-compliance. 33% considered it the main reason for non-compliance.

Box 3: Academic research about deterrence and incentives to comply

Deterrence and incentives to comply have been the subject matter of abundant academic research⁷³. According to the traditional literature on deterrence what motivates compliance are economic incentives. A strong enforcement programme and a considerable risk of detection of infringements can discourage non-compliant behaviour. More recent developments in the academic research on compliance and enforcement focus on the concept of 'responsive regulation' according to which corporate compliance and deterrence of non-compliance are not primarily the result of fear of legal sanctions; it rather stems from a combination of the intrinsic motivation to behave responsibly (i.e. goodwill, dialogue with the regulator and with interested third parties, trust in the regulator), and external influences, such as stakeholder pressure or fear of sanctions. For these reasons responsive regulation advocates that: 1) firms should be initially addressed by regulators with a cooperative, persuasive strategy; 2) only if firms do not respond, a regulator may respond with a variety of escalating interventions⁷⁴. However this "tit for tat" strategy can only be successful when authorities dispose of concrete means to detect non-compliance and when severe sanctions are available as a backup. In particular, if market surveillance authorities are perceived as unwilling or unable to enforce product legislation because they do not have the means to detect and block non-compliant products then deterrence will be low. Incentives to comply are therefore linked on the one hand to trust and cooperation with the regulators/enforcers, dialogue with interested parties, stakeholder pressure; on the other hand cooperative compliance is generally contingent upon persuading those of goodwill that their responsible conduct will not be exploited by free riders who will get away with the benefits of non-compliance without being held to account for it. Thus deterrent and punitive sanctions must still be available in the background.

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

⁷¹ Annex 12 and chapter 6.1.2.1 of the evaluation Regulation (EC) No 765/2008.

⁷² OECD, *ibidem*. See chapters 6.1 and 7.2 of the evaluation.

⁷³ See Annex 13 section 3.

⁷⁴ Therefore, enforcement can best be defined as a dialogue between regulators and firms addressing the various forces and motives for compliance within a firm. Third parties, such as public interest groups, and community organizations, can often exert pressure on firms to behave in a socially responsible way, and so be involved in this dialogue. Furthermore, if regulatees trust regulators as fair umpires who administer and enforce laws or regulations that have important substantive objectives, then the evidence is that compliance will be higher, and resistance and challenges to regulatory action will be low. However, it should also be noted that most accounts that find people to be compliant in response to dialogue, goodwill and trust also find that deterrence is necessary as a back-up for the minority of organisations that do not voluntarily comply. They also find that co-operative compliance is generally contingent upon persuading those of goodwill that their compliance will not be exploited by free riders who will get away with the benefits of noncompliance without being held to account for it. Thus deterrent and punitive sanctions must still be available in the background. See Levi, 1988; Scholz, 1997, p. 262.

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

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

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

To face these developments the authorities would need to rely on a more suitable toolbox, however the authorities' powers contained in the Regulation (EC) No 765/2008 do not explicitly take into account the developments of online trade. Moreover, many market surveillance authorities still lack some important enforcement tools⁷⁶. Furthermore, border controls of imported products remain fairly limited in relation to the number of imports⁷⁷.

Box 4: Enforcement tools of market surveillance authorities

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

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

⁷⁶ See section 6.1.2.2 of the evaluation.

⁷⁷ See section 6.1.3 of the evaluation;

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

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

The table below presents an overview of the enforcement tools.

Table 3: Enforcement tools

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

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

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

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

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

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

⁷⁹ SWD(2015)274.

market surveillance⁸⁰. Many distribution centres ('fulfilment centres') have evolved from mere transport and storing to direct-to-user order fulfilment.⁸¹ It is not always clear when products are placed on the market and by whom, particularly when they are imported from third countries into the EU. Indeed, it is argued that there appears to be ambiguity as to whether making available for purchase on a retail website constitutes placement of the product on the market. Some stakeholders also suggested that there might also be a lack of clarity over the relative responsibilities of different parties; for example, to what extent should end-users be considered as importers of products? To what extent are e-commerce platform providers responsible for products sold via their platforms? According to the limited liability provisions of the Electronic Commerce Directive, intermediary service providers acting as mere conduits, caches, or hosts of information are not liable for online content, unless they were notified of the presence of illegal content and did not act. The increased complexity of the chain of responsibility therefore raises the question of the role of additional economic players such as fulfilment houses, online platforms or social media allowing offer and demand to meet, along with the boundaries between roles (user, consumer, producer, agent, tenderer, seller) and/or the role they can play in making possible corrective action. As explained in the evaluation, the definitions and powers contained in Regulation (EC) No 765/2008 do not address the reality of e-commerce and do not specify the role expected by these new actors. This creates uncertainty for both enforcers and businesses and hampers market surveillance action. 58% of the authorities participating in the public consultation considered that when products are traded online the fact that the business (normally located abroad) contacted does not consider itself as manufacturing, importing or distributing a product limits their ability to obtain information or to take corrective action.

There are very significant practical challenges for market surveillance on products sold online. Market surveillance authorities report considerable difficulties in the identification and interception of products that are delivered to the end-user in single consignments via the conventional postal system. The import of individual parcels renders case-by-case controls at the border inefficient. Moreover, even where market surveillance authorities identify websites selling non-compliant products, they may simply be unable to identify the supplier using the website. On-line sales for which often suppliers and buyers are located in different countries exacerbate the difficulties highlighted in previous sections as regards the limitation of authorities' jurisdiction vis-à-vis business based in other Member States or in a third country⁸².

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

1.4.3.2 The increase in imports from third countries

Imports of harmonised goods from third countries represent a sizable and increasing share of products supplied on the EU market, as it went up from 24% in 2008 to over 30% in 2015. In 2015 they were estimated to value almost 750 € billions⁸³.

Many respondents to the public consultation found it difficult to indicate the proportion of products imported from third countries in their sector⁸⁴; however the general perception

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

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

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

⁸³ See Annex 5

among stakeholders is that imports are affected by non-compliance⁸⁵. The analysis of RAPEX notifications supports the findings that the non-compliance of imports from extra EU is a relevant issue: from 2010 to 2016 notifications concerning imported products were around 75% of yearly published notifications and the percentage remained overall stable over the period. On average, 59% of total yearly notifications concern products from China.

However, the evaluation of Regulation (EC) No 765/2008 concludes that, in light of the increasing importance of EU trade with third countries, checks of imported products are insufficient⁸⁶. It is often difficult to trace and intercept non-compliant products imported from outside the EU and entering through numerous entry points. In addition EU surveillance authorities have difficulties to effectively contact and sanction businesses established outside the EU who sell non-compliant products directly to buyers in the EU. 65% of authorities participating in the public consultation confirm authorities do not know how to identify and contact businesses located in third countries and 59% confirm that businesses contacted do not reply to requests for information/documentation and for corrective action⁸⁷. Despite some existing informal international cooperation arrangements, the number of non-compliant products that can effectively be traced back to the economic operator and sanctioned at the source in 3rd countries remains limited⁸⁸.

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

Furthermore, the procedure for checking products when they enter the EU is fairly outdated. It was conceived in 1993 and slightly updated in 2008 but without any fundamental changes. In 2013 the new EU Customs Code significantly upgraded the use of risk management to target customs controls and established the principle of coordinated 'one-stop shop' controls of customs jointly with other authorities⁹¹. Furthermore the Customs code consolidated the scheme for Authorised Economic Operators⁹² that have a good track-record with customs based on thorough audits and can therefore benefit from certain facilitation of their procedures with customs. The provisions in Regulation (EC) No 765/2008 have not evolved with these changes⁹³. As a consequence there is a suboptimal exchange of information and enforcement cooperation between customs and market surveillance authorities on non-compliant

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

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

86 See section 6.1.3 of the evaluation.

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

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

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

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

91 Union Customs Code Art. 46, 47.

92 Union Customs code Art. 38.

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

products⁹⁴, risks assessment⁹⁵ and economic operators⁹⁶. The provisions on recovery of costs (e.g. for tests or destruction of products) in case of non-compliant products are also not aligned.

1.4.4 Knowledge and information gaps concerning product compliance

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

First of all, market surveillance authorities frequently point out that **lack of knowledge of product rules on the part of businesses** is an important problem to address.⁹⁷ Clearly *ignorantia juris non excusat*, nevertheless unawareness or misunderstanding of requirements seems to explain part of the non-compliances that can be found in the market, as an essential condition for regulatory compliance is that businesses have to be aware and understand their obligations under applicable legislation⁹⁸. The public consultation indicated that 80% of respondents consider lack of knowledge of rules among the three top explanations for non-compliance and 27% consider it as the first reason. Furthermore, 63% of the respondents believe it would be effective to reduce the level of non-compliance if authorities, besides enforcement, would also provide information on applicable requirements. On the other hand, most respondents excluded that non-compliance could be mainly due to ambiguity/excessive complexity of the rules, as only 10% of them considered this the primary explanation for non-compliance.

The Commission evaluation of Union harmonisation legislation in 2014⁹⁹ recommended the expansion of the role of the Product Contact Points to harmonised products so as to provide a first point of contact for and basic information about Union harmonisation legislation to firms.

Second, **consumers and other stakeholders often lack information about the compliance of products** they purchase, use, distribute or compete with. The general public and individual consumers are normally not aware of issues relating to product compliance, which are often not visible to non-experts, unless the product would be clearly dangerous¹⁰⁰. For instance compliance does not appear to be a main criterion when choosing a product to purchase. This is supported by the fact that the compliance or non-compliance of the product does not play a visible role in the contractual terms between the seller and the purchaser of a good. Furthermore, information on risks posed by products does not always reach consumers and

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

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

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

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

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

99 SWD(2014)23, section 7.2

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

other end-users at the same time and in a timely, structured way all across the Single Market. It is also noted that authorities' decisions on non-compliant products often contain business secrets and are hardly made available to the public. This lack of transparency contributes to the low incentives to compliance because it reduces the potential for pressure from other interested parties, such as consumers, trade-unions, industry associations and competitors that can also influence compliance through the mechanisms of reputation and legitimacy. Distributors, according to most directives and regulations, must act with due care in relation to the requirements applicable when they make a product available on the market. Thus they potentially play an important role in preventing the marketing of non-compliant products¹⁰¹. In practice however, provided that distributors, who are to a large extent SMEs, are aware of the relevance of compliance, they rely mostly on documentation made available (or not) from the product manufacturer or the importer, and only a minority of them uses information on non-compliant products such as the Rapex notifications or newsletters by association or consumer organisations¹⁰².

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

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

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

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

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

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

103 See Annex 5 section 2.1 and section 3.

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

The findings of the public consultation confirm that product non-compliance affect negatively citizens and responsible businesses. More specifically non-compliance is considered to have a negative impact on buyers by 76% of respondents (51% consider the impact "significant", 25% "moderate"), while only 8% consider this is not the case and the others reply "I do not know". In practice the type and the seriousness of harm (e.g. injury, property loss, unfair transactions, pollution, security problems) suffered as a consequence of non-compliance depend on the specific product at stake and the degree of the non-compliance presented by the product. For example: toys for children below 3 years old that contain small detachable parts present the risk of choking and may provoke fatal accidents; professional machineries with unprotected cutting parts may provoke cuts or other serious injuries or even death to workers; mobile phones exploding can provoke injury or death to one or more people and damages of different degrees to properties (cars, houses, planes); a faulty meter at petrol pumps may imply economic losses for either the pump manager or the purchasers; energy-using products (e.g. washing machines) consuming more energy than declared on the mandatory label bring about economic harm to the owners; batteries or electronic equipment containing heavy metal will pollute the environment when disposed of; cars producing emissions well beyond the legal limits will exacerbate air pollution. The ecodesign and energy labelling measures in place until 2015 were estimated to save 175 million tons of oil equivalent (mtoe) primary energy per year in the EU¹⁰⁵, yet non-compliance reduces the energy savings by 10%.

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

The competitive advantage enjoyed by rogue traders can be significant since ensuring products made available are compliant implies necessary costs. For example, the total estimated annual costs of compliance of EU legislation on industrial products across eight harmonised product cases (electric motors, laptops, domestic refrigerators/freezers, lifts, gardening equipment, petrol pumps, air conditioners and integrated circuits) have been estimated¹⁰⁶ at €342 million. At a per company level total compliance costs have been estimated to amount to 0,48% of turnover¹⁰⁷. Operators who manufacture or distribute non-compliant products do not incur all these costs and thus enjoy significant savings that will be reflected in the final price of their products, hence distorting competition and causing possible loss of market-share by compliant companies. The price differential at stake, putting compliant firms at a disadvantage, cannot be calculated for product sectors or the market as a whole. While nearly 80% of businesses' respondents in the public consultation indicated that sales or market-shares of compliant companies are affected, an accurate quantification of the negative effects of non-compliance on the sales of responsible businesses is difficult to provide: only 24% of business respondents to the public consultation were able to provide an estimate of the loss in sales experiences due to the competition from non-compliant products.

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

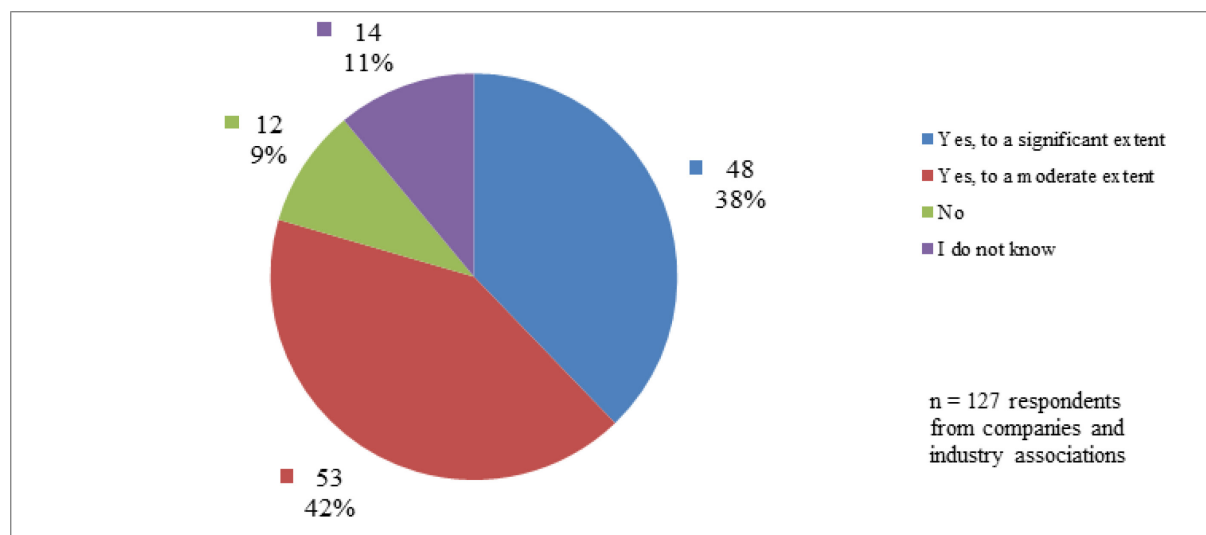
105 SWD(2015) 139 final, p. 15-16 available at: <http://ec.europa.eu/transparency/regdoc/rep/10102/2015/EN/SWD-2015-139-F1-EN-MAIN-PART-1.PDF>

106 Commission Staff Working Document SWD(2014)23.

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

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

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



Source: public consultation

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

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

a) Non-compliance: The previous paragraphs provide a number of indications of non-compliance. Due to the underlying variation in sectors and the multiple interlinked factors that lead to non-compliance, an extrapolation from these data or robust conclusions on trends in non-compliance rates are more difficult to project. However, the analysis of the RAPEX notifications on dangerous products between 2006 and 2015 and information reported by national authorities for the 2010-2013 period¹⁰⁸ conducted during the evaluation of Regulation (EC) No 765/2008 suggest that non-compliance has increased in 2010-2015 with respect to the previous period¹⁰⁹. Although it cannot be excluded that more findings of non-compliance are the results of authorities' increasing efforts, one can reasonably assume¹¹⁰ that non-compliance will persist and probably continue to increase, especially in areas where product testing is expensive or where in-house laboratories are not available:

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

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

¹⁰⁸ The data were included in national reports published according to Article 18(6) of Regulation (EC) No 765/2008.

¹⁰⁹ See section 4.3.1 of Annex 4 of the evaluation.

¹¹⁰ See section 5.3 of Annex 4 of the evaluation.

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

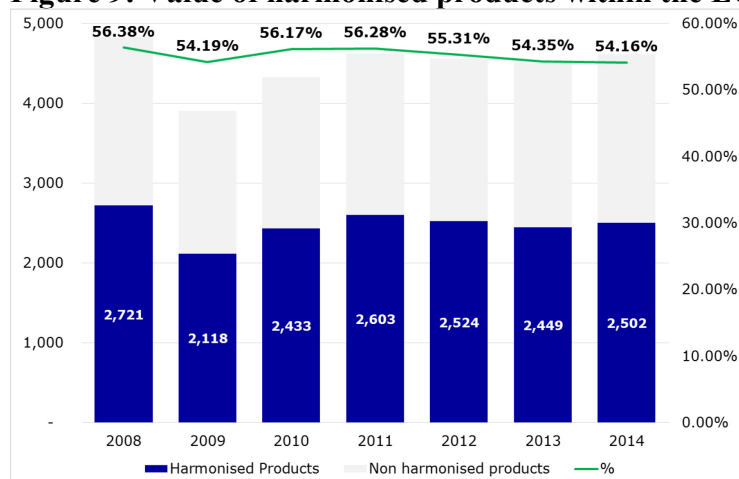
The trend of increasing figures of non-compliance was also confirmed by the national reports, in particular with respect to eco-design and energy labelling and in the pyrotechnics sector:

Table 5: MSAs' Findings of non-compliance¹¹¹

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

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

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



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

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

One can also assume that the **imports of products from third countries** will represent an increasing share of products supplied on the EU market, as it went up from 24% in 2008 to over 30% in 2015. In 2015 they were estimated to value almost 750 € billions¹¹².

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

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

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

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

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

1.7 Conclusions of the evaluations

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

The first is the evaluation of Union harmonisation legislation of 2014¹¹³. One of its main outcomes was that market surveillance is considered to be the weakest part of the implementation system, partly due to the inherently difficult nature of the task and in part due to varying levels of resources and technical expertise available in different countries¹¹⁴. As

¹¹² See Annex 5.

¹¹³ COM(2014)25 and SWD(2014)23.

¹¹⁴ SWD(2014)23, section 4.8.

regards market surveillance, it pointed to the importance of coordination mechanisms, the lack of uniformity in approach to market surveillance across EU28 and differing levels of resources and technical capacity¹¹⁵. This evaluation recommended to expand information and advice to businesses, and to ensure a faster transition to e-market surveillance with more use of digital means to demonstrate compliance and communicate with market surveillance authorities.

The second is the evaluation of the market surveillance provisions of Regulation (EC) No 765/2008 which examined their effectiveness, relevance, coherence and efficiency and added value of action at EU level¹¹⁶. Its main conclusions are as follows:

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

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

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

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

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

Moreover the evaluation identified certain areas where regulatory burdens could be minimised and rules could be simplified, often as part of a wider problem or weakness of the current Regulation¹¹⁷. Specific administrative simplifications are highlighted in the impact assessment section of this report.

115 SWD(2014)23, section 7.1

116 REFIT evaluation accompanying this initiative and impact assessment

117 Evaluation, section 7.6.

Box 6: Evaluation findings REFIT potential

Evaluation	Impact assessment
<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> The discrepancies and definitions in product legislation could be addressed when the sector legislation in question is reviewed. This impact assessment covers the particular issue of the scope of investigative and enforcement powers of market surveillance authorities to cover new players in global and e-commerce supply chains (see section 1.3.3; option 2 (d) common powers for market surveillance authorities)
<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> This issue does not require a change of the Regulation and is already being addressed: In February 2017 the Commission released the first version of an interconnection between RAPEX and ICSMS. In 2016 safeguard notifications were implemented in ICSMS, with a second release due by end 2017;
<ul style="list-style-type: none"> Inconsistencies in the approach followed by Member States authorities while carrying out market surveillance (e.g. interpretation of the concept of appropriate scale of controls, penalties, degree of cross-border cooperation) could be reduced. Coordination mechanisms within Member States should be improved and simplified; 	<ul style="list-style-type: none"> The problem driver of fragmentation of market surveillance and lack of uniformity of control, resulting need for more coordination is set out in section 1.3.1 of this impact assessment. The problem of insufficiencies in the control system and lacking deterrent tools is set out in 1.3.4. Option 3(b) EU Product compliance network would improve cross-border coordination; Options 2(a) effective mutual assistance requests and 3(a) transferability of enforcement evidence and decisions provide for improvement in cooperation tools.
<ul style="list-style-type: none"> The 'market surveillance programmes' and reports on activities carried out could also benefit from simplification and more strategic use; 	<ul style="list-style-type: none"> The sub-optimal use of administrative tools is set out in section 1.3.1. Option 2 (b) member state enforcement strategies aims to improve the programming and reporting of the current Regulation.
<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> The problems with controls on imported products are set out in section 1.3.3.2.

2. WHY SHOULD THE EU ACT?

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

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

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

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

3. WHAT SHOULD BE ACHIEVED

3.1 General policy objectives

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

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

3.2 Specific policy objectives

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

1. **Reinforcing market surveillance cooperation procedures**, reducing fragmentation and inefficiencies;
2. **Increasing operational enforcement capacity**, improving efficiency of market surveillance action, targeting of controls, and availability of resources;
3. **Strengthening the enforcement toolbox**, allowing market surveillance authorities to use more deterrent, effective and future proof tools;
4. **Promoting compliance** with EU legislation on non-food products, improving accessibility of compliance information.

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

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

The Commission recognised the essential role of enforcement networks and set out to encourage and help Member States to improve their capacity to enforce EU law and make sure that administrative authorities and inspectorates are sufficiently and adequately equipped to perform their tasks¹¹⁸.

The policy options take into account similar work recently undertaken regarding enforcement in other areas, for example in the area of food and feed where Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products¹¹⁹ will increase Member States' ability to prevent, eliminate or reduce health risks to humans, animals and plants. Furthermore, the Commission put forward a proposal for the reform of the Consumer Protection Cooperation (CPC) Regulation¹²⁰, which governs the powers of enforcement authorities and the manner in which they can cooperate. In addition, the Commission proposed new rules to enable Member States' competition authorities to be more effective enforcers of EU antitrust rules¹²¹. The proposal seeks to make sure they have all the tools they require to achieve this. It is intended to further empower the Member States' competition authorities. Stronger enforcement powers are also a key issue in other recent legislative initiatives¹²² and data protection laws¹²³ and recent legislative developments in the field of fertilisers¹²⁴.

With increasing product imports yet declining resources for customs, the Customs Union's governance would need to be better geared to current and future challenges. The policy options take into account the advocated coordination and inter-agency cooperation mechanisms, enhanced risk assessments including at the level of the Customs Union to make controls more efficient and effective¹²⁵. Regarding global trade, the Commission reaffirmed its policy based on openness and cooperation. However to combat situations where rules exist

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

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

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

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

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

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

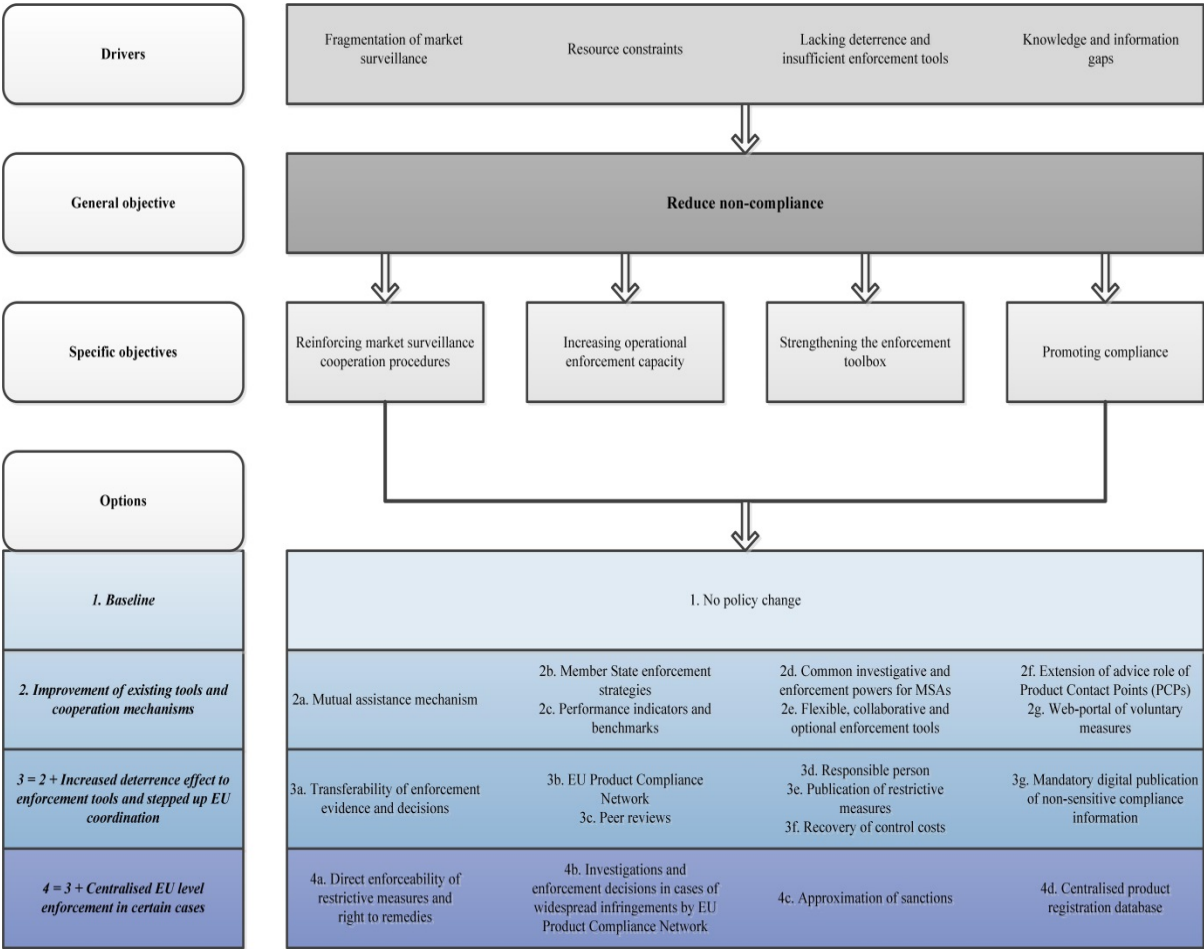
124 COM(2016)157, SWD(2016)64 and 65.

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

but are not respected, the EU would need to have the instruments at its disposal to restore a level playing field and act decisively against countries or companies that engage in unfair practices. Strong enforcement of EU rules would also ensure that all companies present or active in the EU which break the rules are effectively sanctioned, in cooperation with Member State authorities and strengthened EU customs risk management in order to facilitate and accelerate legitimate EU trade, while ensuring the safety and security of citizens by stopping fake or dangerous goods permeating EU borders¹²⁶.

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

Figure 10: Policy objectives and options to achieve them



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

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

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

Box 7: Discarded options

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

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

4.1 Option 1 – Baseline

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

4.2 Option 2 – Improvement of existing tools and cooperation mechanisms

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

The measures in this option are

Reinforcing cooperation procedures

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

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

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

Increasing operational enforcement capacity

2(b) Member State enforcement strategies to improve data and knowledge sharing and to help targeting enforcement and capacity building actions. This measure would entail a modification and streamlining of the existing requirements on Member States to report control programmes and evaluations of their market surveillance activities¹²⁹ and a clearer specification of principles of risks assessment that could be used to select and target controls. The enforcement strategies would in particular contain an assessment of compliance and capacity gaps, priority areas and actions to address these gaps and monitoring. To support the implementation of the strategies and capacity building in Member States, the financing provisions would cover the strategies (within the limits of current multi-annual financial framework, up to 2021; a future expansion of funding could build on the strategies as a tool to access EU co-funding, but is as such not part of this impact assessment¹³⁰). This would contribute to address the problem of lack of resources for controls identified by the evaluation¹³¹.

2(c) Performance indicators and benchmarks. Based on the national strategies, indicators and benchmarks would be built to compare information across Member States and to facilitate monitoring¹³². These measures would address the difficulties highlighted in the evaluation as regards the implementation of the current provisions on market surveillance programmes and reports on activities carried out.¹³³

Strengthening the enforcement toolbox

2(d) Adapting the investigative and enforcement powers of market surveillance authorities to new market developments, the global supply chains and e-commerce¹³⁴. The powers would span the full supply chain, including traders or intermediaries that could be relevant to the investigation¹³⁵. The powers should provide a stronger basis to require cooperation from traders in investigations and/or enforcement and sanction absence of such cooperation or responses, which would be particularly relevant for controls on imports from 3rd countries. With developing e-commerce, the toolbox of authorities should also more explicitly include powers relevant to digital supply chains, such as investigative powers in relation to internet traders, performance

128 See previous section 1.3.1.

129 Regulation (EC) No 765/2008 Article 18 (5) (6)

130 The possibility and in particular the definitive size of a fund or an enforcement component in a new, larger EU fund (including possible continuations of current funds e.g. COSME, Consumer programmes) is not examined as such in this impact assessment. Such an option would depend on the new multi-annual financial framework for the EU budget from 2021 onwards for which the outlines will only become available in the next year(s).

131 See previous section 1.3.2.

132 Besides resources and number of controls, which form the core of the current indicators, this would involve more systematic information collection on compliance gaps and parameters that underlie Member States profiles in terms of market structures, enforcement policies and organisation (see Annex 12).

133 See chapter 7.6 of the evaluation.

134 Member States are required to provide their market surveillance authorities with adequate powers; Article 18(3), 19 (1) of Regulation (EC) No 765/2008.

135 See Annex 13 section 1.2 for investigative and enforcement powers and their current availability in Member States

of on-line test-purchases or, ultimately, enforcement powers to require removal of on-line content related to non-compliant products¹³⁶.

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

Promoting compliance

- 2(f) **An extension of the advice role of the Product Contact Points (PCP).** The PCPs currently inform and advise businesses in the area of mutual recognition of non-harmonised products, based on Regulation 764/2008¹³⁷ ¹³⁸. These PCPs could be tasked to also respond to information requests from businesses on harmonised EU product rules. Typical needs for **tailor-made information or advice** would be which EU product legislation applies to the businesses' product(s) and how several requirements could interact if more legislative acts apply to one product (e.g. in the case of complex products)¹³⁹. A better understanding of whether and how legal requirements would apply to their products would allow businesses to factor these in into their operations, prevent non-compliance and alleviate the need for possible corrective measures by market surveillance authorities.

- 2(g) **A complement to the web-portal hosted by the Commission¹⁴⁰ on voluntary measures taken by businesses on dangerous products.** This new portal would allow businesses to communicate to the EU-wide public any **voluntary measures they undertake to withdraw or recall unsafe, non-compliant products**. Such a web-portal would help businesses to inform consumers and could assist also in reaching traders in complex decentralised distribution chains, local shops or e-commerce intermediaries. The use of the portal would be optional and would not alter the economic operators' existing underlying obligations to take corrective measures and to inform Member States authorities about such measures¹⁴¹.

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

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

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

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

¹⁴⁰ <https://webgate.ec.europa.eu/gpsd-ba/index.do>;

https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main_search

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

Variants of the measures considered but discarded at early stage and not further assessed in detail¹⁴²:

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

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

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

The additional measures in this option are:

Reinforcing cooperation procedures

3(a) Cross-jurisdictional transferability of enforcement evidence and decisions. This measure would add provisions in the market surveillance framework to facilitate re-use of evidence, test-reports and decisions of one market surveillance authority for use in and by authorities in other Member States.

This measure would add legal principles in the market surveillance framework to ensure the **portability of test results**, a **presumption** that products found to be non-compliant in Member State A are also non-compliant in Member State B, and similarly in the area of control of imports, that confirmed non-compliances by market surveillance controls leading to customs' refusal to the release a product for free circulation are communicated and also refused in other Member States¹⁴³.

The legal principles would clarify in particular that market surveillance authorities can issue **restrictive measures**¹⁴⁴ directly to economic operators in other Member State(s) – e.g. a non-compliant product is found in distribution in the authorities' member state while the responsible manufacturer is established in another Member State. This would facilitate the follow-up of national restrictive measures that have been found justified after the safeguard clause mechanisms¹⁴⁵ foreseen in the EU product legislation¹⁴⁶,

¹⁴² For details see Annex 14 (point 2.6) and Annex 12 (point 2).

¹⁴³ A general cooperation and information exchange requirement and communication of decisions from market surveillance authorities to customs are covered by Article 27(5) and 29 (5) of Regulation (EC) N° 765/2008.

¹⁴⁴ For requests to undertake voluntary measures, Article 19 of Regulation (EC) No 765/2008 already provides for direct issuance to economic operators in other member states by market surveillance authorities.

¹⁴⁵ Where a market surveillance authority finds that a non-compliance is not limited to its national territory, the safeguard clause mechanisms requires it to notify any restrictive measure to other member states and the Commission, who can react and/or submit objections within a given period set in the legislative act (normally 3 months). If no objection is raised within the deadline, the notified measure is deemed justified and other member states are required to take restrictive measures against the product concerned. When an objection is raised, the Commission must evaluate the measure, and after consultation with the member states and the economic operator, decides whether or not the notified restrictive measure is justified. In case the measure is justified, all member states are required to take restrictive measures against the product concerned.

¹⁴⁶ See reference provisions R31(4) to R32, Decision (EC) No 768/2008, integrated since 2008 into around 20 EU product harmonisation legislative acts; the 2013 proposal on market surveillance generalised this safeguard mechanism for all products and sectors covered by the horizontal regulation.

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

These measures would help reducing the inefficiency in controls and ambiguity on the jurisdiction of authorities due to the current fragmentation of market surveillance competences in the Single Market identified by the evaluation¹⁴⁷.

Increasing operational enforcement capacity

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

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

This measure would provide a formalised governance structure and step up the operational support capacity, encompassing and expanding existing Commission support (e.g. indicators collection, studies, common IT-tools), ad-hoc co-funding support to market surveillance authorities' control campaigns or projects, organisation of around 50 meetings of sector and market surveillance experts¹⁴⁸.

The Network would be composed of:

- an EU Product Compliance Board, composed of Member States' representatives and the Commission. It would define the priorities for common market surveillance actions and monitor the implementation of the Network's work programme, coordinate and steer the administrative coordination group's activity¹⁴⁹.
- Administrative Cooperation Groups (ADCO's)¹⁵⁰, thematic and sectoral groups of market surveillance competent authorities' representatives. These groups would set-up and coordinate common market surveillance control campaigns, ensure coordinated application of product legislation, develop common practices, methodologies, identify issues of shared interest and suggest common approaches on these.
- Secretariat: it would prepare and organise the meetings of the Board and ADCOs, carry out all the technical, legal analysis and research, IT systems analysis and development necessary to the Network's action. Secretariat staff would also take care of the administrative/financial handling related to joint

147 See previous section 1.3.1.

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

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

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

actions.

For this measure the impact assessment considers different variants of **size** (Secretariat's human and financial resources) to modulate the resources input and relate these to the anticipated increased operational actions that the network could achieve. Resources range from 30 to 90 staff and € 6 – 14 million/year¹⁵¹. The Network could be hosted by the Commission or in an existing EU agency¹⁵², the EU Intellectual Property Office (EU-IPO¹⁵³) in particular.

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

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

Strengthening the enforcement toolbox

- 3(d) Person responsible for compliance information in the EU**¹⁵⁵. To improve the **enforceability of decisions** by market surveillance authorities, especially vis-à-vis 3rd country businesses that place products on the EU market. Such businesses (i.e. non-EU manufacturers) would have to appoint a person responsible for compliance information in the EU when they do not work through an importer or an authorised representative. This will address the problem of lack of jurisdiction of market surveillance authorities vis-à-vis manufacturers located in third countries, as identified in the evaluation¹⁵⁶.

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

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

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

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

154 See chapter 6.1.2 of the evaluation.

155 See also Annex 13 section 2

156 See previous section 1.3.3.2.

obligations of market surveillance authorities to share information on restrictive measures with authorities in other member states and with the Commission¹⁵⁷, to communicate measures concerning products presenting a serious risk through the Rapid Alert system (RAPEX) also published on the Commission's website¹⁵⁸ and to alert users in their territories¹⁵⁹.

- 3(f) Recovery of control costs in the case of non-compliant products.** Common provisions to ensure a more systematic recovery of control costs in the case of non-compliant products, thus generalising the practice of costs recovery. The legal powers for costs recovery as a matter of principle are already available in a majority of Member States¹⁶⁰ but not necessarily applied. A similar tool has been operational for many years in the area of food controls¹⁶¹ and it would align powers of market surveillance in this respect with cost recovery options available to customs¹⁶². In cases of **suspected non-compliance**, market surveillance authorities could also order an economic operator to provide evidence (e.g. tests) to demonstrate compliance, with the costs and the burden of the requested conformity proof being placed directly on the concerned trader (instead of via recovery, which may be uncertain for instance in the case of imports).

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

Promoting compliance

- 3(g) Mandatory digital publication of compliance information.** The publication obligation would be limited to non-sensitive information, in particular the Declaration of Conformity¹⁶⁴. The economic operators concerned are already required to draw up the declaration and to make it available to other economic operators in their supply chain and to market surveillance authorities on request. This measure would add a proactive publication via digital means so that easier and widespread accessibility could be ensured.

¹⁵⁷ Provisions on procedures to deal with products presenting a risk at national level and union safeguard procedures, reference articles R31 to R33 Decision (EC) No 768/2008; Articles 20, 22, 23 of Regulation (EC) No 765/2008.

¹⁵⁸ Article 22 of Regulation (EC) No 765/2008.

¹⁵⁹ Article 19(2) of Regulation (EC) No 765/2008.

¹⁶⁰ In total 21 of 22 Member States that responded to the evaluation survey, indicated they had such powers. In 14 Member States this power is available in over 14 sectors; in a further 7 Member States the power is available in a more limited number of sectors.

¹⁶¹ The approach of imposing administrative fees to recover inspection costs has been for a long time common practice for controls in the food area (https://ec.europa.eu/food/safety/official_controls/legislation_en). In the non-food area has been advocated by stakeholders to help authorities to effectively take action against non-compliant goods, as controls (e.g. laboratory tests) and corrective actions (e.g. recalls and destruction of products) are very costly.

¹⁶² Articles 189, 197 and 198 of the Union Customs Code regulate the sharing or recovery of costs related to the transport of goods to the place of examination, the handling and the taking of samples, as well as costs related to the confiscation or the destruction of goods.

¹⁶³ See previous section 1.3.3.

¹⁶⁴ By drawing up and signing the EU Declaration of Conformity the manufacturer assumes the responsibility for the conformity of the product, declaring that the fulfilment of the applicable EU product requirements has been demonstrated. Authorised representatives and importers are required to keep copies of the declaration. A model declaration is in Annex III of Decision (EC) No 768/2008. For construction products a Declaration of Performance applies.

Variants of the measures considered but discarded at early stage and not further assessed in detail¹⁶⁵:

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

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

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

The additional measures in this option are:

Reinforcing cooperation procedures

4(a) Direct enforceability of restrictive measures and right to remedies. EU law would allow the direct enforceability of restrictive measures taken by a market surveillance authority in one Member State, to all other Member States wherever the same non-compliant product would occur. This measure would extent a national restrictive measure banning a non-compliant product from its national market, to a ban throughout the EU and for any further imports of the same product¹⁶⁶. This measure would involve extending the available mechanisms by which authorities and the Commission currently notify each other and scrutinise restrictive measures with a cross-border aspect (see safeguard clause mechanism, option 3(e) above) to cover also restrictive measures of a market surveillance authority for non-compliances that seem limited to the national territory at the moment of investigation. The precise geographical extent of the non-compliance may not always be clear and/or could change in the future (e.g. complex supply chains such as imports via several wholesalers and retailers). The responsible economic operator (manufacturer, importer) would be heard prior to the confirmation of the initial national measure and the restrictive measure as such would be open to administrative and/or judicial reviews in the Member State in accordance with its national rules.

Moreover, non-compliance of a product leading to a restrictive measure by market surveillance authorities also entails the right to **remedies** for the consumers and professional end-users who purchased such product. They could return a non-compliant

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

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

product and request remedies from the economic operator from whom they bought the product. These remedies would apply the principles to situations of non-compliance¹⁶⁷. Market surveillance authorities in all Member States would also be empowered to order an economic operator to provide remedies on a case-by-case basis to end-users¹⁶⁸.

Increasing operational enforcement capacity

4(b) EU investigations for widespread infringements. An additional mandate to the EU Product Compliance Network (option 3(f) above) to perform investigations and take enforcement decisions, in cases of widespread infringements¹⁶⁹. This measure would introduce the possibility for the EU product compliance network structure to conduct an investigation and take an enforcement decision for widespread infringements with significant impact on a large part of the EU territory. The opening of such an investigation would be subject to the agreement of the Commission and Member States, who would decide on the network's priorities and such EU level investigations and decisions.

Strengthening the enforcement toolbox

4(c) Approximation of sanctions, for different types of non-compliance and levels of sanctions, in particular financial penalties. This measure would define in the legal framework **categories of non-compliance** (e.g. formal and/or substantive non-compliance, categories by severity, extent of the non-compliance) and **corresponding nature/level of sanctions**, both administrative and criminal, including minimum levels of penalties. The measure would complement the current legislative framework which sets out a general obligation on Member States to provide for and apply 'effective, proportionate, and dissuasive' sanctions, including criminal sanctions for serious infringements and possible increased penalties for repeat offenses¹⁷⁰. In some cases the product legislation adds general additional principles to take into account (e.g. the extent of non-compliance and the number of units of non-complying products placed on the EU market¹⁷¹).

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

Promoting compliance

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

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

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

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

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

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

¹⁷² See chapter 6.1.2.2 of the evaluation.

sensitive (technical documentation) as well as non-sensitive information. This measure would involve a centrally managed database, by the Commission, and require economic operators to upload and keep up to date all the relevant technical compliance documentation. Access to the information would be separated into **a public part** (declaration of conformity, measure (a) option 3 above) and **a non-public part** for commercially sensitive technical documentation which would be easily but securely accessible for market surveillance authorities and the Commission¹⁷³.

Variants of the measures considered but discarded at early stage and not further assessed in detail¹⁷⁴:

- Carrying out of investigations and ultimately sanctioning of economic operators by the Commission separate from and instead of Member States.

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

5.1 Option 1 - baseline

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

5.2 Option 2 – Improvement of existing tools and cooperation mechanisms

Effectiveness in achieving the objectives

Reinforcing cooperation procedures

2(a) Mutual assistance would allow for efficient work sharing since market surveillance authorities carry out complementary tasks within the remit of their respective jurisdictions. Thanks to the formalised mutual assistance mechanism in this option, the exchange of cases between Member States would become smoother, with faster responses, as there will be clearer common principles for the assistance requests and deadlines¹⁷⁵. Overall, it should allow reducing the rate of authorities that would never or rarely be able to follow-up on restrictive measures of other Member States, and lead to more regular effective help to the requesting authority¹⁷⁶.

When market surveillance authorities work on the basis of a common toolbox, exchanging cases and responding to assistance requests from other countries will become easier (measure

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

¹⁷⁴ For details see Annex 13 (point 11).

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

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

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

The combination of the mutual assistance and the implementation of certain enforcement powers and tools (system audits, compliance programmes with large manufacturers and importers) would allow over time important efficiency gains¹⁷⁷ (see measures e and f in this option).

Increasing operational enforcement capacity

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

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

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

Strengthening the enforcement toolbox

2(d) Thanks to a clearer defined set of **investigative and enforcement powers**, market surveillance authorities across the EU would be able to work with common effective and deterrent tools, which would facilitate cross-border enforcement¹⁷⁸ and the coherence of enforcement throughout the EU (in similar cases, all authorities would be able to apply equivalent investigation tools and enforcement powers). In the baseline an average 18-19 Member States already have the envisaged powers in a majority or some sectors (in 11-13 Member States market surveillance authorities have the powers in over 14 of 33 product sectors; a further 7-8 Member States in some product sectors)¹⁷⁹. In the future these powers

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

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

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

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

Moreover, the powers to require information and cooperation from any trader, intermediaries and relevant natural or legal persons in the supply chain, and where necessary sanction absence of response¹⁸⁰ would equip market surveillance authorities better for the frequent situations where the economic operator is located in a 3rd country jurisdiction or difficult to trace or elusive (e-commerce)¹⁸¹.

The availability of powers which are particularly relevant for e-commerce would also significantly improve (mystery-shopping, requiring illegal content to be removed from websites, suspension of websites¹⁸²). Availability of such powers directly to market surveillance authorities would allow them to react swiftly which is needed to be effective in the highly versatile e-commerce context. As a result, more non-compliant or unsafe products offers could be removed from the internet faster.

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

2(e) Besides traditional enforcement powers, optional, **collaborative enforcement tools** and **compliance assistance schemes** with businesses would best be integral components of a comprehensive market surveillance regime¹⁸³. This option would incentivise Member States to develop more compliance schemes as part of their enforcement policy mix¹⁸⁴ (together with measures 2(b) and 2(f)). Businesses and market surveillance authorities could justify the cost they deploy for such tools through reduced inspection scope or frequency, and that compliance problems could be addressed efficiently, in a preventative manner instead of by costly corrective action¹⁸⁵. Compliance programmes could help businesses to have more efficient

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

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

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

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

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

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

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

‘one-stop-shop’ contacts with inspections and regulatory bodies, and have access to consistent, coordinated advice¹⁸⁶. This would be especially relevant in Member States where market surveillance is carried out at several levels (national, regional and local).

Market surveillance authorities may however be cautious to engage in structural pro-active co-operation with sector organisations or fees-based assistance to businesses as it may blur the line with their role as independent inspectors (e.g. who decides what should be controlled). While interesting as a source of intelligence, evidence of non-compliance brought forward by businesses, even based on recognised testing-standards, would in many Member States not be admissible as formal evidence in proceedings¹⁸⁷.

Promoting compliance

2(f) Thanks to the extension of the **Product Contact Points** to harmonised product legislation, businesses would have easy access to dependable information and advice¹⁸⁸.

The Product Contact Points are available in all Member States, thus familiar with local chamber of commerce and associations and closer to **smaller businesses** that may have difficulties in easily accessing information or advice from EU centralised sources. By contrast **larger businesses** would be more likely to use the “formal” partnership or compliance programmes¹⁸⁹.

2(g) The **common EU web-portal for voluntary measures** would allow faster and better information for consumers enabling them to timely act and thus protect their health and safety. Distributors would similarly be better informed. Given the overall positive reactions from stakeholders, it can be anticipated that the number of voluntary measures in the portal would increase rapidly, to around at least 800 notifications/year¹⁹⁰.

Stakeholders' views on the option¹⁹¹

2(a) Tools such as the mechanism for **mutual assistance requests** would help to work efficiently across jurisdictional boundaries, as clearly advocated by authorities and businesses on different occasions.¹⁹² The majority of respondents to the public consultation (80% of authorities, 73% of businesses and 73% of consumers and other respondents) agree that stricter obligations for authorities to respond to requests for mutual assistance by other authorities would help enforcement vis-à-vis businesses located in another Member State¹⁹³.

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

186 E.g. Primary authority scheme, UK (Annex 14).

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

188 'Lack of knowledge' by businesses was flagged by 80 % of respondents (190 of 239) in the public consultation among the top 3 reasons underlying non-compliance, and 27% ranked it the top 1 reason.

189 This was confirmed in the review of the 'Primary Authority' scheme in the UK in 2013; the scheme offers businesses the opportunity to establish a partnership with one authority who then coordinates advice and guidance to the business across a range of regulatory matters (one-stop-shop principle) <https://primaryauthorityregister.info/par/images/documents/acl-pa-evaluation.pdf>

190 Estimate based on the number of notifications of voluntary measures via the RAPEX system. Over the past 5 years these averaged 800, increasing from 609 (2012) to 922 (2016)

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

192 See the results of informal consultation of Member States and minutes of the June 2016 public event (see Annex 2 sections 1.2.2 and 4).

193 See of the brief factual summary of the initiative, p. 21 (<http://ec.europa.eu/DocsRoom/documents/21181/attachments/1/translations/en/renditions/native>).

market surveillance in the EU, and compare Member State performance. In the public consultation 69% (131 of 190) of respondents strongly agreed/agreed¹⁹⁴ that better verification by the Commission of the functioning of market surveillance in Member States would make market surveillance in the Single Market more effective (55% of authorities, 78% businesses).

2(d) In the public consultation stakeholders expressed mixed¹⁹⁵ views on the general impact that "more" **powers** for market surveillance authorities could have on deterrence and/or resources. Specific powers were rated with varying degrees of approval: 65% of respondents believe authorities should have power to carry out an inspection on behalf of another EU Member State's authority upon request; 59% of respondents believe authorities should have the power to notify acts on behalf of another EU Member State's authority upon request; 45% of respondents believe authorities should have the power to enforce fines on behalf of another EU Member State's authority upon request. The effectiveness and the necessity of powers to act against non-compliant products even if the economic operator is not based in the EU are supported by business stakeholders¹⁹⁶ and authorities.¹⁹⁷

Member States market surveillance experts recognised that a common set of powers would help to facilitate cross-border cooperation and provide for an enforcement level-playing field across the EU. While some specific powers would need to be used only as last resort (e.g. requiring a take-down of a website, not merely specific illegal content it may feature), the experts expressed broad support for the possible range of powers that could be included in the market surveillance framework¹⁹⁸.

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

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

2(g) A majority of Member States supported²⁰⁰ the creation of a **common European portal on voluntary measures** as long as this entailed a voluntary reporting by the economic

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

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

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

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

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

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

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

operators without any investigation or approval by the national competent authority. Also other stakeholders generally agreed²⁰¹ on the usefulness of comprehensive and up-to-date information on a single website.

Administrative simplifications

As explained in the evaluation most of the enforcement costs stemming from current market surveillance rules are borne by public authorities, while costs on businesses only relate to information obligations (responding to requests from authorities, information on non-compliances detected) and are therefore regarded as insignificant by them²⁰². For this reason this section focuses on measures in this option that would result in specific benefits in terms of administrative simplifications for authorities.

The ability to apply **investigative and enforcement powers** across all relevant parties in the product supply chain, streamlining the applicable definitions, implies an important simplification for market surveillance authorities. They will be able to investigate, require cooperation and act where needed and where their action can be most effective. The flexibility to work across the supply chain would be a major improvement in legal empowerment and certainty for market surveillance authorities who in the current system are confronted with varying definitions and texts, in particular for e-commerce²⁰³. While online sales and market surveillance will increase, it is difficult to project the number of enforcement cases authorities would take on in future years and more in particular the specific proportion of infringement cases linked to new, additional economic players in the supply chain²⁰⁴. In the longer term Member States would also benefit from the opportunity to organise their market surveillance more flexibly, as the powers will be common, independent of specific sectors or legislation.

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

The **reporting requirements** on Member States and communication of control programmes would be streamlined. The common IT-tool (ICSMS) would be used for simpler and quicker notification of competent authorities and exchange information on planned controls. This could result in the short term in some reduction of administrative burden linked to the communication to the Commission of control programmes²⁰⁵. Most costs are linked to the

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

202 See chapter 6.2 of the evaluation.

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

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

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

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

Compliance and implementation costs

Costs for businesses

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

Costs for Member States

2(a) Mutual assistance requests: The authority receiving a request for mutual assistance would incur the operational costs related to the necessary investigative or enforcement steps. The size of the costs would depend on the specific case and number of requests²⁰⁶. In most cases, the authorities receiving a mutual assistance request would only carry out ad hoc steps (e.g. request of information) while the requesting authorities would maintain the responsibility. The additional costs per request would amount only to a relatively small portion of the average costs of inspections (which are estimated roughly to average 703€, ranging from 50€ - 5 000€²⁰⁷). In the baseline scenario, Member States are already required to follow up on other authorities' notifications; the mutual assistance request mechanism may lead to more requests being circulated among Member States. Depending on the nature of the request, this may imply more effort for market surveillance authorities, i.e. more systematic researches of non-compliant products found abroad and, if needed, adoption of a higher number of decisions. On balance the effort would however be off-set by efficiency gains that market surveillance authorities could obtain by receiving assistance for their own cases, and the reliance on systems audits on manufacturers and importers in the Member States where these are operators are established.

2(b) Enforcement strategies: Under the current Regulation (EC) N° 765/2008 Member States are obliged to set up control programmes and assess and report on the effectiveness of such programmes (Article 18 (5) and (6)). The use of 'enforcement strategies' would imply a shift in the contents of such programmes, rather than adding a new layer or reporting obligation²⁰⁸.

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

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

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

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

Besides initial alignment costs to adapt to the new form of programmes (estimated on average 15.000€ per MS²⁰⁹ in the first year), no significant additional administrative burden would be anticipated for Member States²¹⁰.

2(d) One-off training costs to familiarise market surveillance authorities with the **new common powers** can be estimated at 2 000€ per authority (~500 000€ for all Member States)²¹¹. The most affected Member States would be those who currently lack certain investigative and/or enforcement powers: overall 18-19 of Member States provide for the powers either in a majority or in some product sectors. Member States who currently have the least number of powers and who would thus face more adaptation are AT, BE, ES, IE, IT, and to a lesser extent DK and RO²¹². The costs of optional, **collaborative enforcement tools** would depend on the actual uptake by businesses and associations. The main challenge for authorities would seem to be resources, both human and financial. When businesses would pay a fee for the services rendered, authorities would not incur additional costs.

2(f) Product Contact Points²¹³ are already available in all Member States and run by experts in product legislation. Due to the expansion of the remit of PCPs to harmonised goods, it would be likely that the number of information requests would increase quite sharply requiring an estimated 1 to 3 supplementary FTE per PCP (running costs for all 28 Member States could total 3,5 M€/year²¹⁴). Set-up costs would be negligible as the strengthening of the Product Contact Points is already planned to deal with their mutual recognition tasks²¹⁵.

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

Costs for the Commission/EU budget

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

- XXII, impact assessment proposal for a regulation on official controls to ensure the application of food and feed law, SWD(2013) 167 final, May 2013). The transmission of control programmes via the IT tool ICSMS would imply an administrative simplification estimated at 2 days (0,01 FTE/year) by Member State.
- 209 One-off efforts to adapt to new format and contents, around 0.2 to 0.3 FTE in the first year, i.e. 12,400 – 18,600 € (average staff costs 61.971€/year based on EUROSTAT 2006, updated 2010, for category ICSO1 legislators and senior officials; including salary, non-wage labour costs, 25% overhead costs)
- 210 In the longer term, post 2020, the strategies could be the basis for applications for funding, while at the same time constitute an instrument for strategic planning and coordination.
- 211 Estimate aligned with the impact assessment for the Consumer Protection Cooperation. The powers in this initiative are largely aligned with the CPC proposal. Most affected are 32-35% of Member States who would have more new powers to foresee for market surveillance authorities and/or to extend significantly the coverage of powers to more product sectors: 35%*500 authorities*2000€ = 350,000 €, plus general training and familiarisation for others. The estimates of number of Member States concerned are based on a survey carried out as part of the evaluation of Regulation (EC) n° 765/2008, in which 22 Member States responded. The % used is rounded upward to 35% and applied to the full number of 500 authorities in order to include more rather than too few possible adaptation efforts. 15 (68%) of the 22 reporting MS had 10 or more of the 16 powers in over 14 sectors; 7 (32%) Member States had fewer than 10 of the 16 powers in over 14 sectors.
- 212 See availability of powers in Member States, Annex 13.
- 213 Annex 11 (2).
- 214 1 FTE on average 61,971€/year per Member State; 3 FTE would be 185,913 €/year (staff costs based on EUROSTAT 2006, updated 2010, for category ICSO1 legislators and senior officials; including salary, non-wage labour costs, 25% overhead costs)
- 215 Product Contact Point are operational in all Member States, dealing with mutual recognition requests. Reference is made to the impact assessment with respect to the initiative on mutual recognition indicating that most Product Contact Points are integrated in an already existing department dealing with internal market issues. PCPs, at the moment, are served by one person on average. The Product Contact Points would be strengthened to improve the functioning of the mutual recognition principle.

2(b) and 2(c) Enforcement strategies and performance indicators: Based on the existing funding provisions of Regulation 765/2008, and within the existing spending ceilings, grant co-funding could be directed to some first national strategies as pilot cases in the short term (1-3M€/year). A possible new fund or part of a new fund post 2020 to support Member State enforcement strategies would require a considerable co-funding from the EU budget to ensure adequate coverage of all Member States and sectors²¹⁶.

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

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

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

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

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

Social Impacts

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

Environmental impacts

No significant environmental impacts were identified.

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

Impacts on fundamental rights (EU Charter of fundamental rights)	
<p>The implementation of the investigative and enforcement powers in this option may impact on certain fundamental rights (right to due process/effective remedy, rights of defence, freedom to conduct business, data-protection and right to privacy). In accordance with Article 52 of the Charter a careful balancing of limitation to these rights has to be made with the objective of general interest of protection consumers, users and the environment from unsafe and non-compliant products. Market surveillance authorities would use powers on the basis of proportionality and necessity (e.g. possibly more intrusive investigative powers would only be used if needed for the investigation and no less-intrusive alternative would be available to obtain the evidence; certain enforcement powers such as requiring the closure of a website could only be used as last-resort). Moreover the use of the powers would be subject to national procedural safeguards.</p>	
Summary assessment of the option (2)	
Effectiveness in achieving the policy objectives	
<i>Reinforcing cooperation procedures</i>	++
<i>Increasing operational enforcement capacity</i>	+
<i>Strengthening the enforcement toolbox</i>	++
<i>Promoting compliance</i>	++
Costs	
For economic operators	neutral
For Member States	-
For the Commission/Impacts on the EU budget	-
Administrative simplification	++
<p>Magnitude of impact as compared with the baseline scenario (the baseline is indicated as 0): +++ strongly positive; ++moderately positive, + positive; neutral; - - - strongly negative; - - moderately negative, - negative;? uncertain; n.a. not applicable. When talking about costs: + means 'savings', while – means 'cost'</p>	

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

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

their own decisions more systematically on the findings of the initial authority and then consult the concerned businesses, instead of investigating a case from scratch²¹⁷.

Overall, these measures would allow the majority of authorities to follow-up at least regularly on restrictive measures of other Member States²¹⁸. They would significantly reduce duplication of work and the inefficiencies linked to the need to carry out new tests or proceedings in different Member States as regards the non-compliance of the same products (either manufactured in the EU or imported from third countries)²¹⁹.

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

Increasing operational enforcement capacity

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

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

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

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

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

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

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

areas where controls would be weaker in the Single Market.

By the **different size variants** of the Network, moderately (low variant) to significantly more (medium to high variant) activity could be undertaken and corresponding results achieved²²⁰. The most significant tasks and resources of the Network would be concentrated on the management of coordinated actions, market studies and common priority setting for these actions, as well as the management of communication and IT systems that would need to link up market surveillance authorities and customs to exchange relevant enforcement information. The depth and impact of the tasks carried out critically depend on the staffing level and operational budget allocated to the Network. The biggest difference would be:

- The low estimated size of the Network: The number of yearly coordinated control campaigns could double, to around 1 campaign every 2 years in the 25 product sectors where ADCO groups currently exist²²¹.
- The medium and higher estimated size would allow increasing control campaigns more significantly, by a factor 5 to 10, covering more sectors and products, involving more member states and addressing cross-cutting issues (e.g. online sales, complex products)²²². This would allow stepping up joint actions to 35-40/year (~at least 1 campaign/year per sector, medium size) or 75-80/year (~ at least 2 campaigns/year per sector, upper estimated size).
- The yearly number of new product controls records in the IT tool ICSMS could at least double, as all Member States would be linked up to ICSMS and its usage would be stimulated by the joint control campaigns that the EU Product Compliance Network would support²²³. In the lower estimate progress may require a longer period of time and only a more step-wise upscaling of ICSMS would be feasible with fewer resources. The impact of the Network will range from addressing merely the basic needs of the existing systems (lower estimate) to significantly expanding their functionalities to support more extensive monitoring of enforcement actions, interfacing with Member State systems and efficient information relay to a public website (medium estimate), up to ensuring efficient interoperability with Member States and customs systems (upper estimate).

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

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

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

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

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

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

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

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

- Within the Commission the mobilisation of resources would be subject to more constraints compared to the EU-IPO hosting option, which has more flexibility to hire expertise as well as using its own operational budget resources. To establish and maintain the Network's secretariat support structure, the Commission would have to exploit synergies and redeploy staff from different departments in a context of competing policy demands on its resources. The EU-IPO hosting variant would offer better prospects for upscaling of the Network to the medium size variant, which is more performant as regards the impacts it could achieve.
- The legal construct of the Compliance and Enforcement initiative would be more complex in case of hosting of the Network by the EU-IPO, given that its founding regulation would need to be amended to include market surveillance tasks in its mandate²²⁴, as well as some additional financial control and monitoring provisions should the agency require in the future a possible ad-hoc grant or subsidy from the EU budget to complement its existing resources. Given the recent difficult reform of the EU trade mark regulation, this indirect re-opening of the EU-IPO founding regulation may imply a risk regarding the adoptability of the legal proposal.

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

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

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

Strengthening the enforcement toolbox

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

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

information such as the technical file, product samples etc. via such a person responsible for compliance information in the EU²²⁵.

Respectively 85% and 69% of respondents in the public consultation agreed that the inclusion of an obligation to have an authorised representative and the possibility to broaden the responsibility of main contractors of the manufacturer (lacking other responsible persons) would increase effectiveness of enforcement. This would also be consistent with other policy areas such as data protection²²⁶, and obligations in certain product sectors²²⁷.

3(e) The **publication of information on restrictive** measures would increase the transparency of information concerning compliance of products. Besides a blame message, publishing information on enforcement decisions also sends a message about correct behaviour therefore providing guidance to firms as to the correct implementation of product requirements²²⁸. Availability of information on specific examples of non-compliances, especially when further disseminated by chambers of commerce and industry associations, also contributes to the goal of helping economic operators to comply. This measure will increase public opinion's awareness about the relevance of compliance and allow for increasing pressure from civil society and businesses peers²²⁹. Disclosing information on non-compliant products identified by authorities and the companies involved in their supply triggers and empowers third parties (competitors, industry and consumers associations, etc.) to act as watchdogs pressuring companies to comply²³⁰. They also allow responsible buyers to make more informed choice when purchasing products.

3(f) The more systematic **recovery of control costs** in the case of non-compliant products would have an important deterrent effect as it would increase the costs of infringement both in terms of money (recovery of costs borne by authorities for the controls and corrective measures)²³¹ and with the **publication of restrictive measures** also in terms of reputation²³². The wider and more consistent application of cost recovery in all Member States would also level out possible perceived cost advantages or areas with weaker controls that could be exploited by unscrupulous traders.

Promoting compliance

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

225 See Annex 13, chapter 2.

226 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG&toc=OJ.L:2016:119:TOC

227 Cosmetics, medical devices, chemicals (REACH).

228 Judith van Erp, *Naming without shaming*, Regulation and Governance (2011) 5, 287-308

229 See <http://www.howtoregulate.org/wp-content/uploads/2015/04/Handbook-INT-V1-3.pdf> (section 7.11.2)

230 Gunningham N. et al. (2004) *Social License and Environmental protection: why businesses go beyond compliance*. Law and Social Inquiry 29, 307-341.

231 Although these are not fines, in practice they would be perceived as such by business. Therefore, as regards to their impact it is noted that 65% of respondents to the public consultation consider that deterrence of market surveillance would increase by imposing higher fines for serious non-compliance.

232 74% respondents to the public consultation believe deterrence could be increased by giving more publicity to restrictive measures adopted against non-compliance would increase (reputation effect). Similar measures are used for instance by UK authorities to strengthen the enforcement of minimum wages rules: <http://www.bbc.com/news/uk-27751722>.

233 The benefits of such mandatory publication of basic compliance information were rated high compared to voluntary options. Positive impacts were noted regarding access to information, transparency, and ultimately positive impacts on compliance levels, product safety and environment (table 10, Impact digital compliance options, VVA, 2017; annex 14)

Publication in decentralised manner, on the companies' websites, would come at minimal cost and offer flexibility for manufacturers and importers who would be responsible for publishing the declarations of conformity. The drawback is that it would be less easy for all interested parties, including traders, consumers and market surveillance authorities to find the information when it is dispersed over many websites. Additional tools (such as adding automatic object and data identification²³⁴) would however overcome this disadvantage.

Stakeholders' views on the option²³⁵

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

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

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

In March 2017, the Commission consulted Member State market surveillance experts on the possible Network, its key tasks²³⁶ and options to host the Network in the Commission or in an existing EU Agency. While the remit of the Network would be coordination and cross-border enforcement issues, it was made clear in this consultation that the Network would not modify, replace or supersede responsibilities for market surveillance that remain the competence of Member States²³⁷. The experts expressed broad support for an EU Product Compliance network²³⁸, as an administrative support structure that would coordinate and assist implementation of market surveillance actions.

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

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

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

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

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

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

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

Administrative simplifications

As explained in the evaluation most of the enforcement costs stemming from current market surveillance rules are borne by public authorities, while regulatory costs on businesses only relate to information obligations (responding to requests from authorities, information on non-compliances detected) and are therefore regarded as insignificant by them. The enhanced enforcement coordination and priority setting supported by the EU Product Compliance Network and peer reviewed enforcement strategies would result in a better level-playing field, reducing some of the negative impacts of across-the-board enforcement inconsistencies that businesses face²³⁹. The main potential for simplification and burden reduction lie nonetheless with authorities. This section focuses therefore on the measures in this option that would result in specific benefits in terms of administrative simplifications for authorities.

Concrete improvements for authorities would result in the short term from the common principles on **test-reports portability**, **presumption of non-compliance**, and issuance of **restrictive measures** in cross-border cases. These measures would provide more legal certainty to market surveillance authorities, who would find it easier to rely on evidence and enforcement decisions already produced by other authorities elsewhere in the EU. These measures would reduce and/or simplify the handling of infringement cases compared to the current situation where authorities often have to duplicate work also performed by other authorities on the same product²⁴⁰. With clearer possibilities to issue restrictive measures directly to operators in other Member States, following the notification via a safeguard procedure, the authority in the country where the operator is established would not need to intervene in this phase – its role and thus handling costs could be reduced and limited only to cases where no satisfactory enforcement results could be obtained (e.g. residual mutual assistance requests to enforce sanctions).

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

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

239 See chapter 6.2 of the evaluation.

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

associated with tracing traders (in particular for imports) and other evidence gathering in the case of suspected non-compliance, as the person responsible for compliance information could be ordered to take care of this²⁴¹.

Compliance and implementation costs

Costs for businesses

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

3(d) Some businesses located outside the EU that place products directly in the EU (i.e. without an importer such as in the case of on-line sales) and who would not already have a contact in the EU, would incur cost to **appoint a person responsible for compliance information**. The overall cost of businesses regularly supplying the EU market would not increase because most of these businesses, as part of their normal supply chain, already have a business partner in the EU who would answer questions from market surveillance authorities and take steps to remove non-compliant products from the market. For the operators that supply directly to EU consumers from outside the EU, costs would relate to the selection of a party able to fulfil the function of e.g. authorised representative or importer and the set-up of the relative contract. Annual fees would range between about €360 and €1500 per year per business depending on the complexity of products. These costs concern only a portion of third-country businesses and do not imply an unequal treatment vis-à-vis other business, as they actually remedy the current unbalanced situation where EU and third countries businesses with a presence in the EU can be reached and possibly sanctioned by authorities while others cannot²⁴².

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

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

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

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

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

3(g) **Digital publication of compliance information** could cause, for some companies, a one-off setup cost to create an in-house database with electronic versions of the documents to be uploaded. Costs would be limited (only non-sensitive documents are concerned; the declaration of conformity as such is a fairly simple document). Recurrent additional cost would be negligible at company level (estimated at an average of €48/year, according to company size from actual savings to €14/year to €102/year); totalling for all concerned companies in the EU around 22 M€/year²⁴³.

Costs for Member States

3(a) The principles ensuring the possible **re-use of evidence (portability of test-reports)** across all Member States would allow important cost savings for the authorities re-using the evidence, partly or fully. The authorities would not duplicate the investigative phase but would nevertheless incur the costs of adopting own decisions. The total saving would depend on the number of cases in which a market surveillance authority could rely on evidence or decisions produced by others and the sector or type of investigation concerned (e.g. standard, relatively low cost physical testing for some consumer products or more complex tests involving chemical analysis²⁴⁴). Costs of testing equipment and (outsourced) laboratory test represented 30 to 50% of recent market surveillance co-funded projects^{245 246}. No additional costs are anticipated linked to the communication of the initial evidence, since information concerning investigations (test reports, etc.) would be available through the existing cooperation tools (ICSMS).

3(b)/(c) Member States may have adjustment costs to ensure liaison to the **EU product Compliance Network**, including participation in the peer review mechanism²⁴⁷. However on balance the Network would be able to take on project management and coordination tasks that now fall on market surveillance authorities' staff including ADCO chairs. Product testing costs that are part of joint actions could be financed directly by the Network. Pooling of resources (e.g. joint market studies, procurement of tests) would also allow costs savings to Member States²⁴⁸.

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

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

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

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

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

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

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

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

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

For both **3(f) and 3(g)** some limited initial set-up costs compared to option 2 would occur for authorities to familiarise themselves with access and use of digital compliance information and new powers, including possible adjustment of existing provisions at national level²⁵¹.

Costs for the Commission/EU budget

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

3(b) / 3(c) The costs to support the **EU Product Compliance Network** could range from 10 to 26M€ per year in total for the Network's Secretariat²⁵², covering human resources (30 to 90 FTE), building/infrastructure costs and an operational budget (e.g. procurement of market studies, meeting support costs, product testing costs in joint control campaigns):

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

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

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

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

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

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

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

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

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

- In case of Commission hosting of the Network, the costs would be charged in full to the EU budget (staff costs to as administrative costs to heading 5, and the operational budget, in principle Internal Market budget lines, heading 1A in the current Multi-annual Financial Framework).
- In case of EU-IPO hosting, while the costs would be incurred by the agency²⁵³, the charge to the EU-budget would be limited to an ad-hoc grant or balancing subsidy in future years in case the EU-IPO own resources would not suffice (from an Internal market budget line/heading 1A of current Multi-annual Financial Framework)²⁵⁴. One-off start-up costs would be limited and relate to adaption of internal procedures and transfer of IT systems from the Commission²⁵⁵.

In particular in the lower estimated size of the Network (30 staff, 6 M€ operational budget), the cost would be comparatively modest considering the number of sectors to cover by this initiative²⁵⁶. The medium size Network (59 staff, 10 M€ operational budget) would be more performant in achieving more concrete results with more and more regular actual controls and enforcement information exchanges that the input resources would support. While costs would be incurred for the Network at EU level, the joint activities would allow important efficiency gains for Member States and trigger cross-border controls and coordinated enforcement that is currently hampered by a lack of resources. In the baseline only few coordinated control campaigns are conducted and/or co-funded, so that a quantification of impacts over the baseline are difficult to project; however in principle the Network's cost-benefit ratio would be positive. Overall, put into perspective of the 500 market surveillance authorities that the EU Product Compliance Network would coordinate, the staff and costs levels are relatively

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

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

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

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

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

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

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

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

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

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

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

Social Impacts

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

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

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

Environmental impacts

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

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

Impacts on fundamental rights (EU Charter of fundamental rights)

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

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

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

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

Summary assessment of the option (3)

Effectiveness in achieving the policy objectives

<i>Reinforcing cooperation procedures</i>	+++
<i>Increasing operational enforcement capacity</i>	++ /+++
<i>Strengthening the enforcement toolbox</i>	+++
<i>Promoting compliance</i>	+

Costs

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

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

Effectiveness in achieving the objectives
Reinforcing cooperation procedures
<p>4(a) Direct enforceability of national restrictive measures and the right to remedies extended to the whole EU would further reduce duplication of work and different proceedings. The deterrent effect would potentially be very high and improve the response of traders to requests for voluntary measures in the initial phases of the proceedings, preceding the issuance of restrictive measures. Early resolution of non-compliance, avoiding coercive enforcement would add to the efficiency gains for market surveillance authorities²⁵⁸.</p> <p>The intensified consultation on all national restrictive measures as part of the extended safeguard procedures in this measure would contribute to the consistency of enforcement in the EU. The number of restrictive measures could however be significant²⁵⁹, with possible difficulties for the authorities to effectively screen them in an extended safeguard mechanism. The feasibility of the measure may also be lower given that only a minority of stakeholders rated direct applicability of national measures favourably.</p> <p>Overall, the extended direct application of national measures, coupled with approximation of sanctions 4(c), would allow focussing mutual assistance request on demands for complements to an investigation or systems audits, or cases that remain unresolved due to non-responsive traders and/or litigation. The rate of authorities that would never or rarely be able to follow-up on restrictive measures of other member states would be reduced²⁶⁰.</p>
Increasing operational enforcement capacity
<p>4(b) The additional mandate to the Network to investigate and take decisions in case of widespread infringements (e.g. serious non-compliance found with well-known smartphones or toys brands) would improve the effectiveness of enforcement for the cases concerned and significantly raise the visibility of EU action (viz. EU traders and third country operators).</p> <p>The possibility for the Network to conduct investigations and take enforcement decisions, would allow to further streamline work and reduce duplication of investigations and decisions</p>

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

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

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

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

The overall number of individual cases that could be tackled in this way might however be limited²⁶¹. Beyond cases related to widespread non-compliant products, this measure could however also be suitable and effective for certain supply streams or business models (e.g. specific imports supply routes, e-commerce business models involving several traders).

Strengthening the enforcement toolbox

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

However the likelihood of detection and the certainty of sanctions play a more important role than severity of sanctions in deterring crime²⁶². Furthermore, even if all Member States would introduce the same notional minimum penalty into their national criminal codes, this would by no means result in a common penalty level available to the sentencing judge. The lower penalty level available to the sentencing judge is influenced by other legal mechanisms that continue to be diverse across national criminal justice systems. For example, rules on mitigation, aggravation and judicial powers to predetermine the proportion of the sentence that must actually be served can all significantly affect notional minima. Therefore, it is important to note that the *in abstracto* minimum sanctions provided for in the national criminal codes, the nominal minimum penalties, by no means correspond to the *in concreto* sanctions imposed in a specific case. Even if the penalty level could influence deterrence, rules on early and conditional release are also relevant to the calculus²⁶³.

The feasibility of approximation of the types of sanction and corresponding level of penalties may be low as it could be perceived to constitute an undue interference in the design of Member State enforcement systems as this is a fundamental aspect of how enforcement systems are set up²⁶⁴.

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

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

263 Ibidem.

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

Promoting compliance

4(d) With a **Centralised product database**, with commercially non-sensitive information (declaration of conformity, user instructions) as well as the sensitive technical documentation, market surveillance authorities would benefit from the centralised, immediately available documentation. It could especially improve the availability of information on products from 3rd country manufacturers. A centralised database in itself however would not mean that the underlying information is correct and which would be a concern in relation to imports from China in particular. Moreover, for imports and within the EU, most of the interaction between companies and market surveillance authorities when they investigate a product concern specific questions and issues beyond the documentary information²⁶⁵.

Distributors and other intermediaries could not have full access to documentation, but most of the detailed technical documentation would not be relevant for them in order to verify the compliance of the product with the legal requirements. They would find it easier to search a centralised database, instead of researching the information on decentralised websites of companies²⁶⁶.

Stakeholders' views on the option²⁶⁷

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

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

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

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

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

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

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

Administrative simplifications

The direct applicability of national restrictive measures, centralising for widespread cases the investigation and decision into one single process and decision by the EU Product Compliance Network would simplify and reduce the handling of separate national proceedings in the Member States.

Approximated sanctions, including penalties, would further reduce the burden on Member States when they need to follow-up those cases where the trader does not comply with the restrictive measures. A more common framework on the types and levels of sanctions would facilitate the handling of the enforcement phase of cases that originated in other Member States (especially in administrative proceedings).

Compliance and implementation costs

Costs for businesses

4(a) / 4(b) Costs of extended **enforceability of national restrictive measures** and the single investigations and decisions by the EU Product Compliance network would concern businesses trading non-compliant products. They would face single proceedings, instead of multiple ones.

The right to **remedies to consumers** would imply additional costs for businesses selling non-compliant products. Should remedies be contractual this would imply a direct cost for the distributor who made available the product to the consumer, amounting to the selling price of the product, and a cost to the manufacturer against which the distributor has a right to redress, according to procedures under national jurisdictions. Should remedies be non-contractual, damages would largely depend on the type of product and the personal detriment to the consumer.

4(c) Approximation of sanctions as such would not entail costs for businesses. Sanctions when applied would only concern businesses trading non-compliant products.

4(d) Comparatively to the total compliance costs, the additional cost for the companies concerned (manufacturers, importers) to upload and update the documentation in a **central database** is relatively modest: around 122,37 €/year (for different company sizes ranging from 105,52 €/year to 144,54 €/year)²⁶⁸. For larger companies and/or those manufacturing complex products with many compliance documents there may be one-off set-up costs to allow automatic updating or transferring of documents to the central database. These one-off costs could be considerable but are difficult to estimate as they depend on the number of products/compliance documents and the extent of each company's systems²⁶⁹.

The main costs are linked to the risks of undue disclosure or access to commercially highly sensitive information in the technical documentation, and potential loss of confidential information to competitors. Even individual incidents would entail very high costs for the companies concerned and would outweigh possible benefits.

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

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

Costs for Member States

4(a) The extension of **enforceability of national restrictive measures** would not entail costs related to the initial investigation. The more extensive consultation with other Member States may sometimes involve a need for discussion and resolution of objections²⁷⁰. Market surveillance authorities relying on the initial investigation and decision when they encounter the same non-compliant product later, would save an important part of costs (testing, more limited procedural costs).

The introduction of the measure would entail alignment of procedures and legislation in the Member States. The higher number of safeguard notifications to submit and review would require additional effort (1-3 FTE/Member State, 3,5 M€/year).

In most Member States a procedure for **remedies for consumers** and other end-users would need to be adapted or created and this implies additional costs, which however are difficult to quantify due to several different organisational structures.

4(b) The extended **mandate of the EU Product Compliance Network** to perform **investigations and adopt enforcement decisions** would require the coordination and participation of market surveillance authorities for the widespread infringements concerned. On balance market surveillance authorities would save costs, as the joint, single process would be managed by the Network, and allow sharing out efficiently the investigation and legal analysis tasks, according to need. Based on estimates of the average cost of product investigations potentially available everywhere in the Single market rough estimates of cost savings for a single investigation could total at least some 20 000 €²⁷¹.

4(c) The **approximation of sanctions** would entail significant costs for Member States to adapt their national systems for administrative and criminal sanctions including penalties²⁷². The alignment cost of national systems would vary according to the national structures.

Costs for the Commission/EU budget

4(a) The **extended enforceability of national restrictive measures** could entail some additional costs for the Commission, but these are not expected to be very significant²⁷³ (mainly monitoring of the notifications, which could however be facilitated by the EU Product Compliance network (3 b)). The **right to remedies** for consumers would not entail any cost for the Commission.

4(b) The added mandate to the **EU Product Compliance Network to conduct investigations and take decisions** would imply a one-off setting up of internal procedures (0,2 FTE). It would require resources to manage the single investigation and decisions for the widespread infringements and coordinate the consultation and input into the investigations by member states, consultation of economic operator(s) (for each case 0,5-1 FTE, 69,000€-138,000€ and

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

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

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

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

possible testing costs, depending on the products/test a few hundred to thousands € per product²⁷⁴). The number of cases would not be very high in the first years, but would develop with increased coordinated market surveillance (e.g. one or two cases in a majority of sector by year, would total for around 15-20 sectors (the need for 10-20 FTE). This tasks would not seem feasible in the lower variant of the Network (30 FTE, 6 M€ operational budget), but could be more easily phased in the medium (60 FTE) and higher (60 FTE) estimated sizes.

4(d) The Commission would incur the cost of the set-up of the **centralised product database** and the maintenance (set-up 4.5 M€, maintenance costs 450.000€/year²⁷⁵).

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

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

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

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

Social Impacts

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

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

Environmental impacts

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

Impacts on fundamental rights (EU Charter of fundamental rights)

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

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

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

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

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

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

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

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

Summary assessment of the option (4)

Effectiveness in achieving the policy objectives

<i>Reinforcing cooperation procedures</i>	+++
<i>Increasing operational enforcement capacity</i>	++
<i>Strengthening the enforcement toolbox</i>	+++
<i>Promoting compliance</i>	++

Costs

For economic operators	-- / ---
For Member States	-
For the Commission/Impacts on the EU budget	--/---

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

6. HOW DO THE OPTIONS COMPARE?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Costs - Efficiency

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

Coherence

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

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

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

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

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

7. PREFERRED OPTION

7.1 Preferred option contents and costs

Preferred option – 3 Option (2) Improvement of existing tools & Option (3) increased deterrence to enforcement tools and stepped up EU coordination	
<i>Objectives</i>	<i>Measures</i>
Reinforcing market surveillance cooperation procedures	<ul style="list-style-type: none"> • A mechanism for effective mutual assistance requests between market surveillance authorities of different member states (2(a)) • Cross-jurisdictional transferability of enforcement evidence and decisions (3(a))
Increasing operational enforcement capacity	<ul style="list-style-type: none"> • Member State enforcement strategies to improve data and knowledge sharing and to help targeting enforcement and capacity building actions (2(b)) • An EU Product Compliance Network, administrative support structure to coordinate and help implementing joint enforcement activities (3(b)) • Performance indicators and benchmarks (2(c)); Peer reviews of market surveillance authorities (3(c))

Preferred option – 3 Option (2) Improvement of existing tools & Option (3) increased deterrence to enforcement tools and stepped up EU coordination	
<i>Objectives</i>	<i>Measures</i>
Strengthening the enforcement toolbox	<ul style="list-style-type: none"> • Common investigative and enforcement powers for market surveillance authorities, adapted to new market developments, the global supply chains and e-commerce (2(d)) • Additional collaborative enforcement tools, to work in partnership with businesses and stakeholders (2(e)) • Obligation to appoint a person responsible for compliance information in the EU for 3rd country businesses when they do not work through an importer (3(d)) • Publication of restrictive measures taken by market surveillance authorities (3(e)) • Recovery of control costs in the case of non-compliant products (3(f))
Promoting compliance	<ul style="list-style-type: none"> • An extension of the advice role of the Product Contact Points (PCP) (2(f)) • A web-portal hosted by the Commission on voluntary measures taken by businesses on dangerous products (2(g)) • Mandatory digital publication of compliance information (3(g))

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

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

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

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

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

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

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

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

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

- *Knowledge and information gaps concerning product compliance*

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

Costs:

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

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

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

- **Member States** would face costs to adapt and align (some) of their legislation and procedures (set-up costs 700 000€ all Member States), and as main running costs the advice service by Product Contact Points (3.5 M€/year, all Member States). However they would benefit from significant **efficiency gains** and cost savings thanks to the increased joint actions and coordination, assisted by the EU Product Compliance Network. The stronger and more fit-for-purpose enforcement powers, enhanced enforcement cooperation tools and re-use of other Member States' enforcement decision and evidence would allow market surveillance authorities to realise important costs savings and rationalise the market surveillance framework in the EU.
- The preferred option would have minimal costs implications for **businesses** that trade compliant products. The stepped-up enforcement coordination, better knowledge exchange, prioritisation and peer reviewed enforcement strategies supported by the EU Product Compliance Network, would create a more level playing field and a more transparent and predictable enforcement environment across the Single Market. As a result businesses may see a reduction of some of the negative impacts of the across-the-board inconsistencies they currently face. Businesses' regulatory costs stemming from the market surveillance rules relate to their information obligations towards public authorities (e.g. responding to requests from authorities, information on non-compliances detected). These costs only occur occasionally and are considered insignificant especially compared to ensuring product conformity and traceability. The preferred option would only marginally increase costs for some businesses: The mandatory digital publication of some compliance information would imply a cost of 22 M€/year in total for the economic operators concerned (manufactures and importers). Some 3rd country traders might incur some extra costs to ensure a person responsible for compliance information is available in the EU. On the contrary businesses trading non-compliant products would face costs to incentivise them to better internalise the full compliance cost (e.g. via recovery of control costs, reputation costs).

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

7.2 Subsidiarity and proportionality of the preferred option

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

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

A very large majority of stakeholders endorse the need for more coordination of enforcement among Member States, better sharing of intelligence and knowledge²⁷⁶. Pooling efforts in these areas, as envisaged in the EU Product Compliance Network, would allow overall resources for market surveillance to be used more efficiently and increase coordinated, joint control activities in priority areas related to intra-EU trade as well as imports. More exchange of information and discussion among EU authorities would contribute to more consistent enforcement and the easier replication and re-use of evidence and enforcement decisions across jurisdictional boundaries would help to save costs²⁷⁷. The stronger deterrent effect of enforcement tools in the preferred option would be directed at businesses trading non-compliant products.

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

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

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

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

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

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

8. HOW WOULD ACTUAL IMPACTS BE MONITORED AND EVALUATED?

8.1 Practical arrangements of the evaluation: when, by whom

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

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

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

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

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

OBJECTIVES	INDICATORS
1) Reinforcing cooperation procedures	<ul style="list-style-type: none">• Usage of mutual assistance mechanisms by market surveillance authorities (number, types, timelines, outcomes)• Number of measures taken by other authorities 'replicated' in each Member State

OBJECTIVES	INDICATORS
2) Increasing operational capacity	<ul style="list-style-type: none"> • Number and scope of Member States enforcement strategies (performance indicators) • Compliance rates by Member State/sectors and for e-commerce (improvements in availability and quality of information, progress in reduction of compliance gaps) • Number of coordination controls campaigns: scope (number of MS/sectors/ products) finding (detection infringements) and results (corrective measures) • Awareness of EU network and user satisfaction with its services (by economic operators, consumers and other end-users; market surveillance authorities)
3) Strengthening the enforcement toolbox	<ul style="list-style-type: none"> • % of costs recovered by authorities • Availability and accessibility of information on (non)compliance and on restrictive measures • Application of sanctions (infringements detected leading to penalties, types and levels of penalties effectively applied)
4) Promoting compliance	<ul style="list-style-type: none"> • Number, type of requests for information handled by Product Contact Points • Number, type of partnerships/compliance assistance schemes in MS; (usage of schemes, by type of business) • Awareness/understanding of product rules by businesses • Availability and accessibility of relevant compliance information (on economic operators' websites) - by MS, sector, type of operator • Usage of information by market surveillance authorities, consumers and professional end-users • Number of voluntary measures registered in the common web-portal