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Product Safety and Market Surveillance Package

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Product Safety and Market Surveillance Package

A proposal for a Regulation of the European Parliament and the Council on consumer product safety and a proposal for a Regulation of the European Parliament and of the Council on market surveillance for products

{COM(2013) 78 final}
{SWD(2013) 34 final}

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1. PROCEDURE

1.1. Identification

Lead DGs: DG SANCO and DG ENTR - Agenda Planning/WP Reference: 2010/SANCO/031 + 2012/SANCO/019

1.2. Organisation and timing

Work on the Impact Assessment started in September 2009. An Impact Assessment Steering Group chaired by DG SANCO, in cooperation with DG ENTR, was set up and met five times:, on 28 September 2009, 21 January 2010, 21 December 2011, 21 June 2012, and 5 July 2012. SG, SJ, DG ECFIN, MOVE, ENV, MARKT, TAXUD were invited to the meetings, and representatives of SG, DG TAXUD and MARKT attended and contributed to the discussions. The minutes of the last IASG meeting were submitted to the IAB together with the draft IA report.

Annex 1 contains a glossary of the main specialised terms used.

1.3. Public consultation, opinions of stakeholders and external expertise

The impact assessment builds on a very wide and long public consultation of stakeholders:

- The first round of public consultation was organised by the Commission from September 2009 to January 2010. The aim of this consultation was to define - on the basis of the Report on the implementation of the General Product Safety Directive[1] - the scope of the problems on which the revision of the Directive should focus.

- Following the definition of the scope of the impact assessment, the Commission proceeded with the second round of public consultation which took place from May to December 2010. Within the framework of this second round the Commission held between 18 May 2010 and 20 August 2010 (12 weeks) an internet public consultation. The invitation to participate in this online public consultation was published on the "Your Voice in Europe" website of the Commission on 18 May 2010 and on the website of DG Health & Consumers. In this online public consultation the Commission sought feedback through four consultation papers and nine online questionnaires targeting various groups of stakeholders. The public consultation was divided into four topics, namely (i) pre-standardisation procedures under the General Product Safety Directive, (ii) harmonisation of safety evaluations of consumer products, (iii) market surveillance framework in the product safety area and (iv) the alignment with the 2008 Free Movement of Goods Package. Within each of these four areas stakeholders were consulted about the scope and magnitude of the identified problems and about various options proposed to remedy these problems.

[1] COM (2008) 905 final.

- This second round of public consultation was concluded through a Workshop on the revision of the General Product Safety Directive organised on 1 December 2010 within the framework of the International Product Safety Week. The aim of this workshop was to receive feedback from the stakeholders on the process and key conclusions of the online public consultation. The principal message delivered by the stakeholders was a call for a uniform market surveillance framework in the non-food product safety area, simplification of the existing legal framework and more coherence in the enforcement of product safety rules throughout the EU. The summary of the online public consultation is set out in Annex 2.

- Simultaneous to the online public consultation, the Commission received position papers from 16 stakeholders, including consumer organisations, business associations, Member States, and individual economic operators etc. The summary of opinions of these stakeholders is set out in Annex 3.

- The third round of public consultation took place from January to March 2011. It took the form of four targeted stakeholder meetings on the issues of, (i) market surveillance coordination (28 January 2011), (ii) obligations of economic operators with respect to non-food consumer products, in particular traceability and technical file requirements (18 February 2011), (iii) pre-standardisation procedures under the General Product Safety Directive (17 March 2011), and (iv) legislative architecture of general and specific legislative rules (31 March 2011) with the participation of experts for the relevant areas. The conclusions of these targeted stakeholder meetings are set out in Annex 4.

- Stakeholders' views were also discussed in several bilateral meetings that took place continuously between May 2010 and June 2012.

- Furthermore, special consultations aimed at small and medium-sized enterprises (SMEs) and at microenterprises were carried out. The summary of these consultations is contained in Annex 5.

- The European Parliament prepared its own initiative report on the revision of the General Product Safety Directive and market surveillance (the "Schaldemose Report")[2]. This report was adopted on 8 March 2011 in the form of a Resolution on the General Product Safety Directive revision and market surveillance[3]. The Report contained a number of recommendations, for example, to enhance the coherence of EU product safety legislation, to provide more consistency in coordination of market surveillance and customs authorities, to deploy adequate resources for market surveillance activities, including joint market surveillance actions, to put in place mechanisms allowing for the sharing of market surveillance information between the Member States etc.

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2 Report on the revision of the General Product Safety Directive and market surveillance (2010/2085(INI)), European Parliament, Committee on the Internal Market and Consumer Protection, Rapporteur: Christel Schaldemose.

3 European Parliament resolution of 8 March 2011 on the revision of the General Product Safety Directive and market surveillance (**2010/2085(INI)),** P7_TA (2011)0076.

- The Commission has sought the views of national market surveillance authorities of the Member States on possible improvement to the current situation through its expert working group "Senior Official for Standardisation and Conformity assessment - Market surveillance" (SOGS-MSG) and the Committee established under the General Product Safety Directive.

Regarding external expertise, a study on the future of market surveillance[4] was prepared for the purposes of the impact assessment, with the objective of assessing the challenges of product safety market surveillance posed by future development of manufacturing and distribution patterns of non-food products[5]. In addition to this study a number of other existing studies and surveys directly concerning the area of non-food product safety were used as reference documents. These other studies included, for example, a report evaluating business safety measures in the toy supply chain, a feasibility study for a post-manufacturing traceability system between the People's Republic of China and the EU, etc. A list of all studies is provided in Annex 6.

1.4. Scrutiny by the Commission Impact Assessment Board

The Impact Assessment Board of the European Commission assessed a draft version of the present impact assessment and issued its opinion on 19 September 2012. The Impact Assessment Board approved the Impact Assessment Report and suggested certain improvements and modifications.

The Impact Assessment report was amended in line with these suggestions. In particular, the source of the inconsistencies in and ineffectiveness of existing legislation on product safety and market surveillance was explained in more detail and in a more concrete and structured way. The final report better described the content of measures under each identified options and clarified which problem drivers and objectives they are supposed to address. It highlighted what was going to change compared to the status quo and substantiated the expected impacts.

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4 The future of market surveillance in the area of non-food consumer product safety under the General Product Safety Directive", Final Report, March 2011, BSI Development Solutions, May 2011.

5 http://ec.europa.eu/consumers/safety/projects/market_surveillance_enforcement_en.htm

2. POLICY CONTEXT, PROBLEM DEFINITION AND SUBSIDIARITY

2.1. Policy context

The free movement of safe and compliant products is one of the cornerstones of the European Union. This principle constitutes an important pillar of the single market and allows consumers and enterprises to purchase or sell products in another Member State.[6]

The overall architecture of Union product safety and compliance rules which serve as a basis for the proper functioning of the single EU market can be summarised in the following way:

Table 1: Overall architecture of Union product safety and compliance rules

Products[7]	Consumer	Professional
Harmonised	Sector specific Directives and Regulations and the General Product Safety Directive	Sector specific Directives and Regulations
Non-harmonised	General Product Safety Directive	National product safety rules under the 'Mutual Recognition Regulation' Article 34-36 TFEU

The two legal instruments, the General Product Safety Directive 2001/95/EC (the "General Product Safety Directive") and Regulation (EC) 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products guarantee an EU legal basis for market surveillance of all consumer products (harmonised or not) and for all harmonised products (consumers and professional). However, fragmentation of market surveillance rules among various pieces of Union legislation (the Regulation, the General Product Safety Directive and many sector-specific Union harmonisation Directives), as described in the following table, may lead to confusion on the part of both operators and national authorities.[8]

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6 This impact assessment does not relate to agricultural or food and feed products. It concerns primarily the other industrially manufactured products for which the EU adopted harmonisation rules for specific categories of products and the General Product Safety Directive 2001/95/EC for consumer products. This set of EU rules has put in place product safety requirements for a large number of products, while the free movement provisions of the Treaty and the mutual recognition principle govern the remaining product categories.

7 A summary of the applicable EU rules and the description of main categories of so-called harmonised products, non-harmonised products, consumer and professional products are set out in Annex 8.

8 **1. A complex legal framework that requires revision** "*With the adoption of the legislative package on the Free Movement of Goods (also called the "Goods Package"), the EU regulatory landscape on product safety and market surveillance has become very complex and confusing. As part of this package, Regulation 765/2008/EC ("Regulation") sets forth new rules for the market surveillance of products subject to harmonized EU legislation, and Decision 768/2008/EC provides rights and obligations on business operators related to product safety that can be used by the legislator in the adoption of legislation on specific products, as has been done recently in the new Directive on Toy Safety and the new Regulation on Cosmetic Products […] The real confusion comes for consumer products that are subject to harmonized EU rules, such as toys and cosmetics products, which are*

Table 2: Overview of the existing EU regulatory framework in the area of non-food product safety

<table>
<tr><th colspan="5">Overview of the existing EU regulatory framework in the area of non-food product safety</th></tr>
<tr><th rowspan="2">Products
Areas</th><th colspan="2">Non- Harmonised</th><th colspan="2">Harmonised</th></tr>
<tr><th>Non-consumer</th><th colspan="2">Consumer</th><th>Non-consumer</th></tr>
<tr><td>Obligations of economic operators</td><td>National product safety rules under Article 34 – 36 TFEU</td><td>GPSD</td><td>Sector specific Union harmonisation legislation (GPSD as a safety net)</td><td>Sector specific Union harmonisation legislation</td></tr>
<tr><td rowspan="2">Market surveillance on the internal market*</td><td>Regulation 764/2008</td><td rowspan="3">GPSD
(only those dangerous to health and safety of consumers)</td><td>Sector specific Union harmonisation legislation + Regulation 765/2008 + GPSD</td><td>Sector specific Union harmonisation legislation + Regulation 765/2008</td></tr>
<tr><td rowspan="2"></td><td rowspan="2"></td></tr>
<tr><td>RAPEX*</td><td>Regulation 765/2008 referring to GPSD</td><td>Regulation 765/2008 referring to GPSD</td></tr>
<tr><td>Controls on products imported to the EU*</td><td colspan="4">Regulation 765/2008</td></tr>
</table>

The complexity of the EU legislative framework in the area of non-food product safety is due to a fast adoption of Regulation (EC) No 765/2008 and Decision (No) 768/2008/EC necessitated by the events of the "summer of recalls" in 2007.[9] The fast adoption did not allow for proper definition of the relationship between the General Product Safety Directive on the one hand, and Regulation (EC) No 765/2008 and sector specific provisions of New Approach Directives (in the wording of reference provisions of Annex 1 of Decision (No) 768/2008/EC), on the other hand. The relationship between these instruments was defined only in very general terms, such as "mutatis mutandis" use of certain of the provisions on RAPEX system[10] laid down in the General Product Safety Directive for the purpose of Regulation (EC) No. 765/2008 or "lex specialis" application[11] of market surveillance provisions of the

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subject to both the GPSD and the Regulation, as well as the specific provisions included in the specific (toys, cosmetic) regulations in place. To determine which provisions of each of these three sets of rules apply (e.g. safety definition, notification requirements for products presenting a risk, right and obligations of business operators and market surveillance authorities, etc.) a case-by-case analysis is necessary to determine which provision is "more specific" than the other. This creates a situation of legal uncertainty which is very unfortunate given that it concerns essential legal provisions that are applicable in critical situations, for example when companies and authorities need to decide on product withdrawals and recalls." (MayerBrown, The Revision of the EU General Product Safety Directive, Memorandum, January 2011).

9 In the summer of recalls of 2007 various economic operators had to recall a large number of consumer products in the United States as well as in the European Union, in particular toys, because of presence toxic substances in these products.

10 Art. 22 (4) of Regulation (EC) No 765/2008.

11 Art. 15 (3) of Regulation (EC) No 765/2008.

General Product Safety Directive in relation to the market surveillance provisions of Regulation (EC) No. 765/2008.[12]

The Commission tried to clarify the complex issue of which of the aforementioned pieces of EU product safety legislation should apply in which situations by way of interpretation Guidelines,[13] however this was considered to be insufficient.[14]

Regulation (EC) No 765/2008 requires the Commission to submit a report analysing the consistency of EU rules on market surveillance contained in this Regulation, the General Product Safety Directive and any other relevant Union instrument addressing market surveillance issues and, if appropriate to amend and/or consolidate the instruments concerned, in the interests of better regulation and simplification.[15]

Along with a series of other actions, the Single Market Act II[16] identified the Product Safety and Market Surveillance Package as priority initiative that would contribute to boosting growth and creating jobs. The Europe 2020 Strategy for smart, sustainable and inclusive growth should ensure that innovative ideas can be turned into new products and services that create growth by exploiting EU-scale networks and by reinforcing the competitive advantages of our businesses, particularly in manufacturing and within our SMEs.[17]

Finally, this initiative is also in one of the important actions of the European Consumer Agenda adopted by the Commission in May 2012.[18]

2.2. Organisational and institutional context

Market surveillance is a crucial tool to protect both consumers and other users from unsafe and non-compliant products, by ensuring that all economic actors stick to the rules. On the one hand, the organisation of market surveillance is determined by Member States, on the other hand, the General Product Safety Directive and Regulation (EC) No 765/2008 set out certain minimum requirements that the market surveillance structures in Member States should fulfil, such as the obligation to have powers and resources to perform enforcement activities, a minimum set of measures that authorities shall take against dangerous products, an obligation to have a single RAPEX contact point etc. The configuration of market surveillance authorities in Member States differs from one Member State to another: in certain Member States market surveillance is centralised whereas in other Member States it is performed on

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12 The definition of the relationship between the market surveillance provisions of reference provisions of Annex 1 of Decision No. 768/2008/EC, in particular its Article R31, and the market surveillance provisions of the General Product Safety Directive was not defined at all.

13 European Commission, Working Paper on the Relationship between the General Product Safety Directive 2001/95/EC and the market surveillance provisions of Regulation (EC) No 765/2008, 2 March 2010.

14 Another source of complexities and difficulties with the application of the General Product Safety Directive and Regulation (EC) No 765/2008 resulted from the reversal of the order of application of these two instruments. This came about in the final phases of the co-decision procedure in the Council and the European Parliament relating to the adoption of the New Legislative Framework.

15 Article 40 of Regulation (EC) No 765/2008.

16 (COM (2012) 573 final).

17 (COM (2010) 2020 final).

18 (COM (2012) 225 final).

the regional or even on the local level with central authorities performing coordination role only.[19]

At the EU level, the basic market surveillance infrastructures are composed of (i) the RAPEX system through which Member States notify to the Commission (which disseminates them to other Member States) measures taken against products posing serious risks and (ii) the general information support system intended to collect other information about market surveillance activities performed by Member States. In addition, in the area of harmonised products, the so-called 'New Approach directives' include a form of safeguard clause[20] which obliges Member States to restrict or forbid the placing on the market and the putting into service of dangerous – or, according to some directives, otherwise non-compliant – products, or to have them withdrawn from the market.[21]

2.3. Economic context

The internal market for products is enormous. As far as consumer products are concerned (regardless of whether harmonised or not) in between 2008 and 2010 the volume of intra-EU trade amounted to almost EUR 1 trillion. The value of harmonised sectors (including both consumer and professional goods) in the EU-27 is estimated to be no less than € 2 100 billion. [22] The world economy is characterised by globalisation and changing trade patterns to which EU market surveillance and customs authorities will need to adapt. In terms of value, international trade returned to pre-recession levels by mid-year 2010[23], and is expected to continue growing. Growth has also been seen in the numbers of consignments and customs declarations since bottoming out in the first half of 2009. This trend can be expected to continue.[24] Since January 2010 customs and market surveillance authorities are due to cooperate to stop dangerous goods at the border of the EU and important progress has been made in this area. Nevertheless, a significant amount of work is still needed

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19 A detailed description of the organisation of market surveillance in Member States is contained in Annex 2 to the Report on the implementation of Regulation (EC) No 765/2008.

20 As a general rule, this safeguard clause procedure is restricted to products which are covered by 'New Approach directives', CE marked and ascertained by the Member State to present a substantial risk, even if the products are correctly constructed, installed and maintained, and used according to their intended purpose. This procedure was originally designed to allow the Commission to analyse the justification of national measures restricting the free movement of CE marked products (products presumed to comply with requirements). The Commission is responsible for administering the safeguard clause at Union level, and for ensuring that it applies to the whole of the EU. To this end, the Commission consults the interested parties to verify whether or not the action that invoked the safeguard clause can be justified.

21 The safeguard clause procedures are drafted differently in the various directives. Yet, Decision 768/2008/EC.

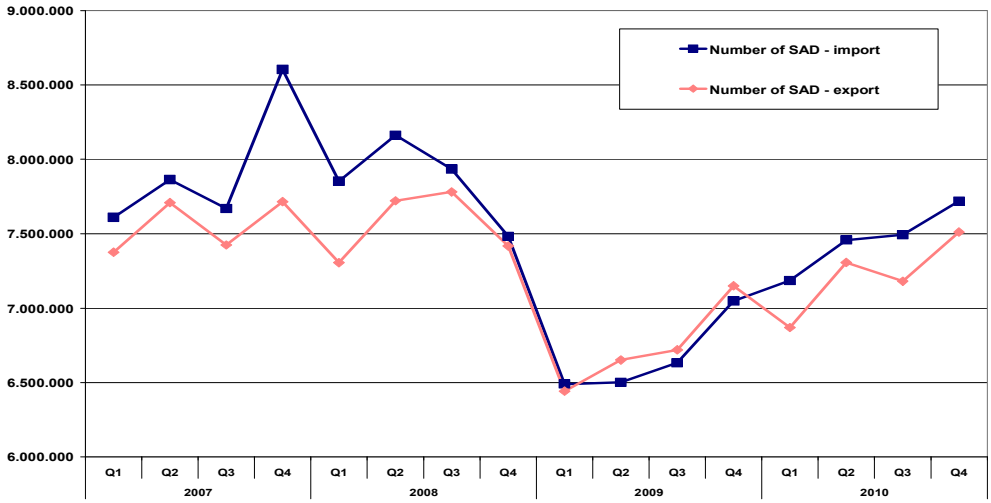
22 This figure is given by the sum of production value for the big electrical mechanical, mechanical engineering, automotive, chemical, and medical devices sectors. A detailed description of the methods of determination of this value, as well as of the total value of consumer products market on the single EU market can be found in Annex 7.

23 According to the European Commission's interim economic forecasts published in September 2010.

24 According to a Commission Communication of 9 November 2010, by 2015, 90 % of world growth is expected to be generated outside Europe, one third by China alone. Cf. Trade, Growth and World Affairs — Trade Policy as a Core Component of the EU's 2020 Strategy; http://trade.ec.europa.eu/doclib/press/index.cfm?id=636&serie=382&langId=en

to train customs officials and to improve cooperation between customs and market surveillance authorities at a national and EU level.

Figure 1: Development of the number of customs declarations



Although there are no statistics that allow the estimation of the number or percentage of non-food dangerous products present on the EU market, there are strong indications that there are still unsafe consumer products being put on the single market. The first indication is the number of notifications sent through RAPEX, the EU rapid alert system that facilitates the rapid exchange of information between Member States and the Commission.[25] In 2009, 1 993 notifications were sent to the Commission, including 1 699 notifications of measures taken against products presenting a serious risk. In 2010, the number of measures notified rose to 2 244, including 1 963 notifications of measures taken against products presenting a serious risk. In 2011, this number decreased to 1 803 with 1 556 serious risk notifications.[26] The relative temporary decline in the RAPEX notifications in 2011 can be attributable to the application of the revised RAPEX Guidelines, including revised risk assessment guidelines, and to the effect of cuts in national budgets for market surveillance reported by a number of Member States. According to the statistics for the first three quarters of 2012, an increase in the number of notifications is expected again in this year.[27]

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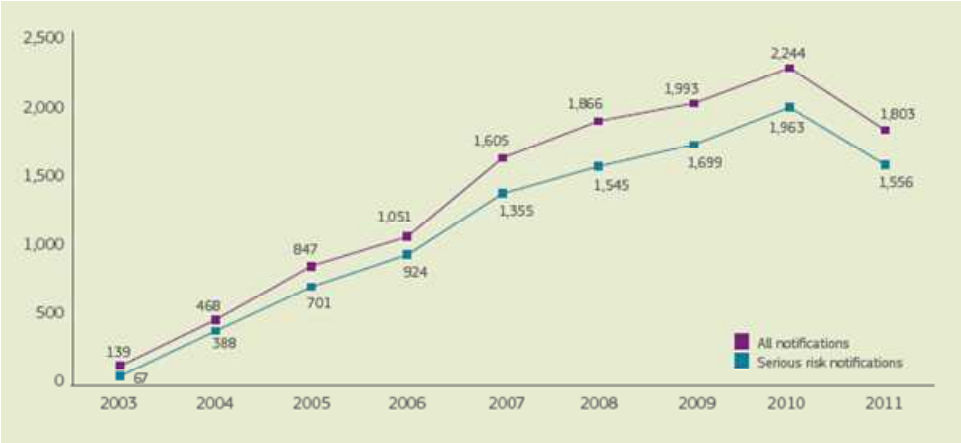
25 With the exception of food, pharmaceutical and medical devices, which are covered by other mechanisms) or to certain other public interests.

26 Detailed information the functioning of RAPEX can be found in Annex 9.

27 An illustrative comparison of the notifications of measures taken against unsafe products between the non-food sector and the food and feed sector can be made, in particular in relation to the notifications provided to the European Commission under the Rapid Alert System for Food and Feed (RASFF). However, it has to be borne in mind that due to certain differences in the legislative frameworks for the two areas different types of measures are notified through the two different systems. Detailed information about measures taken against food and feed products (RASFF) can be found in Annex 9 (section 9.7).

Figure 2: RAPEX notifications (2003-2011) – consumer products



Another source of information about the safety of non-food products on the market are the "Enforcement Indicators" collected yearly by the Commission. According to this data, throughout 2008 and 2009, national authorities in the EU have taken at least 15,000 measures[28] against products presenting a risk to health and safety of consumers or not complying with the applicable legislation.[29] Complementary information on product safety can be drawn the European Injury Database (IDB).[30] Finally, some rough indications on the share of non-compliant products on the market were provided by stakeholders in the course of a public consultation in the field of harmonised products as shown in Annex 9.[31]

2.4. Problem definition - Unsafe consumer and other non-compliant products on the single market

The very existence of unsafe and non-compliant products circulating on the internal market indicates a failure in the functioning of the framework within which the internal market operates. For an unsafe product, there is no free movement on the

28 Not all measures taken by national authorities are supposed to be notified to the Commission. Also, since one measure can cover more than one product or one type of a product, the number of products taken off the EU market is higher than the number of measures notified to the Commission.

29 This information was provided by 23 EU Member States, Norway and Iceland. More detailed information about enforcement indicators can be found in Annex 10.

30 The European Injury Database (IDB) is the only data source that contains standardised cross-national data for developing preventive action against home and leisure accidents in the EU (in 2009, 12 Member States participated in the IDB database). The IDB is based on a systematic injury surveillance system that collects accidents and injury data from selected emergency departments of Member State hospitals, providing a complement to and integrating existing data sources, such as common causes of death statistics, hospital discharge registers and data sources specific to injury areas, including road accidents and accidents at work. However European Injury Database does not (i) give up to date information, (ii) provide a direct link to victims, (iii) identify the full product details, (iv) allow for testing of the actual product. The distribution of injuries according to product categories is compiled on the basis of varying samples in the Member States (e.g. 4 000 injuries in Belgium and 296 000 injuries in the Netherlands). This limits the comparability of data between countries. Moreover, the number of injuries in each country is not exhaustive which makes it impossible to estimate the number of injuries of a certain type per 1000 inhabitants in a certain country. More detailed information on IDB can be found in Annex 9 (section 9.5).

31 SEC (2007) 173. The figures contained in this document should however be interpreted with prudence due to the difficulty of estimating non-compliance and comparing it across sectors.

single market. Unsafe and non-compliant products should never have entered this market. Free circulation of safe products should be promoted whereas unsafe products must be effectively tracked down and removed from the single EU market.[32]

In reality, however, product safety requirements determining whether a product is safe and can circulate on the Union market are not always clear and consistent.[33] Moreover, unsafe products not fulfilling product safety requirements penetrate, in a number of cases, the EU market from third countries due to insufficient coordination of activities by the market surveillance authorities in individual Member States. As a result, compliant economic operators face increased compliance costs. They have to accommodate diverging application of product safety requirements in different Member States while they face an unlawful competition from rogue operators who – due to insufficient coordination of market surveillance authorities from different Member States – manage to market products not respecting applicable product safety requirements, and thus, gain competitive advantage over the compliant economic operators.

At the same time, interests of consumers and other users, in particular their health and safety, are put in danger. If, due to the incorrect safety assessment of a product resulting from the ambiguity of applicable safety requirements, economic operators put on the Union market unsafe or non-compliant products, they not only generate an immediate threat to the safety of consumers but they also undermine consumer confidence.[34] If consumers should have confidence in products available on the EU market, these products must be safe, irrespective of where they are produced.[35] The latest Eurobarometer data indicate a decrease in confidence of consumers in the safety of products sold in the EU (25% in 2011 compared to 20% in 2010 think that a significant number of products are unsafe, 12% in 2011 compared to 16% in 2010 think that essentially all products are safe).[36] The problem of unsafe and non-compliant products is also evidenced by the data from joint market surveillance actions[37] performed by the European Commission and market surveillance authorities of Member States within PROSAFE.[38] Similarly, the data from the study

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32 An effective application of the free movement principle in the product safety area requires that the determination of whether a product is safe or not - and thus, whether it should stay on the market or be removed thereof - is performed in the same way in all Member States.

33 Differing interpretations of product safety requirements laid down in particular in the European harmonised standards or different national safety perceptions result in an identical product being considered safe in one Member State, but not in the other, which represents a source of friction between market surveillance authorities, consumer organisations and economic operators.

34 Consumer consumption represents 56% of the GDP of the European Union. Consumers' confidence is a key element for ensuring a sustained level of consumer consumption which, in turn, is essential for generating economic growth and the proper functioning of the EU market.

35 Data collected through Eurobarometer questionnaires addressed to roughly 30,000 consumers and 7,000 retailers across the EU, show that the safety of products is one of the most important considerations when consumers make purchasing decisions (second after price, but ahead of brand or country of origin).

36 For more details see Annex 9 (section 9.6).

37 For more details see Annex 7 (section 7.3, Table 6) and Annex 14.

38 PROSAFE (the Product Safety Enforcement Forum of Europe) is a voluntary association of market surveillance officers of various EU Member States functioning since 1990.

of the Consumer and Industrial Products Committee of IFIA[39] on electrical products for household use performed in 2012 show a significant number of non-compliances and safety issues of products imported from the outside of the EU which circulate on the internal EU market.[40]

2.4.1. Problem 1: Difficult compliance with EU product safety requirements

Compliance with the EU product safety requirements is often difficult for economic operators since; in general, EU product safety requirements in the area of so-called non-harmonised products are not consistent with those in the harmonised area. Furthermore, the EU product safety requirements in the non-harmonised area are often ambiguous and detailed benchmarks for safety evaluation are missing, whereas in the harmonised area different and overlapping layers of product safety undermine legal certainty.

2.4.1.1. Lack of consistency of EU product safety requirements (for harmonised and non-harmonised products)

In the area of non-harmonised consumer products, economic operators face difficulties in determining which product safety requirements they should apply, in particular due to the lack of consistency between non-harmonised consumer product safety requirements and the harmonised product safety requirements, as shown in Annex 8 (section 8.3).[41] The problems caused by differences in requirements between non-harmonised and harmonised consumer products as well as the differences in the distribution of obligations on different agents in the supply chain generate sometimes non-negligible costs which are however difficult to be quantified even by economic operators themselves.[42]

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39 IFIA (International Federation of Inspection Agencies) is a federation of organizations that provide testing, inspection and certification services, internationally, established in 1982, with global membership of 40 testing and inspection companies.

40 IFIA CIPC, Product Safety in Europe, Results from the 2012 Study, November 2012. For more details se Annex 7 (section 7.3, Table 7).

41 In the public consultation, a large majority (90%) of economic operators responding indicated that they take into account the differences between the consumer product safety requirements and the harmonised product safety requirements. For 33% of these economic operators, these differences represented additional costs for their businesses. The economic operators responding mostly indicated that in general cost of diverging legislation and resulting differing application is non-negligible, but impossible to quantify.

42 The reason for this is twofold: first, the costs of complying either with the consumer product safety requirements or harmonised safety requirements or both represents only a small fraction part of general compliance costs and in general it is impossible to establish the percentage which the costs of product safety requirements represent of the overall compliance costs; second, the product safety compliance costs are composed of costs of the aforementioned general non-risk related obligations and costs of specific risk-related requirements, usually contained in the detailed technical standards. Since the consumer product safety requirements as well as the harmonised product safety requirements concern only the costs attributable to the general non-risk related obligations, in theory these two costs components should be clearly distinguished. In practice, however, these different costs components are impossible to dissociate. Moreover, since the latter product specific risk-related technical requirements will usually impose certain technical solutions, the costs generated by these requirements would largely prevail over the costs of the general non-risk related obligations.

These problems were demonstrated in the case C-132/08[43] where a Member State unsuccessfully tried to impose obligations of manufacturers under the Radio and Telecommunication Terminal Equipment Directive[44] and the General Product Safety Directive on a distributor thus restricting the free movement of products on the internal market in a way that was not compatible with the aforementioned Union legislation and the Treaty.

2.4.1.2. Ambiguity of product safety requirements and lack of specific benchmarks (for non-harmonised consumer products)

Differences in the implementation of certain consumer product safety requirements can also be perceived with respect to the implementation of the obligation to identify the producer under the General Product Safety Directive. This disparity of national rules regarding the identification of the product and the producer in respect of consumer products - although coming within the limits of the General product Safety Directive - causes confusion both for the economic operators as well as for consumers.[45]

Furthermore, in the non-harmonised area, there are a number of European standards published by European Standardisation Organisations. However, the presumption of conformity to the general safety requirement is provided only by few of them despite the fact that a European standard is deemed to be a useful element when it provides for the aforementioned presumptions of conformity, i.e. when it can legally ensure the free movement of product throughout the EU internal market. The scarcity of European standards providing for presumption of conformity with the general safety requirement for consumer products complying with such standards in the non-harmonised area compared to harmonised area deprive all stakeholders of an efficient tool for ensuring the safety of products on the market.

Last but not least, under the current rules, unsafe products on the market or new or emerging risks are not addressed in an efficient and timely fashion. The average timeframe from the initial discussions to establish the safety requirements until the publication of the reference of the standard in the OJEU can be estimated at about six years. Of these, on average, three years (or more) are needed to draft the standard (a process run by the European Standardisation Organisations, independent from the Commission) and the remainder of the time can be ascribed to the current procedures.

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43 Court of Justice of the European Union, judgement of 30 April 2009 (reference for a preliminary ruling from the Fővárosi Bíróság (Republic of Hungary)) — Lidl Magyarország Kereskedelmi bt. v Nemzeti Hírközlési Hatóság Tanácsa, *OJ C 153, 4.7.2009, p. 12–13.*

44 Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity OJ 1999 L 91, p. 10.

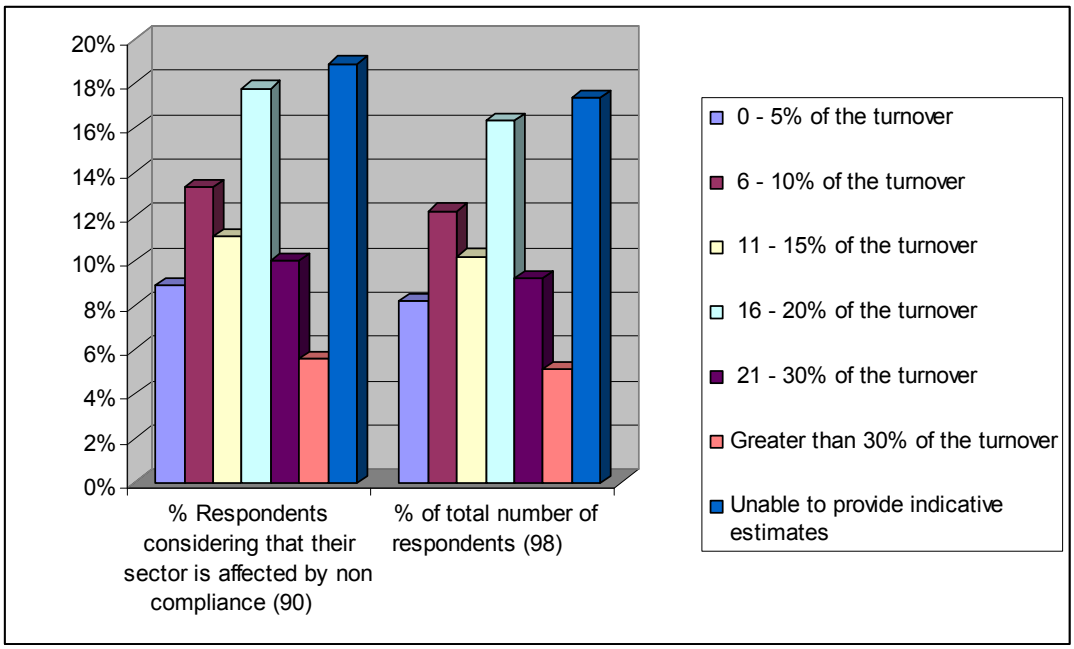
45 The ambiguous formulation of the identification obligation has led to the situation where certain Member States oblige producers to indicate information enabling either the identification of the products and/or the product whereas in other Member States ensuring the identification of the product and the producer remain optional.

2.4.1.3. Complexity of different layers of EU product safety rules (for harmonised consumer products)

Unlike in the area of non-harmonised consumer products, for harmonised consumer products the applicable safety requirements are more clearly spelt out in the sector specific EU product safety legislation. However, with respect to these products there may be some confusion due to the overlap of various layers of legislation.[46] In order to understand exactly which requirements apply to a given non-food product, in particular if it is subject to both consumer product safety requirements as well as to harmonised product safety requirements, a time consuming research or legal advice will often be necessary. The complexity of applicable requirements resulting from the overlapping legislation increases compliance costs for economic operators willing to follow the rules, as they will often request legal advice or engage in time consuming research. Those costs, which are proportionally higher for SMEs, may overall discourage compliance.

Apart from posing risks to consumers and users, unsafe and non-compliant products have important economic consequences: they lead to unfair competition. Operators not adhering to the rules can make significant savings on compliance costs. They can consequently offer their products at lower prices than their competitors who respect the law. In sectors where there is tough competition from imported low-price products, European industry is disadvantaged.[47] The situation "punishes" the law-abiding manufacturer, as compliance becomes a "competitive disadvantage." 87% of economic operators responding to an earlier public consultation on the New Legislative Framework performed in 2006 consider that they suffer from unfair competition due to this situation; during that public consultation, economic operators provided estimates of the size of their losses in terms of their annual turnover, reproduced below:

Figure 3: Perceived losses in % of annual turnover



46 Sector specific New Approach Directives and General Product Safety Directive.

47 For more details see Annex 7 (section 7.3).

2.4.2. Problem 2: Fragmentation of market surveillance in the single EU market

A major reason for the considerable number of non-compliant products on the market is that market surveillance does not operate effectively in the European Union.[48] The principal causes of ineffective and inefficient market surveillance on the single EU market are (i) weak coordination between product safety market surveillance authorities in different Member States, (ii) sub-optimal functioning of EU procedures for exchange of information on product risks and (iii) inconsistent enforcement of EU-wide product safety action.[49]

2.4.2.1. Weak coordination of product safety market surveillance authorities of different Member States

Despite the widespread harmonisation of safety standards and other requirements for products (e.g. environmental) across the Union and the fact that many products are regularly marketed in more than one Member State, the Single Market is policed through 27 separate systems of enforcement. Although the consistency in coordination of enforcement activities of different national authorities at the EU level is crucial for proper functioning of the EU single market, the coordination of national market surveillance activities is rudimentary.[50]

The lack of coordination of market surveillance actions of authorities of different Member States can be demonstrated by the number of reactions to notifications received under the RAPEX system. In theory, on a perfectly integrated internal market both in terms of circulation of products[51] and market surveillance,[52] one RAPEX notification of a dangerous product sent by a Member State should trigger reaction about the presence of the notified dangerous product on the market in other 29 Member States. In reality, however, in 2010 a total of only 2 100 reactions was distributed through RAPEX in respect of 1 556 notification received through the system.[53] This shows that one RAPEX notification triggered on average only 1.35 reactions compared to the maximum possible number of 29 reactions. Although in practice, it would rarely happen than one RAPEX notification would trigger 29 reactions from all 29 EEA Member States, the fact that one RAPEX notification triggers a reaction of only one or two Member States points to a clear lack of coordination of the market surveillance authorities of different Member States.

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48 There is a widely shared perception amongst stakeholders that market surveillance is not sufficiently active and rigorous. The fragmentation of market surveillance has an important impact on its efficiency and effectiveness. It also leads to unequal protection of European consumers and other users and to an uneven playing field for economic operators.

49 The lack of effectiveness of market surveillance in the single EU market has also other grounds, such as the difficulty to trace economic operators in an increasingly globalised market, the limitation of resources of surveillance authorities , particularly in times of economic crisis, the growing number of imports of non-food products from third countries.

50 Description of the main objectives for achieving an effective coordination of market surveillance activities in the single EU market Annex 8 (section 8.4, Table 6).

51 Based on the assumption that each consumer product is sold in all 30 EEA Member States.

52 Based on the assumption that market surveillance authorities of each EEA Member State are able to detect any product sold in another EEA Member State.

53 Only "serious risk notifications" and reactions to them are taken into account, since for "non-serious risk" notifications, there is no obligation to send reactions under the current RAPEX rules.

Another aspect of the problem of weak coordination of market surveillance authorities is that most of the information relevant for market surveillance remains within national borders and does not benefit market surveillance authorities in other Member States. Results of investigation, risk-assessment as well as results of product testing are collected to a higher or lesser extent by all Member States. However, this information is used only nationally. Although over the last years the flow of cross-border information on market surveillance has improved[54] thanks to use of IT systems, such as REIS[55] and currently GRAS-RAPEX,[56] and to other forms of information exchange, such as ICSMS[57]. Yet lots of information is not systematically shared with the Commission and/or other Member States and used in the perspective of the functioning EU internal market. Consequently, due to the lack of sharing and comparability of basic investigation/risk-assessment information, no intelligence-led coordination of market surveillance efforts at the EU level can be performed. This can result in unnecessary doubling of checks of compliant products or economic operators or the fact that testing and risk-assessment of a product determined as dangerous in one Member States has to be re-done in all other Member States.[58] Thus, significant resources are wasted and important synergies are lost.

To ensure that only compliant products circulate 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.[59] However, in contrast to other areas where economic interests of consumers and other users are principally protected, for example, by the Consumer Protection Cooperation Regulation[60] or Services Directive[61] in the area of product safety where health and safety of consumers and other users are at stake, market surveillance authorities do not benefit from the procedures for effective cross-border enforcement.[62]

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54 184 notifications between 1994 and 2004 when no IT system supporting the procedure for exchange of information existed.

55 https://reis.ec.europa.eu

56 https://webgate.ec.europa.eu/sanco

57 The abbreviation of ICSMS stands for internet-supported information and communication system for the pan-European market surveillance.

58 The study "The future of market surveillance in the area of non-food consumer product safety under the General Product Safety Directive", Final Report, March 2011, BSI Development Solutions, May 2011, p. 13.

59 Certain differences appear to exist between Member States as regards enforcement in specific cases. For instance in the electro-technical sector, 80% of economic operators having participated in a public consultation in 2010 considered that the same product can be withdrawn from the market or otherwise restricted in a Member State and circulate freely in another. Public consultation on the alignment of nine Directives to Decision 768/2008/EC. http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/1385&format=HTML&aged=0&language=EN&guiLanguage=en

60 Regulation (EC) No 2006/2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws (the Regulation on consumer protection cooperation) OJ L 364, 9.12.2004, p. 1.

61 Directive 2006/123/EC on services in the internal market OJ L 376, 27.12.2006, p. 36.

62 The differences in market surveillance frameworks in these areas are illustrated in Annex 8 (section 8.4, Table 7).

2.4.2.2. Sub-optimal functioning of EU procedures for exchange of information on product risks

The current EU product safety legislation foresees two procedures for the exchange of information at EU level: the first for the exchange of rapid alert information about risks (the RAPEX procedure) and the second for the purposes of ensuring the proper functioning of the EU internal market (the safeguard procedure).

Both under the General Product Safety Directive and Regulation (EC) No 765/2008 Member States have an obligation to notify measures taken against non-food products which pose a risk (to health and safety of consumers and other users, environment and public security), including a serious risk, to the Commission[63] and to follow up the notification received.[64] This includes an obligation to notify both measures taken by the public authorities (so-called compulsory measures)[65] as well as measures taken by economic operators themselves (so-called voluntary measures).[66]

The experience of the Commission as well as the results of the public consultation show that many Member States still have difficulties complying fully with their obligations under the RAPEX system; in particular, they have problems with notifying the Commission of preventive and restrictive measures and ensuring follow-up action to notifications distributed through the RAPEX system. Only 44% of Member States indicate that they fully comply with the aforementioned obligation under the General Product Safety Directive and Regulation (EC) No 765/2008 to notify all measures taken which pose risk. 28% of Member States notify between 75 to 99% of measures taken to the Commission, 5% between 50 and 75% and 14% notify less than 50% of measures taken that they should have notified.[67] When asked about the main obstacles preventing them from fulfilling their notification obligation under EU law a number of reasons were advanced without any being significantly prevailing): ambiguity of the notification criteria,[68] too complex notification procedure, absence of sufficient information in the RAPEX notification allowing identification of the product on its national market or lack of human or financial resources to send the notifications to the Commission or to follow-up the RAPEX notifications of other Member States.[69] Specifically, on the problem of ambiguity of the notification criteria, authorities indicated an equal level of problems with all of

63 Art. 11 (1) and Art. 12 (2) of the General Product Safety Directive; Art. 22 (1) and 23 (1) Regulation (EC) No 765/2008.

64 Art. 12 (2) of the General Product Safety Directive.

65 Art. 12 (1) sub-p. 1 of the General Product Safety Directive.

66 Art. 12 (1) sub-p. 4.

67 See Annex 2; 9% of authorities were not able to determine the percentage of measures taken which are actually notifies to the Commission. This can be explained by the fact that certain of the authorities consulted did not have the information about the number of measures notified to the Commission since they did not perform at the same time the role of national RAPEX Contact Point which collects the notifications on the national level and sends them to the Commission.

68 The ambiguity of the notification criteria caused that national authority were unsure whether a given measure should or should not be notified under the RAPEX procedure. In such situations of ambiguity national authorities prefer not to notify the measure rather than risk refusal of the notification by the Commission.

69 For more details, see Annex 2 (section 2.2.3.3).

the existing criteria of risk assessment, existence of cross-border effect and the categories of measures to be notified, without any reasons being prevailing.

Similarly to the RAPEX procedure, also the practical implementation of the safeguard clause procedure, as it currently stands, presents some shortcomings. Due to the absence of articulation with the RAPEX procedure, the current framework obliges Member States to send to the Commission parallel notifications with similar information under the RAPEX procedure and safeguard clause procedure. This creates an additional administrative burden for the authorities of Member States without any added value. The "double notification" obligation leads to the general ineffectiveness of both notification mechanisms since Member States see little sense notifying one measure twice through different notification procedures. As a result, the control of the functioning of the EU internal market is weakened.

If, in theory, all compulsory measures taken against products posing risk, including serious risk, subject to Union harmonisation legislation (so-called harmonised products) should be notified to the Commission under the safeguard clause procedure,[70] the data regarding the number of safeguard clause notifications circulated provide a different picture. The greatest number of safeguard clause notification concern electric and electronic products falling within the Low Voltage Directive.[71]

These problems with the effectiveness and efficiency of the RAPEX procedure are attributable, inter alia, to legal rules which shape the functioning of RAPEX, in particular the notification criteria which are seen as too complex and the absence of an effective follow-up obligation.[72] Similar to the RAPEX procedure, the safeguard clause procedure – as it currently stands – lacks in effectiveness and efficiency. The "double notification" obligation leads to the general ineffectiveness of both notification mechanisms since Member States see little sense notifying one measure twice through different notification procedures. As a result, the control of the functioning of the EU internal market is weakened which, in turn, makes it easier to erect barriers to the free movement of safe products on the EU internal market.

2.4.2.3. Inconsistent enforcement of EU-wide product safety action

If the Commission becomes aware of the existence of a serious risk caused by a product on the internal market, it may - under Article 13 of the General Product Safety Directive - adopt a formal decision – a so-called EU product safety measure - requiring all Member States to restrict or prevent the marketing of such a product.[73]

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70 See the notification conditions contained in Art. R31 (2) and (4) of Annex 1 of Decision (EC) No 768/2008.

71 The figures on the number of safeguard clause notifications in the different sectors can be found in Annex 9 (section 9.4, Figure 10).

72 The absence of notification, of enforcement measures, or of appropriate follow-up actions to *RAPEX notifications* in one Member State lowers the protection of consumers against dangerous products not only in that Member State, but also in the other Member States. All these factors diminish the credibility of the RAPEX system in the eyes of national authorities, consumers and other users and economic operators.

73 Under the General Product Safety Directive four EU product safety measures were taken: the ban on phthalates in toys during the period up to the adoption of the permanent ban under Directive 2005/84/EC (the original Decision 1999/815/EC was adopted under the previous General Product Safety Directive 92/59/EEC was extended sixteen times out of which three times under the General Product Safety Directive (Commission Decisions 2004/178/EC (OJ L 55, 24.2.2004, p. 66),

This measure is valid for a maximum period of one year, unless it is renewed for additional periods, none of which shall exceed one year.[74]

Experience with EU product safety measures has shown that the validity of these measures for up to one year is not enough to prepare a permanent solution at the EU level. As a consequence, usually the EU product safety measures have to be repeatedly renewed. For example, the Novelty and Child Resistant Lighters Decision has already been renewed six times.[75] This creates legal uncertainty and considerable confusion for economic operators who are faced with a question of whether or they should make long-term investments to adapt their products to the new product safety requirements or not.

Both national market surveillance authorities and economic operators experienced problems with the application of EU-wide product safety measures.[76] For national market surveillance authorities difficulties were seen in the short time period for national implementation of an EU-wide product safety measure.[77] Respondents considered it important that the EU-wide product safety measures be very clearly described, including technical details, such as test methods, in order to ensure even implementation by all authorities in all Member States. Economic operators viewed inconsistent application of EU product safety measures by Member States as a

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2004/624/EC (OJ L 280, 31.8.2004)), Decision of 11 May 2006 (2006/502/EC (OJ L 198, 20.7.2006, p. 41) requiring Member States to ensure that cigarette lighters placed on the EU market are child resistant and to prohibit the placing on the market of lighters which resemble objects that are particularly attractive to children, the Decision of 21 April 2008 (Commission Decision 2008/329/EC (OJ L 114, 26.4.2008, p. 90) requiring Member States to ensure that magnetic toys placed or made available on the market display a warning about the health and safety risks they pose (expired on 21 April 2009) and a Decision of 17 March 2009 (2009/251/EC (OJ L 74, 20.3.2009, p. 32) requiring Member States to ensure that products containing the biocide dimethyl-fumarate are not placed or made available on the market (the validity of this Decision was extended three times (Commission Decisions 2010/153/EU (OJ L 63, 12.3.2010, p. 21), 2011/135/EU (OJ L 57, 2.3.2011, p. 43), 2012/48/EU (OJ L 26, 28.1.2012, p. 35); it expired on 5 June 2012 upon entry into force of the Commission Regulation (EU) No 412/2002 amending Annex XVII to Regulation (EC) No 1907/2006 concerning biocide dimethyl-fumarate (OJ L 128, 16.5.2012, p. 1)).

74 Member States are obliged to implement this EU product safety measures by ensuring that economic operators comply with the obligations set out in this measure. Since these EU product safety measures are not directly applicable to economic operators, the obligations and requirements set out in these measures must be transposed into national legislation of each Member State.

75 By Commission Decisions 2007/231/EC *(*OJ L 99, 14.4.2007, p. 16), 2008/322/EC *(*OJ L 109, 19.4.2008, p. 40), 2009/298/EC (OJ L 81, 27.3.2009, p. 23), 2010/157/EU (OJ L 67, 17.3.2010, p. 9*),* 2011/176/EU (OJ L 76, 22.3.201, p. 99), 2012/53/EU (OJ L 27, 31.1.2012, p. 24.

76 Formal implementation of EU product safety measures is carried out via a wide variety of means. These range from general legislative measures to a mix of individual regulatory administrative measures, such as letters to individual business associations. Due to these variations, it may be difficult for economic operators active in several Member States to know precisely what their obligations in an individual Member State are. Moreover, a number of Member States did not manage to ensure formal implementation of certain EU product safety measure within the deadlines foreseen. Thus, the entry into force of national measures implementing EU product safety measures can vary by up to one year. Such differences of implementation cause legal uncertainty, both for consumers and other users as well as for economic operators.

77 The enforcement of EU product safety measures causes problems to almost half of the respondents to the public consultation from Member States (43%). For most of these (60%) it is difficult to meet the time-limit for the adoption of national implementation measures. A problem is also the time-limitation of the measures and the repeated renewals (40%). For more details see Annex 2 (section 2.2.3.4).

problem,[78] despite the fact that related compliance costs with the diverging national implementing measures were assessed as "non-negligible" by some of the operators, although none of them were able to quantify these costs. [79]

Finally, the lack of traceability of non-harmonised consumer products to the responsible manufacturer or importer[80], has an important impact on the effectiveness and efficiency of market surveillance.[81] Market surveillance authorities often experience difficulties in identifying the person who has actually manufactured and/or supplied the products, in particular when the manufacturer is located outside the EU and has not appointed an authorised representative.[82] This reduces the scope of market surveillance authorities' action. In addition, if the proper traceability is not ensured, the market surveillance authorities have to spend non-negligible time and resources for uncovering often very complex supply chains in order to be able to impose effective corrective measures.[83]

2.4.3. Who is affected by the problem?

- **Final users of the products**: consumers, workers and professional users. For them, there would be a risk of accidents and injury from unsafe and non-compliant products, as well as economic damage from unsafe and non-compliant products.

- **National market surveillance authorities**: they suffer from higher administrative costs as a consequence of cross-border inefficiencies, ineffective testing and investigation costs if the operator cannot be found.[84]

- **Economic operators**: manufacturers, importers, authorised representatives, distributors suffer from uncertainty and higher costs caused by the

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78 26% of the 23 responding businesses were ever affected by an EU product safety measure of which 66% found it difficult to comply with the measure. For more details see Annex 2 (section 2.2.3.4).

79 Of those who had difficulties to comply, none could indicate the related costs, but 75% considered the costs to be non-negligible. For more details see Annex 2 (section 2.2.3.4).

80 Eight Member States impose of identification of the producer and the product as an obligatory means of compliance with the obligation of economic operators to identify the risks their products pose (Art. 5 (1) sub-p. 3 and 4 of GPSD), whereas remaining nineteen Member States provide the identification of the producer and the product as an optional requirement for complying with the obligation of economic operators to identify the risks their products pose.

81 "The survey revealed that the identification of a dangerous product did not normally lead to a successful investigation of the supply route to determine the point of manufacture or import so that an accurate assessment of the numbers of non-compliant products could be made and proportionate enforcement actions instigated." (Report from the workshop of 10 January 2011 on the future of market surveillance within the framework of elaboration of a study Future of Market Surveillance).

82 The ever growing globalisation of supply chain makes it difficult to determine how and by whom a product is manufactured or who has placed it on the market.

83 Given the tight budgetary conditions in which market surveillance authorities of almost all Member States operate, the necessity to spend part of their resources on tracing down the supply chains prevents them to apply these resources to the part of market surveillance consisting in cleaning the market from products which pose risks to public interests, in particular to health and safety of consumers and other users.

84 A non-exhaustive list of market surveillance authorities can be found at the following address: http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/market-surveillance-authorities/index_en.htm.

complexity and ambiguity of the EU legislation as well as from an unfair competition from "rogue operators" not observing the EU product safety rules

- **Member States**: they have to bear increased costs resulting from reimbursement of health treatment of injuries caused by unsafe products

2.4.4. Foreseen evolution of the problem

2.4.5. Problem 1: Unsafe consumer and other non-compliant products in the single market

The market for non-food consumer products has changed over the last decades. One of the main characteristics of the new environment is the dynamic presence on the EU market of products manufactured in third countries. More developing countries are expected to join the market as producers, while trans-national cooperation will steadily grow, offering a great variety of products. E-commerce will further facilitate cross-border transactions. Consequently, many products marketed in European countries will be manufactured in third countries and then imported in EU. Customs and market surveillance authorities will gradually develop cooperation on the basis of the existing provisions of Regulation (EC) No. 765/2008.

2.4.6. Problem 2: The fragmentation of market surveillance in the single EU market

To respond to the developments of globalisation and e-commerce, market surveillance authorities have an increasingly challenging role to play in the field of product safety. New production technologies demand efficient and updated testing methods. On-the-spot checks at business premises require substantial funds and usually yield lower returns on investment, the more so, the further down the supply chain these checks are carried out. The current economic recession and the consequent lack of resources for market surveillance authorities at Member State level could have a negative impact on the efficiency of market surveillance activities carried out by national authorities.

2.4.7. Action taken by the Commission (baseline scenario)

Under the baseline scenario the existing differences between consumer product safety requirements and harmonised product safety requirements would continue to exist. Maintaining the current specific regime for non-harmonised consumer products would mean that the existing lengthy and burdensome preliminary procedures leading to the adoption of mandates for development of European standards would continue to exist. This approach would also require the creation of parallel pre-standardisation procedures for non-harmonised consumer products in relation to the general rules on standardisation laid down in Regulation (EU) No 1025/2012.[85]

Except for certain minimum coordination requirements introduced by Regulation (EC) No 765/2008 for the area of harmonised products, Member States would continue to undertake pro-active and reactive market surveillance mostly along national lines. Besides the various legal instruments which partly regulate market surveillance for products, the Commission would contribute to market surveillance activities through the following activities:

[85] (OJ L 316, 14.11.2012, p. 12).

- Various joint market surveillance actions are financed by the 'Consumer Programme'[86], including horizontal programmes, such as the EMARS I and II, or sector specific programmes, such as helmets, sunbeds or toys. The list of these market surveillance actions is in Annex 14.[87]

- Controls of products at external borders are facilitated by EU financing under the 'Customs Programme'[88]. In order to facilitate the implementation of Regulation (EC) No 765/2008 the Commission, together with the Member States, has drafted the Guidelines for imports controls in the area of product safety and compliance.[89] The Guidelines are intended as an instrument to assist customs and market surveillance authorities in improving cooperation methods and good administrative practice. At the same time, the Guidelines focus on the practical questions customs are faced with when performing controls related to product safety and compliance.[90] The responsible authorities for market surveillance dispose of GRAS and ICSMS tools to exchange information and coordinate their activities at European level in various contexts:

  (a) **GPSD Committee**: The committee assists the European Commission in several tasks related to the implementation of the GPSD. In particular, when the Commission takes decisions requiring the Member States to urgently introduce temporary measures restricting the placing on the market of products or requiring the withdrawal of products posing serious risks.

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86 Decision No 1926/2006/EC of the European Parliament and of the Council of 18 December 2006 establishing a programme of Community action in the field of consumer policy (2007-2013) [OJ L 404 of 30.12.2006, p. 39] and, possibly, the future Regulation of the European Parliament and of the Council on a consumer programme 2014-2020.

87 The joint market surveillance actions represent only a very small remedy to the problem of the lack of coordination between authorities from different Member States. Given the current level of integration of the single EU market, in particular in area of consumer products, if annually around 2 000 measures taken against unsafe products are notified under RAPEX, i.e. measures against dangerous products which are present in more than one EU Member States, a similar number coordinated market surveillance actions by authorities from different Member States should be expected each year. In comparison, between 2005 and- 2012 only 16 joint market surveillance actions coordinated by the Commission took place. Moreover, as can be seen from Annex 14, none of these actions involved all Member States so that their impact on the overall coordination of actions of market surveillance authorities on the single EU market remains very limited.

88 Decision No 624/2007/EC of the European Parliament and of the Council of 23 May 2007 establishing an action programme for customs in the Community (Customs 2013), OJ L154, 14.6.2007, p. 25.

89 See http://ec.europa.eu/taxation_customs/resources/documents/common/publications/info_docs/customs/product_safety/guidelines_en.pdf

90 The Guidelines consist of a Generic and a Specific Part. The Generic part is essential to understand the overall relevant applicable EU legislation and in particular the obligations on safety and compliance controls and the cooperation between the relevant national authorities. The specific part of the Guidelines consists of practical tools for customs officers, i.e. information sheets and check lists for individual product groups intended to facilitate controls. The Commission is coordinating Member States' efforts to disseminate and use the Guidelines at national level. It is also engaged in an extensive programme of country visits to provide as wide as possible guidance to national officials and to address specific questions they may have.

(b) **Consumer Safety Network:** A network foreseen under Article 10 of the General Product Safety Directive where the Commission and Member States prepare joint market surveillance actions, discuss new emerging product risks and other market surveillance issues.

(c) **Senior Official Group – Market Surveillance Group**: A group of Commission and Member States' experts that discuss market surveillance, accreditation and conformity assessment issues.

(d) **RAPEX Contact Points Group**: Meeting forum of the Commission and persons responsible for managing RAPEX Contact Points in Member States which discusses and solves problems relating to notifications to RAPEX.

(e) **PROSAFE**: non-profit association of market surveillance officers of Member States ensuring realisation of joint actions and putting in practice cooperation among Member States in the market surveillance area.

(f) **Rapid Advice Forum** – another communication platform for authorities run by PROSAFE

Regarding the notification procedures the baseline would maintain the current status quo consisting in keeping the parallel obligations for Member States to notify the Commission under the RAPEX procedure and the safeguard procedure. With respect to the EU-wide product safety action the current situation where EU-wide product safety measures are implemented by Member States in a disparate manner due to their indirect applicability and time limitation would be maintained. The scope of EU-wide product safety measures would be limited to consumer products. Issuing guidelines or producing explanatory documents would not be a solution since none of them could provide for a direct applicability of the EU product safety measures or extend the time-limits of their validity.

2.5. EU right to act

The single market for products is a key achievement of the European Union. Yet, the elimination of national barriers for consumer and other products offered plenty of opportunities to less scrupulous traders who do not apply the consumer safety rules or refuse to implement the EU legislation on products. 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 consumer products and to increase the efficiency of cross-border market surveillance. Article 168 (1) and Article 169 (1) of TFEU complements 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.

The differences in national organisation of market surveillance causes problems when viewed in the framework of the European single market which no longer has internal borders and where controls at national borders have practically disappeared. To ensure that only compliant products circulate 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 beyond the border, authorities must rely on their colleagues in other Member States.

Despite the existence of the single EU market, the enforcement of product safety requirements is the Member States' competence. The way in which market surveillance is performed and organised significantly varies from one Member State to another. 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. The proportionality of the policy options will be subsequently assessed in this report.

3. OBJECTIVES

3.1. General objectives

The general objective of this initiative is to improve the functioning of the single market and to achieve a high level of consumer protection through the reduction of the number of unsafe or non-compliant products on the single EU market.

3.2. Specific objectives

The specific objectives of this initiative are:

- Consolidation and reinforcement of EU product safety requirements
- Better coordination and increased effectiveness of market surveillance activities on the single EU market for goods
- Simplification of the EU legislative framework

3.3. Operational objectives

The operational objectives to be accomplished by this initiative are the following:

- Ensuring consistency of EU product safety requirements
- Reducing ambiguity of product safety requirements for non-harmonised consumer products
- Reinforcing EU cooperation mechanisms
- Making EU product safety procedures more coherent
- More effective EU-wide product safety action

4. POLICY OPTIONS

The presented policy options were established by the Commission in close cooperation with all groups of stakeholders. The Commission proposed a number of policy options and asked all groups of stakeholders to add other possible options and express their opinion on the existing ones within the framework of the general public consultation and targeted stakeholder meetings.[91]

On the basis of those consultations, certain policy options were, however, discarded at an early stage, including (i) the issue of regulation of safety of services, (ii) imposing product safety requirements for non-harmonised professional products, i.e. those which circulate only among professionals and are never used by consumers, such as industrial machines, raw materials and semi-finished products, etc., (iii) regulating the safety of products marketed via the internet, and (iv) the abolition of the general requirement that all consumer products must be safe. A detailed description of discarded options as well as of the reasons for their rejection is presented in more detail in Annex 12.

The remaining policy options, which all contribute to the general policy aim of reduction of unsafe and non-compliant product on the EU internal market, are presented under two broad policy objectives, each accompanied by simplification.

4.1. Policy objective 1: Consolidation and reinforcement of EU product safety rules

The options in the following sub-sections present solutions to the problem of inconsistency of EU product safety requirements.

4.1.1. Ensuring consistency of EU product safety requirements

4.1.1.1. Option 1.A – Baseline scenario: Keeping differences between consumer product safety requirements and harmonised product safety requirements

See above Sections 2.4.1.1 and 2.4.4.

4.1.1.2. Option 1.B – Aligning consumer product safety requirements with harmonised product safety requirements

Under option 1.B consumer product safety requirements would be aligned as much as possible with certain harmonised product safety requirements (with the exception of conformity assessment procedures and CE-marking) as described in the following table. Differences between these two sets of rules described above in Section 2.4.1.1, would be eliminated. For all consumer products, whether harmonised or non-harmonised, a single set of general product safety requirements would apply.[92]

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[91] For more details regarding the public consultation see Annex 2 and Annex 4 with respect to the targeted stakeholder meetings).

[92] The details of this alignment are described in Annex 8 (section 8.3, Table 5).

4.1.1.3. Option 1.C – Consumer product safety requirements to be defined less strictly than harmonised product safety requirements

Under option 1.C consumer product safety requirements would provide for a lighter regime than that which is foreseen under the harmonised product safety rules. This would mean, for example, that the identification of the product and its producer for non-harmonised consumer products would be prohibited.

4.1.1.4. Option 1.D – Consumer product safety requirements to be defined more strictly than harmonised product safety requirements

Under Option 1.D consumer product safety requirements would be made stricter than harmonised product safety rules with respect to certain products or group of products. This would mean that the manufacturer or importer of a consumer product would have to comply with additional product safety requirements than those in harmonised product safety rules. Such additional safety requirements could, for example, consist of the obligation to (i) put on the product a unique identification sign, such as a numeric barcode, radio frequency identifier, or (ii) to indicate on the product, its packaging or accompanying documentation of further information like place or date of manufacturing of the product, address of the company in charge of collecting clients' claims etc.

4.1.2. Reducing ambiguity of product safety requirements for non-harmonised consumer products

4.1.2.1. Option 2.A – Baseline scenario: Necessity of creation parallel pre-standardisation procedures for non-harmonised consumer products

See above Sections 2.4.1.2. and 2.4.4.

4.1.2.2. Option 2.B – Direct applicability of ad-hoc safety requirements

The ad-hoc safety requirements which set the basis for establishment of mandates for the development of European standards for non-harmonised consumer products by the European Standardisation Organisations would become directly applicable. European standards adopted on their basis and published in the Official Journal would provide for presumption of conformity with the safety requirements set out in these directly applicable measures.

4.1.2.3. Option 2.C – Abolition of double adoption of the non-binding ad-hoc safety requirements

This approach would align the regime for developing European standards for consumer non-harmonised products with the reformed general standardisation procedures applicable to the harmonised area under Regulation (EU) No 1025/2012. This alignment would entail abolition of the current double adoption of specific safety requirements for products in the regulatory committees. Abolition of the double adoption of safety requirements would however not mean the abolition of these requirements as such. These safety requirements which provide the basis for the establishment of mandates for the development of European standards by the European Standardisation Organisations would continue to be established, but in a less formal procedure within the framework of the preparation of mandates in an expert discussion within the relevant committee. These mandates for developing

European standards would then be formally adopted in the same way as they are for harmonised products. Once developed by the European Standardisation Organisations, the fulfilment of criteria of high consumer safety would be assessed *vis-à-vis* the general safety requirement.

4.1.2.4. Option 2.D –Fast-track procedure for adopting already existing European standards without mandates

Option 2.D builds on the previous option by providing for a fast-track procedure for adopting already existing European standards developed by the respective European Standardisation Organisation, even if those European standards were not adopted on the basis of previous mandates granted to European Standardisation Organisations by the Commission.

This procedure would allow for referencing existing European standards under the general product safety legislation to provide for the presumption of conformity under this Directive even if they were adopted outside a Commission mandate. In the case of an existing European standard which in the view of the Commission and the Member States satisfies the general safety requirement, the Commission would not have to do complicated "re-engineering" of requests for development of standards which already exist.

4.2. Policy objective 2: Better coordination and increased effectiveness of market surveillance activities on the single EU market for goods

The options in the following sub-sections present solutions for the problem of fragmentation of market surveillance activities on the single EU market. Due to the fact that market surveillance is the responsibility of the Member States (subsidiary principle), the European Commission does not have the power to decide the overall amount of national resources for market surveillance activities. The following options therefore focus on possible means to increase the impact of market surveillance efforts for a given level of resources at the EU level; additional resources for national markets surveillance authorities have to be funded from national budgets of Member States.

4.2.1. Reinforcing EU cooperation mechanisms

Despite the existence of an internal EU market, the intensity of coordination of market surveillance activities of Member States in the non-food product safety area lags significantly behind the level of coordination achieved in other areas, such as in the area of enforcement of economic interests of consumers or in the food safety area. The different options set out below represent different levels of potential coordination of market surveillance in the non-food product safety area: Option 3.B would advance the coordination of market surveillance to the level reached in the areas covered by the Consumer Protection Cooperation Regulation; Option 3.C is a middle step where the intensity of coordination is above the levels of the Consumer Protection Cooperation Regulation, but below the level of coordination in the food safety area; finally Option 3.D describes the most developed level of coordination reflecting that reached in under the EU Food Regulations.[93]

[93] Regulation (EC) No. 178/2002, OJ L 31, 1.2.2002, p. 1 (the "Food Regulation"); Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p.1 and corrigenda OJ L 191, 28.5.2004, p.1) (the "the Official Feed and Food Control Regulation").

4.2.1.1. Option 3.A – Baseline scenario: keep status quo based mostly on voluntary market surveillance coordination

See above Sections 2.4.2.1. and 2.4.4.

4.2.1.2. Option 3.B – Coordination of cross-border enforcement of measures resulting from "in the-field" market surveillance

This option would define procedures for effective cross-border enforcement of measures resulting from "in the-field" market surveillance. Such procedures would consist of (i) a procedure triggered by a request for information, i.e. a process where authorities of one Member State would be able to ask other authorities for information on dangerous products or economic operators, and (ii) a procedure triggered by a request for action, i.e. process under which authorities of one Member State could call on authorities in another Member State to perform simultaneous inspections on economic operators based in the respective Member States.

Providing national market surveillance authorities with tools for coordination of concrete reactive action would help these authorities to cope with the growing globalisation of product supply chains. Thus, these authorities would be able to 'reach out' over national borders by effectively relying on assistance of market surveillance authorities from other Member States.

4.2.1.3. Option 3.C – Overall rationalisation of coordination of market surveillance activities

Option 3.C adds to Option 3.B the possibility of rationalisation of the currently dispersed pre-planned market surveillance activities. Indeed, an intelligence-led market surveillance supporting the proper functioning of the EU internal market needs to be based on the widest possible sharing of information relevant for the interception of unsafe products among the market surveillance authorities of Member States.

In particular, to ensure proper execution and continuation of joint EU market surveillance actions, their coordination would be put on a more permanent footing. This would be achieved by two means: by the implementation of the Multiannual Market Surveillance Plan[94] and through the establishment of a coordination network (referred to as European Market Surveillance Forum) ensuring cooperation of Member States' authorities which would set EU-wide enforcement priorities in close cooperation with the Commission, coordinate the relationship with customs at an EU level, facilitate data exchange between the Member States, develop best practices (e.g. on risk assessment), etc. Similarly, the coordination activities at EU level would be streamlined: the current plethora of coordination groups and committees would become sub-groups of the European Single Market Surveillance Forum of market surveillance officials so that coherence and consistency of messages about the direction of market surveillance at a national level could be ensured.

[94] The Multi-annual Market Surveillance Plan is one of the elements of the Product Safety Package.

Elements that would facilitate the coordination of market surveillance would be the discussion of national market surveillance plans[95] and the introduction of common reporting requirements[96] on the market surveillance activities performed, including self-assessment of their effectiveness.[97]

4.2.1.4. Option 3.D – Centralisation of EU market surveillance in the area of non-food products (EU Market surveillance agency)

Under this Option the intensity of market surveillance and the level of coordination between national market surveillance authorities of Member States would be brought to a similar level as in the food area. This Option 3.D would entail substantial investments into the non-food product safety market surveillance in order to establish the framework existing already in the food area consisting of a general auditing system[98] and a market surveillance agency.[99]

The general auditing system would relate to the checking of the quality of controls, inspections, samplings, testing of products and risk assessment performed. The auditing system would also assess the national market surveillance framework in terms of effectiveness of coordination between the relevant market surveillance services (i.e. coordination of regional, national, sector-specific bodies, including the RAPEX Contact Points), customs authorities, market surveillance authorities of other Member States and with the European Commission.

Furthermore, the market surveillance agency for non-food products would review the measures preventing and/or restricting free movement of products taken by national market surveillance authorities. It would assist national authorities in organising simultaneous market surveillance actions in more than one Member State. It would also elaborate harmonised inspection protocols, methods of risk assessment of products and economic operators and develop a harmonised approach to risk assessment and risk management.

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95 On the basis of Art. 18(5) of Regulation (EC) 765/2008 national market surveillance plan are sent to the Commission. However, the Commission only simply compiles these national plans, no coordination in their preparation takes place in order to ensure a "seamless market surveillance framework" at least in the area of planning of market surveillance activities.

96 Certain benchmarks exists within the Enforcement Indicators initiative, however, the credibility of these indicators is low. See Annex 10 for more details about the collected enforcement indicators.

97 Currently under Art. 9 (1) of the General Product Safety Directive Member States are obliged to ensure that approaches employing appropriate means and procedures are put in place, which may include in particular: (a) establishment, periodical updating and implementation of sectoral surveillance programmes by categories of products or risks and the monitoring of surveillance activities, findings and results; (b) follow-up and updating of scientific and technical knowledge concerning the safety of products; (c) periodical review and assessment of the functioning of the control activities and their effectiveness and, if necessary, revision of the surveillance approach and organisation put in place. However, since there is no obligation provide the programmes, follow-ups and results of assessments to the Commission. Regulation (EC) No 765/2008 is more explicit since it obliges under Art. 18 (5) Member States to shall establish, implement and periodically update their market surveillance programmes and communicate them to the Commission as well as to review and assess the functioning of their surveillance activities and communicate such reports to the Commission, but regarding the latter only at least every fourth year.

98 In the food area the general auditing system is established under Art. 17 (2) of the Food Regulation and Art. 45 of the Official Food and Feed Control Regulation.

99 In the food area the European Food Safety Authority is established under Art. 11 (2) of the Food Regulation.

4.2.2. Making EU product safety procedures more coherent

4.2.2.1. Option 4.A – Baseline scenario: Keeping the parallel notifications under RAPEX procedure and safeguard procedure

See above Sections 2.4.2.2. and 2.4.4.

4.2.2.2. Option 4.B – Simplification of the RAPEX procedure

The RAPEX procedure would be simplified. The requirements conditioning the sending of information on dangerous products to the Commission and other Member States would be made less onerous in order to enable easier and more cost-effective identification of dangerous products in other Member States on the basis of RAPEX notifications. The safeguard procedure, including its parallel notification obligations, would continue to function next to the simplified RAPEX procedure.

4.2.2.3. Option 4.C – Simplification of the RAPEX procedure and streamlining of that procedure with the safeguard procedure

The RAPEX procedure and the safeguard procedure could be streamlined so that only one notification for both procedures would be necessary. Once received and treated under the RAPEX procedure, other Member States or the Commission would have the possibility to raise an objection to such measure notified, in particular in the case of a difficult risk assessment, and thus trigger the Union safeguard procedure at the end of which the Commission will decide whether the adoption of the notified measure was justified or not.

4.2.3. More effective EU-wide product safety action

4.2.3.1. Option 5.A - Baseline scenario: Keeping EU-wide product safety measure indirectly applicable for a period of one year only

See above Sections 2.4.2.3. and 2.4.4.

4.2.3.2. Option 5.B - Extension of the scope of EU-wide product safety measures to harmonised non-consumer products

Extension of the application of EU-wide product safety measures to other non-consumer products is a natural consequence of the creation of a single market surveillance framework. If these measures remained limited only to consumer products, they would become a source of inconsistencies creating barriers to the single EU market.

4.2.3.3. Option 5.C - Making EU-wide product safety measures directly applicable

To avoid significant delays in implementation and differing dates of entry into force of EU-wide product safety measures in Member States as well as to achieve their uniform implementation, the Commission would make these EU product safety measures directly applicable to economic operators as of a pre-determined date.

4.2.4. Option 5.D – Removal of the limited validity of EU-wide product safety measures

To eliminate the confusion caused by repeated renewal of EU-wide product safety measures, the period of validity of the EU-wide product safety measures would be extended: the duration would be specified in the implementing act (either as limited or unlimited) taking into account the gravity of the situation, its urgency and other relevant circumstances.

4.2.4.1. Option 5.E – Combination of options 5.B, 5.C and 5.D

Last option 5.E consists of the cumulative combination of options 5.B, 5.C and 5.D. Under this option EU-wide product safety measures would not only be extended to harmonised non-consumer products and made directly applicable, but also their period of validity would be determined on a case-by-case basis.

5. ANALYSIS OF IMPACTS

5.1. Analysis of impacts of policy options under objective 1 (Consolidation and reinforcement of EU product safety rules)

The impacts of the different baseline scenarios under options 1.A, 2.A, 3.A, 4.A and 5.A are assessed in Sections 2.4.2., 2.4.4. and 2.4.5.

5.1.1. Ensuring consistency of EU product safety requirements

5.1.1.1. Option 1.B – Aligning consumer product safety requirements with harmonised product safety requirements

Decision (No) 768/2008/EC aligned the general non-risk related product safety requirements in the various pieces of harmonised product safety legislation. The same, however, did not happen with respect to consumer product safety requirements. In consequence, similar products in terms of its characteristics and safety properties, for example, toys and childcare articles, are subject to differing sets of rules.[100]

Also, the public consultation showed that 94% of national market surveillance authorities, 65% of other stakeholders consulted, including consumer and business associations, confirmed that the safety of consumers would be better ensured if the harmonised product safety requirements were also applied to non-harmonised products.[101] Thus, from the perspective of health and safety of consumers, aligning of consumer product safety requirements with harmonised product safety requirements would best achieve the objective of ensuring that only safe product circulate on the internal market.

For economic operators, an alignment of the consumer product safety requirements with harmonised product safety requirements would lower information-research costs and costs of legal advice. Economic operators would no longer have to spend additional time or costs on determining whether either the consumer product safety requirements or harmonised product safety requirements apply to the product in question. A reduction of costs of identification of applicable product safety rules could reduce the size of the category of economic operators who are willing to observe the rules, but unable to fully do so, and increase the number of those who are both willing and able to fully respect all product safety requirements. In sum, making consumer product safety requirements compatible with harmonised EU product safety requirements would thus provide the desired clarity and legal certainty since it would eliminate the existing overlap between inconsistent requirements under consumer product safety requirements and harmonised product safety requirements.

For market surveillance authorities, the alignment of consumer product safety requirements with harmonised product safety requirements would also have a positive effect on the effectiveness and efficiency of market surveillance. The effectiveness of market surveillance actions would be increased thanks to the

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100 The differences between these sets of rules are outlined in Section 2.4.1.1 and described in detail in Annex 8 (section 8.3, Table 4)

101 See Annex 2 – Results of the public consultation.

alignment of the requirements. In particular, the requirements concerning the identification of the manufacturer and/or the importer authorities would enable enforcement measures directly at the source of the risk which represents the most effective and the least discriminatory enforcement approach. This option would also contribute to the non-discriminatory treatment of economic operators by market surveillance authorities of different Member States while allowing market surveillance authorities to track down non-compliant economic operators more quickly and at a lesser cost. Where the manufacturer and/or the importer are not identified, the restrictive or preventive measure against the dangerous product is usually addressed to the distributor. This is a less effective approach both from the safety and internal market surveillance perspective: containing the product at the point of sale will always stop a lesser number of products from circulating on the internal market than if stopped directly "at the source", that is at the point where the product is manufactured or imported to the EU as well as it being targeted to the person primarily responsible for the dissemination of the risky product, i.e. the rogue manufacturer or importers to the detriment of final distributors placed in the EU.

If the positive impact of the alignment of general non-risk related consumer product safety requirement and harmonised product safety requirements on the principal stakeholders can be estimated without serious difficulties, the same cannot be affirmed with respect to possible negative cost impacts. On the basis of discussion with relevant stakeholders in the framework of the targeted stakeholder meeting within the process of public consultation, it appears that producers do not structure their product lines or marketing practices according to whether a product is harmonised or not. This means that there are no separate production lines and marketing approaches for harmonised products on the one hand, and non-harmonised products on the other[102]. Thus, once a producer produces a harmonised product, it will extend the application of the harmonised product safety requirements also to non-harmonised product if he produces them simultaneously[103]. At the same time if the product is likely to be used by consumers, thus increasing the risk of liability for the producer, the producer will apply higher standards of care going beyond the requirement prescribed by the legislation. Therefore, it will not be unusual for producers of consumer products to apply certain additional safety requirements and precautionary measures for consumer products even if not prescribed by the legislation.

These statements seem to be confirmed by responses to the public consultation with respect to the general application of two elements of harmonised product safety requirements. With respect to the first example of a harmonised product safety requirement consisting of establishing technical documentation for products, most of the manufacturers appear to establish such documentation even in the non-harmonised area, i.e. in the area where they are not obliged to do so by the harmonised EU product safety requirements. In the public consultation 25% of responding economic operators indicated that they establish technical documentation for non-harmonised products because of the requirements of national law, 55% of responding operators establish technical documentation even without the existence of

102 See Annex 4 – Summary of the targeted stakeholder meetings.

103 Of the economic operators responding to the public consultation, 30% indicated that they produced or imported harmonised products only, 65% stated they produced or imported both harmonised and non-harmonised products (remaining 5% were not able to ascertain whether their products are harmonised or non-harmonised.

any rule obliging them to do so[104]. Furthermore, 30% of responding economic operators to the public consultation stated that they would expect a cost reduction if technical documentation would have to be established in the same way for all the products; 15% would expect a negligible cost increase, 10% a non-negligible cost increase while the remaining 45% was not able to indicate whether this requirement would lead to a cost increase or cost reduction.

Regarding the second example of a harmonised product safety requirement consisting in the identification of the manufacturer and of the product, according to the answers given in the public consultation, all the economic operators were ensuring traceability of products in one way or another: the most widely used means of ensuring traceability of products was the indication (on the product, its packaging or in the accompanying documents) of the identity of the manufacturer (77% of manufacturers responding), followed by the indication of identification of the product (46%), indication of the contact address and keeping the list of component suppliers (both 38,5%) and finally keeping the list of distributors (31%)[105].

On the basis of the above, it can be concluded that this option will have a positive impact on consumers and other users, economic operators other than manufacturers of non-harmonised product who manufacture and sell their products within a single EU Member State, and market surveillance authorities. Although there is a certain probability of the occurrence of negative impacts of the alignment in terms of a very small cost increase for a limited group of producers[106], this increase can be expected to be extremely marginal and would represent a hardly perceptible fraction of operating costs.

5.1.1.2. Option 1.C – Defining consumer product safety requirements less strictly than harmonised product safety requirements

This option will have a positive impact on manufacturers of non-harmonised products only. Given the fact that according to the aforementioned data from the RAPEX system there is no substantial difference between the number of notifications of measures taken against dangerous harmonised consumer products and dangerous non-harmonised consumer products, from the perspective of protection of health and safety of consumers, there seems to be no justification for defining consumer product safety requirements less strictly than harmonised product safety requirements. A concrete example is the electrical equipment covered by the Low Voltage Directive which is applicable to equipment designed to operate with a voltage rating exceeding 50 volts. This option would constitute a risk for the health and safety of consumers if a similar product, designed to operate with a voltage rating not exceeding 50 volts, would be subjected by the EU to less stringent safety requirements.

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104 Remaining 20% of responding economic operators indicated that they do not establish any technical documentation for non-harmonised products.

105 See Annex 2 – Results of the public consultation.

106 This group would involve producers of non-harmonised products only (none of these economic operators responded to the public consultation performed) who would not apply the harmonised product safety requirements already. In theory, this category would comprise, for example, producers who would be marketing their products exclusively in Member States which do not require identification of the producer and the product as an obligatory means of fulfilling the obligation of economic operators to be kept informed of the risk that their product may pose and who would not be following the stricter rules already.

If consumer product safety requirements were defined less strictly than harmonised product safety requirements, the economic operators would face two sets of differing and product safety requirements – consumer product safety requirements and harmonised product safety requirements[107]. The costs of information research and/or the legal advice as to the applicable product safety requirements cases would not be reduced, since economic operators - when ascertaining which sets of requirements apply to their products - would still have to deal with two differing sets of legal requirements[108].

Moreover, keeping two differing sets of product safety requirements would not increase either the effectiveness or the efficiency of market surveillance. As indicated above, the public consultation showed that 94% of national market surveillance authorities, 65 % of other stakeholders consulted, including consumer and business associations, confirmed that the safety of consumers would be better ensured if the harmonised product safety requirements were also applied to non-harmonised products[109].

5.1.1.3. Option 1.D – Defining consumer product safety requirements more strictly than the harmonised product safety requirements

From the safety perspective, there do not seem to be any reasons to define consumer product safety requirements more strictly than harmonised product safety requirements on a permanent basis since the number of dangerous non-harmonised consumer products reported under the RAPEX procedure is not higher than the number of reported dangerous harmonised consumer products.[110] For the electrical equipment covered by the Low Voltage Directive, for example, it would lead to fairly absurd results: this Directive is applicable to equipment designed to operate with a voltage rating exceeding 50 volts but, under this option, a similar product designed to operate with a voltage rating not exceeding 50 volts, would be subject to more stringent safety requirements. This option will have a positive impact on consumers and other users.

For economic operators, the inclusion of additional or stricter requirements for consumer product safety requirements in comparison to the harmonised product safety requirements would not have any positive impact on the problem of legal uncertainty caused by the application of two differing sets of requirements for

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107 Although in theory, the option could bring some benefits to those producers who produce non-harmonised products only, for the same reasons described under previous Option 1.B., these benefits seems to be more hypothetical then practical: the size of the category of producers producing non-harmonised products only seems to extremely limited, the influence of definition of different sets of EU product safety requirements, whether diverging or converging, seems to be non-existent or infinitesimal etc.

108 Although compared to the current situation the assessment of which sets of requirements, i.e. whether consumer product safety requirements or harmonised product safety requirements apply in the concrete case, since there would be two sets of non-overlapping relatively coherent requirements, the determination which set of requirements applies would still be difficult due to the problems in answering the question of which products fall into the category of harmonised products (so that harmonised product safety requirements would apply) and which fall into the category of non-harmonised products. Although useful as a legislative abbreviation, the application of the differentiation between harmonised and non-harmonised products creates significant legal and practical problems.

109 See Annex 2 – Results of the public consultation.

110 See Annex 9.

harmonised consumer products. If this option were retained, economic operators whose products would be subject to harmonised product safety requirements would have to check whether or not additional or stricter consumer product safety requirements do not apply on top of the harmonised product safety requirements. Clearly, this would not bring any reduction of related information research or legal costs to any category of economic operators.

Beyond that, if consumer product safety requirements were to include on a permanent basis additional or stricter requirements in comparison to the harmonised product safety requirements, it appears that this would bring no further added value either in terms of effectiveness or efficiency of market surveillance. For market surveillance authorities the minimum requirements of identification of the manufacturer and/or importer and the product appear to be sufficient for taking a speedy and effective action against dangerous products "at source", i.e. against the producer who put the dangerous product in question on the EU market, not against the distributor at the end of the supply chain.

5.1.2. Reducing ambiguity of product safety requirements for non-harmonised consumer products

5.1.2.1. Option 2.B – Direct applicability of ad-hoc safety requirements

One approach to the simplification of pre-standardisation procedures under the General Product Safety Regulation could consist in reinforcement of the ad-hoc safety requirements by making them directly applicable. On the one hand, making ad-hoc safety requirements directly applicable would make them stronger and more predictable, on the other hand, it would not contribute to the coherence of preliminary EU procedures for requesting standards. If ad-hoc safety requirements were to be reinforced, this would very likely require a heavier procedure in terms of costs both for the Commission and the Member States: as a result, the objective of a more efficient procedure would not be attained which would, in turn, prevent the EU from providing stakeholders with more European standards which ensure a uniform application of product safety rules throughout the internal market.

5.1.2.2. Option 2.C – Abolition of double adoption of the non-binding ad-hoc safety requirements

If the procedure leading to the formal adoption of non-binding ad-hoc safety requirements was simplified by the abolition of double adoption, the length of the period of the preliminary procedure leading to the establishment of mandates for developing EU standards would be substantially reduced. Thus, the Commission could - with the necessary input from the Member States – ask for inclusion of requests for developing European standards under the General Product Safety Regulation into the general standardisation working programme: the length of procedure leading to the establishment of mandates for developing EU standards under the General Product Safety Directive would become equal to the one under the New Approach Directives. At the same time, this approach would preserve the general character of the new Standardisation Regulation and thus contribute to the clarity of procedures leading to the establishment of mandates for developing European Standards.

5.1.2.3. Option 2.D – Fast-track procedure for adopting already existing European standards without mandates

The possibility of fast-track procedure for granting presumption of conformity to existing European standards would make it unnecessary to prepare and adopt mandates to the European Standardisation Organisations asking them for development of a European standard which already exists. In other words, where a European standard under the General Product Safety Regulation was developed already by European Standardisation Organisations outside of a mandate, it would not be necessary to "re-create" such a mandate, but to simply decide that such a standard does or does not comply with the general safety requirement. The artificial "reverse engineering" of mandates for European standards would be eliminated. Thus, allowing granting a presumption of safety for already existing European standard developed by the European Standardisation Organisation outside a mandate would further reduce the unnecessary administrative burden hindering faster development of usable European standards under the General Product Safety Regulation.

5.2. Analysis of impacts of policy options under objective 2 (Better coordination and increased effectiveness of market surveillance activities on the single EU market for goods)

Further improvement of market surveillance for products in the EU through an enhanced effectiveness of the efforts by market surveillance authorities would have a deterrent effect on rogue traders and would increase the detection of unsafe and/or non-compliant products. Consequently, this, would lead to less unsafe and/or non-compliant products becoming or remaining available on the market and to a general positive impact on society (human health, environment, social protection). Yet, these effects would necessarily be indirect so that it is impossible to estimate them precisely.[111]

[111] A preliminary conclusion of the Task Force F on Enforcement Indicators, established within the framework of joint action EMARS II, indicated that effectiveness of market surveillance could be measured by the number of product related accidents prevented by market surveillance action. The efficiency of market surveillance action could be estimated if this indicator was then compared with the amount of funding allocated annually by Member States for the functioning of market surveillance. However, detailed data about the accidents and injuries relevant for market surveillance purposes are very difficult to obtain since these data are not collected in all Member States for the same period of time and in the same form or are not detailed enough to determine exactly which product was involved in the accident and whether it was the product involved which was the direct cause of the accident or whether the accident resulted from the misuse of the product (The existing IDB database indicates only limited information relevant for the market surveillance purposes. To have more information general practitioners would have to inquire, analyse and report about the causes of accidents or injuries of patients upon medical examination of each patient having suffered an injury or accident). The only alternative benchmark available for determining the effectiveness and cost-efficiency of market surveillance in individual Member States would be the amount of funds allocated to market surveillance authorities by Member States. However, this benchmark would be very rough and, as such, would have a very low value in terms of measuring the efficiency of market surveillance for a number of reasons. Firstly, market surveillance is for the relevant authorities in many cases only one task out of many others. The authorities mostly have an overall budget and it is not always easy to determine the exact percentage of that budget spent for market surveillance. The same problem exists with the number of market surveillance inspectors. In most cases market surveillance is only part of their occupation – but it is difficult to determine the time spent exclusively for market surveillance (i.e. to determine the man-years). Secondly, different institutional structures of market surveillance authorities in Member States, which may have an important effect on the "real value" of the amount of funds allocated to market surveillance, are not taken into account. Thirdly, to avoid a “bad” ranking Member States are reluctant

5.2.1. Reinforcing EU cooperation mechanisms

5.2.1.1. Option 3.B – Coordination of cross-border enforcement of measures resulting from "in the-field" market surveillance

Providing national market surveillance authorities with tools for coordination of concrete reactive action would help these authorities to cope with the growing globalisation of product supply chains. Thus, these authorities would be able to 'reach out' over national borders by effectively relying on assistance of market surveillance authorities from other Member States. For example, being able to perform simultaneous checks on economic operators active in different Member States would increase the effectiveness and coherence of market surveillance action on the single EU market. This would in turn positively influence the consistency of protection of consumers and other users within the Union. Therefore, this option will have a positive impact on consumers and other users in the EU.

At the same time this option will improve coherence of market surveillance practices across the Member State and provide a more level playing field for compliant economic operators. As a matter of fact, in the public consultation, 93% of national market surveillance authorities and 81% of economic operators consulted agreed that more intensive information sharing and cooperation between Member States would ensure more equal treatment of economic operators by national market surveillance authorities throughout the EU with respect to similar products[112]. This improvement could be considered a concrete positive impact on economic operators, although not quantifiable[113].

This option will also have a positive impact on compliant economic operators because an improvement of the effectiveness of market surveillance will necessarily reduce the unfair competition by non-compliant economic operators[114]. Conversely, the option would have a negative impact on those who, once the marketing of their dangerous product has been stopped in one Member State, try to sell it to consumers in other Member States where at that moment it would not yet have been prohibited. A negative impact of non-compliant economic operators would, also, have a positive impact for consumers and other users due to the increased level of safety as well as on compliant economic operators thanks to the limitations of unfair competition from non-compliant economic operators. It can be reasonably expected that the consequence of a more coordinated market surveillance framework at EU level would reduce the size of the category of economic operators "unwilling to respect the product safety rules" since certain gaps in the EU market surveillance through which these unscrupulous economic operators can currently escape would be closed.

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to report exact figures spent on market surveillance but rather to give overall budgets or the number of inspectors. Such overall figures are however not too reliable in measuring effectiveness and efficiency since – for example – the overall budget of an authority responsible for market surveillance may be increased while the percentage spent for market surveillance may decrease.

112 See Annex 2 – Results of the public consultation.

113 65% of economic operators were not able to estimate the costs of diverging safety evaluations of market surveillance authorities of different Member States; nevertheless, 88% of those who were able to provide estimations considered these costs to be non-negligible, although they could not estimate the m. 62% of economic operators consulted considered that the cooperation between EU Member States should be improved (See Annex 2 – Results of the public consultation.).

114 As explained in section 2.4.1.3 in some sectors economic operators estimate the loss in turnover due to unfair competition between 5 and 18%.

The costs of market surveillance authorities might increase slightly due to the need to answer the request for assistance (e.g. contact a specific economic operator based in the national territory) by colleagues in other Member States, but the increase is expected to be more than offset by the advantage of benefitting from this assistance.

5.2.1.2. Option 3.C – Overall rationalisation of coordination of market surveillance activities

Option 3.C represents a more ambitious development of Option 3.B: under Option 3.C not only reactive, but also proactive market surveillance would be performed within a coordinated EU framework. This is expected to further improve the overall performance of market surveillance with respect to the previous option.

During the public consultation, 86% of national market surveillance authorities and 96% of other stakeholders, including consumer and business associations agreed that more intensive information sharing and cooperation between Member States would further enhance the safety of consumers throughout the EU[115]. In particular, the coordination of market surveillance activities of the authorities of different Member States was appreciated, since it brings tangible benefits for the enforcement activities at EU level: sharing of expertise with other market surveillance organisations was quoted by the national market surveillance authorities as the most visible benefit of these actions (95%), followed by advice on interpretation issues (60%), joint press activities (49%) and lower costs for surveillance activities, such as sharing of testing costs (46%). The joint market surveillance actions caught the attention of 62% of economic operators consulted, although a large majority of these operators (91%) were not able to give opinions as to whether these actions brought concrete benefits also to businesses[116].

The experience with the functioning of the systematic coordination of pro-active market surveillance activities of Member States has shown that it cannot be effective and work efficiently if it is performed on an ad-hoc basis lacking long-term perspective and planning tools. Consequently, if systematic coordination is to produce tangible added-value with impacts in concrete situations, it needs to be based on an EU defined framework, the functioning of which would be supervised by the Commission. While this systematic coordination has so far mainly focused on assisting the Member States with the administrative activities for joint surveillance actions, experience with horizontal projects[117] has also shown that these projects are beneficial for raising the quality of market surveillance and minimising differences between the Member States.[118] In particular, systematic coordination of different market surveillance fora[119] could help resolve problems of differing safety evaluation of identical products since more coherent approaches could be reached at the EU level.

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115 See Annex 2 – Results of the public consultation.

116 See Annex 2 – Results of the public consultation.

117 Examples of such horizontal activities are the establishment of the Rapid Advice Forum, the development of the best practice handbook, knowledge base and the recall guide, the coordination of input into standardisation, the establishment of a peer review process and training solutions, etc.

118 Details regarding past joint market surveillance actions are set out in Annex 14.

119 As described above in section 2.4.5.

The new elements which would be introduced to the pro-active market surveillance framework (establishment of a coordination network, the streamlining of coordination groups and committees, introduction of common reporting requirements, establishment of common enforcement priorities at the EU level, including the joint market surveillance actions) would bring benefits for a better organisation of the coordination of the market surveillance framework at EU level compared to the baseline scenario of the current situation.[120]

This option would have an important positive impact on consumers and other users in the EU, as well as on compliant economic operators for the same reasons explained under the previous Option 2.B. However, since the intensity of coordination would be stronger than under the previous option, the size of the impacts is also expected to be higher. Similarly, a further reduction of the number of rogue operators could be foreseen.

Under of this option, market surveillance authorities are not expected to bear more costs than under the previous one as most coordination efforts will take place by using EU tools (exchange of information tools, experts' groups meetings).

5.2.1.3. Option 3.D - Centralisation of EU market surveillance in the area of non-food products (creation of EU Market Surveillance Agency)

The centralisation of EU market surveillance in the area of non-food products by the establishment of an EU Market Surveillance Agency could be the next level of the integration of the single EU market. This Option represents a higher degree of market surveillance coordination integrating previous Options 2.B and 2.C so as to bring the intensity of market surveillance and its coordination in the EU to the level achieved in the food area.

On the one hand, the establishment of a general auditing system regularly verifying the fulfilment of pre-established common performance indicators and a European Market Surveillance Agency in the non-food area would constitute a major leap forward in the establishment of a common Union market surveillance framework for the internal market of goods.

On the other hand, the establishment of such a highly advanced coordination framework, including the creation of an EU Market Surveillance Agency in the area of non-food products, would entail very significant costs due to the need for construction of coordination infrastructures and capacity which currently do not exist at EU level. These costs would entail the building and maintenance of the necessary infrastructure, such as (i) establishment of a new EU Agency, *(ii)* hiring EU market surveillance inspectors able to review the activities of national market surveillance authorities and perform their peer assessment, (iii) providing the new Agency with facilities necessary for performance of their activities etc. A precise estimate of these costs is not possible. However, the order of magnitude can be imagined by reference to existing agencies that carry out similar tasks, in particular the European Food

120 "*On the one hand, the fundamental rules of the Internal Market such as the principles of free movement of goods and mutual recognition are being undermined by certain economic operators and Member States. On the other hand, the checks carried out by market surveillance authorities are, for the majority, performed in an entirely random manner. These controls do not sufficiently prioritize the search for non/conforming and/or dangerous products from third countries*." (quote from the contribution of an economic operator, Oxylane-Decathlon, to the public consultation).

Safety Agency (EFSA) – performing pre-marketing approvals as well as market surveillance functions - and the European Commission's Health and Consumers Directorate-General directorate known as the Food and Veterinary Office (FVO) performing market surveillance functions only (system inspection activities). The annual budget of EFSA is estimated around 75 million EUR, which is mainly allocated for carrying out risk assessment activities, including scientific opinions and advice to provide support for policy making at EU level, as well as to support the EU Member States in taking effective and timely risk management decisions. The budget of FVO is estimated at around 30 million EUR annually. In this respect, it can be reasonably envisaged that the total annual budget needed for an EU Agency responsible for risk assessment and market surveillance of non-food products could be estimated to something slightly less than the sum of the budget of the aforementioned too institutions, i.e. slightly below EUR 100 million.[121]

Any EU Agency for market surveillance could not replace the national systems who would certainly maintain a core advantage in carrying out enforcement work in their own countries due to their specific language and market knowledge, proximity and the fact that all individual enforcement decisions are taken under national competences and procedures. Moreover, from a financial point of view, national authorities already spend over 100 million EUR[122] on enforcement activities related to product safety. In spite of this, a reduced capacity to tackle the overwhelming inflows of new products sold in the EU every year is a recognised fact.

The creation of an EU Agency for market surveillance would add a second layer of checks, potentially improving the effectiveness of enforcement, but there are no guarantees and not even reasonable indications that, from a financial point of view, the investment in such a body would be justified and cost efficient in finding the unsafe products among all the products that economic operators bring to the market where there are no mandatory pre-marketing controls.

In the public consultation, the option of the creation of an EU Market Surveillance Agency in the non-food product safety area received only half-hearted support from market surveillance authorities, consumer and business organisations. When asked about how the cooperation between market surveillance authorities could be improved, both national market surveillance authorities and consumer and business organisations, including consumer and business associations, indicated in the first place the option of the increase of financial support for joint market surveillance actions (81% and 78% respectively), and in the second place the possibility of providing more financial support for exchanges and training of the officials (56% and 71% respectively). However, there was also support for the option of establishing a coordination body ensuring cooperation at EU level between national authorities (71%) and for the option of establishing more detailed rules for cooperation at EU level (69%). With the national market surveillance authorities consulted, this coordination body option ranked as third with the support of 54% of the authorities consulted followed by the establishment of more detailed rules for cooperation at EU level (42%).

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121 Since a part of the EFSA tasks is aimed at pre-marketing controls of certain food products the whole equivalent of EFSA budget cannot be used for the projections of the equivalent authority in the area of non-food products where no pre-marketing controls exist.

122 As indicated in the Enforcement Indicators Questionnaire.

In contrast, economic operators indicated in the first place the establishment of a coordination body ensuring cooperation at EU level between national authorities, although with relatively lower support (40%) followed by obligatory participation of national market surveillance authorities in joint actions and other possibilities (both 14%).[123]

In the public consultation 74% of national market surveillance authorities consulted indicated that in the case of divergent safety evaluations in different Member States in respect to identical products, a repeat test in an additional laboratory would resolve the problem of divergent safety evaluations. However, as far as economic operators consulted were concerned 65% were unsure whether an additional test in such a situation would bring the desired solution.

This option could be expected to have a positive impact on consumers and other users in the EU, as well as on compliant economic operators. At the same time it would significantly improve coherence of market surveillance practices across the Member State and enhance the possibilities of spreading know-how and best market surveillance practices. Similarly to the previous option, it would have a negative impact on non-compliant economic operators who, once the marketing of their dangerous product was stopped in one Member State, try to sell it to consumers in other Member States where at that moment it has not yet been prohibited.

The costs of market surveillance authorities will definitely increase as working under the supervision of the EU Agency would imply a reorganisation of current working methods and procedures.

5.2.2. Making EU product safety procedures more coherent

In order to ensure rapid dissemination of information on risky products throughout the EU, it has to be ensured that the RAPEX system is used and applied in each Member State in the same way and that it provides accurate, up-to-date and usable information for market surveillance authorities of other Member States.

On the one hand, the costs of administration of the various notifications provided by Member States to the Commission should be limited as much as possible so that resources can be used for the on-the-field market surveillance enforcement. On the other hand, the simplification of procedures and of the IT systems could trigger an increase in their use (and potential higher costs for Member States), but that would depend on each authority's own willingness to make use of these facilities (beyond the unchanged legal requirements) and their degree of involvement at that particular point in time. [124]

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123 Results of the public consultation on the revision of the General Product Safety Directive, Annex I – replies of market surveillance authorities of Member States, Annex 2 – Economic operators' replies; Annex 3 – Other Stakeholders' replies.

124 Whether any additional costs for national market surveillance authorities will actually arise will depend on a number of factors which are impossible to predict. Putting more "user-friendly" legislative and IT procedures for cross-border cooperation at the disposal of market surveillance authorities for the use in concrete actions does not facilitate a prediction of how much more these procedures will be used. This will depend on the level of occurrence of dangerous products and their geographical spread, frequency and nature of product controls which will continue to be determined at the national level without any intervention of the Commission, the intensity and quality of planning coordination between Member

5.2.2.1. Option 4.B – Simplification of the RAPEX procedure

Main stakeholders overwhelmingly see the positive role of the RAPEX system in the product safety area and consider that it contributes to better protecting the consumers throughout the EU.[125] The notification criteria could be simplified and a clearer obligation to have an effective follow-up could be put in place. According to respondents, changes limited to the RAPEX notification criteria, or making them more precise, would not make the notification process easier.[126]

5.2.2.2. Option 4.C – Simplification of the RAPEX procedure and streamlining of that procedure with the safeguard procedure

The RAPEX procedure and the safeguard procedure could be streamlined so that only one notification for both procedures would be necessary. Once received and treated under the RAPEX procedure, other Member States would have the possibility to raise an objection to such measure notified, in particular in the case of a difficult risk assessment, and thus trigger the Union safeguard procedure at the end of which the Commission will decide whether the adoption of the notified measure was justified or not.

5.2.3. More effective EU-wide action

5.2.3.1. Option 5.B – Extension of the scope of EU-wide product safety measures to non-consumer products

The extension of the scope of EU-wide product safety measures to harmonised non-consumer products is a natural consequence of the creation of a single horizontal regulation of market surveillance of non-food products.

5.2.3.2. Option 5.C – Making EU-wide product safety measures directly applicable

The option of making EU-wide product safety measures directly applicable would provide for clear benefits to all stakeholders: it would (i) provide a clear legal basis for authorities to enforce the obligations laid down in these measures without having to engage in the sometimes cumbersome formal transposition of these measures into national laws, and (ii) save economic operators the cost of searching for different national versions of the obligations resulting from the differing implementation of these EU-wide product safety measures. Also, this solution would prevent unscrupulous economic operators from off-loading and marketing products not complying with the EU-wide product safety measures in those Member States where the delays in formal implementation of such measures on national prevent effective enforcement of such measures by national market surveillance authorities. The

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States (if Member States plan their control activities well, a number of actions will be realised simultaneously without incurring any additional costs).

125 "*RAPEX is conveniently arranged: clear, detailed and informative with a photograph of the hazardous product*." (*Brock, A., A Disadvantageous Dichotomy in Product Safety Law, European Business Law Review, 2009, p. 187*).

126 Majority of Member States' respondents is of the opinion that change of the notification criteria (42%) or their description in a greater detail (51%) would not make the notification process easier. According to respondents, the change of the RAPEX notification criteria should mainly concern 'risk assessment' and 'cross-border effects'. The main problem in applying the 'cross border effects' criterion is the lack of evidence that the notified product was marketed on territories of other Member States.

speedier and more uniform application of EU-wide product safety measures would also benefit consumers since they would be protected in all Member States at the same moment and the risk posed by the products subject to these measures could be eliminated earlier and, thus, ensure more effective protection of consumers throughout the EU.

5.2.3.3. Option 5.D – Removal of the limitation of the period of validity of EU-wide product safety measures

Whereas the option of extending the validity of EU-wide product safety measures offers only a partial remedy, an additional alternative of determining the validity of EU-wide product safety measures in those measures on a case-by-case basis, would completely dissipate the concerns of stakeholders with respect to the unpredictability of EU product safety measures.

5.2.3.4. Option 5.E – Combination of options 5.B, 5.C and 5.D

Combination of options 5.B, 5.C and 5.D would provide for the most effective and powerful solution for establishing a uniform EU product safety requirements for the determined type of a product or groups of products.

5.3. Impacts on the EU budget

The EU financial support for the initiatives included in the proposal comes from a) Title 2 - Enterprise, Chapter 02 03: Internal market for goods and sectoral policies and b) Title 17 – Health and consumer protection – Chapter 17 02: Consumer policy of the ABM: Activity-Based Management – ABB: Activity-Based Budgeting Structure.

The operational budget for the activities under the responsibility of DG Enterprise is estimated at EUR 1.3 million from the internal market budget line (Guidelines, technical expertise and assistance, cooperation with third countries, support to market surveillance authorities (ICSMS)

The operational budget for the activities under the responsibility of DG Health & Consumers is estimated at EUR 3 million, everything already budgeted in the 2014-2020 Consumer Programme (Market surveillance and enforcement actions - joint actions, exchange of officials, the functioning of RAPEX, funding of the Market Surveillance Forum Secretariat).

5.4. Other impacts

Finally, as to the other indirect impacts, such as health, social and environmental impacts, the expected increased compliance resulting from better and more coherently defined product requirements and more effective market surveillance could also have a positive influence on health, social and environmental impacts.

6. COMPARING THE OPTIONS

6.1. Comparison of policy options under objective 1 (Consolidation and reinforcement of EU product safety rules)

6.1.1. Ensuring consistency of EU product safety requirements

In order to provide consumers and other users with an equally high level of protection against unsafe products throughout the EU as well as to prevent barriers on the EU internal market, the EU product safety rules must be clear and compatible across different product sectors.

The comparison of Option 1.B, on the one hand, and Options 1.C and 1.D, on the other hand, consists of assessing whether it is preferable – in terms of costs and benefits for the various stakeholders - to align consumer product safety requirements with harmonised product safety requirements or whether to define these two sets of requirements differently. This assessment is performed in the light of criteria of legal clarity and certainty, information research costs and effectiveness of market surveillance.

Aligning the consumer product safety requirements with the harmonised products safety requirements would bring the desired clarity and legal certainty. The compatibility of consumer product safety requirements with the harmonised products safety requirements would eliminate unjustified information-research costs resulting from the difficulties in determination of the applicable product safety requirements with respect to individual products. Clear product safety requirements applying across the sectors would also contribute to the non-discriminatory treatment of economic operators by the market surveillance authorities of different Member States while allowing market surveillance authorities to track down non-compliant economic operators more quickly and at a lesser cost. Last but not least, it would contribute to the equal protection of consumers and other users against dangerous products.

The introduction of consumer product safety requirements which would be defined differently than harmonised EU product safety requirements, irrespective of whether less strictly (Option 1.C) or more strictly (Option 1.D) - would have a similar effect as the no action option: it would raise the information research costs for economic operators, contribute to the incoherent application of product safety rules, and in the end create potential for further obstacles to the EU internal market.

Table 11: Comparison of the options against the baseline scenario

Options / Issues	Option 1.B	Option 1.C	Option 1.D
Safety of consumers	++	-	++
Legal clarity and certainty	++	+	-
Market surveillance effectiveness and efficiency	++	--	+

Table 12: Comparison of the change in costs for economic operators compared to the baseline scenario

Options / Cost types	Option 1.B	Option 1.C	Option 1.D
Information research costs/legal costs	Decrease	Slight decrease	0
Production costs	0*	0	Increase

* slight increase except for a very small group of producers.[127]

Preferred option: Option 1.B - Alignment of consumer product safety requirements with harmonised product safety requirements

6.1.2. *Reducing ambiguity of product safety requirements for non-harmonised consumer products*

The policy options aimed at reduction in the ambiguity of product safety requirements for non-harmonised consumer products are benchmarked according to the criteria of rapidity of procedures leading to the establishment of mandates for developing of European standards under the general product safety rules and the coherence of these procedures with the general standardisation regime under the Standardisation Regulation 1025/2012 and the costs to public administration, including that of Member States and of EU institutions.

Option 2.B keeps the middle step of the preliminary procedures leading to the establishment of mandates for developing EU standards and makes it a cornerstone for the whole process of preparation of a request to develop a European standard integrating additional decision on the mandate to be sent to the European Standardisation Organisation. As a result, a separate procedure for preparation of requests for standards independently of the regime foreseen under the Standardisation Regulation 1025/2012 would have to be created, since such approach would not be compatible with the procedures set out in this regulation.

In Option 2.C the length of the period of the preliminary procedure leading to the establishment of mandates for developing European standards would be substantially reduced since the formal decisions on setting the ad-hoc safety requirements, would no longer exist. Thus, the Commission could - with the necessary input from the Member States – ask for direct inclusion of requests for developing European standards under the general product safety rules into the general standardisation

[127] See above fn. no. 1066.

working programme: the length of procedure leading to the establishment of mandates for developing EU standards under the general product safety rules would become equal to the one under the New Approach Directives. At the same time, this approach would preserve the general character of the new Standardisation Regulation and thus contribute to the clarity of procedures leading to the establishment of mandates for developing European Standards.

Option 2.D – building upon Option 2.C – would further reduce the length and administrative burden of standardisation procedures under the general product safety rules since, in addition to the simplification foreseen under Option B – it would provide for a fast-track procedure for already existing European standards: where the European standard already exists and in the view of the Commission and the Member States it conforms to the general product safety requirements, it would not be necessary prepare and adopt the request to the European Standardisation Organisations for development of such a an existing European standard. However, the approach of Option 2.D would not be coherent with principles of general standardisation under the Standardisation Regulation 1025/2012 which does not foresee the possibility that a European standard could provide for the presumption of conformity upon its publication in the Official Journal if it was not established on the basis of a mandate issued by the European Commission.

In terms of rapidity and administrative burden reduction Options 2.C and 2.D. can be considered to be superior both to Option 2.B. Between Options 2.C and 2.D produce the criterion of coherence of procedures for requesting standards favours Option 2.C to Option 2.D.

Table 13: Comparison of options against the pre-defined criteria

Options / Criteria	Option 2.B	Option 2.C	Option 2.D
Rapidity	-	+	++
Coherence	-	+	-
Costs for authorities (including national authorities and EU)	Unchanged	Decrease	Decrease

Preferred option: Option 2.C – Abolition of formal adoption of the non-binding ad-hoc safety requirements

6.2. Comparison of policy options under objective 2 (Better coordination and increased effectiveness of market surveillance activities on the single EU market for goods)

6.2.1. Reinforcing EU cooperation mechanisms

The comparison of impacts of envisaged policy options is assessed against the benchmarks of effectiveness of market surveillance, its efficiency in terms of attaining the highest possible level of safety with the given amount of resources and the potential of ensuring seamless market surveillance for the single EU market.

Option 3.A maintaining the market surveillance framework in the existing form in the future would mean that it would neither be able to ensure a high level of protection and safety of consumers and other users throughout the EU, nor would it safeguard the proper functioning of the single EU market. As such, it offers sub-optimal solutions in comparison with the other three options.

Option 3.B is an option of minimum progress with the existing resources. This minimum progress consists of providing market surveillance with tools for cross-border market surveillance which are already successfully used in other areas of consumer protection, in particular the possibility to coordinate reactive market surveillance actions, such as inspections, product checks etc.

Unlike Option 3.B, Option 3.C represents an option of maximum progress with existing resources. It provides for the rationalisation of coordination of the reactive as well as the proactive market surveillance while keeping the existing decentralised model of market surveillance under which concrete market surveillance measures are taken by national market surveillance authorities. The burden of ensuring the rationalisation of market surveillance coordination would be mostly borne by the European Commission. The principal vehicle for carrying out the rationalisation of market surveillance coordination in the EU would be the multi-annual market surveillance plan.

In contrast to Options 3.B and 3.C intending to do more with the same amount of resources, under Option 3.D a delivery of much higher benefits for the single EU market and safety could be expected on the assumption that substantial investments were committed into building a centralised EU framework for market surveillance in the area of non-food product safety. If the EU possessed its own market surveillance enforcement staff which could perform peer evaluation of market surveillance systems and authorities in any Member State, it can be reasonably expected that the safety of consumers and other users as well as the functioning of the single EU market could be better safeguarded. However, in view of the high amount of resources implied by this option, the concrete efficiency of centralisation of EU market surveillance is difficult to estimate.

However, as highlighted above, even under the Option 3.D, only certain activities, such as system inspections, peer reviews of the quality of functioning of market surveillance authorities in Member States, monitoring of the coordination between enforcement authorities and national RAPEX contact points, could be moved to the central EU level. By contrast, core market surveillance actions, such as on-the-site inspections of manufacturers, importers and distributors, testing of products, risk assessment, risk management would have to stay on the national level.

On the basis of the above, Option 3.C seems to be the most appropriate for fulfilling the objective of achieving a coherent and seamless framework for decentralised market surveillance for the single EU market: in terms of benefits it is superior to Option 3.B, although potentially inferior to Option 3.D; in terms of costs it is equal to Option 3.B, but largely superior to Option 3.D.

Table 14: Comparison of the options against the baseline scenario

Options / Issues	Option 3.B	Option 3.C	Option 3.D
Safety of consumers/users	+	++	++
Competitiveness of compliant economic operators	+	++	++
Effectiveness of market surveillance	+	++	+++
Efficiency of market surveillance	+	++	+
Potential of harmonisation of enforcement approaches on the internal market	+	++	+++

Table 15: Comparison of the change in costs for public authorities compared to the baseline scenario

Options / Cost types	Option 3.B	Option 3.C	Option 3.D
Costs for national market surveillance authorities	Slight increase	Slight increase	Increase
Costs for the EU	Slight increase	Slight increase	High increase

Preferred option: Option 2.C – Rationalisation of the overall coordination of decentralised market surveillance on the single EU market.

6.2.2. Making EU product safety procedures more coherent

The compared options are benchmarked against the criteria of effectiveness in tracking dangerous products and the efficiency of administration of the functioning of the EU notification procedures for Member States and the Commission.

If the functioning of the RAPEX procedure was simplified as foreseen under Option 4.B, but without a parallel streamlining of the RAPEX procedure with the safeguard procedure, Member States would still have to provide the Commission with separate notifications for the purposes of the two procedures.

Under Option 4.C both streamlining of the EU notification procedure and simplification of the RAPEX procedure would take place. In comparison with Option 4.B the administrative burden related to the administration of notifications for the RAPEX and safeguard procedure would decrease. As a result, the Option 4.C would guarantee that all the measures restricting or preventing marketing of dangerous products are notified to the Commission and that each such notification received appropriate treatment depending on the seriousness of the risk and completeness of

the information while reducing the administrative costs relating to the notification process both for the Commission and the Member States.

Given that the effectiveness in tracking unsafe products on the internal EU market remains identical under both Options 4.C and 4.B, since under both options simplification of RAPEX notification conditions would be able to achieve that objective, Option 4.C appears to be superior to Option 4.B.

Table 16: Comparison of the change compared to the baseline scenario in relation to public authorities

Options / Benchmarks	Option 4.B	Option 4.C
Effectiveness in tracking down unsafe products	Increase	Increase
Costs for national market surveillance authorities	Slight decrease	Decrease
Costs for the EU	0	Decrease

Preferred option: Option 2.C – Simplification of the RAPEX procedure and streamlining of that procedure with the safeguard procedure

6.2.3. More effective EU wide product safety action

To fulfil the objective of safeguarding prompt and effective action at the EU-level for safety against risks in situations where the individual action of Member States fails to provide a coherent response, the EU product safety measures have to be rapid, predictable and capable of being effectively applied by national market surveillance authorities.

The position of stakeholders towards the envisaged actions under option 5.B, 5.C and 5.D aimed at making the implementation of EU product safety measures more predictable and uniform was positive. Responding national market surveillance authorities expressed large support for direct applicability of EU product safety measures and for the extension of the duration of such measures until a future permanent solution is adopted.[128] Respondents considered it important that the EU product safety measures be very clearly described, including technical details, such as test methods, in order to ensure even implementation by all authorities in all Member States. According to responding economic operators compliance with EU product safety measures would be easier (i) if these measures were directly applicable to economic operators and/or (ii) if they were linked to a clearly defined permanent solution (e.g. adoption of a standard or of primary legislation) or if their validity could be extended to a fixed period of up to three years (with equal

128 In accordance with the above some 71% of the respondents did not see any problem with measures that are directly applicable to economic operators. The Member States respondents considered the enforcement of "emergency" measures to be easier if the measures were directly applicable to economic operators (71%), and if measures were in force until a permanent measure is in place (60%). A simple extension of the validity of the measures, such as up to three years with further 3-years extensions, was considered much less favourably (23%). For more details se Annex 2 (section 2.2.3.4).

subsequent prolongation periods).[129] A large majority of respondents saw no problem if EU product safety measures were made directly applicable to economic operators.[130]

Making EU product safety measures directly applicable combined with the possibility of adopting these measures for a period specified on a case-by-case basis fulfils best the criteria of rapidity, effectiveness and predictability. The EU product safety measures would become directly applicable so that market surveillance authorities could take enforcement measures on the basis of these EU measures without having to wait until the moment when these measures would be formally taken over to a national legislative measure or regulation or having to resort to unsystematic "ad-hoc" individual solutions generating a great deal of legal uncertainty while waiting for the adoption of the formal national measure.

Table 17: Comparison of options 5.B, 5.C and 5.D against pre-defined criteria

Options / Criteria	Option 5.B	Option 5.C	Option 5.D	Option 5.E
Rapidity	0	+	+	++
Predictability	0	0	+	++
Effective application	+	++	0	+++

Preferred option: Option 5.E – Combination of options 5.B, 5.C and 5.D

129 Compliance with EU product safety measures was considered easier if they were directly applicable (39%) or were applicable until entry into force of a permanent solution (44%), still some 26% considered a simple extension of such a measure to up to three years (with equal prolongation periods) as making compliance easier.

130 More than 75% of other stakeholders responding saw no problem if EU product safety measures were directly applicable to economic operators.

6.3. Overview of preferred options in the light of the objectives

GENERAL OBJECTIVES	SPECIFIC OBJECTIVES	PREFERRED OPTIONS
Reduction of the number of unsafe or non-compliant products on the single EU market	Consolidation and reinforcement of EU product safety requirements	Option 1.B – Aligning consumer product safety requirements with harmonised product safety requirements
		Option 2.C – Abolition of double adoption of the non-binding ad-hoc safety requirements
	Simplification of the EU legislative framework	Adoption of a single horizontal regulation for market surveillance
		Abolition of Directive 87/357/EC which by appearing other than they are endanger the health and safety of consumers
	Better coordination and increased effectiveness of market surveillance activities on the single EU market for goods	Option 3.C – Coordination of reactive market surveillance and rationalisation of coordination of pro-active market surveillance
		Option 4.C – Simplification of the RAPEX procedure and streamlining of that procedure with the safeguard procedure
		Option 5.E – Combination of options 5.B, 5.C and 5.D

6.4. Form of the legislative instrument

It is suggested that the selected options would be reflected in two different legal instruments. Problem 1 would be solved through an adoption of the Consumer Product Safety Regulation which would be aligned with the respective provisions of Annex 1 of Decision (No) 768/2008/EC[131]. Problem 2 would be addressed by a new Regulation on market surveillance for non-food products that would constitute the main instrument for product market surveillance. Provisions on market surveillance in the EU internal market legislation which are currently scattered over several Directives and Regulations would be replaced by the provisions of this new Regulation. A Regulation, being directly applicable upon Member States, would achieve a very high degree of harmonisation of the rules on market surveillance and would empower market surveillance authorities to act immediately in case of unsafe consumer products or non-compliance, without the need for transposition of these rules into different national laws. More details about the simplification of the legislative framework can be found in Annex 15.

[131] Articles R1 – R7.

Whereas the Regulation on market surveillance would continue to keep the form of a Regulation, the General Product Safety Directive would be converted into a Regulation. Where the Treaties do not specify the type of act to be adopted in a certain field, the EU institutions shall select it on case by case basis and in compliance with the principle of proportionality.[132] A regulation is directly applicable in all Member States; there is therefore, no need for Member States to transpose EU legislation into national law and no need to provide them with time to do so. Possible national differences regarding the date and/or manner of transposition would be eliminated, which would facilitate consistent enforcement and a level playing field in the internal market. A regulation better ensures that legal requirements are implemented at the same time throughout the Union; it also better achieves streamlining of terminology, important for defining the scope of the legislation, thereby reducing administrative burdens and legal ambiguities.

Table 18: Overview of the proposed EU regulatory framework in the area of non-food product safety

<table>
<tr><th colspan="4">Overview of the proposed EU regulatory framework under the Product Safety and Market Surveillance Package</th></tr>
<tr><th>Products / Areas</th><th colspan="2">Non- Harmonised</th><th>Harmonised</th></tr>
<tr><td></td><td>Non-consumer</td><td>Consumer</td><td>Non-consumer</td></tr>
<tr><td>Obligations of economic operators</td><td></td><td>Consumer Product Safety Regulation</td><td>Sector specific Union harmonisation legislation</td></tr>
<tr><td>Market surveillance on the internal market*</td><td>Regulation 764/2008</td><td rowspan="2" colspan="2">Regulation on market surveillance</td></tr>
<tr><td>RAPEX*</td><td></td></tr>
<tr><td>Market surveillance Controls on products imported to the EU*</td><td colspan="3"></td></tr>
</table>

132 Article 296 TFEU

7. MONITORING AND EVALUATION

Apart from the evaluation of the legislative instrument after 4 years of implementation, the monitoring of the application of EU product safety rules will be performed through the collection of relevant information from (i) the Eurobarometer surveys relating to consumer safety (ii) GRAS-RAPEX information system, (iii) the general information support system (ICSMS) and (iv) the Enforcement Indicators monitoring activity which surveys certain parameters of market surveillance in Member States. The European Injuries Database cannot be used for the evaluation of the implementation of the Product Safety and Market Surveillance Package since the data stored therein is of relatively small relevance for policy purposes. In particular, the current data on accidents and injuries do not reflect whether these accidents or injuries were caused by products or by other factors as well as whether these accidents or injuries were caused by safety defects of products or by their misuse by their user.[133]

Eurobarometer surveys collect perceptions of safety of products from consumers and economic operators. This perception may be a relevant indicator of whether the operational objectives of ensuring consistency of EU product safety requirements and reducing ambiguity of product safety requirements for non-harmonised consumer products have contributed to the increased level of safety of consumer products.

The question to what extent the fulfilment of these operational objectives has also positively influenced the costs compliance of economic operators with the EU product safety measures could be indirectly estimated through various ad-hoc studies performed in particular by industry.

Regarding the objectives related to the better coordination and increase in effectiveness and efficiency of market surveillance on the single EU market, the fulfilment of these objectives could be demonstrated by the collection of relevant information from the existing IT systems and the Enforcement Indicators monitoring activity.

The GRAS-RAPEX information system (launched in May 2012) will collect information on measures taken against products posing risks, including serious risks, provided by Member States to the Commission within the framework of the RAPEX procedure. This information will be accessible through the weekly postings of the lists of measures taken in Member States as well as through the RAPEX Report (published annually since 2004) which includes aggregated data sets on information obtained from RAPEX Contact Points of Member States.

[133] In none of the 13 Member States which currently participate in the European Injuries Database data about the causes of accidents/injuries and the ways in which they occurred are collected. For the collection of such data in a form and content that would be relevant for market surveillance purposes new infrastructures in basically all Member States would have to be established. Such action would require very substantive investments which are beyond the current budgetary possibilities of both the Member States and the European Commission. In 2013, the Commission will launch a study to further examine the feasibility and potential costs of setting up such a Consumer Product Safety Injuries Database.