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Delegations will find attached a **new version** of SWD(2013) 33 final Annexes.

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COMMISSION STAFF WORKING DOCUMENT

Annexes to the 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}

Table of Contents

1. ANNEX 1: GLOSSSARY OF THE TERMS USED

Term	**Definition**
Art. 12 (1) of the General Product Safety Directive	sub-p. 1: Where a Member State adopts or decides to adopt, recommend or agree with producers and distributors, whether on a compulsory or voluntary basis, measures or actions to prevent, restrict or impose specific conditions on the possible marketing or use, within its own territory, of products by reason of a serious risk, it shall immediately notify the Commission thereof through RAPEX. It shall also inform the Commission without delay of modification or withdrawal of any such measure or action. sub-p. 2: If the notifying Member State considers that the effects of the risk do not or cannot go beyond its territory, it shall follow the procedure laid down in Article 11, taking into account the relevant criteria proposed in the guidelines referred to in point 8 of Annex II. sub-p. 3: Without prejudice to the first subparagraph, before deciding to adopt such measures or to take such action, Member States may pass on to the Commission any information in their possession regarding the existence of a serious risk.
Comitology procedure	Means a procedure through which the Commission carries out its implementing powers with the assistance of a committee consisting of representatives from Member States. In the areas covered by the *General Product Safety Directive*, detailed rules for comitology procedure are laid down its Articles 14 and 15.
Consumer product	Means any product – including in the context of providing a service – which is intended for consumers or likely, under reasonably foreseeable conditions to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, an whether new, used or reconditioned.
Consumer Protection Cooperation Regulation	Means Regulation (EC) No 2006/2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws.
Cross-border effect	Means a situation where effects of the risks posed by a dangerous product go or can go beyond the territory of one of the Member States (also called 'international event'). 'Cross-border effect' represents one of the *RAPEX notification criteria* (see *RAPEX notification criteria*).
Decision No 768/2008/EC	.Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC
Directive 98/34/EC	Means Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services.

Distributor	Means any professional in the supply chain whose activity does not affect the safety properties of a product, other than the manufacturer or the importer (who makes a product available on the market.)
DMF-Decision	Means Commission Decision 2009/251/EC of 17 March 2009 requiring Member States to ensure that products containing the biocide dimethylfumarate (DMF) are not placed or made available on the market, (as amended by subsequent decisions*).*
Economic operators	Mean manufacturers, importers and distributors.
European standard (EN)	Means a standard adopted by a *European Standardisation Organisation* and made available to the public.
European standard referenced in the OJEU	Means a *European standard* (EN) the reference of which was published in the *Official Journal of the European Union* which provides for presumption of conformity to the general safety requirement under the *General Product Safety Directive*.
European Standardisation Organisation (ESO)	Means one of the three European Standards Organisations: CEN (European Committee for Standardisation), CENELEC (European Committee for Electrotechnical Standardisation) or ETSI (European Telecommunications Standards Institute).
General product safety legislation	Means the *General Product Safety Directive,* as implemented into national legislations of Member States. The list of national laws implementing the *General Product Safety Directive can be consulted at*: http://eur-lex.europa.eu/Notice.do?val=414664:cs&lang=en&list=414664:cs,&pos=1
General Product Safety Directive	Means Directive 2001/95/EC on general product safety, as amended.
Harmonised products	Mean products for which there is EU legislation harmonising the conditions for marketing. (see also *Sector specific legislation on harmonised products).*
IEC standard	Means a standard adopted by the International Electrotechnical Commission (IEC). IEC is the world's global standardisation organization that prepares and publishes *international standards* for all electrical, electronic and related technologies collectively known as "electrotechnology."
Importer	Means any natural or legal person established within the Union who places a product from a third country on the EU market.
International standard	Means a standard adopted by an international standardisation organisation and made available to the public. Examples of international standards are *ISO standards* and *IEC standards*.
ISO standard	Means a standard adopted by the International Organization for Standardisation (ISO). ISO is the world's largest developer and publisher of International Standards other than electrotechnical or telecommunication ones.

Joint market surveillance actions	Mean joint surveillance and enforcement actions in the area of non-food consumer product safety. They involve administrative and surveillance cooperation between the authorities of several Member States and EFTA/EEA countries and typically focus on product testing, risk assessment, market monitoring, and the exchange of expertise and best practices related to market surveillance. The Commission has supported a number such actions, for example, in the areas of safety of sunbeds and solarium services, cord extension sets, lighting chains, playground equipment etc.
Large enterprise	Means an enterprise not fulfilling the criteria on an *SME.*
Local event	Refers to measures adopted in relation to a product posing a risk that can only have local effects, i.e. the risk posed by a dangerous product do not go or cannot go beyond the territory of one of the Member States. This includes a situation where an authority of a Member State has reason to believe that a product has not been and will not be made available (by any means) to consumers in other Member States, e.g. measures taken with regard to a local product manufactured and distributed only in one Member State. These measures are not notified through RAPEX, but may be notified through the procedure under Article 11 of the *General Product Safety Directive.*
Magnetic Toys Decision	Means Commission Decision 2008/329/EC of 21 April 2008 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.
Manufacturer	Means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark.
Market surveillance	Means the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection
Market surveillance authority	Means an authority of a Member State responsible for carrying out market surveillance on its territory
National standard	Means a standard adopted by a national standardisation body and made available to the public.
Non-harmonised products	Mean products for which there is no EU legislation harmonizing the conditions for marketing.
Notification for information	Means a notification which cannot be sent through the system as a RAPEX notification due to various reasons (such as the non-availability of some of the information required to be present in the *RAPEX notification*, absence of the *cross-border effect*, impossibility to determine whether one or more *RAPEX notification criteria* were met, yet the notification involves information on product safety likely to be of interest for other Member States etc.), but the Contact Point has nevertheless decided to circulate such notification for information purpose.
Novelty and Child	Means Commission Decision 2006/502/EC of 11 May 2006 requiring

Resistant Lighters Decision	Member States to take measures to ensure that only lighters which are child-resistant are placed on the market and to prohibit the placing on the market of novelty lighters (as amended by Commission Decisions 2007/231/EC, 2008/322/EC, 2009/298/EC and 2010/157/EU).
Non-European standards	Mean standards other than *European standards,* including *international standards* and standards produce by states outside the EU.
Obligations of the economic operators with respect to harmonised products	Mean obligations of the economic operators to make sure that products comply with technical legislation, bear the required *product identification*, are accompanied with the adequate safety instructions, product keep a copy of a technical documentation as not to jeopardise safety properties of a product etc.
OJEU	Means the Official Journal of the European Union.
Presumption of conformity	Means that products which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union are presumed to be in conformity with the requirements covered by those standards or parts thereof, set out in the harmonisation legislation.
Product identification	Means the indication on the product, its packaging or in the accompanying documents, the identity of the manufacturer or, if imported, the manufacturer and the importer, i.e. an indication of their firm, trade name or a trademark, and the address where they can be contacted and a product reference or the reference to the batch of products to which the product belongs.
Product safety legislation	Means *General product safety legislation* and *Sector specific legislation on harmonised products.*
RAPEX	Means *the Union Rapid Information System for non-food Consumer Products* which Member States use to notify to the Commission measures taken to prevent or restrict the marketing or use of products posing a serious risk. See also *RAPEX Guidelines.*
RAPEX Guidelines	Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Union Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of the General Product Safety Directive (OJ, L22, 26.01.2010).
RAPEX notification criteria	Under Article 12 of the *General Product Safety Directive*, Member States have a legal obligation to notify the Commission when the following four notification criteria are met: (a) the product is a consumer product, (b) the product is subject to measures that prevent, restrict or impose specific conditions on its possible marketing or use ('preventive and restrictive measures'), (c) the product poses a serious risk to the health and safety of consumers, (d) the serious risk has a cross-border effect.
RAPEX notification	Means a notification of a preventive or restrictive measure(s) against a consumer product posing a serious risk(s) to the health and safety of consumers adopted by an economic operator or a market surveillance organisation of a Member State, sent to the Commission under Article 12 of

	the General Product Safety Directive.
Regulation (EC) No 765/2008	Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
Risk assessment guidelines	Mean procedures for identifying and assessing levels of risks posed by consumer products as set out under point 5 of Part IV of *RAPEX Guidelines*
Schaldemose Report	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.
Sector specific legislation on harmonised products	Means the set of EU directives regulating conditions of marketing and safety aspects o f products in areas such as toys, cosmetics, construction products etc. and their implementation into national legislations of Member States. For more examples of this sector specific legislation, see http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/index_en.htm
Services Directive	Means Directive 2006/123/EC of 12 on services in the internal market.
SME	Means micro, small and medium-sized enterprise. It includes enterprises which employ fewer than 250 persons and have an annual turnover not exceeding €50 million, and/or an annual balance sheet total not exceeding €43 million.
"*Standing or framework mandates*"	*Means* a mandate to the relevant *European Standardisation Organisation* to draft the necessary standards in a specific field, according to the safety requirements established by the Commission, which does not require that the Commission issues a new request for each standard to be delivered or revised, except in cases of new emerging risks which will require a specific mandate from the Commission. It facilitates monitoring and production of deliverables and allows for a more effective organisation of work within the relevant *European Standardisation Organisation*. A standing or framework mandate also includes a work programme to identify which standards are needed or whether existing standards have to be revised to comply with the safety requirements.
Traceability	Means an obligation to ensure that the origin of the product can be determined, for example, by indicating on the product, its packaging or in the accompanying documents, the identity of the manufacturer and/or the importer, i.e. an indication of the firm, trade name or a trademark and the address where they can be contacted, product reference or the reference to the batch of products to which the product belongs, by keeping and providing for documentation necessary for tracing the origin of the product etc.

Technical documentation	Means documentation which makes it possible to assess the conformity of a product to the relevant requirements, includes an adequate analysis and assessment of the risk(s), specifies the applicable requirements and covers, as far as relevant for the assessment, the design, manufacture and operation of the product.

2. ANNEX 2: SUMMARY OF THE PUBLIC CONSULTATION

2.1. Introduction

Following the delimitation of the scope of the revision performed by the Commission in consultations with relevant stakeholders, the Commission concentrated the public consultation around four topics: (i) pre-standardisation procedures under the General Product Safety Directive, (ii) harmonisation of safety evaluations, (iii) market surveillance coordination and (iv) consistency of consumer product safety requirements with harmonised product safety requirements, i.e. alignment of the existing rules under the General product Safety Directive with certain rules contained in the 2008 Free Movement of Goods Package.[1]

For each of these four topics, the Health & Consumers Directorate-General of the European Commission published consultation papers describing the scope of the problems and the actions envisaged to solve them. In parallel, it opened for a period of three months (from mid-May to mid-August 2010) an internet public consultation to seek through online questionnaires views from different stakeholder groups on the issues presented in the consultation papers.

2.2. Results of the internet public consultation

In response to the internet public consultation the Commission received replies to the questionnaires from fifty five national authorities from all EU Member States except one, as well as Norway, Iceland and Switzerland. Moreover, various other stakeholders, including more than thirty business associations, seventeen consumer organisations, and over fifty individual economic operators (including several SMEs) contributed to the consultation.

In total, 305 replies were received to the nine published online questionnaires. In addition, thirteen business and consumer organisations provided separate position papers.[2] Also a number of presentations and direct exchanges with stakeholders (both with business and consumer organisations) were held during the consultation period.

The answers to the internet public consultation questions could be summarised as follows.

2.2.1 Consistency of product safety requirements

Harmonisation of the obligations of economic operators in the non-harmonised area with those in the harmonised area, including traceability requirements and the

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1 In particular, with the rules contained in Annex 1 of Decision (No) 768/2008/EC and Chapter III of Regulation (EC) No 765/2008.

2 The opinions provided in the position papers are summarised in Annex 3.

obligation to establish technical documentation[3], would make enforcement activities more effective. Traceability of manufacturers and importers is a problem for market surveillance authorities. In addition, economic operators and other stakeholders, including consumer organisations and a number of business associations, see more benefits than disadvantages if the obligations of economic operators with regard to harmonised products were applied uniformly to all products.

Several consumer organisations stressed the need for better product traceability to aid recalls. They consider that alignment in this area with the Decision 768/2008/EC is important and also advocate the use of new technologies such as radio frequency identification ("RFID") provided that the advantages and disadvantages are assessed also from a consumer perspective (e.g. as regards privacy, security and health).

(a) National market surveillance authorities

Harmonising the obligations of economic operators in the non-harmonised area with those in the harmonised area, including traceability requirements and the obligation to establish technical documentation, would make enforcement activities more effective. In the case of virtually all NMSAs, the enforcement of product safety rules would be easier if the obligations of economic operators in the harmonised and non-harmonised area were aligned.[4] Almost all NMSAs have experienced problems identifying manufacturers and importers within the framework of their market surveillance activities; a non-negligible minority of NMSAs have faced such problems frequently.[5] A majority of authorities indicated that they request technical documentation from economic even if national rules do not specifically require economic operators to establish it, and most of these authorities indeed manage to obtain the requested technical documentation from economic operators.

(b) Economic operators

An important majority of responding economic operators market both harmonised and non-harmonised products; a minority markets harmonised products only.[6] Economic operators see more benefits than disadvantages if the obligations of economic

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3 The technical documentation would contain the risk evaluation and the indication of the national rule, standard or other requirement with which the given product is supposed to comply.

4 On the one hand, only 30% of authorities claim that they encounter enforcement difficulties in applying harmonised and non-harmonised rules, on the other hand, for 94% of authorities the enforcement would be easier if obligations of economic operators in the harmonised and non-harmonised area were aligned.

5 Identification of the manufacturer or the importer seems to be a bigger problem for market surveillance authorities than the identification of the import: 17% of NMSAs responding indicate that they face problems with the identification of manufacturer often in, 78% sometimes; for importers importer: often: 15% of NMSAs claims to have often problem with their identification, 16% sometimes. With respect to distributors, none of the NMSAs responding indicates to have problems with their identification often, 70% however report to have sometimes problem with their identification.

6 The public consultation suggests that an extremely small number of economic operators, if any, market non-harmonised products only. 30% of responding economic operators were marketing only harmonised products, 65% both harmonised and non-harmonised products. None were marketing non-harmonised products only.

operators with respect to harmonised products, including the obligation to establish technical documentation, were also applied in the area of non-harmonised products.[7]

All respondents indicated that they ensure traceability of products. The most common way in which the traceability of products is ensured by manufacturers and importers is by indicating on the product, its packaging or in the accompanying documents the identity of the manufacturer/importer (name/brand, address) and the identity of the product (batch or series number).[8] A large majority of responding economic operators establish technical documentation[9] in respect of non-harmonised products; over a half of those who do so establish the technical documentation in respect of non-harmonised products, although they are not legally required to do so.[10]

(c) Other stakeholders (including consumers and business organisations)

An important majority of stakeholders are of the opinion that the safety of consumers would be better ensured if the obligations of economic operators in respect of harmonised products, including the obligation to establish technical documentation, were also applied in the area of non-harmonised products.[11] Stakeholder views on whether economic operators ensure traceability of products are divided. The same

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7 An overwhelming majority of economic operators (90%) takes into account obligations both in the sector specific legislation on harmonised products as well as under the general product safety legislation. 39% of economic operators are unable to say whether differing obligations under the sector specific and general rules pose problems for them; for 33% these differences represent a problem, for 28% not. For those who have a problem with differing obligations 67% consider the cost resulting from these differences as non-negligible, but cannot quantify them. 40% of responding economic operators consider the application of obligations with respect to harmonised products also to non-harmonised products to be beneficial for their business. 25% (5) do not think so, 35% does not know. If the obligations of economic operators with respect to harmonised products applied to non-harmonised products, in the opinion of 20% of responding economic operators this would lead to an increase in operating costs, according to 15% of them to their reduction. For 15% of responding economic operators this would have no or negligible impacts on operating costs. 50% of the respondents were not able to provide any cost estimation.

8 70% of responding economic operators do not market products if the required product identification is not performed by economic operators at higher level of the marketing chain. 10% market the product even if certain information is missing, 5% complete the missing information by themselves, 15% take other action.

9 See above footnote no. 7 for the description of the contents of the technical documentation.

10 80% of responding economic operators establish technical documentation in respect of non-harmonised products. Of this 80%, 55% establish the technical documentation in respect of non-harmonised products, although they are not legally required to do so. If economic operators had to establish technical documentation in the same way for all products, in the opinion of 15% of responding economic operators, this would lead to an increase in operating costs, according to 30% of them to their reduction. For 10% of responding economic operators this would have no or negligible impacts on operating costs. 45% of the respondents were not able to provide any cost estimation.

11 65 % of respondents - 64% with respect to technical documentation - is of the opinion that safety of consumers would be better ensured if obligations of economic operators in respect of harmonised products, including the obligation to establish the technical documentation, were also applied to non-harmonised products. 18% consisting exclusively of business organisations disagrees with this opinion. Yet, the same percentage of business organisations 18% agrees.

division can be observed with respect to the question as to whether it is ensured in a uniform way.[12]

2.2.2 Market surveillance coordination

A majority of Member States considered that they undertake sufficient market surveillance. Nevertheless a lack of resources for inspections and training are mentioned as reasons for not doing more. Member States cooperate with each other and consider such cooperation to be very beneficial, although they encounter problems linked mainly to differences in enforcement practices or, again, a lack of resources. Actions to improve cooperation in this area supported by over half of the respondents include providing more financial support to joint surveillance actions and exchanges of officials, and establishing a coordination forum at EU level.

While economic operators and other stakeholders were divided as to whether Member States undertake sufficient market surveillance or whether the cooperation with customs authorities works well, a majority considered that differences between Member States in enforcing product safety legislation were causing problems for businesses. They also believed that cooperation between NMSAs of different Member States needed to be improved. Respondents were overwhelmingly of the opinion that more intensive information sharing and/or cooperation between Member States would enhance the safety of consumers throughout the EU.

Diverging test results as well as diverging interpretation of standards and the risk assessment guidelines,[13] have occasionally caused safety evaluations by one Member State to be contested (whether formally or informally) by another Member State(s). To overcome these divergences, which create barriers to the internal market, all groups of stakeholders favour setting product safety requirements at the EU level. In addition, the creation of a database for risk assessments and the establishment of an EU risk assessment agency were suggested.

(a) National Market Surveillance Authorities

A significant majority of NMSAs consider that they undertake sufficient market surveillance and that cooperation with customs in this area works well.[14] However, a lack of resources, inspections and training were mentioned as reasons for not doing

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12 Stakeholders views on whether economic operators ensure traceability of products are conflicting (yes: 44%, no: 33%). The same strong division exists among those who thinks economic operators ensure traceability of products with respect to the question whether traceability is ensured in a uniform way (yes: 46%, no: 37%).

13 Risk assessment guidelines for consumer products are published in section 5 of Part IV of the "Guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC" (Annex to the Commission Decision 2010/15/EU).

14 Regarding the cooperation with customs, 84% of respondents believe that this cooperation functions well. For those disagreeing, the lack of any cooperation and the lack of experience with customs authorities in checking product safety are seen as the key problem areas.

more.[15] Almost all NMSAs cooperate with authorities in other Member States. They perceive such cooperation to be very beneficial, although they do encounter problems linked mainly to differences in enforcement practices.[16] Specifically with regard to the joint surveillance actions co-financed by the Commission, a majority considers these to be very useful despite a heavy administrative burden and lack of own resources.[17]

Actions to improve cooperation in this area supported by a majority of respondents include providing more financial support to joint surveillance actions and exchanges of officials, and by establishing a coordination body at EU level. Obliging Member States to respond to a cooperation request from another Member State was also mentioned among the possible ways to improve coordination among the NMSAs of different Member States.[18]

About one third of responding NMSAs indicated that their safety evaluations had, on at least one occasion, been contested by authorities in other Member States. This was overwhelmingly due to diverging test results, but also to diverging interpretations of standards.[19] Divergences in safety evaluations were not avoided despite the existence of guidelines for risk assessment set out in the RAPEX Guidelines.[20] Some responding NMSAs suggested the creation of a database with risk assessments which could be used for orientation, or even setting up an EU risk assessment institute or agency. A clear majority of the responding NMSAs considered that lasting divergences between Member States could be solved by setting specific product safety requirements at the EU level. A minority of stakeholders favoured non-binding EU-wide recommendations on the safety assessment of the concerned product.[21]

(b) Economic operators

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15 A majority of Member States consider that they undertake sufficient market surveillance (10% strongly agreed, 70 % agreed, 29% disagreed, 1% strongly disagreed). On a related issue on what should be done to improve the level of enforcement of product safety rules market surveillance authorities indicated on the first place that more resources should be allocated to market surveillance, second that inspectors should receive more and better training and finally that more inspections should be undertaken and more cross-border cooperation should take place (those two scoring equally).

16 While 60% of respondents consider the current GPSD provisions sufficient for effective cooperation between Member States, 28% believes that its provisions are not specific enough or worries about their voluntary nature. Almost all respondents agreed that more intensive information sharing and cooperation between Member States would ensure a more level playing field for economic operators and would enhance the safety of consumer throughout the EU.

17 A lack of resources and too complicated and burdensome procedures were also mentioned as reasons for not participating in such actions.

18 81% of national authorities consider that their cooperation will improve with an increase of financial support for joint cooperation actions, while over 50% were in favour of the establishment of an EU level coordination body and of increasing the financial support for exchanges of officials and trainings.

19 35% of the Member State respondents had their safety evaluations "sometimes" contested by other authorities within the last 5 years. This was overwhelmingly due to diverging test results (83%), and less to the application of a different test method (42%). Further important divergences however concerned the interpretation of standards (58%) and the application of the same risk assessment method (50%).

20 Annex to the Commission Decision 2010/15/EU.

21 A clear majority (60%) of all 35 respondents considered lasting divergences between Member States be solved by setting specific EU wide product safety requirements, although ¼ (26%) favoured non-binding EU wide recommendations on the safety assessment of the concerned product.

While economic operators were divided as to whether Member States undertake sufficient market surveillance[22] or whether the cooperation with customs authorities works well,[23] a majority considers that differences between Member States in enforcing product safety legislation are causing problems for businesses[24] and that coordination and cooperation needs to be improved.[25]

About one third of the responding economic operators were at least sometimes affected by diverging safety evaluations of their products in different EU Member States. The main reasons for divergence were rooted in different test results, but also in diverging risk assessments.[26] An overwhelming majority of economic operators affected by these divergences could not estimate the amount of costs resulting from these divergences, but evaluated them as "non-negligible."[27] A strong majority of economic operators considered binding measures at the EU level to be the best solution to resolve lasting safety assessment divergences between NMSAs of different Member States; non-binding EU-wide recommendations were preferred only by a minority of the responding economic operators.[28]

(c) Other stakeholders (including consumers and business organisations)

While other stakeholders are equally divided as to whether Member States undertake sufficient market surveillance, most of those believing they do not do so considered this to be due to a lack of allocated resources and too few inspections.[29] Respondents

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22 Economic operators responding to the questionnaire are divided as to whether Member States undertake sufficient market surveillance (10 agreeing/9 disagreeing). Of those believing that Member States do not enforce consumer product safety legislation sufficiently, most consider this to be due to a lack of resources.

23 Respondents are also divided as to whether the cooperation between market surveillance and customs authorities works satisfactorily (9 agreeing/7 disagreeing), with those thinking it does not work well considering this is mainly due to the lack of experience with customs authorities in checking safety aspects of products.

24 A majority of respondents (62%) consider that differences between Member States in enforcing product safety legislation are causing problems for businesses. The main problems identified are differences in interpretation of standards, enforcement priorities and administrative practices.

25 62% of respondents consider that cooperation between Member States' market surveillance authorities need to be improved. These respondents consider that an EU level coordination body and the obligation for Member States to undertake joint surveillance actions would be preferable to achieve such improvement. 81% of respondents believe that more intensive information sharing and/or cooperation would ensure a more equal treatment of economic operators, while 90% consider this would also benefit the safety of consumers. Around two/thirds also believe this would lower the operating costs for businesses.

26 34% of respondents) were affected by diverging safety evaluations of authorities in different Member States, mostly sometimes (6 respondents). Diverging test results were the main reason (50%) of divergence, but also diverging risk assessments (38%).

27 An overwhelming majority (88%) of those affected could not estimate the costs, but considered them non-negligible.

28 A strong majority (69%) of all 23 respondents considered binding EU wide measures as best to resolve lasting safety assessment divergences between Member State authorities, while 21% favoured non-binding EU wide recommendations.

29 Other stakeholders responding to the questionnaire are divided as to whether Member States undertake sufficient market surveillance (27 agreeing/27 disagreeing). Of those believing that Member States do not enforce consumer product safety legislation sufficiently, most consider this to be due to a lack of allocated resources and too few inspections. Lack of coordination among different national authorities was also mentioned several times.

are overwhelmingly of the opinion that more intensive information sharing and/or cooperation between Member States would enhance the safety of consumers throughout the EU.[30]

An important majority of stakeholders reported at least occasional problems with diverging safety evaluations from authorities in different Member States.[31] The divergences overwhelmingly occurred in respect to risk assessments, but also as regards test results or for other reasons, such as differing interpretations of safety requirements, standards or legislation.[32] The preferred remedy to resolve diverging safety evaluations of certain products was the adoption of binding measures at the EU level; only a small minority preferred non-binding EU-wide recommendations in such situations.[33]

2.2.3 Simplification

2.2.3.1 Simplification of the overall legislative framework

Stakeholders voiced a uniform call for a single market surveillance regime by simplifying and consolidating the two existing market surveillance systems established under the GPSD and the Free Movement of Goods Package.[34]

2.2.3.2 Prestandardisation procedures under the GPSD

The great majority of respondents considered that the absence of referenced European standards for many products covered by the GPSD made conformity assessment and enforcement more costly. There was also strong support for directly referencing existing European standards even where they are not based on a prior Commission mandate, as long as they provide a high level of consumer safety.

The speed of standardisation procedures under the GPSD was not satisfactory for a majority of responding stakeholders. The idea that the safety requirements formulated in Commission decisions should become mandatory and directly applicable is also

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30 Regarding the ways in which such cooperation could be improved, respondents supported all listed options (i.e. providing more financial support to joint surveillance actions and exchanges of officials, by establishing a coordination body at EU level, by providing more detailed rules on cooperation at EU level, by obliging Member States to respond to a cooperation request from another Member State and by providing more detailed rules for cooperation at EU level).

31 67% of respondents reported problems with diverging safety evaluations from authorities in different Member States. Of these, 70 encountered them "sometimes."

32 The sources of the above divergences were overwhelmingly diverging risk assessments (85%), but also diverging test results (44%) or other reasons (27% = 11 respondents). "Other reasons" were largely differing interpretations of safety requirements, standards or legislation.

33 The best remedy to resolve diverging safety evaluations was considered to be binding EU wide measures (75% of respondents).

34 The main legislative pieces of the Free Movement of Goods Package are: (i) Regulation 765/2008/EC setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 82) and (ii) Decision 768/2008/EC of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

strongly supported as the current method under the GPSD is perceived to leave too much margin of manoeuvre to the European standardisation organisations.

(a) National Market Surveillance Authorities

A large majority of responding NMSAs consider that the absence of referenced standards makes conformity assessment and enforcement more costly.[35] Quantification of these costs was, however, difficult to make.[36] Areas of particular concern are child-care articles, chemicals in products, stationery, ladders, playground equipment, candles, and furniture (e.g. flammability requirements). Furthermore, a significant majority of respondents are in favour of directly referencing existing European standards, in the absence of a Commission mandate, as long as they provide a high level of consumer safety.[37]

Likewise, a large majority of responding NMSAs agreed that the speed of standardisation procedures under the GPSD was not satisfactory.[38] An important number of respondents agreed that safety requirements set in Commission decisions should become mandatory and directly applicable to third parties.[39] A significant number of respondents were in favour of opening up the system to direct referencing of non-European international standards, such as ISO standards,[40] and of introducing "standing" or "framework" mandates.[41]

(b) Economic operators[42]

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35 41% strongly agreed and 31% of NMSAa agreed that conformity assessment costs more in the absence of a referenced EN standard. Difficulties in assessing the safety of a product in the absence of referenced En standard is found sometimes (64%), regularly (13%) and often (13%). In the absence of EN referenced standards, 93% of the respondents rely on national standards (transposing non-referenced EN standards), 77% on global standards (e.g. ISO). Significant also the recourse to "soft-law" tools, such as codes of practices (64%), state of the art and technology (53%) and consumers' expectations about safety (61%) . For the latter, might be interesting to know how and whether they are used in combination with risk assessments.

36 The "costs of enforcement" in the absence of a referenced EN standard was considered as non-negligible by 39% of the responding NSMAs. 13% of NMSAs provided an estimate of these costs. 28% of NMSAs did not know whether they can or cannot estimate the costs of enforcement of safety rules in the absence of EN standards.

37 77% of the respondents would favour the direct reference of an existing standard, provided that it ensures a high level of consumer protection and as long as it is a EN standard (53%). However 36% would favour also the use of non-European standards.

38 The speed of the current standardisation process under the GPSD was considered unsatisfactory by 79,5% of the respondents. 12% did not know.

39 23% strongly agreed and 67% agreed.

40 82% of the respondents would favour the use of non-EN standards, provided that they are global standards issued by formal international bodies (such as ISO/IEC etc). 21% rejected the use of other international or global standards other than ISO/IEC.

41 In addition 72% of the respondents favour the setting up of "standing" or "framework" mandates.

42 On the basis of the additional comments received, it appears – that despite an explanation - a large majority of responding economic operators, were not able to distinguish between the standards and standardisation procedures under the New Approach Directives and under the GPSD. Those who appeared to have understood the differences between these two procedures seemed to have problem with distinguishing between (i) the procedure before a mandate for issuing a European standard is adopted (subject to this public consultation) and (ii) after the procedure the mandate is issued (not

An important majority of responding economic operators considered that the absence of referenced standards made conformity assessment more costly, but were in general unable make a measurable cost-benefit assessment.[43] In the absence of referenced standards, the most frequently used tools for assessing conformity are global standards and other European standards.[44] Furthermore, a significant majority of economic operators were in favour of directly referencing existing European standards, in the absence of a Commission mandate, as long as they provide a high level of consumer safety. [45]

A large majority of responding economic operators agreed that safety requirements set in Commission decisions should become mandatory and directly applicable to them.[46] Compared to the replies from the NMSAs, the responding economic operators have shown a more accentuated tendency to open up the system also to direct referencing of non-European international standards as formal conformity compliance tools.[47] Economic operators would also favour the inclusion of provisions aiming to set up "standing" or "framework" mandates.[48]

(c) Other stakeholders (including consumers and business organisations)

Other stakeholders were more cautious and more divided concerning the use of non-European standards or global standards other than ISO.[49] They were, however, in favour of making safety requirements laid down in Commission decisions binding.[50] A majority would favour simplification of mandating procedures by means of "standing"

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subject to this consultation, but subject to the revision under the draft of the Standardisation Regulation). Thus, of the 30 responding economic operators, only a part of them could have been deemed to be giving informed answers.

43 Although 45% of the respondents could not quantify the additional costs incurred to ensure compliance in the absence of European referenced standards, 20% strongly agreed and 42% agreed that compliance costs are higher in the absence of a referenced European standard.

44 81% of the respondents rely on ISO standards, whereas 61% on national standards (transposing non-referenced EN standards). 42% rely on product safety codes, 29% on the state of the art and technology and 32% on consumers' expectations.

45 67% of the respondents would favour the direct reference of an existing standard, provided that it ensures a high level of consumer protection. Operators expressed a slight preference (38%) to non-European standard, instead confining this solution only to European standards (33%). 61% were in favour to setting up standing or framework mandates.

46 Making safety requirements mandatory and directly applicable would facilitate marketing of product according to 25,8% of operators who *strongly agreed* and to 45% who *agreed*.

47 71% of the respondents would favour the use of non-EN standards, e.g. global standards issued by formal standardisation bodies, such as ISO (45%). However a significant majority of operators would also open up to other international or global standards other than ISO/IEC (39%).

48 "Standing" or "framework" mandates refer to mandates for group of products, e.g. childcare articles, on the basis of which more than one standard could be drafted, either at once or over a period of time.

49 56% of the respondents would favour the use of non-EN standards, provided that they are global standards issued by formal international bodies (such as ISO/IEC etc.). 78% rejected the use of other international or global standards other than ISO/IEC.

50 39,3% strongly agreed and 33% agreed.

or "framework" mandates[51] and direct referencing of existing European standards elaborated outside a Commission mandate.[52]

2.2.3.3 RAPEX procedure

The results of the public consultation also show that many Member States still have difficulties complying fully with their obligations under the RAPEX system;[53] in particular, they have problems notifying the Commission of preventive and restrictive measures and ensuring follow-up action to notifications distributed through the RAPEX system. The main reasons are insufficient human and financial resources, an overly complex notification procedure and insufficiently detailed data provided in RAPEX notifications. Other 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.

(a) National Market Surveillance Authorities

The results of the public consultation show that not all Member States fully comply with RAPEX obligations stemming from the EU product safety legislation. This concerns particularly the obligations to notify to the Commission preventive and restrictive measures[54] and to ensure follow-up action to notifications distributed through the RAPEX system.[55] The main reasons for this seem to be insufficient human and financial resources, a too complex notification procedure and insufficient data provided in notifications.[56]

According to respondents, only changes in the RAPEX notification criteria, or making them more precise, would not make the notification process easier.[57] A majority of

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51 51% of the respondents favour the setting up of "standing" or "framework" mandates.

52 54% of the respondents would favour the direct reference of an existing standard, provided that it ensures a high level of consumer protection.

53 Rapid Alert System for non-food Products.

54 Only 44% of Member States notify through RAPEX *all* measures taken with regard to dangerous consumer products, providing that all the RAPEX notification criteria are met. 14% of Member States notify less than 50% of adopted measures mainly due to the insufficient human and financial resources and too complex notification procedure.

55 Only 26% of Member States ensure follow-up action to *all* RAPEX notifications, while 28% of Member States ensure follow-up action to less than 50% of notifications.

56 According to Member States which take follow-up action to more than 50% of RAPEX notifications, the insufficient product identification (over 71%) and the insufficient information on the companies marketing or distributing the notified product (over 77%) are the key problems in this area. For Member States which take follow-up action to less than 50% of RAPEX notifications, the insufficient human and financial resources (67%) constitute the most significant obstacle in performing follow-up action.

57 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'

NMSAs, however, are of the opinion that some consideration should be given to measures "decided" but not yet adopted, as their exclusion from RAPEX could simplify the notification procedure.[58] Respondents also consider that application of the *'risk assessment*' criterion poses problems in practice.[59]

(b) Economic operators

(The questionnaire did not contain any questions on the functioning of the RAPEX system for economic operators since the problems with the functioning of RAPEX and the action envisaged to remedy these problems would not affect the situation of economic operators.)

(c) Other stakeholders (including consumers and business organisations)

Respondents overwhelmingly see the positive role of RAPEX in the product safety area.[60] They are of the opinion that RAPEX contributes to the better protection of consumers throughout the EU.

2.2.3.4 EU product safety measures

Compliance with EU product safety measures adopted under Article 13 of the GPSD 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 subsequent prolongation periods). Inconsistent application of EU measures on product safety by national market surveillance authorities ("NMSAs") was viewed as a problem by economic operators.

(a) National Market Surveillance Authorities

Responding NMSAs expressed large support for direct applicability of EU product safety "emergency" measures and for the extension of the duration of such measures until a future permanent solution is adopted.[61] Difficulties were seen in the short time

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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.

58 The overwhelming majority of Member States (almost 70%) does not decide on measures without adopting them. Furthermore, over 60% of respondents agree that an obligation to notify through RAPEX exclusively measures adopted (and thus the exclusion of an obligation to notify measures decided but not yet adopted) would simplify the notification procedure.

59 Respondents consider 'risk assessment' (60%), 'cross-border effect' (60%) and 'categories of measures to be notified' (80%) to be the RAPEX notification criteria which are the most difficult to apply in practice.

60 The overwhelming majority of respondents (88%) sees the positive role of RAPEX in the product safety area and is of the opinion that RAPEX contributes to the better protection of consumers through the EU. Only 7 % of respondents hold different view.

61 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

period for national implementation of an EU product safety "emergency" measure.[62] Respondents considered it important that the EU product safety "emergency" 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.

(b) Economic operators

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 subsequent prolongation periods).[63] Inconsistent application of EU product safety "emergency" measures by NMSAs was viewed as a problem by economic operators.[64] 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.[65]

(c) Other stakeholders (including consumers and business organisations)

A large majority of respondents saw no problem if EU product safety measures were made directly applicable to economic operators.[66]

2.2.4 Other

2.2.4.1 Safety of products sold online

Economic operators and other stakeholders do not think that national authorities pay as much attention to products sold online as they do to products sold through other distribution channels. If NMSAs perform market surveillance on products marketed online, they do so in an incidental, fragmented and uncoordinated manner. A large

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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%).

62 The enforcement of "emergency" measures causes problems to almost half of the respondents 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%).

63 Compliance with "emergency" 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.

64 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.

65 Of those who had difficulties to comply, none could indicate the related costs, but ¾ considered the costs non-negligible.

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

majority of NMSAs would find it easier to enforce product safety rules if harmonised rules concerning products sold online were introduced at the EU level.

(a) National Market Surveillance Authorities

Only half of the national authorities have specifically monitored products sold online at a certain point of time during the last three years.[67] A large majority of those NMSAs which performed some monitoring products sold online had difficulties indicating the number of websites checked, the number of products targeted or the number of products sampled for further tests.[68] Certain NMSAs have, however, taken some preventive and/or restrictive measures against products sold through online distribution channels.[69]

Regarding the idea of introducing specific enforcement tools for products sold online, a large majority of NMSAs pointed out that it would be easier to carry out market surveillance with regard to the products sold online if specific harmonised rules were introduced at EU level.[70]

(b) Economic operators

A majority of economic operators think that dangerous consumer products are sold on the internet in the EU by operators based both in the EU and in third countries.[71] Only a minority thinks that attention given by market surveillance authorities to the safety

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67 53% of the responding national authorities monitored the safety of products at some point of time during the last three years.

68 About two thirds of these authorities pointed out that the number of websites checked was significant, but it was difficult to even estimate the numbers; only four NMSAs were able to quantify the number of potential unsafe products found on the internet and chosen for further tests. Only one NMSA was able to indicate the number of websites checked for the purpose of finding unsafe products; only four NMSAs were able to quantify the number of products found on the internet and sampled for further testing in order to assess their potential risks.

69 Three NMSAs were able to estimate the number of actions taken, while fifteen others confirmed that some measures were taken, without being able to quantify.

70 When carrying out market surveillance of products sold online, market surveillance authorities were faced with difficulties with: a) identifying the economic operators (78%), b) enforcing restrictive measures on economic operators (70%), c) the cross-border nature of cases investigated (60%) or d) difficulties in taking product samples (50%). Over 90% of national authorities dealing with cross-border cases have had difficulties when investigating cases of products coming from third countries (outside EU/EEA). 64% of these national authorities also faced problems investigating cases related to products being sold inside the EU/EEA area. Three quarters of all national authorities would find it easier to carry out market surveillance with regard to dangerous consumer products sold on the internet if specific harmonised rules were introduced at EU level.

71 Over 60% of economic operators pointed out that they are aware of dangerous consumer products are sold on the internet in the EU by operators based both in the EU and in third countries.

of products sold online is equal (or higher) compared to that given to products sold through other distribution channels.[72]

(c) Other stakeholders (including consumers and business organisations)

A strong majority of respondents confirmed that they were aware of dangerous consumer products being sold online in the EU.[73] An important majority of the respondents were also of the opinion that, with respect to safety, NMSAs do not treat products sold online in the same way as products sold in shops.[74]

2.2.4.2 Safety of products provided within the context of a service

Finally, in the view of all stakeholder groups the general safety requirement of the GPSD should not be dependent on whether it is the consumer or the service provider who operates the product provided within the context of a service.

(a) National Market Surveillance Authorities

In the view of NMSAs, the general safety requirement under the GPSD should not be dependent on whether it is the consumer or service provider who operates the product provided within the context of a service.[75]

(b) Economic operators

A majority of responding economic operators are convinced that products provided within the context of a service should be safe, irrespective of whether the product is operated by a consumer or a service provider. [76]

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72 Only 28% of economic operators think that the attention given by market surveillance authorities to the safety of consumer products sold online is equal or higher compared to products sold through other distribution channels, while 35% pointed out that in fact the attention is significantly lower.

73 74% of the respondents confirmed being aware that dangerous consumer products are sold online in the EU.

74 Only 10% of the respondents think that the attention given by market surveillance authorities to these products sold online is equal (or higher) to the attention given to products sold via other distribution channels. Over two thirds of the respondents consider that national authorities do not treat products sold online the same way as products sold in shops.

75 An important majority of authorities (73%) thinks that there should not be any differences in the safety requirements for situation where a product is operated by a consumer or a services provider. About the same majority (69%) is convinced that application of a general safety requirement to all products provided within the context of a service without any distinction would lead to the decrease of consumer exposure to risks. 60 % of authorities would favour the rule according to which all products into which the consumer comes into contact would have to be safe.

76 55% of responding economic operators is convinced that products provided within the context of the service should be safe irrespective of whether the product is operated by a consumer or a services provider, 25 % thinks the contrary, 20 % do not know. 30 % of respondents think that exposure of

consumers to risks resulting from a product provided within the context of a service is independent of whether the product by help of which the service is provided is operated by the consumer or the service provider. 50 % of responding economic operators thinks the contrary, 20 % do not know. If a general safety requirement was established at the EU level with respect to all products with which consumers come into contact within the provision of a service, irrespective of whether the product is operated by the provider of a service or a consumer, in the opinion of 10 % of the responding economic operators this would lead to an increase in operating costs, according to 15 % of them to their reduction. For 20 % of responding economic operators this would have no or negligible impacts on operating costs. 55% of the respondents were not able to provide any cost estimation.

(c) Other stakeholders (including consumers and business organisations)

A large majority of stakeholders are convinced that products provided within the context of a service should be safe and submitted to the same regulatory environment irrespective of whether a product is operated by a consumer or a service provider. It is the prevailing opinion of responding stakeholders that exposure of consumers to risks resulting from a product provided within the context of a service is independent of whether the product is operated by the consumer or the service provider.

Detailed results of the public consultation were published on the following website:

http://ec.europa.eu/consumers/safety/prod_legis/gpsd_consultation/gpsd_results/index_en.htm

2.3. Workshop on the GPSD revision during the International Product Safety Week

Within the framework International Product Safety Week, the Commission organised a one-day Workshop on the revision of the General Product Safety Directive with participation of over 150 participants, representing all major stakeholders, including representatives from non-EU countries.

The aim of the Workshop was to inform stakeholders of the results of the internet public consultation, receive feedback from stakeholders on the process and topics of the consultations and discuss the conclusions reached in the consultation. Following the presentation of the results of the internet public consultation given by the Commission, representatives of the key stakeholder groups, presented their views on the revision of the General Product Safety Directive.

2.3.1 Views of stakeholders on the internet public consultation and the revision of EU consumer product safety rules

Michael CASSAR, board Member of PROSAFE and the Head of Market Surveillance Directorate of Malta Standards Authority, speaking on behalf of PROSAFE presented the views of PROSAFE on the revision of the General Product Safety Directive. He stated that Consumers want safe products regardless whether they are harmonized or not and that cooperation between Market Surveillance Authorities considered fundamental for product safety. He expressed support for the alignment of NLF and GPSD to form a single market surveillance framework and intensified cooperation between Member States. On the specific issue of joint market surveillance actions he indicated that these actions constitute today an very good informal means of cooperation, implemented using best practice. In the view of PROSAFE this demonstrates the feasibility of a more formal programme and provides an excellent basis for the development of such a programme.

Mr. Paul Coebergh VAN DEN BRAAK presented the views of BusinessEurope on the revision of the GPSD. The GPSD could be improved as there is currently an overlap with the New Legislative Framework which is quite complex and which allows room

for legal uncertainty. Revision of the GPSD should therefore aim to provide better coherence with the New Legislative Framework. Regarding harmonised consumer products, there is a need to align the market surveillance regime. Standards should remain voluntary. Specific safety requirements should not be used to legislate for entire product groups. Regarding on-line sales, according to him, this is a practical problem, not a legislative one.

Mr. Jean-Philippe MONTFORT from Mayer-Brown presented the views of the legal practitioner, representing companies involved in global and pan-European recalls and helping companies comply with product safety. He outlined the complexity of the legal framework and the confusion which exists particularly since the introduction of the New Legislative Framework. He proposed the adoption of one single product safety legislation (taking over and updating the relevant provisions of the GPSD and the New Legislative Framework) which applies to all products. Other points raised by the legal sector include clarification of circumstances triggering RAPEX notifications and the adoption of corrective measures, suitable rights for operators before notification on RAPEX (e.g. right to be heard; right of access to document (test reports); right for a second opinion) and the proposal of a central role for the European Commission and/or a dedicated EU Agency to act as arbitrator or facilitator.

Ms. Tania VANDENBERGHE, ANEC, and Ms Sylvia MAURER, BEUC, presented a joint position paper on revision of the GPSD. The representative spoke of their concerns and identified certain shortcomings of the GSPD. The GPSD almost entirely relies on standardisation bodies to provide safety requirements. In the absence of a standard, or until it is referenced in the Official Journal, products not meeting safety requirements can still enter the market. The temporary nature of EU product safety "emergency" measures can cause confusion as these measures may not be prolonged at end of validity period even if no solution is found. The representative called for a European framework to encourage more harmonised national market surveillance activities, a transparent, EU-funded accident statistic database and a pan-European contact point for consumers to report unsafe products. She also raised the issue of better product traceability and proposed that requirements regarding manufacturers' obligations be incorporated in the GPSD. RAPEX too should provide more information and it was suggested that the names of retailers be included in the RAPEX notifications. As regards services, ANEC and BEUC support the creation of a European legal framework to cover both the safety of consumer products and services.

Mr. Henk DE PAUW, NORMAPME, presented the organisation which represents SMEs in all sectors of European standardisation and cooperates with CEN and stakeholders in drafting standards. NORMAPME submitted a position paper in response to the public consultation as they felt the questionnaire did not allow for enough space to present their opinions. NORMAPME believes that the GPSD should keep its *lex generalis* character and that specific products should be legislated through specific legislation not under the GPSD. Regarding the standardisation procedures under the GPSD, NORMAPME agrees that the drafting procedure should be shortened and fully endorses the system of framework mandates where industry, in cooperation with CEN & standardisation bodies, can draft standards on their own initiative when needed. NORMAPME agrees that the EU product safety "emergency" measures should be extended from 1 to 3 years. It would welcome a Commission initiative

which resolves differences in interpretation by different Member State enforcement bodies.

Mr. Laurent PARROT, the Technical Service Manager of Fédération Française des Industries Jouet-Puériculture (the French federation of toy and childcare industries) outlined the commitments of the federation in the field of children's products and their role in the standardisation process. He stated that the GPSD is considered as the directive for childcare articles but agreed that the process for mandates is too long. He called on greater participation of Member States in the work of the technical committees and proposed making participation mandatory to improve the understanding of all the different parties involved. Regarding RAPEX, Mr Parrot listed some areas for improvement and spoke of possible "inappropriateness" in some cases, e.g. some notifications are made through the system 2 years after the product is taken off the market.

Mr Hubert J.J. VAN BREEMEN, Confederation of Netherlands Industries and Employers, representing BusinessEurope commented that the GPSD gives authorities the possibility to use non-mandated ISO and CEN standards to determine whether or not a product is safe.

Ms Etelvina ANDREU SANCHEZ, Instituto Nacional del Consumo, Spain, stated that it is very difficult for market surveillance authorities to take measures in the absence of referenced standards and addressing this problem is important. This is particularly necessary when strong measures have to be taken, such as withdrawal from the market. In such cases, a referenced standard gives market surveillance authorities a stronger position in the case of legal appeals**.** Referenced standards also contribute to the transparency and clarification of the legal framework.

Erica SCHMEDT, Authority for Social Affairs, Family, Health and Consumer Protection, Hamburg, Germany agreed that clearer benchmarks, such as standards, should be defined for market surveillance purposes.

Al KAUFMAN, Toys R Us supported the need for consistency amongst national authorities when taking action against dangerous products and agreed that clarity of requirements and standards are very much needed. He added that consideration would have to be given as to whether to have a formal or informal mediation procedure (agreed by both economic operators and enforcement authorities).

Thomas BOURKE, National Consumer Agency, Ireland, urged the use of the precautionary principle to put consumers first. The Irish authorities found the consultation to be useful although suggested some aspects could be improved, such as working relationship between the various Commission DGs as regards interpretation.

Jean-Luc LAFFINEUR, Laffineur Law firm, mentioned that in the case of diverging test results, Member States tend to rely on the tests made by laboratories on their own territory. In situations where differences between the results of laboratories based in different Member States appear, there should be an EU "arbitrator" and the decision should be binding on national authorities.

2.3.2 Conclusion

The Workshop on the revision of the General Product Safety Directive showed a general consensus of all stakeholders on three fundamental aspects: the need for a clear and uniform legislative framework in the area of product safety, faster procedures for elaboration of European standards and a necessity for a deeper coordination of national market surveillance authorities at the European level.

3. ANNEX 3: SUMMARY OF POSITION PAPERS RECEIVED FROM STAKEHOLDERS

3.1. Introduction

Due to the intrinsic limitations of the IT tools serving for the organisation of internet public consultation, the Commission invited all stakeholders to send position papers on the intended revision of the General Product Safety Directive. This possibility was used by all groups of relevant stakeholders, including consumer organisations, business associations, Member States as well as individual economic operators. Certain stakeholders provided more than one position paper, usually in the form of an update in the view of the development of the legislative initiative.[77] In total the Commission received position papers from nine business associations, two consumer associations, two EU/EEA Member States, one market surveillance associations, one economic operator and one common paper from two European Standardisation Organisations.[78]

3.2. Positions of consumer associations - ANEC and BEUC[79]

(a) Consistency of product safety requirements

In the opinion of ANEC-BEUC the safety of consumers would be better ensured, if the obligations of economic operators in respect of harmonised products were also applied to non-harmonised products and if there was an obligation for economic operators to establish and maintain technical documentation in respect of all consumer products, i.e. both harmonised and non-harmonised.

Unlike the more recent Decision, the General Product Safety Directive does not provide a possibility to choose an appropriate conformity assessment level depending on the risks a product may pose. (A common framework for the marketing of products was approved jointly by the European Parliament and Council in 2008 (Decision 768/2008/EC). It describes the modules for the conformity assessment procedures that are to be used in Community legislation. Essentially, the European modular system "provides for a menu of modules, enabling the legislator to choose a procedure from the least to the most stringent, in proportion to the level of risk involved and the level of safety required). This is a major shortcoming bearing in mind that the General Product Safety Directive applies to all consumer products not covered by specific

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77 As - on the basis of the feedback from stakeholders - the scope of the initiative was extended beyond the scope of the General Product Safety Directive, the initiative also changed name to Product Safety Package.

78 Updates to the original positions papers sent by certain organisations were not counted as separate position papers.

79 ANEC, the European consumer voice in standardisation, defends consumer interests in the process of standardisation and certification. BEUC is a European Consumer Organisation with membership of 42 independent national consumer organisations from 31 European countries, including EU, EEA and applicant countries). BEUC represents its members and defends the interests of all Europe's consumers.

directives, even those that could pose significant risks. If the Supplier's Declaration of Conformity (module A) is considered the default level, higher levels seem to be warranted in certain cases. Therefore, ANEC/BEUC propose the introduction of a provision which allows the use of conformity assessment procedures involving third parties for certain products. The selection of a module higher than A should be linked to criteria should be established using a committee procedure.

(b) Market surveillance coordination

ANEC/BEUC pointed out that Member States by lack of staff and funding do not ensure the enforcement of product safety legislation. They stressed there was an urgent need for establishing a European framework for market surveillance in order to ensure the availability of sufficient resources and a coherent approach to market surveillance activities across all 27 Member States.

The revision of the General Product Safety Directive gives an opportunity to introduce more demanding requirements on market surveillance activities of Member States (such as the need to check a minimum number of products of a certain kind agreed at the European level). However, this would only be useful if the lack of resources of market surveillance authorities was addressed. Hence, a pan-European debate on increasing the financing of market surveillance activities should be initiated.

In the opinion of ANEC/BEUC a better product traceability would improve market surveillance cooperation and coordination under the General Product Safety Directive. It is crucial for consumers that the withdrawal of unsafe products from the market, or the recall of products that hold potential risks to health and safety, is done as quickly as possible.

Measures should be taken in order to allow the rapid and easy identification of unsafe or defective products. In this context, the requirements regarding manufacturers' obligations from the Decision on a common framework for the marketing of products should be incorporated, and in particular the following:

"- Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.

- Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. The address must indicate a single point at which the manufacturer can be contacted."

ANEC/BEUC also consider that the application of track-and-trace technologies, and product authentication technologies, would be beneficial to consumer safety. The technology used should ensure consumer safety, be reliable and applicable, and improve tracing mechanisms to allow identification and safe recall, safeguard consumer

privacy, not hinder competition and the environment and have no major impact on the final price of products.

A full assessment of the advantages and disadvantages of each technology should be made. The adverse effects RFID potentially holds for consumer privacy (tracking and profiling of consumers and consumer discrimination), security (ID theft) and health (EMF emissions) should be of concern.

(c) Simplification

(i) Simplification of the overall legislative framework

ANEC/BEUC would agree to include the provisions of the Directive on Dangerous Imitations in the General Product Safety Directive provided that the prohibition of these products would be maintained.

(ii) Pre-standardisation procedures under the General Product Safety Directive

ANEC/BEUC would oppose to apply international standards as an additional benchmark for safety evaluation because international standards are often more difficult to develop and rarely contain requirements that are detailed enough to ensure products are safe. The development of international standards is also more difficult for European consumers to influence. Moreover, in most cases, international standards relevant to the General Product Safety Directive will not be available.

Likewise, ANEC/BEUC would not be in favour of the application of non-European standards (other than international standards) whenever a risk or a product is not covered by a European standard referenced in the OJEU because there is very little influence over non-European standards. However, the option could be supported in principle if a comitology procedure is used and a proper consultation and evaluation involving stakeholders is ensured. If such procedure is in place, it may be useful in some cases to adopt safety standards from non-European countries, e.g. ASTM standards, wholly or partly. For example, the current CEN high chair standard is inferior to its US counterpart. It should also be possible to adopt the provisions of a non-European standard in a modified form under this procedure.

Direct referencing of European standard whereby an existing European standard developed without a mandate from the Commission would be directly referenced in the OJEU, provided that it ensures a high level of consumer protection, could be supported by ANEC/BEUC if an adequate procedure was used to decide about such referencing. That would be the case, for example, if the procedure allowed Member States and stakeholders to object to the standard being referenced in the OJEU (as is done now under the General Product Safety Directive), then ANEC/BEUC could agree. A comitology procedure should be used to this end and a proper consultation and evaluation involving stakeholders would need to be ensured.

Regarding the interests represented in the standards development process, the participation of societal interests can be hampered by many factors such as lack of

resources, insufficient expertise and ineffective coordination. These factors were detailed in the Access to Standardisation study of March 2009 for DG Enterprise. Hence it is vital for public financial support to be continued in order to enable the participation of societal stakeholders directly at European level. We welcome the recommendation of the EXPRESS panel for public funding to be continued to ANEC (ECOS, ETUI-REHS and NORMAPME) in the years to 2020 and beyond. The revised General Product Safety Directive could not be successful without the effective participation of consumers in the standardisation process.

In the view of ANEC/BEUC, the major shortcoming of the current General Product Safety Directive is that it almost entirely relies on the European Standardisation Organisations (ESOs) to provide detailed safety requirements for specific products. ANEX/BEUC's main concern with regard to the procedure is that the initial Commission Decision, determining the safety requirements which the standard must meet, is not legally-binding. As the ESOs are not obliged to accept a Commission mandate and the use of standards is always voluntary, there is no guarantee that the standard will be developed and even if it is, there is no certainty it will reflect what the mandate requires. However, it is true that if a standard is developed but does not meet the safety requirements of the Decision, the Commission, through comitology, can decide not to publish (or to withdraw) its reference in the OJEU. This means that, in any of the situations described above (i.e. in the absence of a standard or until its reference is cited in the OJEU), products that do not meet the safety requirements of the Decision can legally circulate or enter the market thereby putting consumers' health and safety at risk. This 'status quo' can last for many years (up to 5 years and more) before a satisfactory safety measure becomes operational. In case the Commission would in the future favour the application of international standards, they should go through the same procedure as European Standards before being referenced in the OJEU. If the Directive allows for establishing any safety requirement on any product on a temporary or permanent basis it may also be possible to make use of an existing European standard wholly or partly. It should be also possible to adopt the provisions of an existing European standard in a modified form. A comitology procedure shall be used to this end and proper consultation and evaluation including stakeholders must be ensured.

Political issues should be dealt with at the political level and not delegated to the standardisation bodies. An example is the establishment of content limit values for hazardous chemicals in consumer products. The role of standardisation should be limited to providing the *technical means* through which compliance with the political decision is achieved or evaluated. The General Guidelines, which constitute the common understanding between the EU/EFTA and the ESOs confirm that "European standards provide technical solutions for presumption of conformity with legal requirements" and moreover recognise the "distinct responsibilities and competencies" of the EU/EFTA and ESOs in the standardisation process.

Given the shortcomings of some European standards, ANEC/BEUC proposed that the Commission should consider introducing an alternative to standards as a means of supporting the General Product Safety Directive. For instance, ANEC found that seven of nine European standards, proposed by DG SANCO in 2005 to be cited in the OJEU in support of the General Product Safety Directive, did not offer sufficient levels of

safety. In 2009, ANEC rejected most of the standards proposed by DG SANCO to be cited in the OJEU. Both examples arose from the unbalanced influence of industry in the development of standards to support legislation or the wider public interest.

A further shortcoming of the General Product Safety Directive, in the opinion of ANEC/BEUC was the lack of a safeguard procedure which would allow Member States to express a formal objection to a standard (such as Article 14 of the Toy Safety Directive 2009/48/EC). The use of a safeguard procedure should be possible even before a standard is cited in the OJEU.

ANEC/BEUC further submitted that the legislative "framework for the setting of ecodesign requirements for energy-related products (ERP)" (2009/125/EC) be used as a model in the field of product safety. This directive foresees the adoption of "implementing measures" for specific product categories using a regulatory committee procedure complemented by a "consultation forum" involving all stakeholders. The implementing measures are based on research projects funded by the Commission. The Commission also makes funding available to ensure the effective involvement of consumers and environmental NGOs in the implementation process. As in the ERP ecodesign process, ANEC/BEUC believe the General Product Safety Directive should allow the establishment of product specific rules without limitation, either in terms of content or period of applicability. It could then be decided case-by-case which level of detail should be defined in the implementing measure and which aspects left to the standards bodies. Such a mechanism would make the procedure to specify product specific rules as the basis for mandates superfluous. The adopted requirements would have a legal status *per se* and so form a framework for the adoption of mandates. The implementing measures could be adopted for a definite or indefinite time. Emergency measures would not be needed because of the legal status of the implementing measure, except for products covered by vertical product safety regulations (e.g. the Toy Safety Directive) which do not provide for the use of emergency measures. An alternative would be to allow the use of emergency measures in all directives.

(iii) EU procedures for exchange of information on product risks

As far as serious and immediate risks are concerned, ANEC/BEUC were of the opinion that RAPEX contributed to more even protection of consumers throughout the EU. However, in their view RAPEX it had to be improved and enable a wider access to information about dangerous products.

ANEC/BEUC held the view that when a dangerous product was notified by a Member State to the Commission, the authorities and the Commission did not systematically inform consumers or consumer groups unless an action (e.g. a recall) is taken. According to ANEC/BEUC an exception to this was the information and statistics related to the Low Voltage Directive safeguard clause notifications. These are regularly sent by the Commission and the LVD-Administrative Co-operation Group to consumer organisations. The same failure of communication has been shown to happen when national authorities detect a dangerous product and negotiate an agreement with the producer either to remove the product from sale or to modify it. In the latter case, from time to time, the authorities do not notify even other Member States of the voluntary agreement with the producer.

For ANEC/BEUC, the success of any recall is dependent upon the communication of information to consumers. Hence ANEC/BEUC call for the early and widest possible dissemination of information relating to dangerous products. The results of a notification should be made publicly available in order to protect consumers' health and safety and to increase consumers' confidence in the Internal Market.

ANEC/BEUC indicated that RAPEX could be used as the basis for dissemination of information but should be improved in order to provide more detailed information and be made more consumer-friendly. For instance, the column that appears on the right-hand side of the RAPEX overview, indicating the other Member States in which the products have been notified and restriction measures taken, should be filled in systematically. This column provides valuable information at a glance.

Furthermore, consumer organisations should receive information beyond that made publicly available. For example, ANEC would want to be informed about the standards with which dangerous or unsafe products may comply.

Finally, requirements related to the content of recall notices should be defined so as to avoid recall notices being perceived by consumers as advertisements for the products notified.

(iv) EU product safety measures

ANEC/BEUC did not foresee any problem if the EU product safety "emergency" measures were directly applicable to economic operators. In their view, although the General Product Safety Directive allowed regulators to adopt product specific requirements in the form of implementing measures in emergency situations, the adoption process remained extremely slow and the validity of the measures is always time limited. Temporary "emergency" measures, based on Article 13 of the General Product Safety Directive, may be adopted by the Commission, but this instrument has not been used to any great extent. The temporary nature of Article 13 measures could cause confusion and uncertainty among economic operators and consumers because they may not be prolonged at the end of their validity period, even when no solution to the risk has been found. In addition, (multiple) prolongations in the past (lighters, phthalates) have led to an expenditure of resource that could have been avoided if permanent measures had been adopted following a comitology procedure (or safety requirements having a legal status).

(d) Other

(i) European accident database

ANEC/BEUC indicated that in the recent report 'Injuries in the European Union - Statistics Summary 2005-2007' revealed that around 7 million people were admitted to hospital each year, with 35 million more treated as hospital outpatients, as a result of an accident or a violence-related injury. Injury data could be obtained from a wide range of sources, however, most injury databases in the EU were fragmented, limited

in their size and scope or incomplete. This makes it almost impossible to compile reliable statistics or reach conclusions.

In opinion of ANEC/BEUC, even the so-called European Injury Data Base (IDB) could be considered as a reliable and representative database since only 13 Member States were known to collect injury data through hospitals which, in turn, were not always collecting information in a regular and consistent manner. In addition, it was very difficult to gain access to the IDB or receive detailed information.

ANEC/BEUC deemed accident and injury data to be critical in the setting of priorities, the development of policy and the determination of preventive actions and were also needed to evaluate the effectiveness of preventive measures. For instance, reliable and consistent accident and injury data would give a clear indication as to whether the number of injuries and accidents involving a certain consumer product has decreased following the introduction of a new/revised regulation or standard. If no change is observed, regulators could require a review of the legislation or standard related to the product(s) in question.

Last but not least, the efficiency of the legal framework of the New Approach and the General Product Safety Directive depends, in the view of ANEC/BEUC on the ability of the Commission and Member States to identify and recognise problems associated with unsafe consumer products. Such problems can be identified only through a regular surveillance of home and leisure accident data.

ANEC/BEUC urge the creation of an EU-funded accident statistical system, under the co-ordination of the European Commission. Member States should be required to contribute to the establishment of the database and its regular updating. This system could be the IDB system providing that it was improved and adequately funded by the European Union. Relevant stakeholders - such as consumer organisations - should have access to the database.

(ii) Child-appealing products

ANEC/BEUC have encountered diverging safety evaluations with respect to a particular product by the national market surveillance authorities of different Member States and especially cite child appealing products as an example. ANEC/BEUC considered that Member States did not know how to evaluate products as there was no harmonised definition in EU legislation of what should be considered as child appealing. In the case of baby walkers and bath seats some Member States evaluated these products as being unsafe and would prefer to ban them; others disagreed. Same applied to disco soothers. These soothers, popular with teenagers some years ago, contained a battery to make the soothers flash and some batteries exploded. As a result, according to ANEC/BEUC soothers were banned in some Member States, but not in others. Binding EU-wide measures setting specific safety requirements for certain products would best resolve these divergences.

For ANEC/BEUC, the safety of child-appealing products could be ensured by developing a harmonised definition for child-appealing products. In their view, there

was currently a lack of a harmonised definition of what makes a product appealing to children. In general, the child-appealing characteristics of products include shape, size, texture, colour and decorative elements (eyes and feet, for instance). Other characteristics that could also play a role are sound, smell, movement and function (e.g. a lighting function). ANEC/BEUC regretted that there was still no harmonised definition agreed in EU legislation. A legal definition of a child-appealing product can so far be found only in the case of lighters.

Therefore, ANEC/BEUC proposed to introduce a common definition of child-appealing products in the General Product Safety Directive. The Commission Decision on child-resistant lighters states that a "'child-appealing lighter' shall mean a lighter whose design resembles by any means to another object commonly recognised as appealing to, or intended for use by children younger than 51 months of age." In the opinion of ANEC/BEUC this definition could serve as a basis for the definition to be introduced in the General Product Safety Directive. In addition, ANEC/BEUC proposed the same definition to be introduced in other relevant Directives, like the Low Voltage Directive, the R&TTE Directive, the Cosmetics Directive, etc. If the same definition is not applied in other EU legislation, there could be a risk of having different/no definitions for other ranges of products not falling under the General Product Safety Directive.

Furthermore, ANEC/BEUC saw the need in establishing specific safety requirements for child appealing products. A toaster shaped like a cartoon character, a shampoo bottle resembling a doll, a scented candle that looks like a strawberry, a cigarette lighter resembling a toy car that blinks; More and more products are shaped or decorated in a way that makes them appealing to children. The lack of specific safety requirements in product legislation for such child-appealing products undoubtedly raised concern, particularly as children are among the most vulnerable of all consumers.

In the viewpoint of ANEX/BEUC specific legal requirements ought to be developed to ensure that child appealing products are indeed safe for children. In particular, the General Product Safety Directive should explicitly require that, whenever a product features child-appealing characteristics, the product must be safe for children under all conditions of use and foreseeable misuse. If deemed necessary for the protection of children's health and safety, a complete ban should be imposed on certain types of products, determined by a committee procedure. Such a ban should apply to dangerous chemical products (or their packaging) that are appealing to children. With regard to the latter, upon the request of DG SANCO, the Scientific Committee on Consumer Safety (SCCS) is currently assessing the potential risks related to these products. To support this work, the members of ANEC/BEUC submitted examples of products that can be found on the EU market, along with information about related potential risks. The Commission shall take measures against these dangerous products that reflect the SCCS opinion as soon as it is published.

(iii) Reference to persons with disabilities

A specific reference to people with disabilities under categories of consumers at risk should be made under Article 2 (b) (iv) of the General Product Safety Directive, to avoid any potential diverging safety evaluation of products.

(iv) Collective redress mechanisms

ANEC/BEUC believed that consumers suffering from damages due to the same defective/harmful product should be able to gather their claims against the producer in a joint action given that the mass production of consumer goods could lead to the distribution of unsafe products on a large scale, significant number of consumers may be affected. ANEC/BEUC suggested that a collective redress mechanisms should be put in place in all Member States to ensure fair compensation of victims notably in product liability cases. In this context, ANEC/BEUC asked for the General Product Safety Directive to require that information about the redress mechanisms offered, such as reimbursement and/or compensation, should be provided to the public at the same time as other information.

(v) EU complaints handling and reporting point

For ANEC/BEUC, the absence of a system at the EU level which would allow consumers to register problems they identify with the safety of products represented an important shortcoming. In most Member States, consumers have the possibility to report safety problems, incidents or accidents with products to the authorities. However, this information is not gathered or coordinated at EU level, with the exception of the notification of dangerous products that pose a serious risk, which are reported by the national authorities under the EU RAPEX system.

According to ANEC/BEUC, the Commission should establish a system under the General Product Safety Directive through which national consumer complaints reported to Member State authorities are gathered at a single, pan-European report point. In addition, consumers should have the right to notify unsafe or non-compliant products directly to this European report point.

A complaints handling and report point for the registration of unsafe children's items (the 'OKA report point') was set up in December 2005 in the Flanders region of Belgium, as an initiative of the Flemish governmental agency "Kind en Gezin" (Child and Family) in cooperation with three partners, one of whom was ANEC. The philosophy was that parents, foster families, crèches and carers can use the report point (accessible via the Kind en Gezin's website) to report products intended for children between 0 to 3 years of age which have been found to be unsafe or have been involved in accidents or near-accidents. During the First International Workshop on "Accident/Injury data collection for non-food product and service risk assessment", organised by DG Health & Consumers in February 2006, this Flemish project was found to be very simple, to incur very limited costs, and was envisaged as concrete outcome of the workshop as "it constitutes a good pilot for further projects". ANEC/BEUC would strongly support this report point as model for a European report point.

In the view of ANEC/BEUC a supporting European database would enable the timely identification of safety problems or risks and permit national authorities (and economic operators) to take corrective actions more quickly. This pan-European report point and database would have to be complementary to the RAPEX system in order to ensure coherence. ANEC/BEUC did not believe the complaints and data collected necessarily have to be publicly available.

3.3. EU and EEA member states or their regions

3.3.1 DENMARK

(a) Consistency of product safety requirements in the non-food area

In the opinion of Denmark diverging [product safety] requirements led to higher administrative burdens in general for businesses and expectedly higher exposure of consumers to dangerous products. Consequently, the Danish Government would strongly support the alignment with the New Legislative Framework to the highest possible degree leading to fewer legislative differences in Member States while ensuring the independence of legislation not covered by the New Legislative Framework. Providing a clear and uniform set of product safety obligations for economic operators for all kinds of products and ensuring effective and clear product traceability will also ensure better enforcement of existing product safety rules.

(b) Market surveillance coordination

Denmark acknowledged that diverging safety evaluations posed a problem for economic operators, as they thereby face inconsistent application of safety legislation towards their products in different Member States. Denmark would therefore be in favour of considerably improving market surveillance cooperation and coordination as well as the harmonisation of safety evaluations of consumer products amongst Member States.

Denmark would support creation of an improved and more uniform control of products since in its view it is important that authorities of all Member States collaborate and share knowledge about how to plan to protection of consumers in an optimum manner. Yet, Denmark pointed out that it was also important that remedying measures, which are chosen, take into account national and cultural differences and conditions of use of the products in question, while still aiming at supporting the free movement of goods and services across borders to the highest degree possible.

(c) Simplification

(i) The overall legislative framework

Denmark holds the view that alignment with the New Legislative Framework (NLF) should be ensured to the highest possible degree. Following the adoption of the Free Movement of Products package, two sets of rules on general product safety exist. Coexistence of these rules without a substantive and practical alignment of the General Product Safety Directive with the NLF, will leave both economic operators and national market surveillance authorities with differing product safety obligations.

(ii) Pre-standardisation procedures under the General Product Safety Directive

Denmark would be in favour of optimisation of the speed of standardisation procedures providing that the political consensus on the safety requirements within the forum of Member States as well as a high level of consumer protection was maintained and that the speed of these procedures was balanced against transparency, consensus and quality.

(iii) EU procedures for exchange of information on product risks

N/A.

(iv) EU product safety measures

Denmark expressed support for the direct applicability of EU product safety measures to economic operators as well the extension of the period of validity of these measures, by making the period of validity dependent on occurrence of a certain event in future, such as adoption of an EU standard or a permanent EU legislative measure with respect to an identified risk.

(d) Other

(i) Safety of product sold online

Denmark would favour strengthening and easing market control enforcement of consumer products sold on the internet. In its view since the amount of products sold on the internet is steadily increasing, it is important to better protect consumer interest in this area and remove the remaining barriers to cross border trade. Denmark would support creation a specific market surveillance guideline containing a best practice on market surveillance on products sold online.

(ii) Safety of services

Denmark was of the opinion that the safety of services, if they were to be regulated, should be included in the scope of the Services Directive, and not as an integral part of the General Product Safety Directive.

(iii) Introduction of a safety requirement that the product would not become dangerous in their expected lifetime

Denmark suggested an introduction of a safety requirement that the product would not become dangerous in their expected lifetime. This requirement would need to take into account reasonable maintenance to be carried out by the consumer. Justification for the introduction of this requirement into the directive is that a wide range of products are not yet covered by standards, that normally takes aging into account. For the sake

of consumer safety, in the view of Denmark, this requirement was necessary for proper enforcement.

3.3.2 GERMAN LÄNDER[80]

In the opinion of German Länder this review should be seen in the context of the Commission's efforts towards a new Single Market Act and of the European Parliament's resolution on the revision of the product safety directive and on market surveillance dated 8th March 2011. An essential element of this review is the adaptation of the directive to the New Regulatory Framework for the Marketing of Products (New Legislative. The repeal of Directive 87/357/EEC and the integration of these regulations for products which may be confused with food into the product safety directive would be welcomed.

3.3.3 NORWAY

(a) Consistency of product safety requirements in the non-food area

Norway indicated that the definitions of economic operators differ in the General Product Safety Directive from those contained in Regulation (EC) No 765/2008 and Decision (EC) 768/2008, which could cause problems. In its opinion it was not clear, in particular, how an authority in one country should deal with dangerous products imported to the EU by an importer not located in that country. If the importer of a dangerous product was located in another country and only the distributor was located in Norway, Norway could not carry out measures directly towards the importer. In its view, according to Regulation (EC) No 765/2008 Norwegian authorities could not ask for detailed safety documentation from distributors, only from importers and manufacturers.

(b) Market surveillance coordination

Norway expressed concerns about the proposal from the Commission about obligatory participation in at least one joint market surveillance action per year. One year the joint action might include products not considered to be a problem in Norway. Due to cultural differences, different products and different use, products which were considered as a problem in one country might not automatically pose a problem in another country. Norway did not want to be committed to participate in a joint action when it would not consider the product in question to pose a significant risk in Norway.

(c) Simplification

(i) Overall legislative framework

[80] Baden-Württemberg, Bavaria, Berlin, Brandenburg, Bremen, Hamburg, Hesse, Mecklenburg-Vorpommern, Lower Saxony, North Rhine-Westphalia, Rhineland-Palatinate, Saarland, Saxony, Saxony-Anhalt, Schleswig-Holstein, Thuringia.

Norway strongly supported the alignment of the General product Safety Directive with the new Legislative Framework and believes that it will be easier for both authorities and economic operators because economic operators have difficulties in understanding regulations in the non-harmonised area.

(ii) Pre-standardisation under the General Product Safety Directive

Norway expressed its concern about non-mandated standard referencing, and highlighted that it had to be ensured that this type of standards would not favour some economic operators (e.g. the ones who developed the standard originally). There should be some kind of assessment to ensure that the standard covers all the essential safety regulations.

(iii) EU procedures for exchange of information on product risks

N/A.

(iv) EU product safety measures

Norway was positive in respect of a direct application of product safety emergency measures to economic operators, as it most likely would be an effective tool to ensure safe products for consumers, but stressed the need to hear the views if economic operators before the measure was adopted.

3.4. Business associations

4.1 BUSINESSEUROPE[81]

(a) Consistency of product safety requirements in the non-food area

BUSINESSEUROPE favoured a coherent legislative framework in the product safety area. According to BUSINESSEUROPE, this should be achieved by limiting the application of consumer product safety requirements under the General Product Safety Directive only to products not regulated by harmonised product safety requirements. For non-harmonised consumer products BUSINESSEUROPE is of the opinion that the general safety requirement adequately covers the safety risks of those products.

On the specific issue of identification of the manufacturer and/or importer responsible for putting the product on the market, BUSINESSEUROPE considered, on the one hand, that it was an essential tool to deny rogue economic operators an easy route to ignore the law, but, on the other hand, it deemed existing traceability rules to be sufficient. In the view of BUSINESSEUROPE requirements of identification of the manufacturer and/or importer responsible for putting the product on the market should

[81] BUSINESSEUROPE is an organisation whose members are 41 central industrial and employers' federations from 35 countries, working together to achieve growth and competitiveness in Europe.

be defined differently for consumer non-harmonised products (more lightly) than for harmonised products (whether consumer or professional ones).

(b) Market surveillance coordination

BUSINESSEUROPE expressed a strong preference for one market surveillance Regulation which would bring together the instruments for swift action against products posing risks. In its view, the regulatory action should aim uniformity of rules on market surveillance, covering all possible products placed on the market.

(c) Simplification

(i) Overall legislative framework

BUSINESSEUROPE supported a coherent legislative framework in the product safety area and called for elaboration of a horizontal market surveillance Regulation. In its view, the overlap between market surveillance provisions of the General Product Safety Directive and Regulation 765/2008 created confusion amongst market surveillance authorities with regard to the enforcement of relevant legislation and generated legal uncertainty for economic operators and consumers.

(ii) Pre-standardisation procedures under the General Product Safety Directive

BUSINESSEUROPE saw no compelling reason for changes to the procedure for the adoption of standardisation mandates and the elaboration of European standards as foreseen under Article 4 of the General Product Safety Directive. At the same time, it would like to have a consistency of procedures between the harmonised and the non-harmonised domains.

(iii) EU procedures for exchange of information on product risks

N/A.

(iv) EU product safety measures

N/A.

3.4.2 CONFEDERATION OF BRITISH INDUSTRY (CBI)[82]

(a) Consistency of product safety requirements in the non-food area

CBI considered that there was a limited scope for alignment between the General Product Safety Directive and the New Legislative Framework,[83] i.e. between

[82] The CBI is the UK's leading business organisation, speaking for some 240,000 businesses that together employ around a third of the private sector workforce. With offices across the UK, as well as representation in Brussels, Washington, Beijing and Delhi, the CBI communicates the British business voice around the world.

consumer product safety requirements and harmonised product safety requirements. It thought that the need to ensure that overlap and duplication are avoided between the sectoral directives and the General Product Safety Directive was all the more important under current economic circumstances where the focus was on achieving "more with less". The duties and responsibilities of the various economic parties in the supply chain should be clearly set out.

(b) Market surveillance coordination

CBI believed that the issues which were highlighted in the Commission documents, stemmed from lack of uniformity in the application of the legal rules; these could be addressed through steps to bring about a more even application and enforcement of the regulatory provisions, ensuring greater coherence of approach by regulatory authorities across Member States, rather than through regulatory changes.

According to CBI the first step should be to seek increased alignment at an administrative level, encouraging improved co-operation and exchanging best practice among enforcement authorities. CBI would support measures which would improve consistency of approach between Member States including measures to enhance co-operation at EU level between national authorities. The establishment of a stable co-ordination platform to oversee and ensure such improved co-operation would be welcome, subject to a certain level of scrutiny by stakeholders of its overall operation.

CBI considered that binding EU-wide measures setting specific safety requirements for certain products would be a disproportionate response to the problem of divergences in application of product safety requirements by individual Member States. If Member States' views were divergent because of different interpretations at national level, this could be addressed through a mechanism of dialogue to include interested stakeholders.

(c) Simplification

(i) Overall legislative framework

The CBI welcomed measures which would bring about greater clarity and consistency in the general product safety regulatory regime. The CBI expressed itself in favour of the alignment of definitions in the General Product Safety Directive with those in Regulation No 765/2008 and Decision 768/2008/EC.

(ii) Pre-standardisation procedures under the General Product Safety Directive

In the opinion of CBI there may be some benefit in aligning the standardisation process as between the General Product Safety Directive and the NFL, subject to the important proviso that there is full stakeholder involvement in the process and that the development of standards is based on robust scientific evidence.

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[83] Consisting in particular of Regulation (EC) No 765/2008 and Decision 768/2008/EC.

(iii) EU procedures for exchange of information on product risks

N/A

(iv) EU product safety emergency measures

N/A.

(d) Other

(i) Safety of products sold online

In the view of CBI the General Product Safety Directive should contain no additional rules possibly conflicting with the distance selling Directive 97/7/EC.

(ii) Safety of chemicals

According to CBI chemical safety issues should be dealt with under REACH Regulation.

3.4.3. EUROPEAN PARTNERSHIP FOR ENERGY AND ENVIRONMENT (EPEE)[84]

(a) Consistency of product safety requirements in the non-food area

N/A

(b) Market surveillance coordination

EPEE saw the main challenges in market surveillance on the internal market in differing resource levels among EU Member States. Differing resource levels may lead to uneven implementation and uneven national application of market surveillance may result in further market fragmentation within the EU.

To address these problems EPEE suggested that the Commission encourage the Member States to take enforcement seriously, recognize the need for robust and implementable market surveillance systems, and cooperate with the industry on market surveillance in order to find efficient and cost-effective systems to ensure compliance.

In the view of EPEE, the absence of an effective market distorts the market and comes at the expense of the environment, consumers, and industry. Non-compliance is detrimental to the environment since it results in the sale of equipment that use banned

84 The European Partnership for Energy and the Environment (EPEE), represents the heat-pump, air-conditioning, and refrigeration industry (HVACR) in Europe. Founded in 2000, our membership is composed of 40 member companies and national associations across Europe realising a turnover of over 30 Billion Euros and employing more than 200,000 people in Europe.

chemicals, are not energy efficient and properly disposed of. According to EPEE non-compliance comes at the expense of consumers: they purchase equipment that turns out more costly to operate than expected. Non-compliance also undermines the climate change and energy efficiency goals of governments who assume certain levels of equipment performance to achieve energy savings and to reduce carbon emissions. It considered that the current situation was unfair for companies who make the effort to comply: whilst free riders could just declare compliant performance values without making any additional effort, compliant companies have to modify design, add material and/or use more expensive parts to meet the target performance required under EU legislation. EPEE feared that if non-compliant products were not quickly identified and removed from the market, compliant companies might go out of business due to higher cost and lower price competitiveness due to their compliance with EU legislation.

(c) Simplification

N/A.

3.4.4 EUROCOMMERCE[85]

(a) Consistency of product safety requirements in the non-food area

EuroCommerce expressed support for the revision of the General Product Safety Directive if the consistency with other pieces of legislation such as the Free Movement of Goods Package[86] was ensured. In its view the Free Movement of Goods Package provides clear definitions of roles in the supply chain together with adapted regimes of responsibilities. This provides legal certainty for all operators, in particular with respect to who is responsible for what. As envisaged by Article R5 of Annex I of Decision 768/2008, the future alignment of product safety legislation should proceed on the basis that the precise responsibilities of distributors were clearly differentiated and exhaustively listed without exceeding those contained in Article R5 of Annex I of Decision 768/2008.

EuroCommerce indicated that while authorities in some Member States considered the name and address of the manufacturer to be a sufficient proof of showing the compliance with the relevant product safety requirements, authorities in other Member States were asking for the immediate transmission of all technical documentation. This has implications for companies and their relationship with their industrial partners when they ask their suppliers to provide technical documentation in order to check all

85 Established in 1993, EuroCommerce represents the retail, wholesale and international trade sectors in Europe. Its membership includes commerce federations in 31 countries, European and national associations representing specific commerce sectors and individual companies.

86 See above fn. no. 7.

the markings/warnings. Possessing this type of documentation leads to many problems with suppliers - including issues of confidentiality and copycatting.[87]

EuroCommerce would favours more consistent and clearer rules on product liability, which recognise that the responsibility of retailers should be limited to their sphere of competence.

The Commission should provide clarification on the retailers' obligations as it is laid down in Article R5 of Annex 1 of Decision 768/2008 to verify markings and documents accompanying products. In particular, in the view of EuroCommerce the obligation of the distributor to verify markings should be limited to what can be controlled with the information the distributor has in his/her possession. Moreover, the obligation not to make the product available to the consumer if there is a reason to believe that it is non-compliant with specific provisions should not be interpreted as meaning that distributors should verify markings of all specific requirements of each Directive. This can be very technical and it would require that the distributor is provided with the technical documentation from the manufacturer.

In the opinion of EuroCommerce, the Commission should ensure that requests from national authorities are reasoned to the extent that they concern elements of the technical documentation that are necessary for the investigation. Authorities should fix a deadline for receipt, unless a shorter deadline is justified in the case of a serious and immediate risk. Furthermore, the Commission should ensure that the distributor has the possibility, when having received a reasoned request, to contact the importer, manufacturer or the authorised representative in order to arrange that the request is sent directly to the authority. Finally, the Commission should consider that in a truly functioning internal market, the manufacturer or its representative in Europe should have to communicate information directly to the authorities.

(b) Market surveillance coordination

EuroCommerce would be in favour of market surveillance coordination provided that they possess the human and financial resources necessary to carry out their activities. EuroCommerce considered that improving cooperation between national market authorities would prove to be beneficial to further increase the level of protection of the public interests at stake. Nevertheless, it reminded that since national market surveillance authorities often lack the necessary resources so that any improvement in coordination should seek to increase their efficiency rather than introduce bureaucratic requirements that may further impact negatively on the limited resources of national authorities. EuroCommerce also advocated introduction of a peer assessment system of national market surveillance activities.

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87 The reason why suppliers are reluctant to provide the technical documentation is understandable since it contains confidential data and the Directive does not oblige the suppliers to provide this information to the distributor.

In the view EuroCommerce, to minimise diverging safety evaluations of an identical product in different Member States, EuroCommerce members consider it essential to dispose of accepted European-wide test methods and interpretations of their results. The assessment of the risk should be made on a common definition of what is a "serious risk" and specific attention should be devoted to ensuring that only certain kinds of risks have to be notified to avoid all systems being blocked and thus causing a decrease in efficiency. To that end the adoption of a single set of risk assessment guidelines for use by enforcement authorities would contribute to the achievement of this objective. This would help to remove diverging legal interpretations by national authorities while providing economic operators with a clearer legal framework.

EuroCommerce would welcome the proposal to reinforce market surveillance within the entire EU if such proposal was accompanied by better cross-border cooperation among national authorities along the lines of Article 9 of the Regulation on consumer protection cooperation so that market surveillance measures could be taken "at source" and avoid penalising distributors who did not produce the product, but only made it 'available on the market'. Passing on responsibility to retailers for activities that go beyond their sphere of activity should be strongly opposed.

Furthermore, EuroCommerce would appreciate the encouragement of digital communication to improve the efficiency of communication between business and national authorities: EuroCommerce therefore suggested to establish a common database gathering test reports on products. At the same time, national authorities should ensure a mutual recognition of test reports. This would lead to a reduction in the cost analysis impacting professionals and Member States, a decrease in the storage time of goods waiting to be placed on the market.

Finally, EuroCommerce emphasised that the concept of "isolated cases" should be integrated in all implementation guidelines related to product safety and other guides related to corrective actions and a reference to isolated cases into the new General Product Safety Directive provisions should be integrated, correlating to Article 5(2) of the existing General Product Safety Directive.

(c) Simplification

(i) The overall legislative framework

EuroCommerce would be in favour of a coherent and effective legal framework for product safety and market surveillance.

(ii) Pre-standardisation procedures under the General Product Safety Directive

EuroCommerce did not believe that the procedures should be accelerated, as transparency and consultation of all stakeholders, and in particular SMEs, requires more time. EuroCommerce would oppose any modification of the General Product Safety Directive that would lead to make specific safety requirements in standardisation mandates directly applicable.

(iii) EU procedures for exchange of information on product risks

In the opinion of EuroCommerce, RAPEX notifications should take place only when other corrective measures would be inappropriate or inefficient to guarantee the safety of users and/or consumers. The Commission should also develop a common definition of serious risk in relation to RAPEX and RASFF notifications in order to reduce the number of (e.g. isolated cases) notifications.

(iv) EU product safety measures

For the sake of efficiency and on the basis of the experience gained, EuroCommerce members considered that EU product safety measures should be directly applicable to economic operators, following a process of consultation of stakeholder organisations.

(d) Other: Safety of products sold online

With respect to online sales, EuroCommerce stressed that rogue trading occurred in all kinds of supply chains and trade distribution networks. As a result, the sales of unsafe products should be banned, however it saw be no need to define a specific regime for online sales that would defer from the one applicable for traditional forms of distribution. The same rules should apply since the same sort of interests to be protected is at stake.

3.4.5 MOUVEMENT DES ENTREPRISES DE FRANCE (MEDEF)[88]

(a) Consistency of product safety requirements in the non-food area

N/A.

(b) Market surveillance coordination

N/A.

(c) Simplification

(i) The overall legislative framework

MEDEF would appreciate if the Directive on food imitating products were also revised.

[88] MEDEF serves as lobbyist group for businesses, ensuring that their voice is heard by decision makers in the local, regional or national level of the government. It is the largest organization of employers in France with more than 700,000 member firms. The majority are SMEs, with less than 50 employees.

(ii) Pre-standardisation procedures under the General Product Safety Directive

N/A.

(iii) EU procedures for exchange of information on product risks

MEDEF saw the need to improve the functioning of RAPEX, principally in order to promote a similar behavior of the different Member States when they submit notifications to RAPEX. Companies consider that RAPEX could be more rigorous. In the opinion of MEDEF, it is problematic that the Member States are obliged to undertake a risk assessment while they lack a definition of serious risk. Therefore, Member States may submit a notification although the risk actually cannot be considered to be serious.

(d) Other

In the opinion of MEDEF the term of the consumer should be defined in the General Product Safety Directive and the definition of serious risk specified.

3.4.6 ORGALIME[89]

(a) Consistency of product safety requirements

In the view of Orgalime the fact that certain consumer products are not subject to sector specific new Approach or Old Approach Directive setting out essential safety requirements for the given product is a sufficient proof that such products do not pose a danger. Therefore, the product safety requirements of non-harmonised products should not be regulated at the EU level. The regulation of such products at the national level subject to the principles of Mutual Recognition Regulation is, in the view of Orgalime, an adequate regulatory response.

(b) Market surveillance coordination

With respect to market surveillance Orgalime submitted that the Commission should establish a single EU market surveillance regime, which should be consistent with Regulation 765/2008/EC in order to ensure, without unnecessary administrative burden, the safety of both consumers and professional users in both the harmonised and the non-harmonised areas.

Regarding monitoring of market surveillance authorities in the opinion of Orgalime the objective should be to ensure better monitoring of market surveillance in the EU primarily on the basis of existing tools, e.g. annual "Enforcement Indicators." Orgalime would welcome any initiative that would be conducive to Member states

[89] Orgalime is the European federation representing the interests at the level of the EU institutions of the European mechanical, electrical, electronic and metal articles industries as a whole. Orgalime's member federations directly or indirectly represent some 130,000 companies of an industry which employs 10.2 million people.

carrying out more efficient market surveillance is welcome and reiterated the need for reinforcing the actual means of market surveillance authorities at national level, without imposing on them bureaucratic reporting requirements, which will become a drag on their often insufficient resources.

Orgalime called on Member States and the European Commission to allocate significant resources to market surveillance and to increase their co-ordination efforts, so as to ensure that the acquis communautaire of the Single European Market is preserved and strengthened to the benefit of both consumers and responsible manufacturers."

Finally, in this context Orgalime would welcome a peer assessment system of national market surveillance activities and procedures, with the support of an advisory board open to stakeholders (including consumer and industry organisations) that would develop recommendations on the basis of best practices. Orgalime indicated PROSAFE could be chosen for such a purpose, acting as a facilitator in operating targeted market surveillance campaigns, upstream communication with customs authorities and downstream communication with manufacturers, trade and consumer organisations."

(c) Simplification

(i) The overall legislative framework

N/A.

(ii) Pre-standardisation procedures under the General Product Safety Directive

In the opinion of Orgalime a faster adoption of standardisation mandates should not hamper the necessary consultation of all standardisation stakeholders including European trade associations such as Orgalime. Orgalime believes that speeding up the standards development should be balanced with the application of the principles of WTO/TBT agreement (transparency, openness, impartiality and consensus, effectiveness and relevance, coherence). Openness and wider consultation of all stakeholders, including the SMEs that often need a summary in their own language, call for more time.

Orgalime would strongly oppose to any change in the General Product Safety Directive that would lead to making specific safety requirements in standardisation mandates directly applicable for the following reasons: In its view, "product specific safety requirements" should be laid down through the co-decision procedure with the European Parliament and Council, in directives and regulations applying to products, especially to those that would be made "directly applicable to economic operators", should the General Product Safety Directive be transformed into a Regulation.

(iii) EU procedures for exchange of information on product risks

Orgalime expressed support for linking up RAPEX with ICSMS – an IT tool serving as a general information support system – in order to create a common platform for exchange of information in case of non-compliant products and an across-policy tool could enhance the speed and efficiency of EU-wide market surveillance and contribute to removing both unsafe and otherwise non-compliant products from the market.

(iv) EU product safety measures

Orgalime suggested "emergency measures", whether for the harmonised or the non-harmonised area, could be decided by comitology provided that they are proportionate to the risk arising and remain of temporary nature. For the sake of efficiency, such decisions might be directly applicable to economic operators, provided that the impacted stakeholder organisations are duly consulted beforehand. Any decision that may affect, in the longer run, a product group should not, in the view of Orgalime, be decided by the Commission alone in comitology, but by the legislator via the co-decision procedure after an impact assessment.

(d) Other

(i) Safety of products sold online

For Orgalime, there is no need to introduce specific measures, legal and/or administrative tools into a revised General Product Safety Directive to tackle the issue of dangerous consumers products sold on the Internet.

(ii) Safety of services

With respect to the safety of services Orgalime argued that it would be disproportionate to establish general obligations to apply to all situations and all particular cases of service provision.

(iii) Risk assessment guidelines

Furthermore, Orgalime called for a single set of Risk Assessment Guidelines for use by enforcement authorities. (...) Such clear risk assessment guidelines for authorities would contribute to building a common approach to the market surveillance of non-food products and removing varying legal interpretations by authorities and consequent legal uncertainty for manufacturers." Also, with respect to notifications, the qualification of "serious risk" for rapid alert notifications should be clarified for products in both the harmonised and the non-harmonised area.

(iv) European consumer agency

Orgalime expressed itself against the creation of a European consumer safety agency.

(v) Strengthening criminal laws for placing dangerous products on the market

Member States should, in our view, strengthen their criminal laws on the placing of dangerous or non-compliant goods on to the Community market.

4.7 OXYLANE[90]

(a) Consistency of product safety requirements in the non-food area

N/A

(b) Market surveillance coordination

Oxylane indicated that in its experience the checks carried out by market surveillance authorities are, for the majority, carried out in entirely random manner. These controls do not sufficiently prioritize the search for non-conforming and/or dangerous products from third countries.

(c) Simplification

(i) The overall legislative framework

N/A.

(ii) Pre-standardisation procedures under the General Product Safety Directive

As the Commission points out European standards are published in the OJEU repositories for all Member States. Their main effect is to ensure an equal minimum level of safety for all consumers, irrespective of their Member State of residence. Oxylane is favourable to the Commission proposal idea of publishing a standard under the Directive on General Product Safety that would not have been developed under a mandate from the Commission. This procedure appears to Oxylane indispensable. Products that may be deemed contrary to the principle of General Product Safety are placed on the market at the expense of the consumers. This also has the effect of establishing unfair competition between economic operators. A publication under European standards on Product Safety developed without a Commission's mandate would improve the safety of products marketed or made available and that are risky for users and, since the current European standard would be considered satisfactory in terms of safety. Currently, no procedure in force provides equivalent safety for consumers or for traders. Such a procedure is essential for economic operators with operations in several Member States.

(iii) EU procedures for exchange of information on product risks

[90] Oxylane designs, manufactures and markets innovative technical products, adapted to each sport. Oxylane employs around 50,000 people, all passionate about sport, and generates an annual turnover of 6 billion Euros. Its main brand store, Decathlon, is present in 15 countries with 560 stores.

N/A.

(iv) EU product safety measures

N/A.

(d) Other: European Injuries Database

The European standardisation system should be improved by making statistical data on injuries available. Within standardization committees, the lack of comprehensive and reliable statistical data is often felt in the course of normative work. Regularly, standardization experts debate, seek consensus due to the absence of statistical data on accidents or due to unreliable statistical because often provided by manufacturers. Thus, the requirements laid down in the European standards are not sufficiently grounded to meet the needs of health and safety of consumers.

The availability of such statistics would promote the principle of general product safety. Indeed, this data would be useful not only to standardization experts but also to market surveillance authorities. The different market surveillance authorities could better identify the national products (and services) that do not comply with the rules regarding general product safety and thus this would improve the effectiveness of their controls. Similarly, the legislators, both national and EU will be able to better identify failings which they can take into account when adopting new regulations. Therefore, it will be necessary to establish a European tool for ensuring that the data on injuries related to products (and services) marketed or made available to consumers is complete and reliable.

Today, such a tool does not exist. Within Member States, it is very difficult to obtain data on accidents. The same applies to the EU.

4.8 UNION OF GROUPS OF INDEPENDENT RETAILERS OF EUROPE (UGAL)[91]

(a) Consistency of product safety requirements in the non-food area

The template of responsibilities of laid down in the Annex of Decision (No) 768/2008/EC and the sectoral product safety legislation clearly lay down the obligations of manufacturers, importers and distributors in the supply chain. This approach determining the obligations of each person in the supply chain is the best way to ensure that retailers play their part in ensuring a safe supply chain. In the view

[91] UGAL – the Union of Groups of Independent Retailers of Europe – is the European association that acts as an umbrella organisation for the main groups of independent retailers in the food and non-food sectors. UGAL represents almost 300,000 independent retailers with a combined retail turnover of more than 623 billion euros and more than 540,000 sales outlets, 25 groups and associations of groups in Europe employing a total of over 5 millions people and generating wholesale turnover of more than 260 billion euros.

of UGAL this reduces uncertainty about the way how risks should be dealt with in the supply chain.

(b) Market surveillance coordination

N/A.

(c) Simplification

N/A.

(d) Other: Isolated cases

UGAL raised the problem of the concept of "isolated cases" contained in the General Product Safety Directive and requested more detailed clarification of the concept in the revised General Product Safety Directive.[92] In its view, the current definition of "isolated cases" in the General Product Safety Directive and the related Guidelines is insufficient. The legal text of the revised General Product Safety Directive should specify more in detail what the distributor should do if an "isolated case" is present.

From the point of view of UGAL, whether or not a particular identified incident represents an isolated case, will not always be immediately obvious to a retailer; producer input is required to confirm the existence or not of an isolated case. If a retailer is uncertain as to whether or not an isolated case is present, two particular consequences can arise: 1) Only very obvious public health risks will be passed on to competent authorities when identified, leaving considerable potential important risk

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92 The issue of "isolated cases" is dealt with in Annex 1 of the GPSD *ANNEX I* - REQUIREMENTS CONCERNING INFORMATION ON PRODUCTS THAT DO NOT COMPLY WITH THE GENERAL SAFETY REQUIREMENT TO BE PROVIDED TO THE COMPETENT AUTHORITIES BY PRODUCERS AND DISTRIBUTORS

1. The information specified in Article 5(3), or where applicable by specific requirements of Community rules on the product concerned, shall be passed to the competent authorities appointed for the purpose in the Member States where the products in question are or have been marketed or otherwise supplied to consumers.

2. The Commission, assisted by the Committee referred to in Article 15, shall define the content and draw up the standard form of the notifications provided for in this Annex, while ensuring the effectiveness and proper functioning of the system. In particular, it shall put forward, possibly in the form of a guide, simple and clear criteria for determining the special conditions, particularly those concerning isolated circumstances or products, for which notification is not relevant in relation to this Annex.

Art. 5 (3) of the GPSD: Where producers and distributors know or ought to know, on the basis of the information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement, they shall immediately inform the competent authorities of the Member States thereof under the conditions laid down in Annex I, giving details, in particular, of action taken to prevent risk to the consumer.

The Commission shall adapt the specific requirements relating to the obligation to provide information laid down in Annex I. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(5).

information under the radar (the 'tip of the iceberg' problem) 2) The retailer may take a highly cautious view and may contact the competent authorities immediately, often unnecessarily, thereby leading to notification overload of competent authorities.

In addition, UGAL considered that the lack of clarity about the "isolated cases" might lead to unjustified notifications in the RAPEX system and potential liability of retailers vis-à-vis producers for having passed information about dangerous products to public authorities.

4.9 UNION EUROPÉENNE DE L'ARTISANAT ET DES PETITES ET MOYENNES ENTREPRISES (UEAPME)[93]

(a) Consistency of product safety requirements in the non-food area

According to UEAPME the new market surveillance rules, applying from 1 January 2010 clearly showed a fragmentation related to the two legislative regimes, one for harmonised and one for non-harmonised products. This fragmentation could be noticed due to the different product safety obligations of the economic operators. For this reason UEAPME calls for same principles for harmonised and non-harmonised products.

(b) Market surveillance coordination

Furthermore, according to UEAPME the coordination at EU-level for surveillance efforts is quite burdensome. The inappropriate coordination and the related interpretation difficulties lead to uncertainty for SMEs. This needs to be rectified.

(c) Simplification

(i) The overall legislative framework

Not addressed.

(ii) Pre-standardisation procedures under the General Product Safety Directive

UEAPME agreed with the fact that the procedure for issuing mandates and publishing standards takes too long, although from the average six years development and publications period the actual drafting procedure only took three years. The last three years are due to the slow administrative policy. UEAPME considers that the process

[93] UEAPME is the employer's organisation representing the interests of European crafts, trades and SMEs at EU level. UEAPME is a recognised European Social Partner and acts on behalf of crafts and SMEs in the European Social Dialogue and in discussions with the EU institutions. It is a non-profit seeking and non-partisan organisation. As the European SME umbrella organisation, UEAPME incorporates 83 member organisations consisting of national cross-sectorial SME federations, European branch federations and other associate members, which support the SME family. Across the whole of Europe, UEAPME represents over 12 million enterprises with nearly 55 million employees.

has to carefully be accelerated. Drafting standards is a time consuming activity and its quality is more than crucial. For this reasons the most important issue is to reduce the time related to the administrative part of the procedure.

(iii) EU procedures for exchange of information on product risks

UEAPME saw the need to simplify the notifications in the RAPEX procedure, and strengthen the whole system so that unfair trading practices can be tackled.

(iv) EU product safety measures

UEAPME was convinced that changes should be made to the ways of implementation od product safety emergency measures.

(d) Other: Safety of products sold online

Concerning market surveillance of the safety of products sold on the internet UEAPME would not support any special (legal) measures for this kind of distribution. The same measures have to be valid for face-to-face and internet selling. Anything else would lead to a distortion of competition, as different regimes would mean either for the one or the other unfair benefits. The same rules should apply for face-to-face and internet based market surveillance.

4.10 BRITISH RETAIL CONSORTIUM (BRC)[94]

(a) Consistency of product safety requirements in the non-food area

The BRC considered that definitions e.g. of economic operators and their roles should be developed. The revised General Product Safety Directive should contain better definitions of economic operators and their responsibilities.

(b) Market surveillance coordination

BRC would support the cooperation between the surveillance authorities on the basis of proportionate, risk based, intelligence lead enforcement. BRC believed that there was a potential for a lack of action or inappropriate action at Member State level to drive the Commission to take more control from the centre. The strengthened cooperation between the Member States surveillance authorities should, in the view of BRC, be overseen by a European wide product safety authority, with cross border powers. BRC supported the proposals on harmonisation of risk evaluations and called for "single European risk assessment guidelines."

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94 The BRC is the UK Trade Association which represents the interests of the majority of small and large UK retailers, including on-line, catalogue and mail order sellers and those in the city centres and out of town retail sites. Our policies are developed and endorsed by Committees representative of the membership as a whole.

BRC suggested a creation of European a testing 'ombudsman' who could review test results that disagree or appear to have been interpreted incorrectly and provide a legally binding interpretation. This would then be fed back to the standards body to correct the error in the standard - without the need to go to court.

(c) Simplification

(i) The overall legislative framework

N/A.

(ii) Pre-standardisation procedures under the General Product Safety Directive

BRC concurred that the standards making process takes time but it was not convinced that a speedier process would be of benefit to industry. Having standards ratified through due process would reduce inconsistency but that process should not be accelerated if this results in poorly designed standards.

(iii) EU procedures for exchange of information on product risks

BRC would be in favour of a better designed RAPEX system that would be of help to business and consumers as well as the enforcers. To improve the operation of the system, better definition of notification criteria would be needed as well as a consistent method of risk assessment and better communication. BRC suggested to take the inspiration from the CPSC model operated in the United States where the emphasis is put on providing detailed information to the consumer to protect their interests. This would serve the additional purpose of disseminating the information to the enforcement community and the economic operators.

(iv) EU product safety measures

EU product safety measures should remain to be used only in exceptional circumstances and have a sunset clause during which time a more permanent solution should be created. An option of longer term emergency measures would be preferable to the other option of measures being directly applied to economic operators.

(d) Other: European accident database

In addition, BRC suggested to establish a product accident database collecting information on product-related injuries throughout the EU.

3.5. EUROPEAN STANDARDISATION ORGANISATIONS - CEN[95]/CENELEC[96]

(a) Consistency of product safety requirements

N/A.

(b) Market surveillance coordination

(c) Simplification

N/A.

(i) The overall legislative framework

N/A.

(ii) Pre-standardisation procedures under the General Product Safety Directive

CEN and CENELEC welcomed the European Commission efforts to develop standardization mandates in order to allow the further citation of currently available as well as the citation of future European Standards. The European Commission's need for safe products coincides with the need (and work) of CEN and CENELEC stakeholders to have European Standards providing a high level of safety. CEN and CENELEC would favour the continuation of the current practice of establishing specific safety requirements under the General Product Safety Directive which could be laid down, for example, in annexes to the General Product Safety Directive leaving to standardization the development of technical solutions to meet such requirements.

CEN and CENELEC further indicated that they recognized the primacy, whenever possible, of international standards.[97] By contrast, they would not support a more formal role for non-European standards, since such action might multiply the number of standards on the internal market impeding its cohesion, making the life of the

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95 CEN (European Commiteee for Standardisation) is one of the three European standardisation organisations providing European Standards and technical specifications. Through its services it creates a platform for the development of European Standards and other technical specifications. CEN's 33 National Members work together to develop voluntary European Standards (ENs).

96 CENELEC (European Committee for Electrotechnical Standardisation) is another of the three European standardisation organisations responsible for standardisation in the electrotechnical engineering field. CENELEC prepares voluntary standards, which help facilitate trade between countries and support the development of a Single European Market.

97 This is ensured through the Vienna and the Dresden agreements that link the two ESOs with their respective international counterparts ISO and IEC. It is worth highlighting that 80% of CENELEC European standards and 30% of the total collection of CEN standards are actually international standards (or based thereon). On top of that, the efficiency of this system and the preservation of European interests are guaranteed by a strong European presence and an influent expertise at international level through the involvement of experts in Technical Committees.

stakeholders, especially SME's, consumers, trade unions more difficult because of the need to monitor/contribute to different channels.

(iii) EU procedures for exchange of information on product risks

N/A.

(iv) EU product safety measures

N/A.

3.6. PROSAFE[98]

(a) Consistency of product safety requirements

For PROSAFE, consumers expect the products they use and consume are safe regardless of the legal framework that is established to deal with different product sectors. This perspective, on its own, demands a greater alignment between the so-called harmonised and non-harmonised product sectors. The emergence of best practice through the previous revisions of the General Product Safety Directive and now with the implementation the New Legislative Framework should promote this objective. Addressing this issue would undoubtedly impact on the arrangements for market surveillance and safety assessments. PROSAFE hoped that the best practice identified in the Joint Actions carried out in recent years in both the harmonised and non-harmonised product sectors would help provide a basis for a consistent and coherent approach to be adopted across the different product sectors.

(b) Market surveillance coordination

The strategy for the enhancement of market surveillance in the EU/EEA, agreed within the framework of the first EMARS project, clearly identified the need for the professionalization of support for closer cooperation amongst market surveillance authorities and sustainable funding for a central resource at the European level. The existence of such a resource was identified as essential to the continued improvement of market surveillance in Europe.

[98] PROSAFE is a non-profit professional organisation for market surveillance authorities and officers from throughout the EEA. Its primary objective is to improve the safety of users of products and services in Europe.

Diverging safety evaluations of consumer products obviously distort the internal market and adversely affect the level of consumer protection Europe's citizens can enjoy. The experience of PROSAFE with the Joint Actions showed that clear guidelines and promoting dialogue at an early stage between market surveillance authorities can dispel some of the misunderstandings that can arise further on in the process and improve the transparency of the decision-making process.

According to PROSAFE the support to the joint market surveillance actions should be reinforced. In the past five years, over fifteen joint actions were launched and the response to these Actions was very favourable. The social and economic stakeholders welcomed the transparency such coordinated Joint Actions bring to the European marketplace and they have endorsed these activities and sought to participate actively themselves.

(c) Simplification

(i) The overall legislative framework

N/A.

(ii) Pre-standardisation procedures under the General Product Safety Directive

In the view of PROSAFE, there is a need to improve the procedures under the General Product Safety Directive to help ensure that the standards better reflect the needs of the public authorities and that the standards system is responsive to mandates and feedback from the results of joint market surveillance actions. The entry into force of a new or revised standard has also prompted market surveillance authorities to target specific product groups for joint market surveillance actions, e.g. lighters and baby walkers.

(iii) EU procedures for exchange of information on product risks

N/A.

(iv) EU product safety measures

N/A.

(d) Other: Safety of product sold online

PROSAFE stated that it was s aware that in other consumer protection fields joint market surveillance actions on electronic commerce are carried out, to great effect, on a regular basis and obviously this is something that could be considered in the

consumer product safety sector. The need greater cooperation and coordination to deal with new channels of distribution is, in the view of PROSAFE, clearly there.

4. ANNEX 4: SUMMARY OF THE TARGETED STAKEHOLDER MEETINGS

4.1. Introduction

On the basis of the results of the internet public consultation (held between May and August 2010) and the Workshop on the revision of the General Product Safety Directive (held on 1 December 2010 in the framework of the International Product Safety Week), the Commission organised four targeted stakeholder meetings in order to discuss concrete ways of how to put in practice the conclusions reached in the public consultation.

To this end the Commission distributed four consultation papers outlining the principal options of implementation of the general objectives. These options were discussed in four targeted stakeholder meetings:

- Reinforcement of coordination of national market surveillance activities (31 January 2011)
- Clear and uniform legislative framework (consistency of product safety requirements for economic operators) (16 February 2011)
- Faster procedures for elaboration of European standards (17 March 2011)
- Clear and uniform legislative framework (overall legislative framework and market surveillance rules) (31 March 2011)

A balanced and proportionate representation of all relevant stakeholder groups, including consumer organisations, business associations, representatives of market surveillance authorities as well as economic operators, was ensured in these meetings. In particular, the representatives who contributed to the public consultation were invited in order to further clarify and detail their views and opinion.

4.2. Conclusions

4.2.1 Reinforcement of coordination of national market surveillance activities

4.2.1.1 Coordination tasks

The participants agreed that a pre-condition for the reinforcement of coordination of national market surveillance authorities is an establishment of a knowledge centre for the collection, storage and dissemination of knowledge about, for example, products, procedures, standards, risk assessment, training, etc. This would not necessarily mean for the organisation to collect and store this information itself but to know where it can be found and provide easy access to it. In any case, a proliferation of databases should be avoided.

Another necessary step for achieving deeper coordination of national market surveillance activities would consist in maintaining an inventory of national plans, administrative assistance and coordination of joint actions, organising joint testing, developing common definitions, etc. This would also involve acting as an interface with business and consumer organisations. Driving quality improvements should be focused on, for example, improving horizontal skills, assisting weaker Member States, etc. This could be achieved by, among others, exchanges of officials, peer reviews and (in the future) more formal (voluntary) "audits".

A better coordination of handling of consumer complaints was also mentioned since consumers are not always aware to whom they should address complaints and, consequently, information about unsafe products does not always reach the safety authorities. In fact, the ICSMS website has a facility for consumer complaints. Moreover, the General Product Safety Directive already provides for national systems to be established by the Member States.

4.2.1.2 Organisation of coordination of national market surveillance authorities

When asked to consider the organisational set-up ensuring the implementation of the reinforced coordination activities, participants suggested a creation of a central EU body. Regarding the relation with the Member States, it was widely agreed that it should be obligatory for Member States to be involved in the functioning of this body but that it should not be its role to 'force' Member States to cooperate. Member States should also have some form of oversight over the organisation and the activities it undertakes. Regarding the relation with the European Commission, it was suggested that the envisaged body should be formally linked to the EU but not a part of it. The EU could give direction to the body and discuss the (multi) annual plans which could be drawn up by the body with the Member States. Regarding the relation with other stakeholders, it was proposed that the envisaged body should be obliged to consult stakeholders, although care would have to be taken to ensure the independence of the market surveillance authorities. The 'Consultation Forum' as it has been established under the Eco-design Directive was mentioned as an example of best practice in this context.

As regards resources the most important issue would be to ensure the permanence of the proposed body. It was felt that the qualifications of staff depended on the tasks to be undertaken by the body. Brussels was generally considered to be the best location for such a body. One suggestion made was to have a dual funding model: one for funding the operation and one for funding activities. No matter what the tasks of the body would be, it was stressed that there should be a clear distinction between the role and legal obligations of the Commission, the Member States and this organisation, which should ideally focus on 'practical' activities to support the operational effectiveness and efficiency of market surveillance in the EU/EEA.

4.2.2 General obligations of economic operators, in particular the issue of identification of the responsible manufacturer or importer

4.2.2.1 Differentiation between "harmonised" and "non-harmonised sectors"

Participants commented that they were not aware of any data which could specify the proportion of "harmonised" and "non-harmonised" products in circulation. They were of the opinion that it was practically impossible to provide any reasoned estimates of such figures.

It was pointed out that it was sometimes difficult to find out whether a given product is a "harmonised" or a "non-harmonised" product,[99] in particular when it is subject to regulations like the REACH Regulation, which applies only to particular chemical substances in a given product.

Participants expressed the opinion that products are not manufactured or marketed differently according to whether they fall into the category of "harmonised" or "non-harmonised" products. The key criteria which determine the way in which products are manufactured and/or marketed are their "complexity" and the risks they pose. It was stressed that "risk" is the key issue and the guiding principle for determining the related obligations**,** regardless of the sector. The only difference lies in the fact that for "harmonised" products, the evaluation of risk is easier than in the "non-harmonised" area where no specific safety requirements exist and standards are relatively rare. It was stated by one participant that whether or not a product should contain safety instructions depends on whether the product poses a risk, not whether the product is "harmonised" or "non-harmonised".

In certain companies, it was said that a safety assessment of products is performed regardless of whether according to the legislation the product is "harmonised" or "non-harmonised". The only difference between these two groups of products is that, thanks to the more detailed regulation of safety properties of "harmonised" goods, it is easier for a product safety professional to check whether the given product respects the safety requirements laid down in the "harmonised" legislation. One participant added that a key determinant in the way products are manufactured and marketed may be the size of the company, the number of products produced and the type of product manufactured.

The Chair concluded that the difference between harmonised and non-harmonised products did not seem to be a key determinant structuring production and/or marketing processes. The key determinant appeared to be the risk potential of the product to the final user.

4.2.2.2 Technical documentation for non-harmonised consumer products

Participants agreed that manufacturers should perform a risk assessment for the products they supply to consumers regardless of whether these products are "harmonised" or "non-harmonised". They also agreed that the fact of performing a risk assessment should be documented.

[99] A "harmonised" product is considered to be a product subject to Community harmonisation legislation which is defined as "any Community legislation harmonising the conditions for the marketing of products." (Article 2 (21) of the Regulation (EC) No 765/2008.

Some participants mentioned that they already produce technical documentation containing the aforementioned minimum requirements, both in respect to harmonised and non-harmonised products, so its extension to non-harmonised products would not entail any additional costs for their businesses.

However it was mentioned by one participant that it is crucial that technical documentation is required only in respect to one type of a product, not for each piece of a product or for different versions of a product where risk elements do not differ. For example, in the case of T-shirts, technical documentation should be required in respect of one type of a T-shirt, not for each different colour of the same T-shirt, provided, that is, that the chemical risks of the different colours in which the T-shirt is dyed do not differ.

Conclusion: - The Chair observed that the use of technical documentation also for non-harmonised consumer products would have an added value, provided that it contains information for market surveillance authorities which would allow them to make a more objective and better quality risk assessment and that the amount of information contained in the technical documentation is proportionate to the level of risk posed by products so that no unnecessary administrative burdens are created for businesses.

4.2.2.3 Requirements of identification of the responsible manufacturer or importer

There was support for the need for traceability regardless of whether the product is "harmonised" or "non-harmonised". One participant indicated that his organisation provides the information at three places: on the product, the packaging and on shipping cartons.

As regards the inclusion of importer information, this can pose a problem if stickers are used since they must be permanent. Testing stickers for durability is under consideration. Also, the obligation to include the importer's address can pose difficulties in cases where a company has a centralised customer service to which they would prefer enquiries be addressed. As packaging is usually discarded, one participant thought it preferable to put the information on the product itself where possible, although the challenge could be the size of the product and the manufacturing process. It was proposed that legislation could address this issue.

It was suggested by some participants that large products could be marked with batch codes as these are useful in the case of recalls. Traceability information was also considered to be in the interest of the manufacturers as it can allow them to limit the extent of any recalls.

One participant commented that it is important to decide whether traceability information should be placed on the product or on the packaging and added that the cost of adding labels also needs to be taken into account. There was concern that if the name of the importer is also required, this might mean that the importer would have to open product packaging in order to mark them - and in such cases who should decide where the traceability information should be positioned.

In conclusion, the Chair noted that participant businesses used traceability rules going beyond the minimum established by EU legislation and that, in consequence, they have not encountered problems resulting from differing national traceability requirements in Member States. The Chair also observed that participants viewed traceability of products as a useful requirement which should apply across different product sectors regardless of whether products are "harmonised" or "non-harmonised". Participants shared the view that a number of businesses already use traceability practices and consider them useful, in particular when they have to perform a recall of a product. If clear, cross-sectoral, traceability requirements are laid down in the general product safety rules, they should respect flexibility and proportionality. This flexibility and proportionality could be achieved by non-legislative means, for example, by providing guidelines specifying in more detail the positioning of traceability requirements on the product, its packaging and in accompanying documents.

4.2.2.4 Costs of application of general product safety obligation

One participant stressed that the information on costs, especially their quantification, is impossible to obtain. Another added that the question of compliance costs was related to the risk and that there was no "cost" distinction between harmonised or non-harmonised products in this respect.

4.2.3. Pre-standardisation procedures under the General Product Safety Directive

4.2.3.1 Role of ad-hoc Decisions on safety requirements under the General Product Safety Directive

Participants agreed there was a need for a sound procedure under the General Product Safety Directive for mandates on the basis of which European standardisation bodies establish European standards ("EN standards") in the "non-harmonised" area.

The discussion confirmed the results of the public consultation. Directly applicable safety requirements is an option generally accepted, provided that all relevant stakeholders are consulted from the onset of the process, and that a good balance is found between the contents and level of specificity of these requirements and what should be left to standardisation.

4.2.3.2 Referencing of standards developed outside Commission mandate

The majority of participants agreed that EN standards should be referenced in the OJEU but participants did not think it appropriate to reference other standards as they had another legal basis and might contain certain elements that are not relevant in the EU - this would be the case, for example, of non-global/international standards (e.g. ASTM). It was proposed, however, that ISO/IEC standards could be referred to as an interim measure while awaiting a more permanent solution, but this should be considered on a case by case basis. There was strong support for this option, as far as existing EN (European standards) are concerned. References to ISO/IEC (global standards) should be considered on a case by case basis and/or as an interim solution.

The proposal concerning references to non-global/international standards (or standards from third-party organisations other than ISO/IEC) was rejected.

4.2.3.3 Review of the provisions on the objections to European standards

There was wide support to align these provisions to the New Approach area solution.

4.2.3.4 Representation of stakeholder groups in "standardisation" procedures under the General Product Safety Directive

Participants agreed that such consultation should take place prior to the adoption of the decision defining the safety requirements for the given product, which then leads to the adoption of a mandate to European standardisation bodies. There was a consensus among participants that this consultation procedure should be formalised. One participant suggested that national consultations could also take place in parallel. However, it was stressed that any discussion groups created for this purpose should contain sufficient expertise to interpret the EN standards.

A more formal procedure should be established for the consultation of stakeholders and this should take place before issuing a mandate. These consultations should also be accompanied in parallel by consultations at national level. Stakeholders participating in these consultations should also have the necessary expertise to make a constructive contribution.

Some participants were in favour of setting up new, dedicated, group for these consultations. However the Commission did not favour the idea of setting up new groups in addition to the existing ones.

4.2.4. Legislative architecture of consumer product safety rules and harmonised product safety rules

4.2.4.1 Simplification of legislative environment in the product safety area

Participants stated that the General Product Safety Directive worked well as a structure and that overall its rules were well implemented and “internalised” by Member State market surveillance authorities. They appreciated the “gap-filling” role of the General Product Safety Directive in the harmonised area and stressed that this should be maintained. They considered the structure of the General Product Safety Directive to be consistent, but sometimes too vague to prevent divergent application of market surveillance rules by national authorities

Participants stressed that the most important objective in the revision process is to achieve legal certainty and to be able to predict how the market surveillance authorities in Member States will act vis-à-vis economic operators, in particular in crisis situations. If EU product safety rules are unclear, they are applied differently by different market surveillance authorities and this leads to unjustified differences in the treatment of economic operators in different Member States. All these issues increase costs for economic operators and create barriers in the internal market.

Participants did not consider that the simple addition of certain rules of the General Product Safety Directive to the Regulation 765 would bring clarity to the market surveillance rules as demanded by stakeholders. In their view, merging the provisions covering the obligations of economic operators, specific provisions on standardisation for non-harmonised products, provisions for market surveillance, rules on accreditation and conformity assessment bodies and CE marking into one instrument would contribute to increase of confusion among stakeholders.

Participants proposed that the current distinction between market surveillance rules for "harmonised" and "non-harmonised" products be abolished because of its artificial character and replaced by the distinction between "consumer" and "non-consumer" products. Participants indicated that he could hardly imagine situations where the recall of a professional product not presenting a risk to the health and safety of humans could be justified on the basis of proportionality.

Another participant suggested that the General Food Law, Regulation (EC) No 178/2002 be taken as a good example of consistency and clarity for market surveillance rules and used as a template when drafting the new joint market surveillance rules.

4.2.4.2 Exchange of information about measures taken against products posing risks

According to participants, the parallel application of these different notification systems appears to be causing confusion for market surveillance authorities as well as for economic operators.

To simplify the notification systems, it was mentioned that it would be useful to have only one EU notification system in a single EU legal instrument on market surveillance. This notification system would cover both harmonised and non-harmonised products, as well as all types of risks, including serious and non-serious risks posed to different public interests, e.g. the health and safety of consumers, other users, the environment, etc. There is also a need to explore whether it would be possible to uniformly define the elements of such a notification system (such as the obligation to notify measures taken, the notification criteria, the content of the notification and the obligation to follow-up notifications), or whether there is any justification for differences to exist with respect to certain product sectors.

Participants appreciated the specification in Regulation (EC) No 765/2008 concerning the 10-day period whereby economic operators have the right to be heard following the adoption of a market surveillance measure, such as a recall or withdrawal. However, they indicated that often the period of 10 days is not respected by national market surveillance authorities. In addition, market surveillance authorities do not always inform economic operators concerned about the measures taken or provide test reports or risk assessments on the basis of which the measures were taken. This fact can "de facto" eliminate the usefulness of the right of the economic operator to be heard. Furthermore, if the market surveillance authorities of a Member State do not give the economic operator the required time to be heard, or do not provide him with documents on the basis of which they decided to take measures, but immediately notify the measure via RAPEX, other Member States will already start to take action

on the basis of this RAPEX notification. However, if – after distribution of the RAPEX notification to the Commission and to Member States - the economic operator proves that his product is safe and that the original measure was not justified, it may be impossible for him to reverse any action taken by the authorities of other Member States on the basis of the original, incorrectly sent, RAPEX notification.

In this respect, participants suggested that the European Commission verify that the 10-day "right to be heard" period is respected and that economic operators are notified of any measures taken by national market surveillance authorities and receive the "test reports" which served as the basis for taking such measures. Participants also asked whether it would be possible to include in the new legislation the right for economic operators to be informed of the fact that a national market surveillance authority is going to or has notified a product to RAPEX and, possibly, to introduce a right for an economic operator to appeal against making a RAPEX notification.

A Commission representative asked whether the seriousness of the risk is not sometimes artificially upgraded due to the existence of different notification channels for products posing serious risks (RAPEX) or products posing less than serious risks (Art. 11 of the General Product Safety Directive, Art. 23 of the Regulation 765, sector specific safeguard clause mechanisms). Participants agreed that the intensity of a risk is sometimes upgraded due to the existence of various notification systems. In their opinion, there should be one horizontal notification system based on the condition that products pose a risk and the Commission should verify more thoroughly that the level of intensity of the risk is correctly established by national market surveillance authorities.

4.2.4.3 General product safety rules and rules for non-harmonised professional products under Mutual Recognition Regulation (EC) No 764/2008

Participants felt that it would be inconsistent and unworkable to have overlapping systems. They felt that the current delimitation of the scope of application between the rules for non-harmonised, non-consumer products under Regulation 764 and the General Product Safety Directive is not clearly defined and gives rise to confusion as to which legislation should apply under which circumstances.

4.3. List of participants

4.3.1 Reinforcement of coordination of national market surveillance activities (31 January 2011)

ASSER Jeff	UK Department for Business, BIS, UK
COLIJN Marijn	Dutch Food and Product Safety Authority
FARQUHAR Bruce	Private Expert
HUNTER Noel	PROSAFE
LEIMON Mitchell	BIS, UK

MAURER Sylvia	BEUC
MURPHY Robert	EFTA Market Surveillance Authority
NIEDERMEYER Hans-Georg	Bavarian Ministry for Labour, Social Affairs, Family & Women
OLIE Nico	PROSAFE
PERZ Helmut	Federal Ministry of Labour, Social Affairs and Consumer Protection
RAHBEK Torben	Private Expert
RUSSELL Stephen	ANEC

4.3.2 Clear and uniform legislative framework (consistency of product safety requirements for economic operators) (16 February 2011)

BROWN Jim	TOYS R US
DOWNHILL Paul	HOME RETAIL GROUP
DRAGSDAHL Annette	BUSINESSEUROPE
ERKENS Sabine	UEAPME
LUIJKX Gerard	UNILEVER
LASALLE Guy	NIKE EMEA
MAURER Sylvia	BEUC
MONTFORT Jean-Philippe	MAYER & BROWN
RICHARDSON Jennifer	VIEWSONIC
VOULOT Charles	EUROCOMMERCE
ZAKRZEWSKI Michael	CECED

4.3.3 Faster procedures for elaboration of European standards (17 March 2011)

RUSSELL Stephen	ANEC
MAURER Sylvia	BEUC

MISSIROLI Cinzia	CEN
HÜHLE Haimo	BUSINESSEUROPE
SCHMEDT Erika	Authority for Social Affairs, Family, Health and Consumer Protection
DE PAUW Henk	NORMAPME
JOCK Stephane	OXYLANE-DECATHLON
ARVIUS Christen	SOGS STANDARDISATION
ROED Jan	Market surveillance (Denmark)
CONSOLI Thomas	Market surveillance (Malta)
DORTLAND Rob	Market surveillance (the Netherlands)
PAUL Spencer	Market surveillance (the Netherlands)
SVAREN Jesper	Market surveillance (Sweden)

4.3.4 Clear and uniform legislative framework (overall legislative framework and market surveillance rules) (31 March 2011)

MONTFORT Jean-Phillipe	Mayer Brown (law firm)
FREEMAN Rod	Hogan Lovells International (law firm)
LAFFINEUR Jean-Luc	Laffineur (law firm)
SCHLIESSNER Ursula	McKenna Long (law firm)
JOCK Stephane	Oxylane-Decathlon (in-house lawyer)

5. ANNEX 5: SMALL AND MEDIUM ENTERPRISES, INCLUDING MICRO-ENTERPRISES: CONSULTATIONS AND ANALYSIS OF IMPACTS (SME TEST)

5.1 Consultation of small and medium-sized enterprises

Due to their size and scarce resources, small and medium-sized enterprises (SMEs)[100] can be affected by the costs of regulations more than their bigger competitors. At the same time, the benefits of regulations tend to be more evenly distributed over companies of different sizes. SMEs may have limited scope for benefiting from economies of scale. SMEs in general find it more difficult to access capital and as a result the cost of capital for them is often higher than for larger businesses. SMEs play a key role in shaping Europe's economy, accounting for 99 % of enterprises, of which 92 % are micro-enterprises. They provide more than two thirds of private sector employment and play a key role in economic growth. Generally, on average, where a big company spends one euro per employee to comply with a regulatory duty a medium-sized enterprise might have to spend around four Euros and a small business up to ten Euros.[101] Depending upon the relevance of the initiative for SMEs and in particular micro-enterprises, appropriate consultation to ensure input on the needs and interests of SMEs, in particular micro-enterprises alongside large enterprises, should be used.[102]

5.1.2 Consultation of SMEs via the European Enterprise Network

The consultations of SMEs were performed through the European Enterprise Network[103] in the same time framework as the general internet public consultation (May – August 2010).[104] For the purposes of the consultation, an invitation for SMEs to fill in a internet questionnaire and a letter explaining the reason and goals of the initiative (in English and French version) were sent to SMEs via the European Enterprise Network (covering 44 countries, including all EU/EEA Member States with more than 600 local partners). SMEs were requested, in particular, to express any opinions and views on the actions envisaged by the Commission described in the

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100 The definition of an SME covers all enterprises with less than 250 employees and equal to or less than either €50 million turnover or €43 million balance sheet total. Micro-enterprises are the smallest category of SME, with less than ten employees and a turnover or balance sheet total equal to or lessthan €2 million.

101 Report from the Expert Group on "Models to Reduce the Disproportionate Regulatory burden on SMEs", May 2007.

102 Annex 8.4(1) of the Impact Assessment Guidelines contains specific suggestions on how to consult SME representatives.

103 European Enterprise Network is a network launched by the European Commission in 2008. It is the largest network of contact points that provide information on EU matters, in particular with respect to SMEs covering a large spectrum of product groups.

104 A consultation via the European Business Test Panel was requested in order to evaluate the economic impact of the revision against the data possessed by the relevant economic operators. However, the evaluation of the revision of the General Product Safety Directive was refused by the EBTP for being "too specific."

accompanying letters and proposals of any further action which could enhance the functioning of the EU general product safety regime.

According to the information from the Contact Points of the European Enterprise Network responding to the request the invitation to participate in the questionnaire and the accompanying letter were distributed to circa 7200 SMEs and 19 business associations as described in the following table:

Table 1: Details of public consultation of SMEs

EEN Contact Point	Number of SMEs reached[105]	Distribution channel	Response
Barcelona (ES)	946	- published on a website - Newsletter sent to subscribers	N/A
Czech Republic (general)	N/A	- published on a website - Newsletter sent to subscribers	N/A
Glasgow (UK)	900	- Direct contact by email - Published on the website	N/A
Grenoble (FR)	N/A	- published on a website	N/A
London (UK)	1500 5 associations	- direct contact by email	3 SMEs
München	Five Bavarian Chambers of Trade and Crafts	- Published on the websites of Bavarian EEN consortium and the Bavarian portal for foreign trade information - Sent to five Bavarian Chambers of Trade and Crafts	N/A
Ostrava (CZ)	1560	-Newsletter sent to subscribers - Published on the	

105 The figures presented in table do not take into account possible unregistered visits of the internet websites by individual SMEs.

		website	
Stuttgart (DE)	650	Newsletter sent to subscribers	N/A
Thessaloniki (EL)	N/A	- Published on the website	N/A
Torino (IT)	1652	- Direct contact by email - Newsletter sent to subscribers - Published on the website	N/A
Vilnius (LT)	- General public (website) - 39 SMEs and 9 associations	- EEN website - Direct emails to companies	2 SMEs and 1 association
Total			
11 (in 10 Member States)	7208 SMEs and 19 associations	---	5 SMEs and 1 association

As can be seen from the table and as confirmed by the EEN Contact Point Members, it has been extremely difficult to collect any views or opinions on the issues related to the revision of the General Product Safety Directive because of lack of interest of economic operator. In sum, despite the efforts of the European Enterprise Network to reach as many SMEs as possible in result only very few SMEs completed the internet questionnaire.

5.1.3 Internet public consultation

Response of SMEs to the internet public consultation (May – August 2010):

- Pre-standardisation procedures questionnaire 15 (out of 31) – 8 selling locally only within one Member State
- Harmonisation of safety evaluation questionnaire: 9 (out of 23) – 4 selling locally only within one Member State
- Market surveillance coordination questionnaire: 7 (out of 22) – 1 selling locally only within one Member State
- Market surveillance coordination questionnaire: 7 (out of 20) – 3 selling locally only within one Member State

5.1.3 Position papers

Two business associations, namely UEAPME[106] and UGAL,[107] submitted separate position papers.[108]

5.1.4 Use of the results of the SME consultation within the framework of the impact assessment of the "omnibus alignment"

Within the framework of the impact assessment of the "omnibus alignment", the Commission performed From June to October 2010 a public consultation of economic operators, including SMEs. It consisted of four targeted questionnaires for economic operators, authorities, notified bodies and users and we received 300 replies.[109] In view of the high number of SME active in the sectors concerned, a specific SME consultation was carried out in addition to the general consultation. 603 SME were consulted through the Enterprise Europe Network in May/June 2010. The Commission's minimum consultation standards were fully met.

SME were specifically consulted through the Enterprise Europe Network during the months of May and June 2010. A significant number of SME participated in the exercise. The following table gives details of the number of stakeholders having participated in the SME and public consultations by category of respondents and by sector.

Table 2: Overview of stakeholders by category of respondent and by sector

	Electrical & Electronic goods	Lifts	Pressure equip	Measuring Instr.	Civil explosive.	Pyrotechnic articles	Equp. For use in explosive atmospheres
SME	332	63	78	67	8	24	25
EO	44 (14 BO)	8 (2 BO)	6	35 (8 BO)	0	1	4
NB	16	9	23	13	4	2	9
AUT	28	11	15	21	6	9	11
Users	5	1 (CO)	11	6	0	2	8

Due to the similarity of the scope and the nature of problems submitted to the consultation, in particular the overall simplification of the legislative framework in the non-food area, the issue of further coordination of market surveillance authorities of

106 Union Européenne de l'Artisanat et des Petites et Moyennes Entreprises (European Association of Craft, Small and Medium-sized Enterprises).

107 Union of Groups of Independent Retailers in Europe.

108 The summary of these position papers can be found in Annex 3.

109 A summary of the results is available at http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/index_en.htm

Member Stats, the results of this SMEs consultation could be taken into account in this context.

5.2 Analysis of impacts on small and medium-sized enterprises (SME test)

5.2.1 Impact of the existing EU product safety requirements on SMEs

If large companies have generally no problems in bearing the costs of lack of legal certainty about the applicable rules, this may not necessarily be the case with SMEs. In the public consultation the business representatives agreed that as far as the observation of product safety requirements is concerned, three types of economic operators can be identified:[110] (i) those willing and able to respect the product safety rules (mostly large companies), (ii) those willing to respect the product safety rules, but unable to do so (mostly SMEs), and (iii) those unwilling to respect the product safety rules (so-called rogue operators - usually very small importers of products who can quickly disappear in the case of a problem).[111] The inconsistencies in the product safety legislation gave an impact on those who are willing and able to follow product safety (usually big multinationals) as well as those who are willing to respect the product safety rules but unable to do so (usually SMEs), but in a different way.

For both categories of potentially compliant economic operators, i.e. both for the willing and able as well as for the willing and unable, the inconsistencies between consumer product safety requirements and the resulting diverging application of these rules, not only represent an additional cost burden,[112] but also determine the number of economic operators belonging to the first or the second group. The higher these additional costs resulting from inconsistencies in the applicable rules will, the bigger will be the group of economic operators willing to observe the applicable safety requirements, but unable to do so and at the same time the smaller will be the group of "willing and able." Indeed, if the inconsistency of the different pieces of legislation exceeds a certain point, certain economic operators will no longer be able either to spend more time or pay more costly legal advice in order to determine what the applicable rules are; when certain economic operators reach that moment they will move from the category of "willing and able" to the category of "willing, but unable" to respect the existing product safety requirements.

The aforementioned distinction between different groups of economic operators as well as its consequences appear to be confirmed by market surveillance authorities. Market surveillance authorities from the Member States have reported that SMEs and microenterprises often lack the knowledge regarding the rules of product safety. Therefore, SMEs and microenterprises often do not comply with the product safety

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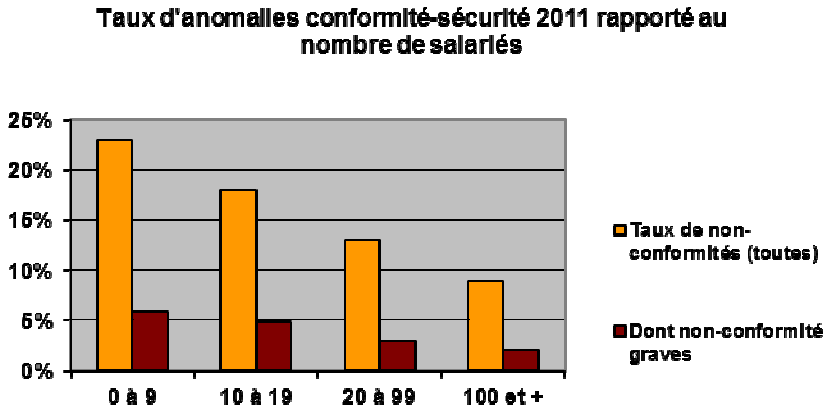
110 This typology of economic operators was described by one of the representatives of the businesses and found and is shared by the business community active in the non-food product sector in general.

111 The rogue operators are not concerned by the impact of the described inconsistencies between the consumer product safety requirements and the harmonised product safety requirements since they do not respect either of these requirements.

112 The correct knowledge and compliance with several pieces of legislation, even if consistent, not to speak of inconsistent pieces of legislation, is time consuming and costly, both in terms of human ressources and education.

legislation. According to market surveillance authorities microenterprises import a big share of the products causing safety problems.

According to an estimation based on product safety and compliance measures taken in 2011 by French authorities, there is a correlation between the number of employees in a company and the compliance with rules regarding product safety (see below the diagram and table). In particular, in a company with less than 10 employees the risk not to comply with rules regarding product safety is nearly twice as high compared to a company with 10 and more employees.



Effectif salarié	0 à 9	10 à 19	20 à 99	100 et +
Taux de non-conformités (toutes)	23%	18%	13%	9%
Taux de non-conformités graves	5,9%	4,8%	3,0%	2,0%

In the experience of the Commission, these results would likely not be different in other Member States.

5.2.2 Impact of the options on SMEs

5.2.2.1 Impact on SMEs

On the one hand, as described in section 2.1 the inconsistencies in the product safety requirements in the current situation generate higher costs for all types of economic operators, but for SMEs represent relatively heavier costs than for large economic operators. If these inconsistencies in product safety requirements will be eliminated it can be expected that they would produce the positive effects on all types of economic operators, but with respect to SMEs, these effects may be more accentuated, i.e. have relatively higher positive benefits. Clearer and more understandable product safety requirements will become more easily accessible to a higher number of SMEs. The costs savings resulting from the enhanced legal clarity would make it possible for a number SMEs to become able to follow and respect all product safety requirements.

On the other hand, the capacity of SMEs to fulfil the applicable product safety requirements, even if made clearer and more understandable, will always be lower for SMEs. An SME will have smaller resources to obtain expertise in the applicable

legislation or technical standards than a large economic operator as well as it will be less equipped to perform tests and conduct controls and risk analysis for its products. Likewise, an SME will usually be less able to cope with circumstances requiring the withdrawal or recall of products. In some cases, this lack of resources and organised procedures may make it difficult for SMEs to conduct a removal operation or larger recall, which would expose consumers to a risk not mastered and would cause the taxpayer to bear the cost of these failures. Moreover, for SMEs it will not necessarily be possible to remedy these deficiencies in internal organisation by use of services of external providers as this may be beyond the financial capacities of such small operators.

5.2.2.2 Differentiated treatment of SMEs and other economic operators

Applying a differentiated treatment in respect of the level of compliance with product safety requirements in order to further reduce the relative imbalance which the applicable product safety legislation has on the SMEs does not appear to produce the desired outcomes for SMEs. The impacts of such option would be similar to the abolition of consumer product safety requirements, i.e. legal problems, internal market difficulties, discrimination issues, market distortions etc.[113]

Moreover, the differentiated treatment of SMEs and other economic operators would be – as far as product safety requirements are concerned – inapplicable in practice. Due to the absence of effective traceability of non-food products, it is often impossible to identify who put the product on the market: in consequence, under the current situation it would be difficult effectively applying "a SME exemption or a lighter regime" since it would be impossible to find out whether a concrete product was put on the market by a SME or a non-SME.

An effective application of a lighter regime for SMEs in respect of the applicable safety requirements would necessitate a control by public authorities of the size of all the operators in the whole supply chain - from the producers of raw materials via the component makers up to the manufacturer of the final product – in order to make sure that only SMEs were entitled to apply lower safety requirements are involved in the manufacturing of the product. Such control of the supply chains by public authorities would either be technically impossible to implement or extremely costly with adverse effects on the functioning of the supply chains since all the operators in the supply chain would have to be continuously reporting economic data to public authorities to justify that they are entitled to benefit form the special "SME regime." Beyond that such controls would be impossible to put in place for the parts of the supply chains outside the EU: if a manufacturer from a third country producing a component of a consumer product sold in the EU claimed the application of the lighter SME regime to him, authorities of Member States would not have – in such a hypothetical example – any means of checking whether such a third country manufacturer fulfils the conditions of an SME in order to benefit from the lighter SME regime in respect of product safety requirements.

[113] Annex 15, section 1.3.

Application of a lighter regime for SMEs in respect of the applicable safety requirements to producers, i.e. manufacturers and importers, would be unfair and discriminatory to distributors, in particular retailers which are often SMEs. Due to this lighter regime for producers liability and enforcement would be shifted on distributors who have much lesser information about safety properties of the given product than producers and are less able to remedy any potential safety problems.

Furthermore, even if all the practical obstacles were resolved and lighter SME regime in respect of product safety was applied not only to manufacturers, importers and distributors, this differentiated treatment of SMEs would result in creation of two production and marketing chains: one for big brands in which safe products would be marketed and one for SMEs where less safe products would be sold. This would a number of negative results for SMEs: as consumers might at the end prefer big brands just because only these would ensure safety of their products, the competitiveness of SMEs would suffer in general compared to bring brands to which consumers would most probably shift only out of fear of buying dangerous products with SMEs. At the same time, it would negatively impact SMEs producing high quality – high safety products, since products made and sold by SMEs in general would get in the perception of average consumers the label of being unsafe and it would be very difficult for SMEs producing high quality – high safety products to convince the consumers about the opposite.

In addition, lighter product safety regime would not exempt economic operators from criminal liability in the case of an accident caused by a product produced according to lighter safety standards only by SMEs and marketed by SMEs. In consequence, loosening administrative rules would have a paradoxical effect of probable higher use of criminal sanctions which would go to the detriment of both the SMEs and market surveillance authorities.

Last but not least, "a SME exemption or a lighter regime" from product safety rules would paradoxically provide incentive for economic operators to ignore safety rules and market unsafe products.

5.2.2.3 Mitigating measures

As a part of contribution to the creation of growth and jobs, the reduction of regulatory burden in particular in relation to SMEs is being continuously considered when reviewing and preparing new legislation. In addition, an active search for adapted solutions for SMEs is performed in all relevant cases.

To further alleviate the costs of compliance with the consumer and harmonised product safety requirements, it could be considered whether the Product Contact Points established under Regulation (EC) No 764/2008 with the aim of could extend their scope of action also to the area of products covered by the General Product Safety Directive and harmonised Union legislation and could provide SMEs with education on the applicable consumer and harmonised product safety requirements and their relationship.

5.2.3 SME test summary

(1) Consultation with SME representatives	SME were specifically consulted through the Enterprise Europe Network during the months of June and August 2010. (See above sections 1.2 and 1.3)
(2) Preliminary assessment of businesses likely to be affected	According to the findings of the consultation, SME are among the economic operators affected by the problems identified. (See above section 2.1)
(3) Measurement of the impact on SME	If envisaged options are applied indistinctly to all economic operators irrespective of their size, it can be expected that they would produce the same positive effects on all types of economic operators. With respect to SMEs, these effects may be more accentuated since the costs savings resulting from the enhanced legal clarity would make it possible for certain SMEs to become able to follow and respect all product safety requirements. (See above section 2.2.2). As regards negative impacts, it did not appear in the impact assessment that the overall impact of this policy action would bring about significant costs increases both for SMEs as well as other economic operators.
(4) Assess alternative options and mitigating measures	There was no indication of the need of SME specific measures in order to ensure compliance with the proportionality principle, in particular due to the practical impossibility to apply differentiated treatment to SMEs and other economic operators as far as product safety requirements were concerned. An application of certain mitigating measures could however be envisaged, if necessary (See above section 2.2.3).

5.3 Consultation on micro-enterprises

In order to minimise the regulatory burden on very small companies to the absolute minimum, the Commission outlined in November 2011 its new policy on *"Minimizing regulatory burden for SMEs - Adapting EU regulation to the needs of micro-enterprises".*[114] The implementation of this policy on microenterprises is detailed in operational guidelines.[115]

According to this new policy, the Commission's preparation of all future legislative proposals is based on the premise that in particular micro-enterprises[116] should a priori be excluded from the scope of the proposed legislation unless the necessity and proportionality of their being covered can be demonstrated. Where micro-enterprises must be covered by legislative proposals for public policy reasons recourse to adapted solutions and lighter regimes will be sought concerning all forms of regulatory burden including, in particular regarding administrative requirements. The demonstration of the proportionality of covering micro-enterprises and the assessment of possible adapted solutions should be included in the Impact Assessment, thus adding a specific micro-enterprises dimension to the 'SME test'.

Although the aforementioned documents acknowledge that "*much legislation will remain applicable to SMEs and micros, covering fundamental public policy obligations, for example, product safety standards that are integral to trading throughout the single market*,"[117] since they do not contain any exemption from the obligation to assess the consequences and impacts of the non-application of EU product safety legislation to microenterprises, the analysis of the impact of exclusion of microenterprises from consumer product safety obligations has to be performed.[118]

5.3.1 Consultation performed

Under the specific operational guidelines on the question of microenterprises public and stakeholder consultations should be used to collect information, statistics and views of all relevant stakeholders in order to be able to estimate the potential positive and negative impacts on the proposed regulatory action micro-enterprises.

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114 COM(2011)803.

115 Ref. Ares(2012)557005 - 07/05/2012

116 Enterprises with less than 10 employees and a turnover or balance sheet total equal to or less than €2 million.

117 (COM (2011) 803, p. 3 – 4).

118 *"From January 2012 the Commission's preparation of all future legislative proposals will be based on the premise that in particular* ***micro-entities should be excluded from the scope of the proposed legislation unless the proportionality of their being covered can be demonstrated.*** *This demonstration is a new element to be included in the SME test. Thus modified, the test will de facto reverse the burden of proof and focus the preparation of EU law on the specific situation of SMEs and micro companies. From the same date the Commission will also ensure that, in cases where micro enterprises must be covered by its legislative proposals for wider public policy reasons, its proposals will be substantiated via the introduction of a micro-entities dimension in the "SME test" which forms part of the regular Impact Assessment." (COM (2011) 803, p. 5).*

DG Health & Consumers of the European Commission consulted all relevant stakeholders, including the Member States, businesses as well as consumer associations via the General Product Safety Directive Committee.[119]

5.3.1.1 Questions asked

In the framework of the consultation the following two questions were asked:

"(1) Please indicate whether you possess any information about the possible impact of:

(i) the current product safety rules on micro-enterprises, and

(ii) the non-application of product safety rules on micro-enterprises.

(2) Please feel free to provide any figures you may have. It would be especially helpful if you could indicate:

(i) what part of mandatory corrective action decisions (such as withdrawals, recalls etc.) were addressed to micro-enterprises (over the last year), and

(ii) what part of the voluntary corrective actions were notified to your authorities by micro-enterprises (over the last year).

Also please feel free to provide comments in quantitative ways if possible or even in qualitative terms on what would be the effect on the market if those enterprises were excluded from the application."

5.3.1.2 Distribution of the questions to stakeholders

This question was sent by DG Health & Consumers of the European Commission to the aforementioned stakeholders by email and through the CIRCA information tool on 30 January 2012. The question as well as the answers provided were then discussed in the GPSD Committee on 14 February 2012. Following the GPSD Committee the aforementioned questions were resent to all Members of the GPSD Committee through CIRCA tool as a part of "follow-up" actions. On 16 May 2012 DG Health & Consumers of the European Commission sent a third request for answers of the aforementioned questions to all Members of the GPSD Committee.

[119] In the GPSD Committee three business associations, namely Businesseurope, Eurocommerce and UEAPME as well as two consumer organisations, namely ANEC and BEUC, have a status of observers.

5.3.2 Results and data provided

5.3.2.1 Summary of written responses

Of twenty-seven EU Member States, three Member States of EEA, three business associations and two consumer organisations consulted on the question of microenterprises, DG Health & Consumers of the European Commission received answers from 18 EU Member States, 1 EEA Member State, 1 acceding country, one business association and one consumer organisation. The answers provided are summarised in the following table.

Stakeholder (Member State)	Application of consumer product safety requirements to microenterprises?	Summary of reasons	Economic data on microenterprises
EU Member States			
Austria	YES	Experience from market surveillance indicates that microenterprises are reluctant to take the necessary measures even though a big share of products causing safety problems is imported from third countries by microenterprises and dangerous product are always dangerous regardless the size of the company.	Most of the companies in Austria are micro-enterprises. (e.g. in the year 2010 : 308.735 companies established in Austria, among which 269.899 had 0 to 9 employees and an average turnover of EUR 406.000).
Czech Republic	YES	A limitation of the scope will foil the objectives of the GPSD (consumer safety, especially protection of health, life and property). The consumer is an inferior party also in relation to micro-enterprises; consumer safety must prevail when the burden for microenterprises is considered. A different legislative regime for microenterprises would lead to legislative confusion, legal uncertainty, non-transparency and to an increase in the workload of market surveillance bodies. Competition might be distorted.	According to the register of economic operators of tle Czech Statistical Bureau (as to 31 March 2012), there are 236 438 active microenterprises in tle Czech Republic. Most of the companies in the Czech Republic are microenterprises.
Denmark	---	---	N/A
Estonia	YES	Consumer product safety requirements do not constitute a burden to microenterprises.	Most of the enterprises in Estonia are small or micro-enterprises.
Spain	YES	Microenterprises (usually importers, not manufacturers, selling products with reduced	One of our authorities from an autonomous

Stakeholder (Member State)	Application of consumer product safety requirements to microenterprises?	Summary of reasons	Economic data on microenterprises
		price, most of which are run by third country nationals) often do not comply with the rules regarding product safety. Therefore, many actions of removal and prohibition of trade is directed to microenterprises. The level of consumer safety would be decreased and unfair competition promoted. Unsafe products would invade the market with no competent market surveillance body responsible for these products and no punishment of the producer, which would foreseeably lead to an increase in accidents. Contracts of labour might be terminated in order to establish microenterprises.	community informed us that in 2011 it made a total of 9,585 performances on product safety - 9494 cases concerned "micro-enterprises" with fewer than 10 employees. This means that if microenterprises were exempted from product safety obligations, this would reduce the amount of inspections by 99%. Last year 89 corrective actions in the Autonomous Community, consisted in withdrawing from the market (destruction or return to base) a total of 672 units of 56 different products. All these actions in bazaars with fewer than ten employees.
Finland	YES	Consumer safety must prevail when the burden (e.g. financially) for microenterprises is considered. The workload of surveillance authorities would be increased because of the need in each individual case to clarify if the company in question is a microenterprise or not. There is a risk of artificial company arrangements.	N/A
France	YES	The aim is to achieve and ensure a high level of consumer safety and not to decrease it. Economic operators and certain jurisdictions may be misled: Economic operators may consider their civil and criminal liability not to be at stake and certain jurisdictions may restrict the liability for microenterprises.	See above the market surveillance data provided in respect of SMEs

Stakeholder (Member State)	Application of consumer product safety requirements to microenterprises?	Summary of reasons	Economic data on microenterprises
		Competition might be distorted.	
Germany	YES	The burden limitation of microenterprises may not put consumer safety at stake. A dangerous product is dangerous regardless the size of the company.	
		Producers could choose the product safety provisions applicable by finding artificial arrangements and establishing microenterprises.	
		Micro- enterprises do not always comply with the rules regarding product safety.	
		Even when exempted from the obligations of the GPSD, regardless of their size, micro-enterprises remain liable for defective products according to the Directive 85/374/EEC.	
		Market surveillance bodies would meet difficulties to distinguish products from microenterprises and such from larger companies making an obligatory marking on the product necessary.	
		A new market surveillance body would have to be created, which would examine the company's size and administrate a register for all existing microenterprises.	
Greece	YES.	The burden limitation of microenterprises may not put consumer safety at stake.	Many microenterprises mainly do trade and are less active in the field of production.
Hungary	---	---	---
Italy	YES	The non-implementation of the harmonized legislation could lead to the exclusion of products from microenterprises from the European market.	An important share of the companies established in Italy are micro-enterprises.
Latvia	YES	A limitation of the scope will foil the objectives of the GPSD and the Consumer Agenda. The aim to achieve a high level of consumer safety must be ensured	83,9% of the companies are micro-enterprises, among which there is a significant number

Stakeholder (Member State)	Application of consumer product safety requirements to microenterprises?	Summary of reasons	Economic data on microenterprises
		regardless the size of the company. The size of the company is no suitable criterion of distinction from a viewpoint of a consumer and poses a threat to fair competition.	of importers placing products in the EU market. Most of all non-compliances (about 50-60%) are found in micro-enterprises.
Malta	YES	Many products are manufactured by microenterprises and the GPSD encompasses a very vast range of products.	
Netherlands	YES	Microenterprises do not always comply with the rules regarding product safety. Unsafe products would be invading the European market.	98000 of 100000 companies are economically active and considered small companies (maximum of 5 employees).
Portugal	---	---	Micro-enterprises play a significant role in the Portuguese context.
Romania	YES	---	N/A
Slovenia	YES	A limitation of the scope will foil the objectives of the GPSD.	N/A
Slovakia	YES	---	Most of distributors covered by the GPSD are microenterprises in the Slovak Republic.
EEA Member States			
Norway	YES	Consumer safety must prevail when the burden for microenterprises is considered. The regulatory burden for microenterprises is neither extensive nor substantial. Microenterprises often do not comply with the rules regarding product safety due to the insufficient knowledge about these rules for the consumer-products they are offering.	In Norway a considerable part of different products are offered to consumers by small- and microenterprises.
Acceding countries			
Croatia	---	Microenterprises often do not comply with the rules regarding product safety due to the insufficient knowledge about	N/A

Stakeholder (Member State)	Application of consumer product safety requirements to microenterprises?	Summary of reasons	Economic data on microenterprises
		these rules for the consumer-products they are offering.	
Business associations			
BusinessEurope	YES, unless non-application to all economic operators	Consumer product safety requirements must apply indistinctly to all economic operators. If exemption for certain enterprises, such as microenterprises, exemption for all enterprises.	N/A
Consumer organisations			
BEUC	YES	N/A	N/A

5.3.2.2 Summary of opinions expressed in the GPSD Committee

Most of the Member States indicated that they are not able to provide any data on microenterprises since they do not collect them within the framework of their market surveillance activities.

In the view of Ireland the safety of consumers shall not be compromised despite the need for better regulation and the administrative burden to microenterprises, even if the compliance with product safety requirements might be more costly and time consuming for microenterprise than for large companies.

According to Austria in particular small operators do not carry out quality controls. Therefore, an exemption would be counter-productive and would distort competition between large and small enterprises.

Bulgaria emphasized the aim to achieve a *general* product safety which should not be compromised; a directive on "partial product safety would not be acceptable. A two-speed legislation allowing for safe and unsafe products depending on the size of the producer or distributor would run against consumers' interests. There is also a significant risk of abuse of such a possible rule, as companies could start to divest themselves into smaller units in order to circumvent any product safety rules.

Italy highlighted that while substantive administrative simplification was fundamental, consumer safety must not be compromised. In its view the simplification could already be achieved by the ensuring the compatibility of different product safety requirements in the future legislation.

France stressed that SMEs do not always comply with the rules regarding product safety. Due to the high number of SMEs in France, an exclusion of SMEs from the scope of the General Product Safety Directive would be difficult to accept.

Spain contested the application of the principle of *an a priori* exclusion of microenterprises from the scope of EU legislation to the consumer product safety area. Consumer safety could not be compromised due to the lack of data on microenterprises. Spain indicated that differentiated treatment of economic operators depending of their size would significantly raise the costs and effectiveness of market surveillance, since market inspectors would have to find out a lot of data about the operators inspected; such data may not be available or their retrieval could be very time consuming.

Finland confirmed that in its experience product safety problems were associated in particular with SMEs.

According to Sweden, 90% of Swedish companies are micro-enterprises. In the view of Sweden, microenterprises would not benefit from the exclusion from consumer product safety rules. Consumers already put more confidence in bigger brands. If parts of the market are unsafe, branding and marketing will become more important to the detriment of the smaller companies. Micro-enterprises would then need to prove to consumers that they are just as safe as the big players. Micro-enterprises need standards in order to compete effectively so that they can prove the same level of safety.

Poland stated that it had no specific data at the moment but in general micro-enterprises make up a significant number of businesses in Poland. In its opinion, product safety must not be sacrificed by shifting the focus to reducing the administrative burden.

BEUC highlighted that exclusion of microenterprises from consumer product safety requirements would undermine all Commissions initiatives to promote consumer confidence.

5.3.3 Impact of the options on microenterprises

5.3.3.1 Impact of the existing EU product safety requirements on microenterprises

Impact of the existing EU product safety requirements on microenterprises can be expected to be similar as to SMEs (as described above in section 5.2.1).

5.3.3.2 Impact of the options on microenterprises

Neutralisation of the aforementioned disadvantages by application of differentiated treatment to microenterprises and other economic operators would cause similar difficulties and negatives consequences as described above in sections 5.2.2.1 and 5.2.2.2. with respect to SMEs. By contrast, application of mitigating measures in the form of providing education and information on the applicable safety requirements could be envisaged for microenterprises in the same way as for SMEs (see above section 5.2.2.3).

6. ANNEX 6: EXTERNAL EXPERTISE – LIST OF STUDIES AND REPORTS

6.1 General

1. 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

2. Best Practice Techniques in Market Surveillance, PROSAFE, The Product Safety Enforcement Forum of Europe, 2009

3. RAPEX Annual Reports 2007 – 2011, including RAPEX-China reports 2007 – 2011

4. Market Surveillance in the Member States, commissioned by European Parliament - Internal Market and Consumer Protection Committee, IP/A/IMCO/ST/2009/04, Ramboll Management Consulting, October 2009

5. Market Surveillance and the revision of the General Product Safety Directive, commissioned by European Parliament - Internal Market and Consumer Protection Committee, Ramboll Management, Ramboll Management Consulting, IP/A/IMCO/ST/2010-03, September 2010

6. RPA (Risk & Policy Analysts), Establishing a Comparative Inventory of Approaches and Methods Used by Enforcement Authorities for the Assessment of Safety of Consumer Products covered by Directive 2001/95/EC on General Products Safety and Identification of Best Practices

7. Collaboration and Market Surveillance: Success Factors for Collaboration, Report of the Association of Swedish Engineering Industry and the Swedish Trade Federation, September 2009

8. Consumer Market Scoreboard (Editions 1 to 7)

Perception of safety by consumers and retailers

Number of injuries and accidents per categories of a product

Tracking Progress for Market Retail Integration

9. Attitudes towards cross-border sales and consumer protection, Analytical report, October 2009, Flash Eurobarometer 282 – The Gallup Organization

10. Consumer protection in the internal market, Report, October 2008, Special Eurobarometer 298 – TNS Opinion & Social, Special Eurobarometer 298 / Wave 69.1.

11. Business attitudes towards cross-border sales and consumer protection, Analytical report, July 2008, Flash Eurobarometer 224 – The Gallup Organization

12. Business attitudes towards enforcement and redress in the internal market, Analytical report, November 2009, Flash Eurobarometer 278 – The Gallup Organization

13. Consumer attitudes towards cross-border trade and consumer protection, Flash Eurobarometer Series, #282 - The Gallup Organization

14. Evaluating Business Safety Measures in the Toy Supply Chain, Final Report, European Commission, May 2008 *(Note: according to the study conclusions of the study can be applied across consumer product sectors)*

15. Feasibility Study for a Post-Manufacturing Traceability System between the People's Republic of China and the European Union, EU-China Trade Project, prof. Dr Louis J. Balme, November 2008

16. Freshfields Bruckhaus Deringer, Getting It Right: Product Recall in the EU, March 2008

17. The revision of the EU General Product Safety Directive, Mayer Brown, Memorandum, January 2011

18. Report of the Expert Panel for the review of the European Standardization system Standardization for a competitive and innovative Europe: a vision for 2020, February 2010

19. Guide to General Market Surveillance Procedure, UNECE Working Party on Regulatory Cooperation and Standardization Policies, September 2009, I. Hendrikx

20. EU Injury Database Annual Report 2009

21. Improving the product and services dimension in the IDB, A feasibility study, Dutch Consumer Safety Institute, December 2006

22. Concept note for the Workshop on "Traceability: a tool for managing risks", UNECE Working Party on Regulatory Cooperation and Standardization Policies, August 2011

23. Eurobarometer/OPTEM, The European consumers' attitudes regarding product labelling, Qualitative study in 28 European countries, May 2005

24. Evaluation of the feasibility of a consumer safety mark, European Commission – DG Enterprise and Industry, GHK Consulting Ltd., October 2008

25. The Empirical Economics of Standards, DTI Economics Paper No. 12, June 2005

26. Economic benefits of consensus-based standards, The ISO Methodology, Geneva (Switzerland), ISO Central Secretariat, January 2010

27. Gesamtwirtschaftlicher Nutzen der Normung, DIN Deutsches Institut für Normung e. V., Beuth Verlag, 2000

28. Impact assessment study on the "Standardisation Package", Final Report, technopolis group, March 2010

29. Baltic Sea market Surveillance Network, Report of sixth cooperation – results 2010 and final summary of Best-Practice-Example "Cooperation with Customs in the Field of Technical Consumer Products", December 2010

30. A More Open and Safe Single Market, REGERINGEN, Danish Enterprise and Construction Authority, June 2010

31. Réseau de surveillance de l'Internet : le bilan 2007, DGCCRF, avril 2008

32. The European Online Marketplace: Consumer Complaints 2004 – 2010, A summary and analysis of consumer complaints reported to the European Consumer Centre Network, ECC-Net

33. En finir avec la mondialisation déloyale, Jacob, Y., Guillon, S., Rapport – Ministère des Affaires Etrangères et européennes - Ministère de l'Economie, des Finances et de l'Industrie, Janvier 2012

34. Technische Überwachung Bd.47 (2006), Nr. 3 –März, p. 47 – 52

6.2. Sector specific

35. Child Appealing Research: Research into Child Awareness of Risk: Use of electrical Equipment, A Report by Intertek Research & testing Centre for the Department of Trade & Industry, dti Technical Report, July 2004

36. Cross Border Market Surveillance, LVD-ADCO, Luminaires 2006, voedsel en waren authoriteit, Project IP0106LUM

37. Assessment of Best Practices in Fairgrounds and Amusement Parks in Relation to Safety of Consumers, Risk & Policy Analysis Ltd., March 2005

38. Study on Safety of Trampolines, Austrian Committee for Protection from Accidents in Child age, January 2008

39. Study on Safety of Summer Sliding Facilities in Austria, Kuratorium for Transport Safety, July 2008

40. Study on Risk of Certain Sports and Recreational Activities – the Role of Services, Dutch Consumer Safety Institute, March 2009

41. Best Practices in Prevention of Skiing Accidents in Europe: The New Challenge, 2007

7. ANNEX 7: MONETARY VALUE OF MARKETS OF CONSUMER AND CERTAIN HARMONISED NON-FOOD PRODUCTS IN THE EU

7.1. The value of non-food consumer products sold in the EU

7.1.1 Method 1

To illustrate the broad coverage of the market surveillance legislation, the total value of non-food products sold in the EU-27 is estimated. The following table, compiled using Eurostat data[120] concerning final consumption expenditure of households provides an overview of the size of the EU-wide consumption for non-food products in relation to the whole EU GDP. Between 2007 and 2010, the EU GDP remained relatively stable in nominal terms at circa 12,000 billion EUR. The total household consumption (goods and services) was also relatively stable at 58% of GDP or roughly 7,000 billion EUR. Over two thirds of these expenses were linked to services, while approximately one third went into purchases of goods (both food and non-food products). Each year, the consumption of non-food products accounted for roughly 900 billion EUR, which represents 13% of the total household consumption or about 7.5% of the total EU GDP.

Table 1: Structure of household consumption in the EU (source: EUROSTAT)

EU-27	2007	2008	2009	2010
Total GDP (billion EUR)	12390.02	12479.02	11770.04	12268.38
Total household consumption expenditure (products & services, billion EUR)	7090.53	7171.11	6865.52	7154.89
Total household consumption expenditure on products (food and non-food, billion EUR)	2199.51	2227.84	2126.09	N/A
Total household consumption expenditure on non food products (billion EUR)	946.20	939.72	887.34	N/A

7.1.2 Method 2

The second way to estimate the value of all non-food consumer products sold in the EU is to examine the turnover of stores and companies which specialise in selling such products[121]. The turnover of economic operators involved in specialised retail sale of

120 "Final consumption expenditure of households by consumption purpose - COICOP 2 digit - aggregates at current prices" [nama_co2_c] and "GDP and main components" (t_nama_gdp)

121 EUROSTAT data on Annual Detailed Enterprise Statistics on Trade (sbs_na_3b_tr) based on the NACE Codes (rev. Rev.1.1 G) for 2006 and 2007 and Annual Detailed Enterprise Statistics on Trade (sbs_na_dt_r2) based on the NACE Codes (rev. Rev. 2 G) for 2008 (latest data available)

non-food products confirms our initial estimate that the value of non-food products sold to consumers in the EU every year is approximately 1000 billion EUR.

Table 2: Total turnover of companies selling non-food consumer product in the EU (source: EUROSTAT)

2006	NA
2007	EUR 989.07 Billion
2008	EUR 1 092.35 Billion

7.2. Value of harmonised product sectors (including consumer as well as non-consumer products) in the EU-27

The value of harmonised sectors in the EU-27 is estimated to be well above € 2 100 billion. This figure is derived from the sum of production value for the big electrical mechanical, mechanical engineering, automotive, chemical and medical devices sectors, as provided below. The figures do not include the value of other harmonised sectors such as gas appliances, pressure equipment, radio and telecommunications equipment, recreational craft, and rail. Furthermore, they do not include any estimate of harmonised construction products.

Table 3: Key data of certain harmonised product sectors

	Products	Size of the industry (market output)	Trade balance (share of imports)	Industry structure, SME presence	Number of NB in the EU[122]
Electro-technical sector (Low Voltage Directive (LVD) and electro magnetic compatibility directive (EMC))	Electric welding and soldering tools, electric domestic appliances, computers and other information processing equipment, electric motors, generators and transformers. electricity distribution and control apparatus, insulated wire and cable (LVD only), lighting equipment and electric lamps (LVD only), other electrical equipment, electronic valves and tubes and other electronic components (LVD only), television and	€ 235.59 billion (equipment covered by LVD) € 200.12 billion (equipment covered by EMC)	Negative trade balance: LVD: € 103.93 billion of imports and € 83.09 billion of exports. The internal consumption is estimated at € 256.42 billion. EMC: € 100.78 billion of imports and € 76.07 billion of exports. The internal consumption is estimated at € 224.83 billion	The structure of the industry is characterised by a few large corporations producing a wide range of electrical equipment, and many small companies specialised in niche markets.	148 (LVD) 131 (EMC)

122 NANDO database on 3 January 2011 http://ec.europa.eu/enterprise/newapproach/nando/

	radio receivers, sound or video recording or video recording or reproducing apparatus and associated goods.		Most imports come from China, followed at a considerable distance by the USA, Japan and South Korea.		
ATEX	Mechanical, electrical and telecommunication equipment, protective systems and devices, to be used in potentially explosive atmospheres (in underground mines, petrochemical plants, oil refineries, filling stations and other places where flammable gases may be present, and also premises like flour mills and agricultural warehouses where airborne dust can present an hazard): mechanical gears, brakes and seals; gas and steam turbines; electrical motors, pumps, fans; electrical tools and instrumentation; fork lift trucks; filter units and vented silo bins; switches, control and detection systems and components; torches; plugs and sockets outlets; heating cables; computers, phones and other similar equipment; vent panels; enclosures; sparks arrestors; temperature protective devices; etc.	€ 2.2 billion	Positive trade balance: Imports amount to € 400 million. Internal consumption estimated at € 1.9 billion, 86% of internal production.	The ATEX sector is characterised by a large number of SME and micro enterprises, around 90%, mainly based in France, Germany, Italy and the United Kingdom, but also with significant presences and market shares in Denmark, the Netherlands, Norway, Poland, Spain, Sweden as well as in Switzerland.	55
Pressure Equipment (incl simple pressure vessels)	Pressure vessels, piping, boilers, steam generator, safety accessories and pressure accessories, etc…	No data available	Manufacturing of pressure equipment is gradually shifting to low cost countries.	A substantial number of SME is involved in production	237[123] 95 (simple pressure vessels)

[123] This figure includes recognised third party organisations and user inspectorates.

NAWI	Non-automatic weighing instruments, i.e. measuring instruments serving to determine the mass of a body and requiring the intervention of an operator during weighing	€ 2.5 billion	Not available	Small companies (< 50 employees) clearly dominate with 60%. 35% are medium sized enterprises with 50-250 employees and 4% are large companies with more than 250 employees-	270
Measuring Instruments	Water meters, gas meters, electricity meters, heat meters, meters for liquids other than water, weighing machines, taximeters, material measures to measure length, dimensional measuring instruments and exhaust gas analysers.	€ 3.25 billion	Around 20-25% of measuring instruments in the EU27 are imported	There are around 900 manufacturers active in the 10 sectors covered by the MID not including the large number of SMEs operating as distributors, importers or providers of repair services.	140
Mechanical Engineering[124]	Machines and other mechanical equipment: General purpose machinery , Agricultural and forestry machinery , Industrial processing machinery , Domestic appliances .	€ 498 billion (2007)	Highly export-oriented industry – equipment exports worth €210 billion in 2007 represented 42% of the total value of its production		
Of which **Lifts**	Lifts permanently serving buildings and constructions intended for the transport of persons, persons and goods or goods alone if the car is accessible as well as safety components for use in such lifts	€ 3.17 billion	Very positive trade balance: € 36 million of imports and € 693 million of exports. Internal consumption: € 2.51 billion	The structure of the industry is characterised by four multinational lifts companies and many small companies specialised. designing and installing new lifts and producing safety components for this lifts	192
Civil Explosives	Explosive substances and articles which are not used by the armed forces or the police, but commercially. The main end-users of civil	€ 1.35 billion.	Trade with third countries is limited. Imports play a significant role only in niche markets like	20 manufacturers of explosives and approximately 500 distributors are active in the EU. At manufacturers'	13

[124] 29 NACE.

	explosives are the mining industry, the quarrying industry, and the construction and civil engineering industry (primarily for demolition, land clearance and tunnelling)		explosives used for offshore drilling operations. Important trading partners are Norway, Switzerland and the USA. Importers in the EU are generally large companies with specific demands, for example in the oil drilling industry.	level, there are no SME: Around 4 000 people are directly employed by these companies. Nearly all of the distributors, on the other hand, are SME employing around 5 000 people. Thus, a total of 9 000 people are employed by the civil explosives industry.	
Pyrotechnic articles	Fireworks, theatrical pyrotechnic articles, pyrotechnic articles for technical purposes and automotive pyrotechnic articles (automotive restraint systems, i.e. most importantly gas generators used in airbags and seatbelt tensioners).	€ 1.4 billion (fireworks) € 2.8 billion (automotive)	95% of all consumer fireworks are manufactured overseas.	Fireworks industry: mainly SME; altogether employing in total an estimated 15 000 to 20 000 people. Automotive pyrotechnic articles: big international automotive supplier companies, around 40 000 employees.	10
Automotive[125]	Manufacture of motor vehicles, trailers and semi-trailers	turnover of over €780 billion	Positive trade balance (2007): Exports of cars from EU-27 countries amounted to€125 billion, with imports of €65 billion.		
Chemicals[126]	fertilizers and biocides, paints and coatings, soaps and detergents, perfumes and cosmetics, explosives, plastics, rubber products and many more (over 70 000 products)	Turnover of €537 billion (2007)		The EU chemicals industry consists of about 27,000 enterprises, 96% of which are SMEs The Petrochemicals	

125 NACE 34.

126 NACE 24 (24.1, 24.2, 24.3, 24.5 24.6, 24.7) and 25.

127 NACE 24.5.

				sub-sector is vertically and horizontally integrated to a high degree	
Of which **Cosmetics**[127]		€63.5 billion (2006)	EU exported €8.6 billion worth of cosmetics products in 2005.. The EU exports nearly four times more it imports.	Fine and Specialty chemicals, which is predominantly composed of specialised niche companies	
Construction products and services[128]	Onsite construction, Manufacturing of construction materials, Professional construction services	Turnover of € 2 389 billion (2007)		This sector is characterized by a dominance of small and medium sized enterprises, and a very large number of micro enterprises, which produced about 80% of the total turnover of this industry	
Of which **construction products**	Manufacture of builders' carpentry and joinery, bricks, tiles products in baked clay, cement, plaster, artciles of concrete, paster or cements, etc.	< € 700 billion [129].			
Medical devices	Many products from simple bandages to the most sophisticated lifesupporting products	sales of €72.6 billion (2007)		The medical device industry is highly heterogeneous and characterised by sub-markets at different stages in the product life cycle, and requiring different amounts of	

128 NACE Rev 1.1.

129 Manufacturing of construction materials poses particular problems because of the subsector's composite nature that cuts across the standard structure of the NACE classification scheme of economic activities. This makes it difficult to obtain data that pertain to the subsector. The estimate of max €700 billion is provided by the difference between the overall value of construction products and services minus that of services relating to demolition and site preparation (NACE Group 45.1), general construction activities (NACE Group 45.2), installation work (NACE Group 45.3),completion work (NACE Group 45.4), renting of construction equipment (NACE Group 45.5). It is estimated that those construction services in the EU-27 generated in 2008 a turnover of €1,590 billion (SEC(2009) 1111 final, Brussels, 30.7.2009). The value of €700 billion is however still expected to include professional construction services (architectural and technical consultancy activities) and real estate services.

				resources. There are about 11,000 medical technology companies in Europe. More than 80% of these are SMEs.	
Toys	Toys and games	€4.7 billion (2003)	Negative balance: exports of traditional toys in 2010 were €1.05 billion. imports of traditional toys in 2010 were €6.96 billion. China is the leading supplier which accounts for 86% of total imports.	There are over 2 000 manufacturers. Around 80% of the sector is composed of SMEs which have less than 50 employees; only 5% are large companies	

7.3. Non-compliant products in the EU

Table 4: Indications on the share of non-compliant products

Source	Share of non-compliant products on the market
SME Test panel (2006)	The majority of SMEs could not provide figures. Where figures were given, they differed considerably from sector to sector as well as between Member States. The figures ranged from 4%-51%, the average being 24%.
Enterprise questionnaire (2006)	Most respondents could not provide figures but indicated that the problem was important. However, below is an overview of the estimates provided: Electro-technical sector: 10-30% (up to 50 % in the luminaries' sector) Mechanical sector: 5-7 % Medical devices: 10-30% Construction products: 10-30%
Market surveillance authorities (2006)	Electro-technical 10-70 % Medical Devices 2-20 % Construction products 2-30 % Recreational Craft 1 %

In addition, a more recent consultation concerning a few harmonised products (both consumer and professional) shows that many stakeholders (economic operators, authorities, notified bodies, users) consider that their sector is affected by non-

compliance (see table 4). [130] It appears that the problem is more strongly felt in large sectors like that of electro-technical products (including electric domestic appliances, computers, generators and transformers, lighting equipment, etc.), and less felt in specialised sectors like ATEX or civil explosives, although a few cases of non-compliance have been reported also for the latter.

The electro-technical sector is indeed the sector in which stakeholders and in particular industry associations have been most active in pointing out the problem[131] The market surveillance authorities responsible for the application of the Low Voltage Directive have undertaken three cross border actions in the last few years, on portable household lights[132], cord extension sets[133] and Christmas lighting[134]. Only 5% of the household lights tested showed no shortcomings (either administrative or technical). Whilst not causing immediate danger to consumers, the shortcomings were considered serious enough to require remedies. Only one in six cord extension sets fully complied with the requirements. 58% of the cord extension sets tested were considered sufficiently unsafe by the authorities to justify a sales ban. Similar findings were obtained in three market surveillance campaigns carried out recently by the Administrative Cooperation group (ADCO) for the implementation of the Electro-magnetic Compatibility Directive. The campaigns focused on Energy Saving Lamps[135], Power Tools[136] and Consumer Entertainment Electronic Products[137]. The results of these campaigns showed that the level of technical non-compliance was 23% for the Energy Saving Lamps, 20% for the Power Tools and 50% for the Consumer Entertainment Electronic Products. Further general conclusions drawn from the campaigns were that the share of non-compliant imported products was generally higher than the share of non-compliant products originating from EU countries, and that for a considerable part of non-compliant products the origin could not be determined.

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130 Commission Staff Working Document, Impact Assessment, Accompanying document to 10 proposals to align technical harmonisation legislation to Decision 768/2008/EC– SEC(2011) 1376, Brussels 21.11.2011.

131 See e.g. ORGALIME position paper Call for an effective pan-European market surveillance system http://www.orgalime.org/Pdf/PP_Orgalime ANEC_on%20market%20surveillance_apr09.pdf

132 See http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/615&format=HTML aged=0&language=EN

133 See http://ec.europa.eu/enterprise/sectors/electrical/files/lvd-adco/20080903_lvd_adco_-_final_report_-_extension_leads_-_2007_project_en.pdf

134 See http://ec.europa.eu/enterprise/sectors/electrical/files/lv/report_luminaires_en.pdf

135 See Report on campaign concerning Energy Saving Lamps available at http://ec.europa.eu/enterprise/sectors/electrical/files/emc/ms-campaign-first_en.pdf

136 See Report on campaign concerning power tools http://ec.europa.eu/enterprise/sectors/electrical/files/emc/ms-campaign-second_en.pdf

137 Report on campaign concerning Consumer Entertainment Products available at http://ec.europa.eu/enterprise/sectors/electrical/files/emc/ms-campaign-third_en.pdf

Table 5: Percentage of respondents to the public consultation considering that their sector is affected by non-compliance (both consumer and professional goods)

	Electro-technical	ATEX	Civil explosives	Pyrotechnic articles	Lifts	Measuring instruments	Pressure equipment	Total
Economic Operators	96%	75%	-	0% (100% don't know)	88%	94%	83%	92%
Authorities	86%	64%	0% (50% don't know or No)	78%	55%	52%	80%	66%
Notified Bodies	94%	44%	25%	50% (50% don't know)	44% (55% No)	31% (40% don't know)	65%	60%
Users	100%	25% (75% don't know)	-	0% (50% don't know or No)	100%	67%	82%	64%
SMEs	53%	44%	12,5%	0% (50% don't know or No)	35% (40% No)	41%	49%	48%

The problem of non-compliances is also strongly felt by the industry in certain (mostly) professional sectors like the machinery sector. At the European Commission Conference on Market Surveillance and Machinery held in Brussels at the end of November 2011, various stakeholders emphasised the size of the non-compliance problem. For instance from a CECE survey of members, 49% of respondents had seen a non-compliant machine working on site, 37% had lost business when their customer had opted to purchase a non-compliant product and 39% thought that the problem is increasing[138]. Another industry representative referred to over 50 non-compliant machines (industrial trucks) exhibited at the 2011 CeMAT logistics exhibition[139].

138 http://www.erarental.org/news/Rental-Benefit/CECE-launches-survey-on-equipment-compliance-127.html.

139 http://www.fem-eur.com/data/File/MktSurv%20-%20VDMA%20PR%20CeMAT%20IT.pdf

Table 6: Results of PROSAFE joint market surveillance actions

Title of the action	Date	Member States involved	Inspections/ samples	Results
LIGHTNING CHAINS	2007 - 2009	Hungary, Germany, Slovakia, Slovenia	196 samples taken:	30,4% serious non-compliance and 40,2% less serious non-compliance
SUNBEDS 1	2008 - 2009	Belgium, Cyprus, Czech Republic, Denmark, Finland, Germany, Hungary, Latvia, The Netherlands, Poland and Switzerland	Over 300 locations and 500 sunbeds checked	20% incorrect labelling, 32% sunbed type not listed, 52% no UV warning, 70 of 84 sunbeds with too high radiation
HELMETS	2009 - 2010	Cyprus, Czech Republic, Germany, Iceland, Latvia, Lithuania, Norway, Slovenia, Spain, Sweden, The Netherlands	367 samples inspected	63% non-compliant

Table 7: Number of non-compliance and safety issues in the electrotechnical consumer sector[140]

Product categories	Total number of safety testing and certification projects completed in 2011	Weighed % of products NOT meeting safety requirements for any reason	Weighed % of products NOT meeting requirements for safety-critical reasons only	Weighed % of products that never reached compliance
ELECTRICAL PRODUCTS FOR HOUSEHOLD USE	74 508	42,2%	15,1%	2.8%

Manufacturers, importers and distributors who abide by the law (and especially SMEs). The most recent statistics[141] show that manufacturing is the largest of the NACE sections within the EU-27's non-financial business economy both in terms of persons employed and value added; it contributed 24.2% of the workforce in 2008 and 27.1% of value added. Overall, 2.1 million manufacturing enterprises employed

140 IFIA CIPC, Product Safety in Europe, Results from the 2012 Study, November 2012. For the purposes of the study product categories that have wide market distribution, established safety standards, relevant potential of causing harm to consumers were chosen as fair representatives of imported electrical goods. These included (i) battery chargers/adapters, (ii) luminaires (LEDs, classic), (iii) Hair dryers/curlers (iv) room heaters, (v) Electric Fans, (vi) Toasters, grills and similar. Samples (only CE-Marked, no third-party marks) were purchased from regular stores, in Denmark, Poland, Germany, UK and Italy and were tested in an independent laboratory. A consensus was reached on the test/analysis to be conducted on each product type. The laboratory tests took place in the period of May – July 2012.

141 See Report on campaign concerning Energy Saving Lamps available at http://ec.europa.eu/enterprise/sectors/electrical/files/emc/ms-campaign-first_en.pdf

33.0 million persons in 2008. The largest subsectors (at the NACE division level) were food and beverages manufacturing (which are not concerned by this impact assessment) and the manufacture of fabricated metal. The share of manufacturing within the nonfinancial business economy's value added varied in 2008 from 13.2% in Cyprus to 37.6% in Hungary. The range in employment terms was similar, from 13.5% in the Netherlands to 40.0% in Slovakia.

In 2008, there were about 2,123,000 enterprises active in manufacturing, employing approximately 32,961,000 people in the EU. 80.2% of the enterprises are micro-enterprise, 15.3% small enterprises, 3.7% medium-sized enterprises and 0.8% large enterprises. In the sector of manufacturing, the proportion of SMEs in the field of distributive trades is much higher. For these enterprises, unsafe and non-compliant products lead mainly to losses in turnover and market share due to unfair competition from competitors not complying with the rules.

Importers and distributors are mainly active in the field of distributive trade where most activities involve the purchase and resale of goods. The turnover is typically high: distributive trades generated 36.6% of non-financial business economy turnover in the EU-27 in 2008, which can be contrasted with an 18.7% share of value added. The substantial difference in these two output shares was reflected in the 5.1% gross operating rate, which was by far the lowest among the NACE sections in the non-financial business economy. Distributive trades is characterised by high levels of part-time employment, and this sector's workforce of 32.8 million persons, equivalent to almost a quarter (24.1%) of the EU-27 non-financial business economy workforce, was only slightly smaller than that for manufacturing. Among the 6.1 million enterprises classified to distributive trades and employing some 32,816,000 people. There are a small number of large national and international groups and a very high number of SMEs often providing proximity services: 93.4% are micro-enterprises, 5.8% are small enterprises, 0.7% are medium-sized enterprises and only 0.1% are large enterprises.

8. ANNEX 8: DIFFERENCES BETWEEN CONSUMER/NON-CONSUMER PRODUCTS AND HARMONISED/NON-HARMONISED PRODUCTS, INCLUDING DIFFERENCES RELATING TO PRODUCT SAFETY AND MARKET SURVEILLANCE OBLIGATIONS

8.1. Definitions

The so-called harmonised products are commonly understood to be products subject to Union harmonisation legislation, that is products subject any Union legislation harmonising the conditions for the marketing of products.[142] The indicative list of product sectors subject to these Directives is contained in section 2 below.

The so-called non-harmonised products are commonly understood to be products outside the scope of the Union harmonisation legislation. The definition of product subject to Union harmonisation legislation covers products sectors regulated by any of the New Approach or Old Approach Directives. The harmonisation of products properties can be full or partial. Products in the following sectors can be considered to be harmonised. In most cases these sectors include both consumer and professional products.

The so-called consumer products are commonly understood to be any product — including in the context of providing a service — which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.[143] A consumer product can be either a harmonised or a non-harmonised product: whether a concrete product will be or not a consumer product will depend on whether such product is "*intended for consumers or can be reasonably used by them*." Such determination would have to be done on case-by-case basis.

8.2. Indicative taxonomy of products depending on whether they consumer/professional and harmonised/ not-harmonised

There is a clear overlap between the area of consumer products and the area of harmonised products. The following table provide a very rough indication of the characterisation of main product categories as consumer/non-consumer or harmonised/non-harmonised.

This taxonomy is purely indicative as it can happen that a consumer product is subject to harmonised ruled for certain characteristics but not for other. Its classification in this case depends on the specific characteristics of the product that have raised the concern of a market surveillance authority. For instance a textile product (e.g. clothes) containing a substance prohibited under EU chemical legislation will be considered as harmonised; however if the same garment presents a risk because of the length of its cords, it will be considered as non-harmonised.

The list of products under each section of the table is non-exhaustive.

142 Art. 2 (21) of Regulation (EC) No 765/2008.

143 Art. 2 (a) of the General Product Safety Directive.

Table 1: Indicative taxonomy of products

Products	Consumer	Non-consumer
Harmonised	Certain chemical products Communication and media equipment Cosmetics Electrical appliances and equipment Certain gas appliances and components • Automotives • Certain construction products • Certain medical devices • Certain mechanical equipment (machinery, lifts) • Measuring instruments (meters, scales) Pressure equipment and simple pressure vessels (pressure cookers and fire extinguishers) Aerosols • Radio and telecommunications terminal equipment (R&TTE) • Toys • Recreational crafts Pyrotechnical articles (fireworks) Maritime equipment Any product indicated in the non-harmonised list if contains prohibited chemical substances/preparations	Certain chemical products Certain gas appliances and components • Automotives • Certain construction products • Electrical equipment • Equipment intended for use in potentially Explosive Atmospheres (ATEX) • Civil explosives • Certain medical devices Certain mechanical equipment (machinery, lifts) Professional measuring instruments • Pressure equipment and simple pressure vessels • Pyrotechnical articles for professional use (e.g. in airbags) • Rail Maritime equipment
Non-harmonised	Childcare articles and children's equipment Clothing, textiles and fashion items Decorative articles Furniture Hobby/sports equipment Jewellery Kitchen/cooking accessories Laser pointers Lighters Gadgets	See following section

Table 2: Description of the overall EU product safety infrastructure for categories of products

Products	Consumer	Non-consumer
Harmonised	Sector specific New and Old Approach Directives and the General Product Safety Directive	Sector specific New and Old Approach Directives
Non-harmonised	General Product Safety Directive	National product safety rules under a Mutual Recognition Regulation

Table 3: Examples of non-harmonised products[144]

Product code	Label
27012000	BRIQUETTES, OVOIDS AND SIMILAR SOLID FUELS MANUFACTURED FROM COAL
37012000	INSTANT PRINT FILM IN THE FLAT, SENSITISED, UNEXPOSED, WHETHER OR NOT IN PACKS
37013000	PHOTOGRAPHIC PLATES AND FILM IN THE FLAT, SENSITISED, UNEXPOSED, WITH ANY SIDE > 255 MM
37019100	PHOTOGRAPHIC PLATES AND FILM IN THE FLAT, SENSITISED, UNEXPOSED, OF ANY MATERIAL OTHER THAN PAPER, PAPERBOARD OR TEXTILES, FOR COLOUR PHOTOGRAPHY 'POLYCHROME' (EXCL. INSTANT PRINT FILM)
37019900	PHOTOGRAPHIC PLATES AND FILM IN THE FLAT FOR MONOCHROME PHOTOGRAPHY, SENSITISED, UNEXPOSED, OF ANY MATERIAL OTHER THAN PAPER, PAPERBOARD OR TEXTILES (EXCL. X-RAY FILM AND PHOTOGRAPHIC PLATES, FILM IN THE FLAT WITH ANY SIDE > 255 MM, AND INSTANT PRINT FILM)
37023120	PHOTOGRAPHIC FILM 'INCL. INSTANT PRINT FILM', IN ROLLS, SENSITISED, UNEXPOSED, WITHOUT PERFORATIONS, WIDTH <= 105 MM, FOR COLOUR PHOTOGRAPHY 'POLYCHROME', LENGTH <= 30 M (EXCL. THAT OF PAPER, PAPERBOARD OR TEXTILES)
39261000	OFFICE OR SCHOOL SUPPLIES, OF PLASTICS, N.E.S.
39263000	FITTINGS FOR FURNITURE, COACHWORK AND THE LIKE, OF PLASTICS (EXCL. BUILDING COMPONENTS FOR PERMANENT MOUNTING ON PARTS OF BUILDINGS)
42022210	HANDBAGS, WHETHER OR NOT WITH SHOULDER STRAPS, INCL. THOSE WITHOUT HANDLES, WITH OUTER SURFACE OF PLASTIC SHEETING
42022900	HANDBAGS, WHETHER OR NOT WITH SHOULDER STRAP, INCL. THOSE WITHOUT HANDLE, WITH OUTER SURFACE OF VULCANISED FIBRE OR PAPERBOARD, OR WHOLLY OR MAINLY COVERED WITH SUCH MATERIALS OR WITH PAPER
42023210	WALLETS, PURSES, KEY-POUCHES, CIGARETTE-CASES, TOBACCO-POUCHES AND SIMILAR ARTICLES CARRIED IN THE POCKET OR HANDBAG, WITH OUTER SURFACE OF PLASTIC SHEETING
42023900	WALLETS, PURSES, KEY-CASES, CIGARETTE-CASES, TOBACCO-POUCHES AND SIMILAR ARTICLES OF A KIND NORMALLY CARRIED IN THE POCKET OR HANDBAG, WITH OUTER SURFACE OF VULCANISED FIBRE OR PAPERBOARD, OR WHOLLY OR MAINLY COVERED WITH SUCH MATERIALS OR WITH PAPER, INCL. SPECTACLE CASES OF MOULDED PLASTIC MATERIAL
42029211	TRAVELLING-BAGS, TOILET BAGS, RUCKSACKS AND SPORTS BAGS, WITH OUTER SURFACE OF PLASTIC SHEETING
42029215	MUSICAL INSTRUMENT CASES WITH OUTER SURFACE OF PLASTIC SHEETING
46012110	MATS, MATTING AND SCREENS, FLAT-WOVEN OR BOUND TOGETHER IN PARALLEL, OF PLAITS OR SIMILAR PRODUCTS OF PLAITING MATERIALS OF BAMBOO, WORKED LENGTHWISE
46012190	MATS, MATTING AND SCREENS, OF BAMBOO PLAITING MATERIALS, FLAT-WOVEN OR BOUND TOGETHER IN PARALLEL (EXCL. THOSE OF PLAITS OR SIMILAR PRODUCTS OF PLAITING MATERIALS WORKED LENGTHWISE)
46012210	MATS, MATTING AND SCREENS, FLAT-WOVEN OR BOUND TOGETHER IN PARALLEL, OF PLAITS OR SIMILAR PRODUCTS OF PLAITING MATERIALS OF RATTAN, WORKED LENGTHWISE
46012290	MATS, MATTING AND SCREENS, OF RATTAN PLAITING MATERIALS, FLAT-WOVEN OR BOUND TOGETHER IN PARALLEL (EXCL. THOSE OF PLAITS OR SIMILAR PRODUCTS OF PLAITING MATERIALS WORKED LENGTHWISE)
46012910	MATS, MATTING AND SCREENS, OF VEGETABLE PLAITING MATERIALS, FLAT-WOVEN OR BOUND TOGETHER IN PARALLEL, OF PLAITS OR SIMILAR PRODUCTS OF PLAITING MATERIALS WORKED LENGTHWISE (EXCL. OF BAMBOO AND RATTAN)
46012990	MATS, MATTING AND SCREENS, OF VEGETABLE PLAITING MATERIALS, FLAT-WOVEN OR BOUND TOGETHER IN PARALLEL (EXCL. OF BAMBOO AND RATTAN AND THOSE OF PLAITS OR SIMILAR PRODUCTS OF PLAITING MATERIALS WORKED LENGTHWISE)
46019205	PLAITS AND SIMILAR PRODUCTS OF BAMBOO PLAITING MATERIALS WORKED LENGTHWISE, WHETHER OR NOT ASSEMBLED INTO STRIPS (EXCL. TWINE, CORD AND ROPE; PARTS OF FOOTWARE OR HEADGEAR)
46019210	PLAITING MATERIALS, PLAITS AND SIMILAR PRODUCTS OF BAMBOO PLAITING MATERIALS, FLAT-WOVEN OR BOUND TOGETHER IN PARALLEL, MADE OF PLAITS OR SIMILAR PLAITING MATERIALS WORKED LENGTHWISE (EXCL. MATS, MATTING AND SCREENS; WALLCOVERINGS OF HEADING 4814; PARTS OF FOOTWARE OR HEADGEAR)
46019290	PLAITING MATERIALS, PLAITS AND SIMILAR PRODUCTS OF BAMBOU PLAITING MATERIALS, FLAT-WOVEN OR BOUND TOGETHER IN PARALLEL (EXCL. THOSE OF PLAITS OR SIMILAR PRODUCTS OF PLAITING MATERIALS WORKED LENGTHWISE; MATS, MATTING AND SCREENS; WALLCOVERINGS OF HEADING 4814; PARTS OF FOOTWARE OR HEADGEAR)
46019305	PLAITS AND SIMILAR PRODUCTS OF RATTAN PLAITING MATERIALS WORKED LENGTHWISE, WHETHER OR NOT ASSEMBLED INTO STRIPS (EXCL. TWINE, CORD AND ROPE; PARTS OF FOOTWARE OR HEADGEAR)
46019310	PLAITING MATERIALS, PLAITS AND SIMILAR PRODUCTS OF RATTAN MATERIALS, FLAT-WOVEN OR BOUND TOGETHER IN PARALLEL, MADE OF PLAITS OR SIMILAR PLAITING MATERIALS WORKED LENGTHWISE (EXCL. MATS, MATTING AND SCREENS; WALLCOVERINGS OF HEADING 4814; PARTS OF FOOTWARE OR HEADGEAR)
46019390	PLAITING MATERIALS, PLAITS AND SIMILAR PRODUCTS OF RATTAN PLAITING MATERIALS, FLAT-

144 http://ec.europa.eu/enterprise/intsub/a12/index.cfm?fuseaction=a12.menuproducts#).

	WOVEN OR BOUND TOGETHER IN PARALLEL (EXCL. THOSE OF PLAITS OR SIMILAR PRODUCTS OF PLAITING MATERIALS WORKED LENGTHWISE; MATS, MATTING AND SCREENS; WALLCOVERINGS OF HEADING 4814; PARTS OF FOOTWARE OR HEADGEAR)
46019405	PLAITS AND SIMILAR PRODUCTS OF VEGETABLE PLAITING MATERIALS WORKED LENGTHWISE, WHETHER OR NOT ASSEMBLED INTO STRIPS (EXCL. OF BAMBOO AND RATTAN, AND TWINE, CORD AND ROPE; PARTS OF FOOTWARE OR HEADGEAR)
46019410	PLAITING MATERIALS, PLAITS AND SIMILAR PRODUCTS OF VEGETABLE MATERIALS, FLAT-WOVEN OR BOUND TOGETHER IN PARALLEL, MADE OF PLAITS OR SIMILAR PLAITING MATERIALS WORKED LENGTHWISE (EXCL. OF BAMBOO AND RATTAN; MATS, MATTING AND SCREENS; WALLCOVERINGS OF HEADING 4814; PARTS OF FOOTWARE OR HEADGEAR)
46019490	PLAITING MATERIALS, PLAITS AND SIMILAR PRODUCTS OF VEGETABLE PLAITING MATERIALS, FLAT-WOVEN OR BOUND TOGETHER IN PARALLEL (EXCL. OF BAMBOO AND RATTAN; THOSE OF PLAITS OR SIMILAR PRODUCTS OF PLAITING MATERIALS WORKED LENGTHWISE; MATS, MATTING AND SCREENS; WALLCOVERINGS OF HEADING 4814; PARTS OF FOOTWARE OR HEADGEAR) OTHER
46019905	PLAITS AND SIMILAR PRODUCTS OF NON-VEGETABLE PLAITING MATERIALS WORKED LENGTHWISE, WHETHER OR NOT ASSEMBLED INTO STRIPS (EXCL. TWINE, CORD AND ROPE; PARTS OF FOOTWARE OR HEADGEAR)
46019910	PLAITING MATERIALS, PLAITS AND SIMILAR PRODUCTS OF NON-VEGETABLE PLAITING MATERIALS, FLAT-WOVEN OR BOUND TOGETHER IN PARALLEL, MADE OF PLAITS OR SIMILAR PLAITING MATERIALS WORKED LENGTHWISE (EXCL. WALLCOVERINGS OF HEADING 4814; PARTS OF FOOTWARE OR HEADGEAR)
46019990	PLAITING MATERIALS, PLAITS AND SIMILAR PRODUCTS OF NON-VEGETABLE MATERIALS, FLAT-WOVEN OR BOUND TOGETHER IN PARALLEL (EXCL. THOSE MADE OF PLAITS OR SIMILAR PRODUCTS OF PLAITING MATERIALS WORKED LENGTHWISE; WALLCOVERINGS OF HEADING 4814; PARTS OF FOOTWARE OR HEADGEAR)
48021000	HANDMADE PAPER AND PAPERBOARD OF ANY SIZE OR SHAPE
48022000	PAPER AND PAPERBOARD OF A KIND USED AS A BASE FOR PHOTOSENSITIVE, HEAT-SENSITIVE OR ELECTROSENSITIVE PAPER AND PAPERBOARD, UNCOATED, IN ROLLS OR IN SQUARE OR RECTANGULAR SHEETS, OF ANY SIZE
48184011	SANITARY TOWELS OF PAPER PULP, PAPER, CELLULOSE WADDING OR WEBS OF CELLULOSE FIBRES
48184013	TAMPONS OF PAPER PULP, PAPER, CELLULOSE WADDING OR WEBS OF CELLULOSE FIBRES
48184019	FEMININE HYGIENE PRODUCTS OF PAPER PULP, PAPER, CELLULOSE WADDING OR WEBS OF CELLULOSE FIBRES (EXCL. SANITARY TOWELS AND TAMPONS)
48184091	'NAPKINS AND NAPKIN LINERS FOR BABIES, OF PAPER PULP, PAPER, CELLULOSE WADDING OR WEBS OF CELLULOSE FIBRES'
48184099	'SANITARY ARTICLES, OF PAPER PULP, PAPER, CELLULOSE WADDING OR WEBS OF CELLULOSE FIBRES, FOR EXAMPLE, INCONTINENCE CARE ARTICLES (EXCL. SANITARY TOWELS, TAMPONS, NAPKINS AND NAPKIN LINERS FOR BABIES)'
48189090	PAPER, CELLULOSE WADDING OR WEBS OF CELLULOSE FIBRES, OF A KIND USED FOR HOUSEHOLD OR SANITARY PURPOSES, IN ROLLS OF A WIDTH <= 36 CM, OR CUT TO SIZE OR SHAPE; ARTICLES OF PAPER PULP, PAPER, CELLULOSE WADDING OR WEBS OF CELLULOSE FIBRES FOR HOUSEHOLD, SANITARY OR HOSPITAL USE (EXCL. TOILET PAPER, HANDKERCHIEFS, CLEANSING OR FACIAL TISSUES AND TOWELS, TABLECLOTHS, SERVIETTES, SANITARY TOWELS AND TAMPONS, NAPKINS AND NAPKIN LINERS FOR BABIES AND SIMILAR SANITARY ARTICLES, AND ARTICLES OF A KIND USED FOR SURGICAL, MEDICAL OR HYGIENIC PURPOSES NOT PUT UP FOR RETAIL SALE)
48201010	REGISTERS, ACCOUNT BOOKS, ORDER BOOKS AND RECEIPT BOOKS, OF PAPER OR PAPERBOARD
48201030	NOTEBOOKS, LETTER PADS AND MEMORANDUM PADS, WITHOUT CALENDARS, OF PAPER OR PAPERBOARD
48201050	DIARIES WITH CALENDARS, OF PAPER OR PAPERBOARD
48201090	WRITING PADS AND THE LIKE, OF PAPER OR PAPERBOARD
48202000	EXERCISE BOOKS OF PAPER OR PAPERBOARD
48203000	BINDERS (OTHER THAN BOOK COVERS), FOLDERS AND FILE COVERS, OF PAPER OR PAPERBOARD
48205000	ALBUMS FOR SAMPLES OR COLLECTIONS, OF PAPER OR PAPERBOARD
48209000	BLOTTING PADS AND SIMILAR ARTICLES OF STATIONERY, OF PAPER AND PAPERBOARD, AND BOOK COVERS OF PAPER OR PAPERBOARD (EXCL. REGISTERS, ACCOUNT BOOKS, NOTEBOOKS, ORDER BOOKS, RECEIPT BOOKS, LETTER PADS, MEMORANDUM PADS, DIARIES, EXERCISE BOOKS, BINDERS, FOLDERS, FILE COVERS, MANIFOLD BUSINESS FORMS AND INTERLEAVED CARBON SETS, AND ALBUMS FOR SAMPLES OR FOR COLLECTIONS)
48234000	ROLLS, SHEETS AND DIALS, PRINTED FOR SELF-RECORDING APPARATUS, IN ROLLS OF A WIDTH <= 36 CM, IN RECTANGULAR OR SQUARE SHEETS OF WHICH NO SIDE > 36 CM IN THE UNFOLDED STATE, OR CUT INTO DIALS
48239040	PAPER AND PAPERBOARD USED FOR WRITING, PRINTING OR OTHER GRAPHIC PURPOSES, N.E.S.
49011000	PRINTED BOOKS, BROCHURES AND SIMILAR PRINTED MATTER, IN SINGLE SHEETS, WHETHER OR NOT FOLDED (EXCL. PERIODICALS AND PUBLICATIONS WHICH ARE ESSENTIALLY DEVOTED TO ADVERTISING)
49019100	DICTIONARIES AND ENCYCLOPAEDIAS, AND SERIAL INSTALMENTS THEREOF
49019900	PRINTED BOOKS, BROCHURES AND SIMILAR PRINTED MATTER (EXCL. THOSE IN SINGLE SHEETS; DICTIONARIES, ENCYCLOPAEDIAS, PERIODICALS AND PUBLICATIONS WHICH ARE ESSENTIALLY DEVOTED TO ADVERTISING)
49021000	NEWSPAPERS, JOURNALS AND PERIODICALS, WHETHER OR NOT ILLUSTRATED OR CONTAINING ADVERTISING MATERIAL, APPEARING AT LEAST FOUR TIMES A WEEK

49029000 NEWSPAPERS, JOURNALS AND PERIODICALS, WHETHER OR NOT ILLUSTRATED OR CONTAINING ADVERTISING MATERIAL (EXCL. THOSE APPEARING AT LEAST FOUR TIMES A WEEK)
49030000 CHILDREN'S PICTURE, DRAWING OR COLOURING BOOKS
49040000 MUSIC, PRINTED OR IN MANUSCRIPT, WHETHER OR NOT BOUND OR ILLUSTRATED
49051000 GLOBES, PRINTED (EXCL. RELIEF GLOBES)
49059100 MAPS AND HYDROGRAPHIC OR SIMILAR CHARTS OF ALL KINDS, INCL. ATLASES AND TOPOGRAPHICAL PLANS, PRINTED AND IN BOOK FORM (EXCL. GLOBES, AND MAPS AND PLANS, IN RELIEF)
49059900 MAPS AND HYDROGRAPHIC OR SIMILAR CHARTS OF ALL KINDS, INCL. ATLASES, WALL MAPS AND TOPOGRAPHICAL PLANS, PRINTED (EXCL. THOSE IN BOOK FORM, AND MAPS, PLANS AND GLOBES, IN RELIEF)
49060000 PLANS AND DRAWINGS FOR ARCHITECTURAL, ENGINEERING, INDUSTRIAL, COMMERCIAL, TOPOGRAPHICAL OR SIMILAR PURPOSES, BEING ORIGINALS DRAWN BY HAND; HANDWRITTEN TEXTS; PHOTOGRAPHIC REPRODUCTIONS ON SENSITISED PAPER AND CARBON COPIES OF THE FOREGOING
49070010 UNUSED POSTAGE, REVENUE OR SIMILAR STAMPS OF CURRENT OR NEW ISSUE IN THE COUNTRY IN WHICH THEY HAVE, OR WILL HAVE, A RECOGNISED FACE VALUE
49070030 BANKNOTES
49070090 STAMP-IMPRESSED PAPER; CHEQUE FORMS; STOCK, SHARE OR BOND CERTIFICATES AND SIMILAR DOCUMENTS
49090000 PRINTED OR ILLUSTRATED POSTCARDS; PRINTED CARDS BEARING PERSONAL GREETINGS, MESSAGES OR ANNOUNCEMENTS, WHETHER OR NOT ILLUSTRATED, WITH OR WITHOUT ENVELOPES OR TRIMMINGS
49100000 CALENDARS OF ANY KINDS, PRINTED, INCL. CALENDARS BLOCKS
49119100 PICTURES, PRINTS AND PHOTOGRAPHS, N.E.S.
49119900 PRINTED MATTER, N.E.S.
65010000 HAT-FORMS, HAT BODIES AND HOODS OF FELT, NEITHER BLOCKED TO SHAPE NOR WITH MADE BRIMS; PLATEAUX AND MANCHONS, INCL. SLIT MANCHONS, OF FELT
67021000 ARTIFICIAL FLOWERS, FOLIAGE AND FRUIT AND PARTS THEREOF, AND ARTICLES MADE OF ARTIFICIAL FLOWERS, FOLIAGE OR FRUIT, BY BINDING, GLUEING, FITTING INTO ONE ANOTHER OR SIMILAR METHODS, OF PLASTICS
67029000 ARTIFICIAL FLOWERS, FOLIAGE AND FRUIT AND PARTS THEREOF, AND ARTICLES MADE OF ARTIFICIAL FLOWERS, FOLIAGE OR FRUIT, BY BINDING, GLUEING, FITTING INTO ONE ANOTHER OR SIMILAR METHODS (EXCL. OF PLASTICS)
67042000 WIGS, FALSE BEARDS, EYEBROWS AND EYELASHES, SWITCHES AND THE LIKE, OF HUMAN HAIR, AND ARTICLES OF HUMAN HAIR, N.E.S.
68043000 HAND SHARPENING OR POLISHING STONES
68051000 NATURAL OR ARTIFICIAL ABRASIVE POWDER OR GRAIN, ON A BASE OF WOVEN TEXTILE FABRIC ONLY, WHETHER OR NOT CUT TO SHAPE, SEWN OR OTHERWISE MADE UP
68052000 NATURAL OR ARTIFICIAL ABRASIVE POWDER OR GRAIN, ON A BASE OF PAPER OR PAPERBOARD ONLY, WHETHER OR NOT CUT TO SHAPE, SEWN OR OTHERWISE MADE UP
68053010 NATURAL OR ARTIFICIAL ABRASIVE POWDER OR GRAIN, ON A BASE OF WOVEN TEXTILE FABRIC COMBINED WITH PAPER OR PAPERBOARD, WHETHER OR NOT CUT TO SHAPE, SEWN OR OTHERWISE MADE UP
68053020 NATURAL OR ARTIFICIAL ABRASIVE POWDER OR GRAIN, ON A BASE OF VULCANISED FIBRE, WHETHER OR NOT CUT TO SHAPE, SEWN OR OTHERWISE MADE UP
68053080 NATURAL OR ARTIFICIAL ABRASIVE POWDER OR GRAIN, ON A BASE OTHER THAN OF MERELY WOVEN TEXTILE FABRIC OR OF MERELY PAPER OR PAPERBOARD OF WOVEN TEXTILE FABRIC COMBINED WITH PAPER OR PAPERBOARD OR OF VULCANISED FIBRE, WHETHER OR NOT CUT TO SHAPE, SEWN OR OTHERWISE MADE UP
70181011 GLASS BEADS, CUT AND MECHANICALLY POLISHED (EXCL. ARTICLES THEREOF)
70181019 GLASS BEADS (EXCL. BEADS, CUT AND MECHANICALLY POLISHED, AND ARTICLES THEREOF)
70181030 IMITATION PEARLS OF GLASS (EXCL. ARTICLES THEREOF)
70181051 IMITATION PRECIOUS AND SEMI-PRECIOUS STONES OF GLASS, CUT AND MECHANICALLY POLISHED (EXCL. ARTICLES THEREOF)
70181059 IMITATION PRECIOUS AND SEMI-PRECIOUS STONES OF GLASS (EXCL. BEADS, CUT AND MECHANICALLY POLISHED, AND ARTICLES THEREOF)
70181090 IMITATION CORAL AND SIMILAR GLASS SMALLWARES (EXCL. ARTICLES THEREOF AND IMITATION PEARLS, PRECIOUS AND SEMI-PRECIOUS STONES)
70182000 GLASS MICROSPHERES <= 1 MM IN DIAMETER
70189010 GLASS EYES, ARTICLES OF GLASS BEADS, OR OF IMITATION PEARLS, IMITATION PRECIOUS OR SEMI-PRECIOUS STONES, OR OF OTHER GLASS SMALLWARES (EXCL. PROSTHETIC ARTICLES AND IMITATION JEWELLERY)
70189090 STATUETTES AND OTHER ORNAMENTS OF LAMP-WORKED GLASS (EXCL. IMITATION JEWELLERY)
71011000 PEARLS, NATURAL, WHETHER OR NOT WORKED OR GRADED, BUT NOT STRUNG, MOUNTED OR SET, NATURAL PEARLS, TEMPORARILY STRUNG FOR CONVENIENCE OF TRANSPORT (EXCL. MOTHER-OF-PEARL)
71081100 GOLD, INCL. GOLD PLATED WITH PLATINUM, FOR NON-MONETARY PURPOSES
71081200 GOLD, INCL. GOLD PLATED WITH PLATINUM, UNWROUGHT, FOR NON-MONETARY PURPOSES (EXCL. GOLD IN POWDER FORM)
71159010 ARTICLES OF PRECIOUS METAL, N.E.S.

71159090 ARTICLES OF METAL CLAD WITH PRECIOUS METAL, N.E.S.
71161000 ARTICLES OF NATURAL OR CULTURED PEARLS, N.E.S.
71162011 NECKLACES, BRACELETS AND OTHER ARTICLES, WHOLLY OF NATURAL PRECIOUS OR SEMI-PRECIOUS STONES, SIMPLY STRUNG, WITHOUT FASTENERS OR OTHER ACCESSORIES
71162019 ARTICLES MADE WHOLLY OF NATURAL PRECIOUS OR SEMI-PRECIOUS STONES, N.E.S.
71162090 ARTICLES OF PRECIOUS OR SEMI-PRECIOUS STONES 'NATURAL, SYNTHETIC OR RECONSTRUCTED', N.E.S. (EXCL. MADE WHOLLY OF NATURAL PRECIOUS OR SEMI-PRECIOUS STONES)
71181010 SILVER COIN (EXCL. COIN BEING LEGAL TENDER, MEDALS, JEWELLERY OF COINS, COLLECTORS' COINS, WASTE AND SCRAP)
71181090 COIN (EXCL. COIN BEING LEGAL TENDER, GOLD AND SILVER COIN, MEDALS, JEWELLERY OF COINS, COLLECTORS' COINS, WASTE AND SCRAP)
71189000 COIN OF LEGAL TENDER
73130000 BARBED WIRE OF IRON OR STEEL; TWISTED HOOP OR SINGLE FLAT WIRE, BARBED OR NOT, AND LOOSELY TWISTED DOUBLE WIRE, OF A KIND USED FOR FENCING, OF IRON OR STEEL
73160000 ANCHORS, GRAPNELS AND PARTS THEREOF, OF IRON OR STEEL
73269010 SNUFFBOXES, CIGARETTE CASES, COSMETIC AND POWDER BOXES AND CASES, AND SIMILAR POCKET ARTICLES, OF IRON OR STEEL
83013000 LOCKS USED FOR FURNITURE, OF BASE METAL
83017000 KEYS PRESENTED SEPARATELY FOR PADLOCKS, LOCKS, CLASPS AND FRAMES WITH CLASPS INCORPORATING LOCKS, OF BASE METAL, N.E.S
83025000 HAT-RACKS, HAT-PEGS, BRACKETS AND SIMILAR FIXTURES OF BASE METAL
83030010 ARMOURED OR REINFORCED SAFES AND STRONGBOXES, OF BASE METAL
83030030 ARMOURED OR REINFORCED DOORS AND SAFE DEPOSIT LOCKERS FOR STRONGROOMS, OF BASE METAL
83030090 CASH OR DEED BOXES AND THE LIKE, OF BASE METAL (EXCL. ARMOURED OR REINFORCED SAFES, STRONGBOXES, DOORS AND SAFE DEPOSIT LOCKERS FOR STRONGROOMS)
83040000 FILING CABINETS, CARD-INDEX CABINETS, PAPER TRAYS, PAPER RESTS, PEN TRAYS, OFFICE-STAMP STANDS AND SIMILAR OFFICE OR DESK EQUIPMENT, OF BASE METAL (EXCL. OFFICE FURNITURE OF HEADING 9403 AND WASTE PAPER BINS)
83051000 FITTINGS FOR LOOSE-LEAF BINDERS OR FILES, OF BASE METAL (EXCL. DRAWING PINS AND CLASPS FOR BOOKS OR REGISTERS)
83052000 STAPLES IN STRIPS, OF BASE METAL
83059000 OFFICE ARTICLES SUCH AS LETTER CLIPS, LETTER CORNERS, PAPER CLIPS AND INDEXING TAGS, OF BASE METAL, INCL. PARTS OF ARTICLES OF HEADING 8305 (EXCL. FITTINGS FOR LOOSE-LEAF BINDERS OR FILES, STAPLES IN STRIPS, DRAWING PINS AND CLASPS FOR BOOKS OR REGISTERS)
83061000 BELLS, GONGS AND THE LIKE, NON-ELECTRIC, OF BASE METAL (EXCL. MUSICAL INSTRUMENTS)
83063000 PHOTOGRAPH, PICTURE OR SIMILAR FRAMES, OF BASE METAL; MIRRORS OF BASE METAL (EXCL. OPTICAL ELEMENTS)
83081000 HOOKS, EYES AND EYELETS, OF BASE METAL, OF A KIND USED FOR CLOTHING, FOOTWEAR, AWNINGS, HANDBAGS, TRAVEL GOODS OR OTHER MADE-UP ARTICLES
83089000 CLASPS, FRAMES WITH CLASPS WITHOUT LOCKS, BUCKLES AND BUCKLE-CLASPS, OF BASE METAL, FOR CLOTHING, FOOTWEAR, HANDBAGS, TRAVEL GOODS OR OTHER MADE-UP ARTICLES, INCL. PARTS OF ARTICLES OF HEADING 8308, OF BASE METAL (EXCL. HOOKS, EYES, EYELETS AND TUBULAR OR BIFURCATED RIVETS)
83100000 SIGN-PLATES, NAMEPLATES, ADDRESS-PLATES AND SIMILAR PLATES, NUMBERS, LETTERS AND OTHER SYMBOLS, OF BASE METAL, INCL. TRAFFIC SIGNS (EXCL. THOSE OF HEADING 9405, TYPE AND THE LIKE, AND SIGNAL BOARDS, SIGNAL DISCS AND SIGNAL ARMS FOR TRAFFIC OF HEADING 8608)
84842000 MECHANICAL SEALS
87142000 PARTS AND ACCESSORIES FOR CARRIAGES FOR DISABLED PERSONS, N.E.S.
89071000 INFLATABLE RAFTS
89079000 RAFTS, TANKS, COFFER-DAMS, LANDING STAGES, BUOYS, BEACONS AND OTHER FLOATING STRUCTURES (EXCL. INFLATABLE RAFTS, VESSELS OF HEADING 8901 TO 8906 AND FLOATING STRUCTURES FOR BREAKING UP)
90172011 DRAWING SETS
91111000 CASES FOR WRIST-WATCHES, POCKET-WATCHES AND OTHER WATCHES OF HEADING 9101 OR 9102, OF PRECIOUS METAL OR OF METAL CLAD WITH PRECIOUS METAL
91112000 CASES FOR WRIST-WATCHES, POCKET-WATCHES AND OTHER WATCHES OF HEADING 9101 OR 9102, OF BASE METAL, WHETHER OR NOT GOLD- OR SILVER-PLATED
91118000 CASES FOR WRIST-WATCHES, POCKET-WATCHES AND OTHER WATCHES OF HEADING 9101 OR 9102, OF MATERIALS OTHER THAN PRECIOUS METAL, CLAD WITH PRECIOUS METAL OR BASE METAL
91119000 PARTS OF CASES FOR WRIST-WATCHES, POCKET-WATCHES AND OTHER WATCHES OF HEADING 9101 OR 9102, N.E.S.
91122000 CLOCK AND WATCH CASES (EXCL. FOR WRIST-WATCHES, POCKET-WATCHES AND OTHER WATCHES OF HEADING 9101 OR 9102)
91129000 PARTS OF CLOCK AND WATCH CASES, N.E.S. (EXCL. FOR WRIST-WATCHES, POCKET-WATCHES AND OTHER WATCHES OF HEADING 9101 OR 9102)
91131010 WATCH STRAPS, WATCH BANDS AND WATCH BRACELETS, AND PARTS THEREOF, OF PRECIOUS METAL, N.E.S.
91131090 WATCH STRAPS, WATCH BANDS AND WATCH BRACELETS, AND PARTS THEREOF, OF METAL CLAD WITH PRECIOUS METAL, N.E.S.
91132000 WATCH STRAPS, WATCH BANDS AND WATCH BRACELETS, AND PARTS THEREOF, OF BASE METAL,

WHETHER OR NOT GOLD- OR SILVER-PLATED, N.E.S.
91139080 WATCH STRAPS, WATCH BANDS AND WATCH BRACELETS, AND PARTS THEREOF, N.E.S.
92021010 VIOLINS
92021090 STRING MUSICAL INSTRUMENTS PLAYED WITH A BOW (EXCL. VIOLINS)
92029080 MANDOLINS, ZITHERS AND OTHER STRING MUSICAL INSTRUMENTS (EXCL. WITH KEYBOARD, THOSE PLAYED WITH A BOW AND GUITARS)
92051000 BRASS-WIND INSTRUMENTS
92059030 MOUTH ORGANS
92059090 WIND MUSICAL INSTRUMENTS (EXCL. BRASS-WIND INSTRUMENTS, ACCORDIONS AND SIMILAR INSTRUMENTS, MOUTH ORGANS, KEYBOARD PIPE ORGANS, AND HARMONIUMS AND SIMILAR KEYBOARD INSTRUMENTS WITH FREE METAL REEDS)
92060000 PERCUSSION MUSICAL INSTRUMENTS, E.G. DRUMS, XYLOPHONES, CYMBALS, CASTANETS, MARACAS
92081000 MUSICAL BOXES
92089000 FAIRGROUND ORGANS, MECHANICAL STREET ORGANS, MECHANICAL SINGING BIRDS, MUSICAL SAWS AND OTHER MUSICAL INSTRUMENTS NOT FALLING WITHIN ANY OTHER HEADING IN CHAPTER 92; DECOY CALLS OF ALL KINDS; WHISTLES, CALL HORNS AND OTHER MOUTH-BLOWN SOUND SIGNALLING INSTRUMENTS
92093000 MUSICAL INSTRUMENT STRINGS
92099940 METRONOMES, TUNING FORKS AND PITCH PIPES
92099950 MECHANISMS FOR MUSICAL BOXES
92099970 PARTS AND ACCESSORIES 'E.G. CARDS, DISCS AND ROLLS FOR MECHANICAL INSTRUMENTS', FOR ACCORDIONS AND SIMILAR INSTRUMENTS, MOTH ORGANS, MUSICAL BOXES , FAIRGROUND ORGANS, MECHANICAL STREET ORGANS AND OTHER MUSICAL INSTRUMENTS, N.E.S. (EXCL. METRONOMES, TUNING FORKS, PITCH PIPES, MECHANISMS FOR MUSICAL BOXES, MUSICAL INSTRUMENT STRINGS, AND THOSE FOR PIANOS, STRING MUSICAL INSTRUMENTS WITHOUT KEYBOARDS, KEYBOARD PIPE ORGANS, HARMONIUMS AND SIMILAR KEYBOARD INSTRUMENTS AND WIND MUSICAL INSTRUMENTS)
94049010 ARTICLES OF BEDDING AND SIMILAR FURNISHING, FILLED WITH FEATHER OR DOWN (EXCL. MATTRESSES AND SLEEPING BAGS)
96031000 BROOMS AND BRUSHES, CONSISTING OF TWIGS OR OTHER VEGETABLE MATERIALS BOUND TOGETHER, WITH OR WITHOUT HANDLES
96032100 TOOTH BRUSHES, INCL. DENTAL-PLATE BRUSHES
96032980 SHAVING BRUSHES, NAIL BRUSHES, EYELASH BRUSHES AND OTHER BRUSHES FOR USE ON THE PERSON (EXCL. TOOTH BRUSHES, DENTAL-PLATE BRUSHES AND HAIR BRUSHES)
96033010 ARTISTS' AND WRITING BRUSHES
96033090 BRUSHES FOR THE APPLICATION OF COSMETICS
96034010 PAINT, DISTEMPER, VARNISH OR SIMILAR BRUSHES (EXCL. ARTISTS' AND SIMILAR BRUSHES OF SUBHEADING 9603.30)
96034090 PAINT PADS AND ROLLERS
96035000 BRUSHES CONSTITUTING PARTS OF MACHINES, APPLIANCES OR VEHICLES
96039010 HAND-OPERATED MECHANICAL FLOOR SWEEPERS, NOT MOTORISED
96039091 ROAD-SWEEPING BRUSHES; HOUSEHOLD TYPE BROOMS AND BRUSHES, INCL. SHOE BRUSHES AND CLOTHES BRUSHES; BRUSHES FOR GROOMING ANIMALS (EXCL. BRUSHES CONSTITUTING PARTS OF MACHINES, APPLIANCES OR VEHICLES, AND BROOMS OR BRUSHES CONSISTING OF TWIGS OR OTHER VEGETABLE MATERIALS)
96071100 SLIDE FASTENERS FITTED WITH CHAIN SCOOPS OF BASE METAL
96071900 SLIDE FASTENERS (EXCL. FITTED WITH CHAIN SCOOPS OF BASE METAL)
96072010 PARTS OF SLIDE FASTENERS OF BASE METAL
96072090 PARTS OF SLIDE FASTENERS (OTHER THAN OF BASE METAL)
96100000 SLATES AND BOARDS, WITH WRITING OR DRAWING SURFACES, WHETHER OR NOT FRAMED
96110000 HAND-OPERATED DATE, SEALING OR NUMBERING STAMPS, AND THE LIKE; HAND-OPERATED COMPOSING STICKS AND HAND PRINTING SETS
96121010 TYPEWRITER OR SIMILAR RIBBONS, INKED OR OTHERWISE PREPARED FOR GIVING IMPRESSIONS, WHETHER OR NOT ON SPOOLS OR IN CARTRIDGES, OF PLASTICS (EXCL. WOVEN OF TEXTILE MATERIALS)
96121020 RIBBONS MADE FROM MAN-MADE FIBRES, OF A WIDTH OF < 30 MM, PERMANENTLY ENCLOSED IN PLASTIC OR METAL CARTRIDGES, OF A KIND USED IN AUTOMATIC TYPEWRITERS, AUTOMATIC DATA-PROCESSING EQUIPMENT AND OTHER EQUIPMENT
96121080 TYPEWRITER OR SIMILAR RIBBONS, INKED OR OTHERWISE PREPARED FOR GIVING IMPRESSIONS, WHETHER OR NOT IN SPOOLS OR CARTRIDGES, MADE FROM FIBRES OR PAPER (EXCL. THOSE MADE FROM MAN-MADE FIBRES OF SUBHEADING 9612.10.20)
96122000 INK-PADS, WHETHER OR NOT INKED, WITH OR WITHOUT BOXES
96151100 COMBS, HAIR-SLIDES AND THE LIKE OF HARD RUBBER OR PLASTICS
96159000 HAIRPINS, CURLING PINS, CURLING GRIPS, HAIR-CURLERS AND THE LIKE, AND PARTS THEREOF, N.E.S. (EXCL. ELECTRO-THERMIC APPLIANCES OF HEADING 8516)
96161010 SCENT SPRAYS AND SIMILAR TOILET SPRAYS
96161090 MOUNTS AND HEADS FOR SCENT SPRAYS AND SIMILAR TOILET SPRAYS
96162000 POWDER PUFFS AND PADS FOR THE APPLICATION OF COSMETICS OR TOILET PREPARATIONS
96180000 TAILORS' DUMMIES AND OTHER LAY FIGURES, AUTOMATA AND OTHER ANIMATED DISPLAYS USED FOR SHOP WINDOW DRESSING (EXCL. THE ARTICLES ACTUALLY ON DISPLAY, EDUCATIONAL MODELS AND TOY DOLLS)

	PAINTINGS, E.G. OIL PAINTINGS, WATERCOLOURS AND PASTELS, AND DRAWINGS EXECUTED
97011000	ENTIRELY BY HAND (EXCL. TECHNICAL DRAWINGS AND THE LIKE OF HEADING 4906, AND HAND-PAINTED OR HAND-DECORATED MANUFACTURED ARTICLES)
97019000	COLLAGES AND SIMILAR DECORATIVE PLAQUES
97020000	ORIGINAL ENGRAVINGS, PRINTS AND LITHOGRAPHS
97030000	ORIGINAL SCULPTURES AND STATUARY, IN ANY MATERIAL
	POSTAGE OR REVENUE STAMPS, STAMP-POSTMARKS, FIRST-DAY COVERS, POSTAL STATIONERY,
97040000	STAMPED PAPER AND THE LIKE, USED, OR IF UNUSED, NOT OF CURRENT OR NEW ISSUE IN WHICH THEY HAVE, OR WILL HAVE, A RECOGNISED FACE VALUE
97060000	ANTIQUES OF > 100 YEARS OLD

8.3 Differences between product safety obligations between non-harmonised consumer products and harmonised products and their alignment

Table 4: Differences between certain consumer product safety requirements and harmonised product safety requirements with respect to producers (manufacturers and importers)

Non-harmonised consumer product safety requirements[145]	Harmonised consumer product safety requirements[146]
GENERAL OBLIGATION TO PUT ONLY SAFE PRODUCTS ON THE MARKET	
Obligation of producers* to put only safe products on the market (the general safety requirement)	Obligation of manufacturers to put on the market only products designed and manufactured in accordance with the essential safety requirements [set out in the relevant sector-specific harmonised legislation].
* Producer includes manufacturer and importer (providing that with respect to the latter, there is no manufacturer's representative established within the EU if the manufacturer is not established within the EU)	Obligation of importers to place only safe products on the EU market.
Manufacturer is defined as a person established within the EU and any other person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product.	Manufacturer is defined as any natural or legal person who manufactures a product or has a product designed or manufactured and markets that product under his name or trademark.
Importer is not specifically defined in the General Product Safety Directive.	Importer is defined as any natural or legal person established in the Union who places a product from a third country on the Union market.
OBLIGATION TO KEEP RELEVANT TECHNICAL DOCUMENTATION	
Not explicitly defined in the General Product Safety Directive, but the obligation of producers to keep relevant technical documentation can be implied from (i) the general obligation to put only safe products on the market, (ii) the obligation to keep oneself informed of the risks that the product may pose and (iii) the obligation to provide market surveillance authorities with all necessary information relating to the product in question.	Obligation of manufacturers to keep the relevant technical documentation and make sure that her products comply with technical documentation, including products produced in series production.
OBLIGATION TO EQUIP THE PRODUCT WITH SAFETY INSTRUCTIONS	
Obligation of producers to inform consumers so that they can assess risk which their products may pose and to take appropriate precautions.	Obligation of manufacturers to accompany the product with safety information and instructions, if justified.
OBLIGATION TO IDENTIFY THE PRODUCT AND THE PRODUCER (THE	

145 Under the General Product Safety Directive.

146 Under Decision (No) 768/2008.

MANUFACTURER AND/OR THE IMPORTER)	
Obligation of producers to keep informed of risks which products may pose, for example, by: (i) identifying the producer[147] (by giving information on identity and details), (ii) identifying the product (by giving product reference or the batch of products to which it belongs). The aforementioned information should appear on the product or its packaging, except where not to give such indication is justified.	Obligation of manufacturers to (i) indicate name, registered trade name or registered trade mark and the address on which they may be contacted (a single point of contact), and (ii) ensure that products bears a type, batch or serial number or other element allowing for the identification of the product. Obligation of the importer to indicate name, registered trade name or registered trade mark and the address on which they may be contacted (a single point of contact), [in addition to the manufacturer] The aforementioned information should appear on the product or, where that is not possible, its packaging or in a document accompanying the product.
OBLIGATIONS DURING TRANSPORT OF THE PRODUCT	
This obligation of producers is not explicitly laid down in the General Product Safety Directive, but it can be implied from the general obligation to put only safe products on the market.	Obligation of importers to ensure that while the product is under their responsibility, storage and transport conditions do not jeopardise its compliance with the requirements [set out in the relevant sector-specific harmonised legislation].

147 Either manufacturer or importer.

Table 5: Alignment of non-harmonised consumer product safety requirements with harmonised product safety requirements

Non-harmonised consumer product safety requirements[148]	Harmonised consumer product safety requirements[149]	WHAT WOULD CHANGE?
GENERAL OBLIGATION TO PUT ONLY SAFE PRODUCTS ON THE MARKET		
Obligation of producers* to put only safe products on the market (the general safety requirement) * Producer includes manufacturer and importer (providing that with respect to the latter, there is no manufacturer's representative established within the EU if the manufacturer is not established within the EU) Manufacturer is defined as a person established within the EU and any other person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product. Importer is not defined in the General Product Safety Directive.	Obligation of manufacturers to put on the market only products designed and manufactured in accordance with the general safety requirement. Obligation of importers to place only safe products on the EU market. Manufacturer is defined as any natural or legal person who manufactures a product or has a product designed or manufactured and markets that product under his name or trademark. Importer is defined as any natural or legal person established in the Union who places a product from a third country on the Union market.	The contents of the obligation to put only safe products on the market does not change. However, the change in the definitions of the manufacturer and the importer makes clear that also manufacturers established outside the EU, but producing products for the EU market are subject to the general safety requirement.
OBLIGATION TO KEEP RELEVANT TECHNICAL DOCUMENTATION		**WHAT WOULD CHANGE?**
Not explicitly defined in the General Product Safety Directive, but this obligation of producers to keep relevant technical documentation can be implied from (i) the general obligation to put only safe products on the market, (ii) the obligation to keep oneself informed of the risks that the product may pose and (iii) the obligation to provide market surveillance authorities with all necessary information relating to the product in question.	Obligation of manufacturers to keep the relevant technical documentation** and make sure that her products comply with technical documentation, including products produced in series production. ** Technical documentation is defined as a document which shall include an adequate analysis.	The currently implied obligation becomes an explicit and clearly defined obligation to keep the technical documentation: the content of the technical documentation is spelled out for non-harmonised consumer products.
OBLIGATION TO EQUIP THE PRODUCT WITH SAFETY INSTRUCTIONS		**WHAT WOULD CHANGE?**

148 Under the General Product Safety Directive.

149 Under Decision (No) 768/2008/EC.

Obligation of producers to inform consumers so that they can assess risk which their products may pose and to take appropriate precautions.	Obligation of manufacturers to accompany the product with safety information and instructions, if justified.	A general obligation is replaced by a more precise and clear cut obligation for manufacturers and importers.
OBLIGATION TO IDENTIFY THE PRODUCT AND THE PRODUCER (THE MANUFACTURER AND/OR THE IMPORTER)		**WHAT WOULD CHANGE?**
Obligation of producers to keep informed of risks which products may pose, for example, by: (i) identifying the producer (by giving information on identity and details), (ii) identifying the product (by giving product reference or the batch of products to which it belongs). The aforementioned information should appear on the product or its packaging, except where not to give such indication is justified.	Obligation of manufacturers to (i) indicate name, registered trade name or registered trade mark and the address on which they may be contacted (a single point of contact), and (ii) ensure that products bears a type, batch or serial number or other element allowing for the identification of the product. Obligation of importers to indicate name, registered trade name or registered trade mark and the address on which they may be contacted (a single point of contact), [in addition to the manufacturer] The aforementioned information should appear on the product or, where that is not possible, its packaging or in a document accompanying the product.	The general obligation of the producer (including manufacturer and importer) to keep themselves informed of risks which their product may pose by means of various requirements, is replaced by a more detailed obligation to identify the product and the person responsible for its putting on the market, except where due to the size or the nature of the product (for example, due to the intended of reasonably foreseeable use or the value of the product). The possibility to put the required identification information "in a document accompanying the product is added."
OBLIGATIONS DURING TRANSPORT OF THE PRODUCT		**WHAT WILL CHANGE?**
This obligation is not explicitly laid down in the General Product Safety Directive, but it can be implied from the general obligation to put only safe products on the market.	Obligation of importers to ensure that while the product is under their responsibility, storage and transport conditions do not jeopardise its compliance with the general safety requirement.	Instead of being implied, the obligation of importers to ensure that while the product is under their responsibility, storage and transport conditions do not jeopardise its compliance with the general safety requirement, will be explicitly defined.

8.4 Market surveillance framework for consumer and harmonised products and harmonised products

Table 6: Description of the main objectives for achieving a completed coordination of market surveillance activities in the single EU market

Aspects	Objectives	Is the objective fulfilled?
General aspects	Uniform legislative market surveillance framework	NO
	Clear institutional framework	NO
	Single general information IT system accessible EU-wide	At the preparation stage
Planned coordination activities	Common key performance indicators (KPI) for measuring market surveillance effectiveness and efficiency	NO
	Annual planning of market surveillance activities at the EU level	YES, but not coordinated
	Annual reporting based on KPIs by all Member States (informing, in turn, the planning activities)	NO
Coordination of "on-the-field" activities	Common enforcement actions complementing national enforcement actions	YES, but rather an exception than a rule
	Real-time sharing of information about measures taken against products posing risk within the enforcement actions	YES, but insufficient and often not real-time
	Mechanisms ensuring coherence of national measures taken	YES, but inefficient and ineffective

Table 7: Market surveillance instruments in different domains

AREA	PRODUCT SAFETY	UNFAIR CONTRACT TERMS, CONSUMER PRACTICES	SERVICES
Interests protected	**Health and safety of consumers and other users**	**Economic interests of consumers**	**Free movement of services**
Request for information*	NO	**YES**	**YES**
Request for action**	NO	**YES**	**YES**
Possibility of coordinated action of authorities of different Member States	NO	**YES**	**YES**
Secured EU IT system communication tool	YES, partially	YES	YES

* An action by which 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

** An action under which authorities of one Member State call on authorities in another Member State to perform simultaneous inspections on economic operators based in the respective Member States.

9. ANNEX 9: MARKET SURVEILLANCE DATA – RAPEX, INCLUDING RAPEX-CHINA, SAFEGUARD CLAUSE NOTIFICATIONS AND OTHER DATA

9.1. RAPEX

RAPEX is a European rapid alert system for dangerous products. It ensures that information about dangerous products withdrawn from the market and/or recalled from consumers anywhere in Europe is quickly circulated between Member States and the European Commission, so that appropriate action can be taken everywhere in the EU. Thirty countries currently participate in the system. The participating countries are all the European Union countries and the EFTA/EEA countries: Iceland, Liechtenstein and Norway.

The most common measures are ban/stop of sales; withdrawal of a dangerous product from the market or its recall from consumers; import rejection by the customs authorities. The scope of RAPEX covers dangerous non-food products intended for consumers (e.g. a toy, a cosmetic, clothing) and for professionals (e.g. a power drill, a machine, a construction product) which pose a serious risk to various public interests, such as 'health and safety of consumers', 'environment' (risk for trees, water, air, soil, etc. from dangerous chemicals contained in a product), 'health and safety at the workplace' and 'public security'.

9.2. Statistics on RAPEX

In 2011, a total of 1 803 notifications on dangerous products posing risks to the health and safety of consumers were submitted through the RAPEX system by Member States. This constitutes 20% less notifications than in 2010 (2 244 notifications). Of the 1.803 notifications, 1 556 notifications concerned products which posed a serious risk to consumers. Other notifications refer to moderate risk or information only.

In 2011, for the first time since the start of the operation of the current RAPEX system (in 2004), the total number of notifications decreased by 20%. This is compared with annual increases of 81% in 2005, 24% in 2006, 53% in 2007, 16% in 2008, 7% in 2009 and 13% in 2010. While this decrease, which occurred mainly in the first quarter of the year, might be also in part to budget cuts and subsequent resource constraints in the national administrations, it must be noted that the RAPEX system has now reached a level of stability and maturity and that the more active use of the risk assessment guidelines has led to the streamlining of notifications, with improvements in their quality.

Figure 1: Number of notifications 2003-2011

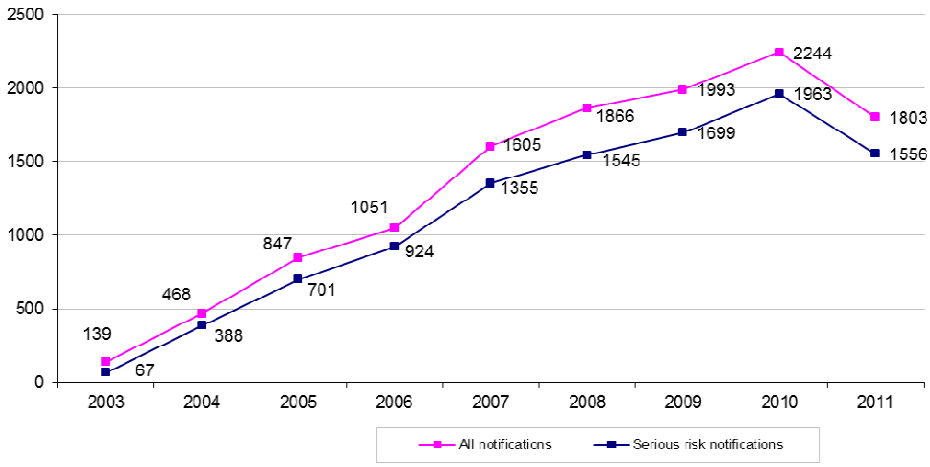
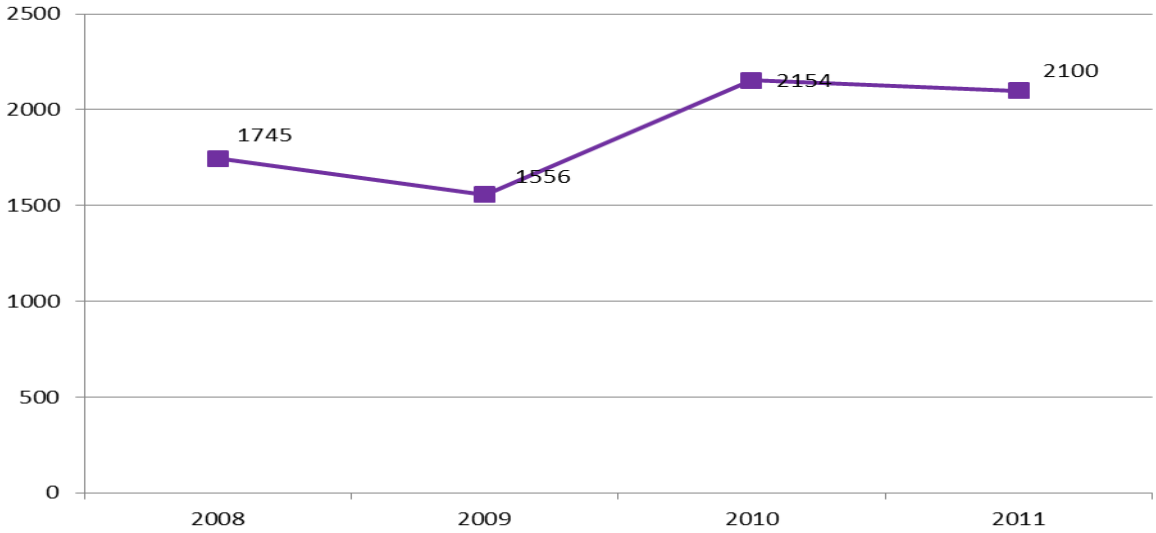


Figure 2: Number of reactions 2008-2011



In 2011, EU Member States and the EFTA/EEA countries sent a total of 2,100 reactions to all notifications distributed through RAPEX. 2,059 reactions were sent in response to notifications concerning a serious risk (98%); 19 reactions concerned notifications of products with lower risk levels (1%); and 22 reactions were sent in relation to notifications sent for information only (1%). The number of reactions received per notification varied between 1 and 17. More than 45 notifications received at least 10 reactions.

9.2.1 Percentage of notifications that received at least one reaction per year (all notifications):

In 2011, 35% of all notifications have received at least one reaction, a decrease compared to the previous years, when the percentage has been above 40%. This means that in more than 60% of the cases there was no follow-up done by recepients of Rapex notifications, mainly because national authorities indicate the notified product was not found on their respective national markets.

9.2.2 The ratio between the total number of reactions and the total number of notifications

With 30 countries taking part in the RAPEX system, each notification submitted by a country could trigger up to 29 reactions from the other participants, provided that the same product is sold everywhere and it has the same potential risks.

In practice, there are many products sold in just a few countries. Moreover, it is rather difficult for market surveillance authorities to detect dangerous products when these lack adequate traceability information. This means that the number of reactions received from the Member States is actually much lower than it could potentially be.

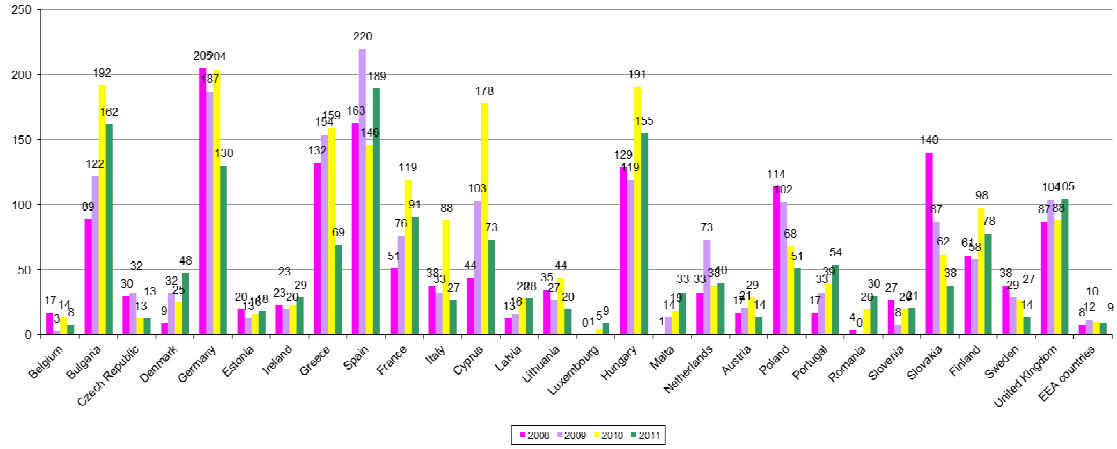
The ratio between the total number of reactions and the total number of notifications is slightly higher than 1, which shows that measures taken by authorities in the notifying country are followed by at least as many measures taken by the other Member States as follow-up.

In 2011, the 1803 measures taken by the authorities and notified in RAPEX were followed by another 2100 measures taken by other Member States.

Table 1: Reactions/Notifications Ratio

	% of Notifications with at least one Reaction	Reactions/Notifications Ratio
2008	44%	1.07
2009	41%	1.28
2010	43%	0.96
2011	35%	1.16

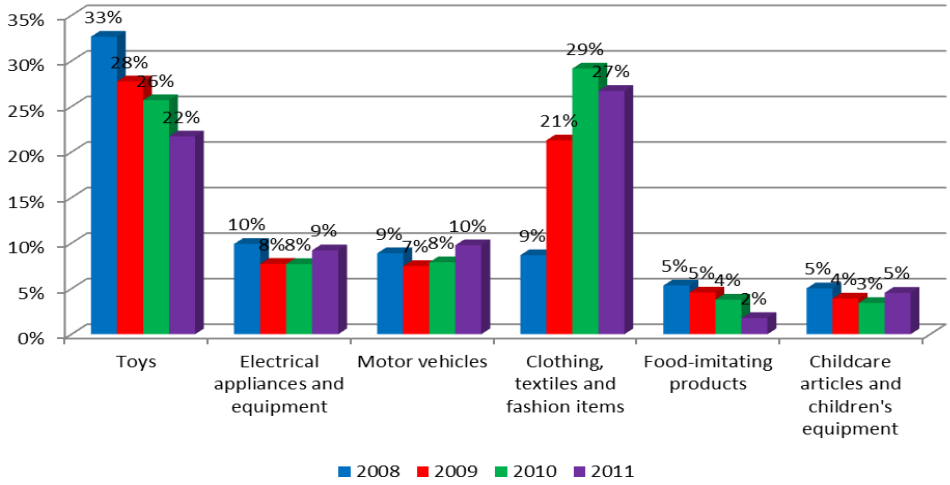
Figure 3: Number of notifications by notifying country: comparison with previous years (serious risk only)



In 2011, half of the participating countries notified fewer dangerous products than in 2010.

It should be stressed that RAPEX statistics do not reflect all market surveillance activities carried out in Member States. Legitimate reasons may exist for the fact that some measures taken against dangerous products in Member States do not result in notifications sent to the RAPEX system. Some products, for instance, are not sold outside of the Member State concerned. The participation rate of countries in RAPEX is the result of various factors, such as the different way in which the national market surveillance networks are organised, the different size of the countries, and the different production and market structures that exist across the EU. The Commission has undertaken several actions in 2010 and 2011 in order to facilitate the participation of Member States in RAPEX, including the publication of the new RAPEX Guidelines, the development of a new risk assessment application with an improved IT tool and the organisation of several RAPEX seminars.

Figure 4: The six most notified product categories: comparison with previous years

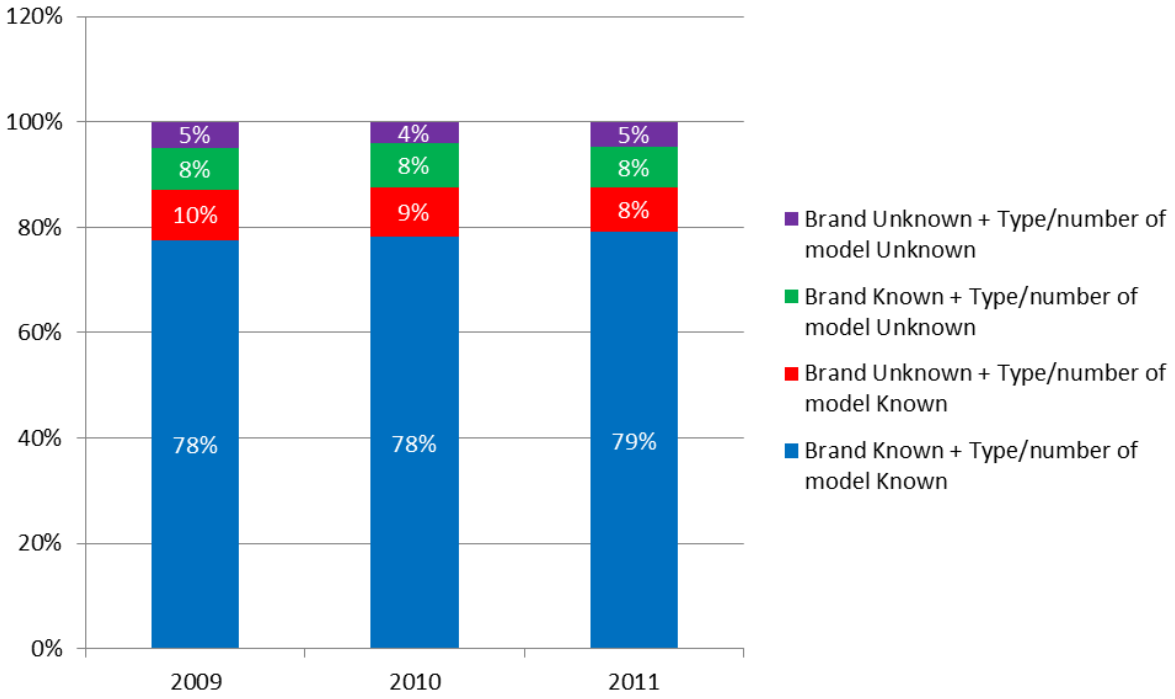


The product categories most frequently notified through the RAPEX system in 2011 were:

- Clothing, textiles and fashion items (423 notifications, 27%)
- Toys (324 notifications, 21%)
- Motor vehicles (171 notifications, 11%)
- Electrical appliances and equipment (153 notifications, 8%)
- Cosmetics (104 notifications, 7%).

These categories of consumer products accounted for 74% of all products notified in 2011. This year the product category "Clothing, textiles and fashion items" was the most notified (27%), followed by "Toys" (22%). Both categories account together for almost half (48%) of all notifications distributed through the RAPEX system in 2011

Figure 5: Number of notifications in which brand and model numbers are known/unknown:



1 308 notifications validated in 2011 (84%) concerned products for which both the brand and the type/model number were known, which ensures a better identification and therefore traceability of the notified products. In 14% of the cases, either the brand or the type/model number was known. In only 30 cases (2%) both the brand and the type/model number were unknown.

9.2.3 Notifications by country of origin of the notified product

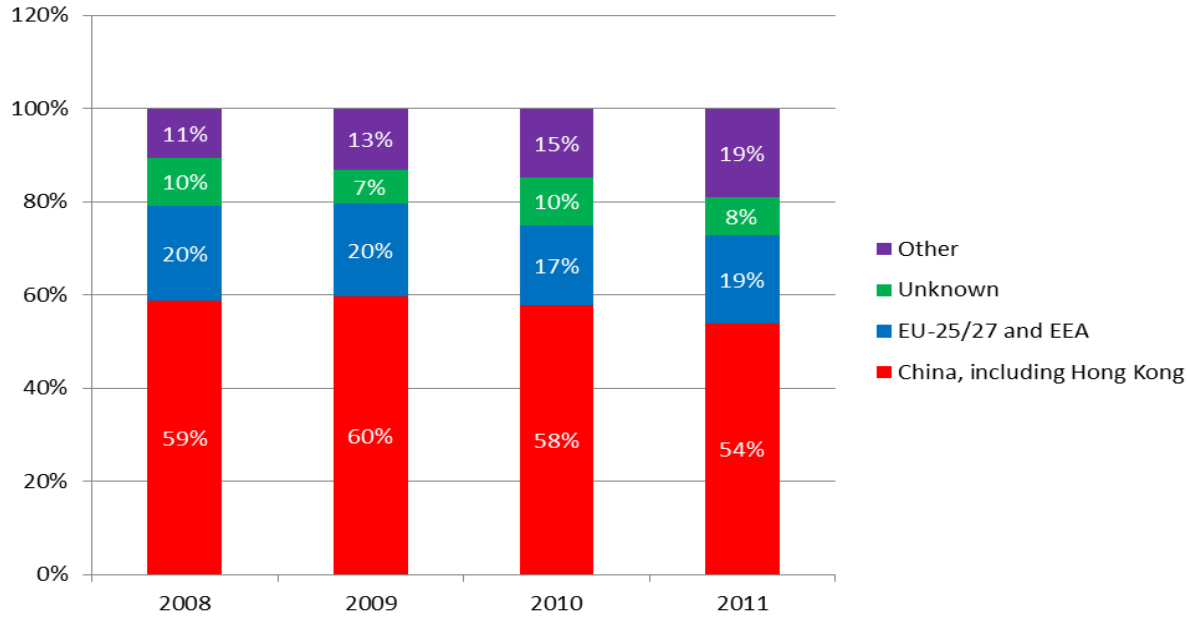
In 54% of all notifications sent through the RAPEX system in 2011 (i.e. 839 notifications), the country of origin of the notified products was China (including Hong Kong). That this number is still very high results from the significant market penetration of Chinese-manufactured consumer products in European markets. Products are checked according to the same, stringent safety requirements regardless of their origin, usually based on typical risks associated with the product category. The consistent intensification of contacts with the Chinese administration and businesses is yielding significant returns in terms of improved product identification and traceability for corrective measures and will continue.

293 notifications (19% of all notifications sent through RAPEX) concerned products originating from the 27 EU Member States and 3 EFTA/EEA countries. This is consistent with the data from previous years (17% in 2010, 20% in 2009, 20% in 2008, 22% in 2007 and 21% in 2006).

128 notifications (8% of all notifications sent through RAPEX) contained no information about the country of origin of the notified product. Nevertheless, this figure should be seen as a significant improvement in the operation of the RAPEX system as even though this figure is slightly higher than the 7% recorded in 2009, it is lower than the 10% recorded in 2010. In fact, it remains a very low level given that, in 2004, the number of cases with an unidentified country of origin was as high as 23%.

The overall drop indicates that market surveillance authorities in Europe are increasingly aware of the importance of finding identification data that is helpful to partner authorities in other Member States and, ultimately, in the country of origin of the product.

Figure 6: Notifications by country of origin of the notified product



9.2.4 Notifications by type of risk

In 2011, the five most frequently notified risk categories were:

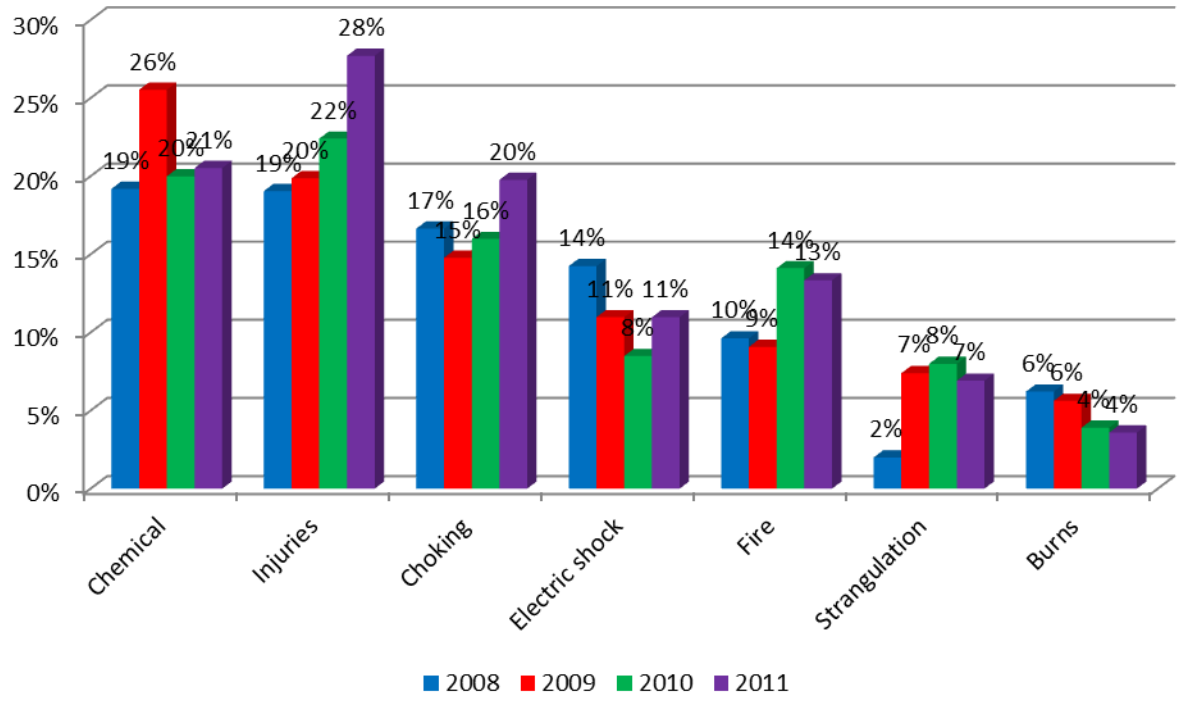
- Injuries (481 notifications, 26%)
- Chemical (347 notifications, 19%)
- Strangulation (275 notifications, 15%)
- Choking (224 notifications, 12%)
- Electric shock (216 notifications, 12%).

These five risk categories account for 84% of all notified risks.

It should be noted that some RAPEX notifications concern products presenting more than one risk. For example, a toy can pose a choking risk due to small parts and, simultaneously, a chemical risk due to excessive levels of a restricted substance. The total number of notified risks is accordingly higher than the total number of notifications. On the basis of RAPEX data, it can also be concluded that each product category is likely to expose consumers to specific types of risk. For example, the main risks arising when playing with unsafe toys are choking (often associated with the presence of small parts) and reactions to chemicals (often associated with the presence of significant amounts of chemical substances such as certain phthalates, lead and

other heavy metals), while the most common risk for electrical products is electric shock, often combined with the risk of fire.

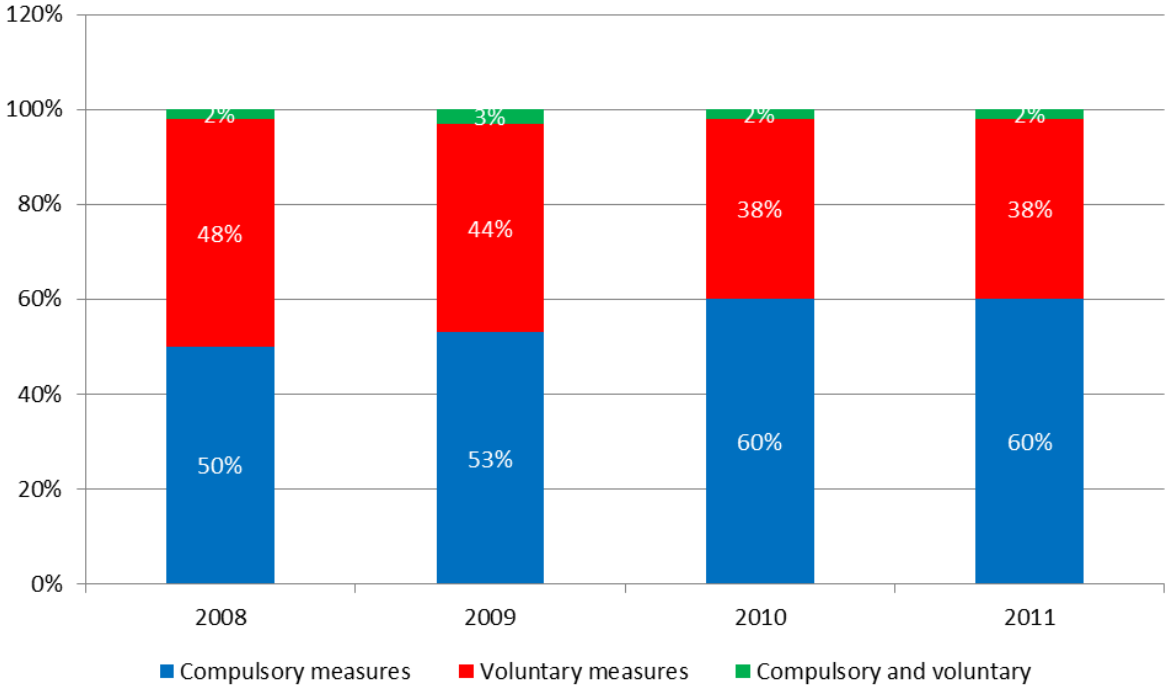
Figure 7: The seven most notified type of risk: comparison with previous years



9.2.5 Notifications by type of measure: comparison with previous years

In 2011, 922 of the 1 556 RAPEX serious risk notifications concerned compulsory preventive and restrictive measures ordered by national authorities (60% of the total). In 598 notified cases (38%), economic operators took preventive and restrictive measures on a 'voluntary' basis, i.e. they complied with their legal obligations without the formal intervention of a national authority. In 36 cases (2%), 'voluntary' actions were complemented by compulsory measures taken by the national authority. In this situation, even though an economic operator has ceased selling a product, national authorities still believe further action needs to be taken and accordingly order, for example, the product to be withdrawn from the market or recalled from consumers who have already bought it.

Figure 8: Notifications by type of measure: comparison previous years



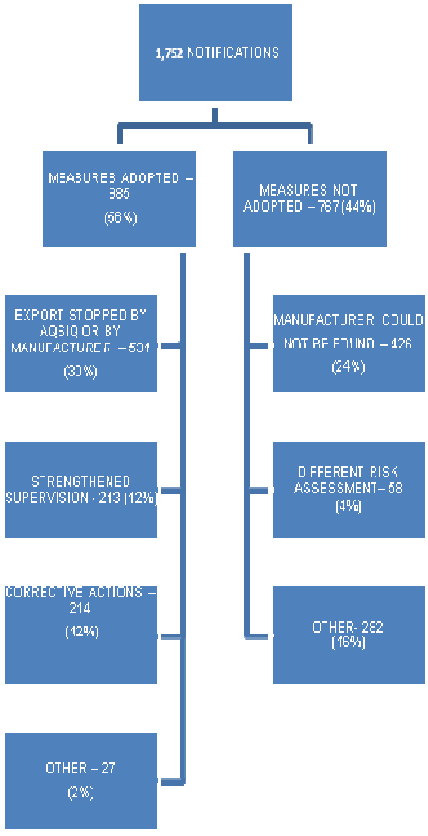
9.3. Statistics on RAPEX-China

The RAPEX-China on-line system was established in September 2006 and facilitates regular and rapid transmission of data between the EU and Chinese product safety administrations. The European Commission provides the Chinese authorities with information on consumer products originating from China which have been notified through RAPEX.

AQSIQ has submitted 19 reports to DG SANCO on enforcement actions carried out with regard to RAPEX notifications exchanged via RAPEX-China between September 2006 and October 2011.

During this period, AQSIQ has investigated and, where necessary, adopted measures in relation to 1,752 RAPEX notifications. Analyses of the reports received show that, on average, AQSIQ investigates 92 RAPEX cases over a three-month period. Summary analyses are regularly made available at: http://ec.europa.eu/consumers/safety/rapex/index_en.htm

Figure 9 – Actions taken by AQSIQ (total figures)



9.4 Data on safeguard clause notifications

Figure 10: Number of safeguard clause notifications for a subset of harmonised legislation

Directive (name and No.)	No. of measures communicated under "safeguard clause"			Position taken by Commission on measures			
	2009	2010	2011	Positive (1)	Negative (2)	Pending	No need for position (3)
Directive 2010/35/EU on transportable pressure equipment	0	0	0	0	0	0	na
Regulation EC No 2003/2003 of fertilisers	0	0	0	0	0	0	na
Lifts Directive 95/16/EC	0	0	0	0	0	0	na
Directive 2007/23/EC on pyrotechnic articles	0	0	0	0	0	0	na
Directive 93/15/EEC on civil explosives	0	0	0	0	0	0	na
Regulation 648/2004 on detergents	0	1	0	1	0	0	na
Directive 94/9/EC on equipment for use in explosive atmospheres	0	1	0	1	0	0	na
Directive 90/385/EC on active implantable medical devices	0	0	0	0	0	0	na
Directive 93/42/EC on medical devices	0	0	0	0	0	0	na
Directive 98/79/EC on in vitro diagnostic medical devices	0	0	0	0	0	0	na
Directive 2000/9/EC on cableways	0	0	0	0	0	0	na
REACH Regulation 1907/2006	0	0	0	0	0	0	na
Ecodesign Directive 2009/125/EC	na	na	1	0	0	1	na
Marine Equipment 96/98/EC	1	0	3	1	1*	2	na
Machinery Directive 2006/42/EC	5	5		2	0	8	na
Directive 89/686/EEC on Personal Protective Equipment	1	6	2	1	0	8	na
Low Voltage Directive 2006/96/EC	331	345	360	0	0	1	1035
Directive 88/378/EEC on toys	41	20	37	**			na

(applicable until July 2011)	(472 Rapex)	(488 Rapex)	(324 Rapex)	
Directive 2009/48/EC on toys (applicable since July 2011)	na	na	2	2

(1) It means that measures were found to be justified; (2) It means that measures were found to be unjustified; (3) Because no Member State objected to the measures notified. This option is only applicable to directives which set out the possibility of objections by Member States (e.g. currently only the Low Voltage Directive and the new Toys Directive)

* The case was withdrawn by the Member State before the publication of Commission decision

** Due to the high number of measures taken in this sector, the Commission and the Member States developed the practice of exchanging views on Rapex notifications and resort to formal safeguard clause decisions only if outstanding issues remained.

9.5 Data from the European Injury Database

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.

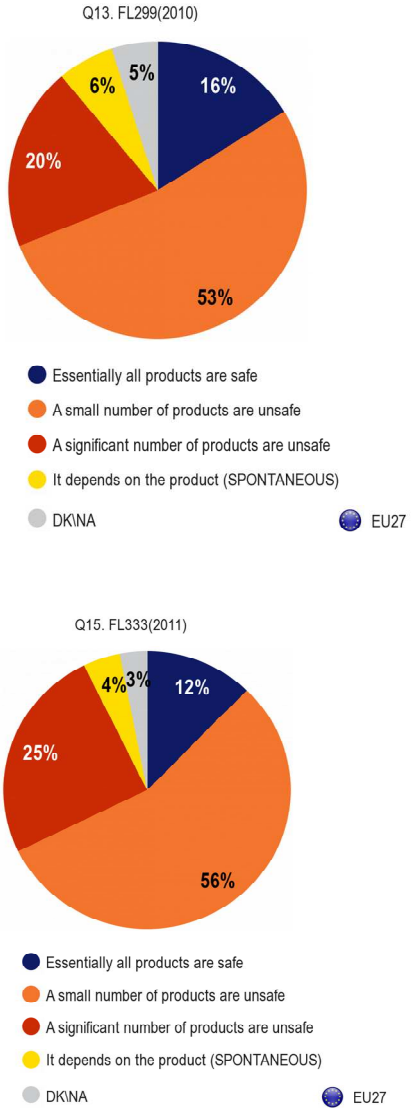
Figure 11: Causes of home injuries

Product category involved in the accient or inury	AT	BE	CY	CZ	DK	EE	FR	DE	EL	IT	LV	LU	MT	NL	PT	SI	ES	SE	UK
Building (component) or related fitting	13,5%	13,3%	37,4%	13,5%	11,6%	9,3%	12,0%	8,4%	5,3%	7,0%	8,6%	9,3%	21,6%	6,0%	1,5%	8,6%	21,8%	7,1%	23,9%
Equipment mainly used in sports/recreation	16,4%	4,2%	0,3%	4,9%	5,5%	7,5%	7,4%	3,1%	2,1%	4,6%	1,5%	5,6%	2,9%	3,6%	0,7%	2,2%	5,3%	10,0%	4,4%
Hot object/substance	3,2%	17,8%	10,0%	2,9%	2,9%	1,9%	3,7%	2,8%	1,1%	1,2%	10,3%	0,9%	3,9%	0,8%	6,9%	2,7%	1,6%	1,4%	11,0%
Ground surface	6,3%	7,4%	3,4%	3,7%	4,2%	2,7%	6,2%	7,1%	6,5%	5,0%	1,9%	3,9%	2,2%	2,6%	1,2%	1,5%	5,7%	4,1%	4,4%
Item mainly for personal use	2,1%	1,2%	1,4%	1,2%	2,5%	0,4%	2,8%	6,4%	1,9%	1,0%	0,4%	1,2%	0,7%	0,3%	0,4%	0,4%	1,9%	1,9%	1,2%
Tool, machine, apparatus mainly used for work-related activity	2,6%	2,1%	1,3%	0,3%	1,5%	0,3%	1,6%	1,1%	1,6%	1,6%	0,2%	0,3%	1,0%	1,2%	0,3%	1,2%	1,6%	2,3%	3,7%
Furniture/furnishing	0,7%	1,8%	0,3%	0,2%	2,1%	0,2%	2,2%	0,7%	0,7%	2,2%	0,3%	0,8%	0,8%	1,3%	0,3%	0,3%	4,6%	2,5%	1,1%
Appliance mainly used in household	1,4%	1,4%	2,7%	0,9%	1,0%	0,4%	0,8%	1,3%	0,4%	0,8%	0,4%	2,2%	0,9%	1,0%	0,2%	0,2%	2,6%	1,0%	1,4%
Infant or child product	0,1%	0,3%	2,0%	0,2%	0,1%	0,3%	0,0%	0,1%	0,0%	0,0%	0,6%	0,0%	0,5%	0,0%	0,0%	0,2%	0,1%	0,0%	0,0%
Fire, flame, smoke	0,0%	0,2%	0,2%	0,0%	0,1%	0,1%	0,1%	0,1%	0,0%	0,0%	0,3%	0,0%	0,2%	0,1%	0,0%	0,1%	0,3%	0,1%	0,2%
Utensil or container	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%
Other, unspecified and not-product related cases	53,6%	50,3%	41,0%	72,2%	68,4%	77,0%	63,3%	68,8%	80,2%	76,6%	75,5%	75,7%	65,3%	83,1%	88,5%	82,5%	54,5%	69,4%	48,7%
Total	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**
Data from years:	'06-'08	'05, '06	'06-'08	'05, '06	'06-'08	'06, '07	'07-'05	'06-'08	'01	'05	'06-'08	'00	'06-'08	'06-'08	'06-'08	'06-'08	'00	'06-'08	'00
Cases (sample) n= (thousands)	26	4	12	5	189	2	227	7	69	34	101	1	5	296	54	86	11	120	184
P = Pilot data		P		P		P													

9.6 Data from the Eurobarometer

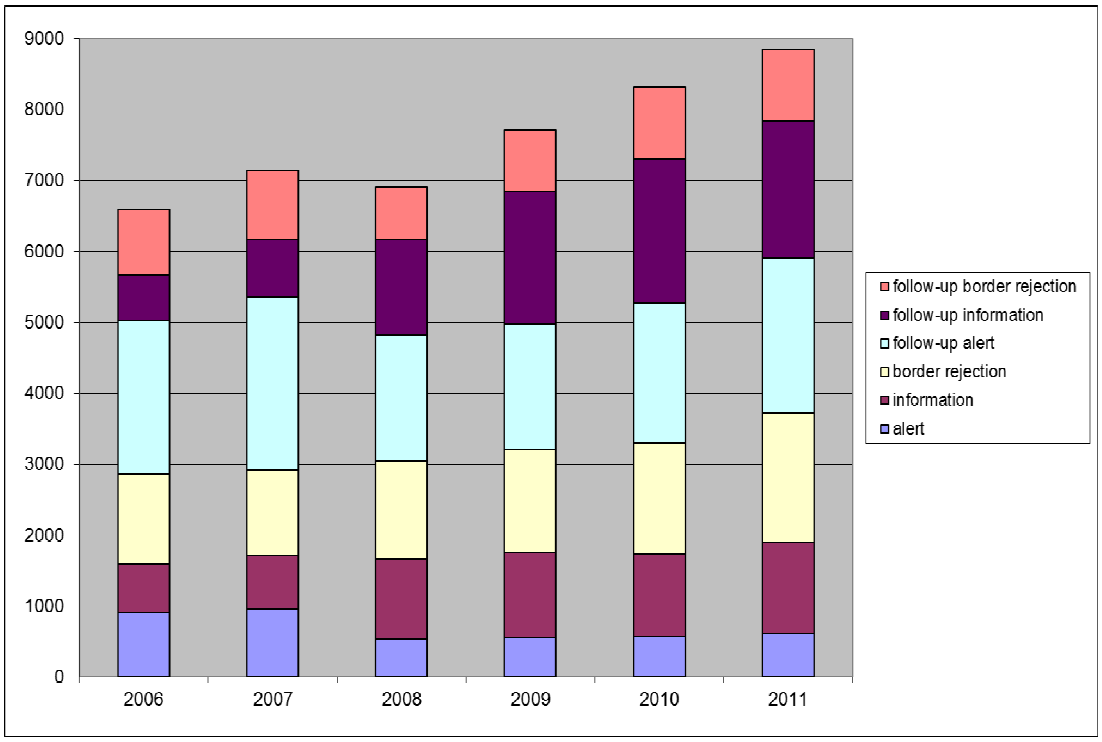
The latest Eurobarometer data shows a decrease in confidence of consumers in the safety of products sold in the EU (25% in 2011 compared to 20% in 2010 think that a significant number of products are unsafe, 12% in 2011 compared to 16% in 2010 think that essentially all products are safe).

Figure 12: Safety perceptions



9.7 Market surveillance data from the food sector

Figures 13 and 14: Information about measures taken against food and feed products (RASFF)



	original			follow-up		
year	alert	information	border rejection	follow-up alert	follow-up information	follow-up border rejection
2006	910	687	1274	2157	640	923
2007	952	761	1211	2440	796	978
2008	528	1138	1377	1789	1329	743
2009	557	1191	1456	1775	1861	871
2010	576	1168	1552	1977	2027	1014
2011	617	1285	1828	2185	1920	1017
%	7,1	10,0	17,8	10,5	-5,3	0,3
	3730			5122		

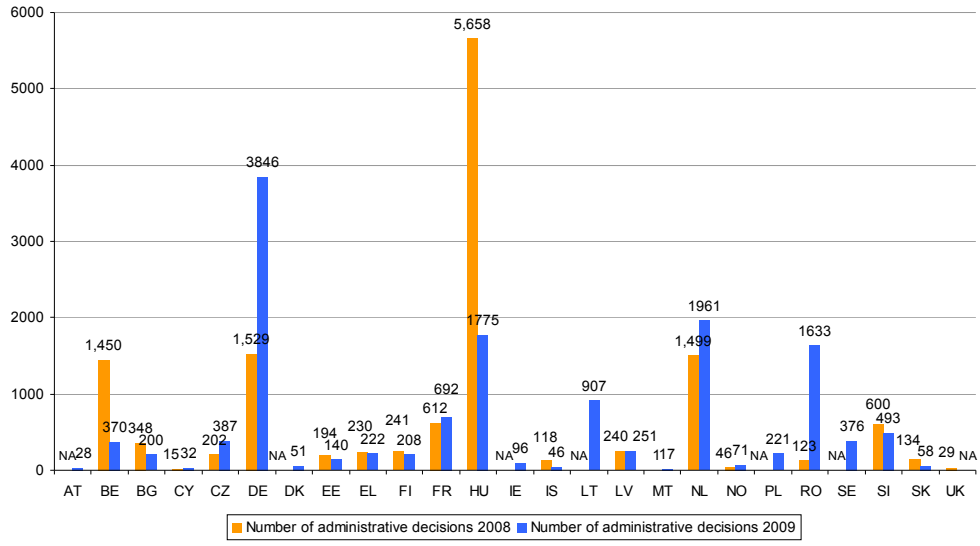
10. ANNEX 10: ENFORCEMENT INDICATORS

10.1 Introduction

In 2008 the European Commission established and improved a data collection tool dedicated to enforcement and market surveillance in the Member States. Following a successful pilot, between 2008 and 2011 Member States have been collecting data which measure the key activities of national authorities in charge of product safety enforcement.

These enforcement indicators are collected through an on-line questionnaire addressed to 27 Member States, Norway and Iceland. Figures in the table below show a selection of the most relevant information provided by national authorities. The data were rescaled by the number of retailers[150] present in the country. This gives an indication of the size of the market in each country and enables to better compare indicators within the 27 Member States. Since the indicators have been launched, the definitions have been fine-tuned but the list of the indicators has not been changed.

Figure 1: Number of administrative decisions taken by Member States (2008 and 2009)



10.2. Explanations

So far, a list of approximately 15 indicators has been developed and is made of input and output indicators.

150 The number of retailers is taken from Eurostat's annual detailed enterprise statistics on trade. The category of retailers is called "retail trade, except of motor vehicles, motorcycles, repair of personal and households goods and the figures refer to 2008.

10.2.1 Input indicators (resources)

In particular, among the input indicators, the budget and number of inspectors (columns 1 – 4) have been identified to be the most pertinent and relevant for such exercise. Indeed, the amount spent on enforcement activities depicts and assesses Member States' enforcement capabilities. This has become even more crucial due to the budgetary cuts Member States are confronted with during this serious economic crisis that affects the EU economy as a whole. As a result, the protection and safety of consumers may be seriously affected by inadequate funding of market surveillance.

10.2.2 Output indicators (actions and measures taken)

Concerning the output enforcement indicators, three subgroups of indicators measure the compliance of traders with laws and provide quantitative information on the key activities Member States carry out to ensure this compliance. These indicators reflect three consecutive stages of the enforcement and market surveillance process:

(i) Preventive and investigative activities ensuring compliance (columns 5 – 8): These include the number of inspections and the number of laboratory tests. The former refers to any control undertaken by an inspector and aimed at verification of compliance of a single trader with product safety laws. The later concerns the tests made to verify compliance with applicable safety requirements, such as checking the presence of dangerous substances or components or checking for possible structural defects.

(ii) Results of compliance checking (column 9): The aim is to measure the number of detected infringements and irregularities as a result of the preventive and investigative activities carried out by the relevant authorities. Examples of such indicators are the number of products identified as posing a serious risk. Authorities carry out risk assessment to determine if products inspected are potentially harmful for consumers and take measures when necessary.

(iii) Corrective measures (columns 10 – 14): This is the ultimate stage of the procedure when authorities find a product that is not safe. This means that authorities will launch administrative procedures to impose obligations on producers, distributors or retailers to take corrective measures. These can be, for example, product withdrawals from the market, product recalls from consumers; or suspensions of products at the border.

10.3. Accuracy of the data provided

The data was provided by the national authorities responsible for product safety enforcement under the General Product Safety Directive. Often, data provided comprises information from multiple authorities (regional or sectoral) and thus should not necessarily be considered as a complete and accurate picture of product safety enforcement across Europe.

10.4. Conclusions

As a general conclusion, the quality and the comparability of data have improved. However, compared to 2009, in 2010 Member States have allocated fewer resources to product safety activities; this clearly reflects the general trend of budget reductions and spending cuts. Furthermore, in 2010 the number of inspectors decreased and fewer laboratory tests were being carried out. In addition, fewer dangerous products have been identified and consequently, fewer measures (withdrawals, recalls) were taken.

		Budget (€)	*Budget (€) rescaled for the umber of retailers*	*Number of inspectors*	*Number of inspectors rescaled for the number of retailers*	*Number of Inspections*	*Number of inspections rescaled for the number of retailers*	*Number of products tested in labs*	*Number of products tested in labs rescaled for the number of retailers*	*Number of dangerous products posing a serious risk (product categories)*	*Number of administrative decisions (product categories)*	*Number of products withdrawn from the market(product categories)*	*Number of products recalled from consumers (product categories)*	*Number of decisions taken by customs authorities to suspend products at the border*	*Number of decisions to reject products at the border*
AT	**2010**	**960,000**	**23**	**19**	**1**	**8,280**	**204**	**50**	**1**	**97**	**56**	**30**	**200**	**10**	**2**
	2009	NA	NA	30	1	18	424	1,450	34	115	28	NA	NA	NA	NA
	2008	NA	NA	18	0	9,071	214	NA	NA	NA	NA	300	200	NA	3
BE	**2010**	**2,790,030**	**36**	**34**	**0**	**11,867**	**154**	**663**	**9**	**193**	**190**	**194**	**0**	**NA**	**262**
	2009	2,350,000	32	32	0	6,85	93	300	4	30	370	200	NA	300	200
	2008	1,530,000	21	24	0	5,5	75	400	5	30	1,45	260	NA	160	125
BG	**2010**	**461,207**	**5**	**120**	**1**	**11,645**	**127**	**125**	**1**	**193**	**190**	**194**	**0**	**1,484**	**4**
	2009	633,975	7	120	1	10,672	117	222	2	257	200	259	0	4	4
	2008	550,828	6	112	1	7,902	86	6	0	153	348	334	NA	NA	NA
CY	**2010**	**NA**	**NA**	**55**	**5**	**6,331**	**12,181**	**99**	**8**	**181**	**NA**	**281**	**NA**	**0**	**16**
	2009	NA	NA	24	2	5,919	513	272	24	103	32	159	0	NA	NA
	2008	NA	NA	12	1	4,917	426	21	2	44	15	154	0	NA	NA
CZ	**2010**	**12,850,849**	**102**	**339**	**3**	**20,625**	**125,885**	**707**	**6**	**87**	**461**	**463**	**67**	**56**	**44**
	2009	7,622,646	61	418	3	30,705	246	715	6	79	387	65	6	23	0
	2008	12,125,654	97	360	3	58,111	466	1,653	13	57	202	79	NA	NA	0
DE	**2010**	**NA**	**NA**	**440**	**2**	**53,216**	**197**	**28,057**	**104**	**204**	**6,444**	**1,202**	**411**	**1,612**	**1,004**
	2009	NA	NA	803	3	67,516	229	25,850	88	187	3,846	1,374	841	714	248

	2008	NA	NA	962	3	76	258	20,194	68	240	1,529	490	231	634	292
DK	**2010**	**5,620,000**	**244**	**57**	**3**	**2,065**	**90**	**169**	**7**	**73**	**125**	**59**	**2**	**89**	**87**
	2009	4,010,000	164	45	2	1,177	48	409	17	45	51	35	13	58	50
	2008	5,400,000	220	43	2	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EE	**2010**	**232,220**		**15**	**4**	**2,309**	**536**	**268**	**62**	**28**	**160**	**98**	**5**	**319**	**189**
	2009	288,016	71	18	4	3,73	919	320	79	53	140	59	11	262	204
	2008	296,961	73	19	5	3,961	976	342	84	86	194	111	16	194	135
EL	**2010**	**3,263,000**	**NA**	**88**	**NA**	**NA**	**NA**	**1,190**	**NA**	**111**	**447**	**137**	**10**	**2**	**2**
	2009	4,400,000	23	105	1	2,479	13	1,536	8	80	222	222	250	4	4
	2008	4,846,000	25	127	1	2,05	11	305	2	199	230	205	18	155	9
FI	**2010**	**6,600,000**	**282**	**72**	**3**	**2,975**	**127**	**1,656**	**71**	**39**	**183**	**74**	**32**	**807**	**175**
	2009	7,286,000	313	90	4	3,067	132	2,717	167	35	208	100	5	646	146
	2008	7,286,000	313	90	4	2,852	122	1,640	70	52	241	150	21	780	128
FR	**2010**	**16,700,000**	**38**	**202**	**1**	**28,61**	**64**	**3,076**	**7**	**133**	**605**	**111**	**NA**	**1,286**	**375**
	2009	39,912,282	87	191	0	26,372	57	2,717	6	75	692	166	NA	871	232
	2008	40,309,121		190	0	26,26	57	2,804	6	52	612	147	NA	921	197
HU	**2010**	**14,454,900**	**146**	**310**	**3**	**3,886**	**39**	**546**	**6**	**191**	**1,510**	**53**	**121**	**116**	**29**
	2009	11,133,214		320		14,097		668	NA	157	1,775	32	134	59	37
	2008	12,996,296	132	345	4	17,47	177	287	3	158	5,658	39	158	234	120
IE	**2010**	**750,000**	**35**	**8**	**0**	**564**	**27**		**NA**	**23**	**119**	**0**	**0**	**0**	**1**
	2009	750	45	8	1	336	20	4	0	20	96	0	0	NA	1
	2008	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
IS	**2010**	**401,691**	**NA**	**18**	**NA**	**223**	**NA**	**1**	**NA**	**27**	**27**	**23**	**5**	**NA**	**NA**
	2009	128,759	NA	14	NA	264	NA	NA	NA	25	46	17	NA	31	13
	2008	253,331	NA	15	NA	486	NA	41	NA	13	118	18	0	31	31
LT	**2010**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**
	2009	2,098,571	48	85	2	6,524	151	1,314	30	98	907	98	98	43	43
LV	**2010**	**685,886**	**51**	**139**	**10**	**4,702**	**350**	**1,466**	**109**	**30**	**276**	**238**	**6**	**46**	**41**
	2009	1,644,260	127	89	7	2,387	185	358	28	26	251	26	14	25	38
	2008	1,279,444	99	33	3	4,189	324	215	17	16	240	53	5	54	38
MT	**2010**	**159,031**	**NA**	**4**	**NA**	**502**	**NA**	**38**	**NA**	**19**	**1**	**1**	**0**	**NA**	**156**

	2009	NA	NA	4	1	518	64	178	22	14	17	4	13	12	12
	2008	43,888	NA	3	0	65	8	98	12	9	1	1	0	NA	NA
NL	**2010**	**11,400,000**	**143**	**40**	**1**	**8,132**	**102**	**5,009**	**63**	**38**	**2,248**	**NA**	**0**	**NA**	**NA**
	2009	13,481,000	171	41	1	9,087	115	4,491	57	73	1,961	NA	0	NA	NA
	2008	14,300,000	182	37	1	8,051	102	5,837	74	33	1,499	NA	NA	NA	NA
NO	**2010**	**335,000**	**12**	**11**	**1**	**554**	**20**	**NA**	**NA**	**6**	**60**	**33**	**6**	**NA**	**16**
	2009	206,5	7	24	1	647	23	75	3	16	71	13	4	NA	52
	2008	207,5	8	20	1	643	23	59	2	2	46	34	2	0	2
PL	**2010**	**5,682,188**	**15**	**587**	**2**	**23,616**	**62**	**2,572**	**7**	**82**	**1,749**	**330**	**1**	**613**	**509**
	2009	7,309,317	20	878	2	19,569	53	2,729	7	108	221	47	0	715	572
RO	**2010**	**3,393,087**	**25**	**355**	**3**	**3,853**	**28**	**997**	**7**	35	1,768	NA	N/A	N/A	N/A
	2009	3,549,065	27	367	3	6	0	NA	NA	0	1,633	6,009	NA	NA	NA
	2008	865,868	6	350	3	5,368	40	NA	NA	4	123	123	NA	NA	NA
SE	**2010**	**5,363,648**	**90**	**49**	**NA**	**1,16**	**26**	**489**	**8**	**213**	**222**	**124**	**199**	**35**	**32**
	2009	3,450,000	58	41	1	1,716	29	640	11	180	376	298	161	14	12
	2008	4,774,000	81	87	2	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SI	**2010**	**NA**	**NA**	**16**	**2**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**
	2009	NA	NA	16	2	8,397	1,178	487	68	8	493	NA	18	133	84
	2008	NA	NA	20	3	6,499	912	96	13	23	600	49	37	109	55
SK	**2010**	**979,465**	**106**	**56**	**6**	**9,907**	**1,074,16**	**780**	**85**	**69**	**91**	**67**	**0**	**24**	**0**
	2009	7,533,425	828	170	19	3,113	342	818	90	66	58	58	0	15	0
	2008	285,911	31	461	51	39,339	4,324,40	425	47	159	134	159	159	159	10
UK	**2010**	**NA**	**NA**	**NA**	**NA**		**NA**	**NA**	**NA**	**98**	**NA**	**NA**	**NA**	**NA**	**NA**
	2009	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	2008	NA	NA	NA	NA	NA	NA	NA	NA	95	29	29	1	NA	NA

11. ANNEX 11: OVERVIEW OF PROBLEMS, OBJECTIVES AND OPTIONS

Table 1: Overview of problems and consequences

General problem	Specific problem	Causes (Drivers)	Consequences
Unsafe consumer products and non-compliant products on the EU market	**Difficult compliance with EU product safety requirements**	– Lack of consistency of EU product safety requirements (for harmonised and non-harmonised products)	– Consumers' and other users: danger for health and safety; possible economic damage due to non performing goods – Lack of consumer confidence in product safety – ensuring sustained level of consumer consumption is essential for generating economic growth – Compliant businesses lose market shares – Disparities of treatment of economic operators and products depending on location/uneven playing field – Unequal protection of consumers
		– Ambiguity of product safety requirements and lack of specific benchmarks (for non-harmonised consumer products)	
		– Complexity of different layers of EU product safety rules (for harmonised consumer products)	
	Fragmentation of market surveillance	– Weak coordination of product safety market surveillance authorities on the single EU market – Sub-optimal functioning of EU procedures for exchange of information on product risks – Inconsistent enforcement of EU-wide product safety action	

Table 2: Overview of problems and objectives

<table>
<tr><th colspan="3">Problems</th><th colspan="3">Objectives</th></tr>
<tr><th>General problem</th><th>Specific problems</th><th>Drivers (causes)</th><th>General objective</th><th>Specific objectives</th><th>Operational objectives</th></tr>
<tr><td rowspan="6">Unsafe consumer products and non-compliant products on the EU market</td><td rowspan="3">Difficult compliance with EU product safety requirements</td><td>Lack of consistency of EU product safety requirements (for harmonised and non-harmonised products)</td><td rowspan="6">Reduction of the number of unsafe or non-compliant products on the single EU market.</td><td rowspan="2">Consolidation and reinforcement of EU product safety requirements</td><td>Ensuring consistency of EU product safety requirements</td></tr>
<tr><td>Ambiguity of product safety requirements and lack of specific benchmarks (for non-harmonised consumer products)</td><td>Reducing ambiguity of product safety requirements for non-harmonised consumer products</td></tr>
<tr><td>Complexity of different layers of EU product safety rules (for harmonised consumer products)</td><td colspan="2">Simplification the EU legislative framework</td></tr>
<tr><td rowspan="3">Fragmentation of market surveillance</td><td>Weak coordination of product safety market surveillance authorities on the single EU market</td><td rowspan="3">Better coordination and increased effectiveness of market surveillance activities on the single EU market for goods</td><td>Reinforcing EU cooperation mechanisms</td></tr>
<tr><td>Sub-optimal functioning of EU procedures for exchange of information on product risks</td><td>Making EU product safety procedures more coherent</td></tr>
<tr><td>Inconsistent enforcement of EU product safety requirements</td><td>More effective EU-wide product safety action</td></tr>
</table>

Table 3: Overview of objectives and policy options

Objectives			Policy options
General	**Specific**	**Operational**	
Reduction of the number of unsafe or non-compliant products on the single EU market.	Consolidation and reinforcement of EU product safety requirements	*Ensuring consistency of EU product safety requirements*	Option 1.A – Baseline scenario: Keeping differences between consumer product safety requirements and harmonised product safety requirements
			Option 1.B – Aligning consumer product safety requirements with harmonised product safety requirements
			Option 1.C – Consumer product safety requirements to be defined less strictly than harmonised product safety requirements
			Option 1.D – Consumer product safety requirements to be defined more strictly than harmonised product safety requirements
		Reducing ambiguity of product safety requirements for non-harmonised consumer products	Option 2.A – Baseline scenario: Necessity of creation parallel pre-standardisation procedures for non-harmonised consumer products
			Option 2.B – Direct applicability of ad-hoc safety requirements
			Option 2.C - Abolition of double adoption of non-binding ad-hoc safety requirements
			Option 2.D – Fast-track procedure for adopting already existing European standards without mandates
	Simplification 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	*Reinforcing EU cooperation mechanisms*	Option 3.A – Baseline scenario: keep status quo based mostly on voluntary market surveillance coordination
			Option 3.B – Coordination of cross-border enforcement of measures resulting from "on the-field" market surveillance
			Option 3.C – Overall rationalisation of coordination of market surveillance activities
			Option 3.D – Centralisation of EU market surveillance in the area of non-food products
		Making EU product safety procedures more coherent	Option 4.A – Baseline scenario: Keeping the parallel notifications under RAPEX procedure and safeguard procedure
			Option 4.B – Simplification of the RAPEX procedure
			Option 4.C – Simplification of the RAPEX procedure and streamlining of that procedure with the safeguard procedure
		More effective EU-wide product safety action	Option 5.A – Baseline scenario: Keeping EU-wide product safety measure indirectly applicable for a period of one year
			Option 5.B – Extension of the scope of EU-wide product safety measures to non-consumer products
			Option 5.C – Making EU-wide product safety measures directly applicable
			Option 5.D – Extension of the period of validity of EU-wide product safety measures
			Option 5.E – Combination of options 5.B, 5.C and 5.D

12. ANNEX 12: DISCARDED OPTIONS

12.1 Overview

The early phases of the impact assessment process identified certain issues which could be subject to an EU legislative action. However, a brief assessment of these showed that either it is not appropriate to deal with these issues under the new General Product Safety Product Directive or the new Market Surveillance Regulation, although it may be worth treating these issues outside these legislative tools, or that these issues should be discarded without further analysis. Consequently, the following issues were excluded from further analysis within the impact assessment process:

(1) safety of services,

(2) product safety requirements for non-harmonised professional products,

(3) safety of products marketed via the internet, and

(4) abolition of consumer product safety requirement

12.2. Safety of services

At the current state of EU legislation, no general legislative framework on safety of services exists. The General Product Safety Directive did not cover the safety of services, but required the Commission to identify the needs, possibilities and priorities for Community action on the safety of services and submit to the European Parliament and the Council, before 1 January 2003, a report, accompanied by proposals on the subject as appropriate.[151]

The 2003 Report on the safety of services for consumers (the "Report on Services Safety")[152] indicated that all Member States adopted policies, legislation and administrative measures concerning service safety, but the approaches varied significantly. Certain Member States have introduced general legislation specifically on the safety of consumer services, which supplements sector specific policies and legislation (Finland, France, Portugal, Spain Sweden, Belgium, Bulgaria, Denmark, Estonia, Latvia, Netherlands, Slovak Republic, Cyprus, Malta). A few Member States cover the horizontal aspects of consumer, user and public safety of services via their occupational health and safety legislation. All Member States have sector specific approaches, with a variety of provisions directly or indirectly relevant for the safety of various categories of services. Codes of practice and voluntary measures have also been established in some Member States, but on an ad-hoc basis and just for a few specific service sectors. In addition to the specific direct measures, regulation in other areas like safety of buildings and occupational safety is of significant indirect importance. The Report concluded that due to the complexity and variety of the relevant measures, it was very difficult to make a comparative assessment of the

151 Art. 20 of the General Product Safety Directive.

152 COM(2003) 313 final.

regulatory situation in the Member States and to identify specific gaps and weaknesses in the approaches in place or in their practical application and enforcement.[153]

Following the publication of the Report on Services Safety the overall situation has not appeared to change significantly. The 2009 Report on the implementation of the General Product Safety Directive[154] highlighted - with respect to the safety of consumer services - the lack of consensus among Member States regarding the appropriate level of Community action and the lack of comparable data. The lack of comparable data has not, however, prevented the Commission from pursuing new initiatives, where the focus was on the data collection,[155] awareness raising, and encouraging stakeholders to address priority areas for Community action, such as hotel safety.

In the first phase of the impact assessment process when the scope of problems the impact assessment should dealt with was being established, the Commission included within this scope also the possibility of taking a legislative action in the area of safety of services. An alternative to this approach would be to continue to monitor the different national approaches to the issue of safety of services, to collect the necessary data and evidence, in particular on the accidents and injuries occurring as a result of the provisions of services and on that basis pursue an appropriate non-legislative action, such as elaboration of a white paper mapping in detail the situation in different Member States regarding the safety of services for consumers.

When considering the choice of the most appropriate action in the area of safety of services, the Commission decided to take the latter approach. This conclusion was reached on the basis of the fact that on 28 December 2011 the Directive 2006/123/EC of 12 December 2006 on services in the internal market (the "Services Directive") partly dealing with the issue of safety of services, although principally from the perspective of free movement, entered into force.[156] Moreover, positions of stakeholders both at general level as well as within certain stakeholders signalled an important rift. On the one hand, consumer organisations, such as BEUC and ANEC strongly argued for a comprehensive horizontal framework for consumer safety, covering both product and service safety. In their view, the lack of an overarching

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153 Report on Services Safety, p. 2 – 3.

154 COM(2008) 905 final.

155 In 2007, the Commission adopted a proposal for a draft framework Regulation concerning Community statistics on public health and health and safety at work (COM(2007) 46).

156 OJ L 376, 27.12.2006, p. 36–68. The Services Directive guarantees the freedom is guaranteed to provide services within the European Union. In absence of harmonisation and exceptionally in a case-by-case basis, a Member State may take measures which derogate from the freedom of services on the basis of the case law of the Court of Justice, if there is an overriding reason relating to the public interest, for example due to the safety reason. If a Member State becomes aware that the service could cause a serious damage to the health or safety of persons or the environment, it shall inform the Member State of Establishment (in case it differs from the notifying Member State), the other Member States concerned and the Commission within the shortest possible period of time through the IMI system (System for exchange of information on service safety). The Services Directive also provides room for standardisation in the area of services.

legal framework for service safety and quality is of fundamental concern to consumers and consumer organisations and constitutes a loophole in the EU legislation since the Services Directive deals with the safety of services only very partially. On the other hand, business associations, such as BUSINESSEUROPE and Orgalime opposed the introduction of any legislative proposal covering safety of services in general. They believed that the scope of the General Product Safety Directive with regard to services should not be revised since in their opinion the establishment of a general services safety requirement would be disproportionate.[157]

Among the Member States the positions on the question of establishing a general framework for safety of service showed similar division. The positions of individual Member States on this issue more or less reflected the legislative situation in the Member State concerned. Thus, those Member State which had adopted general rules on the safety of services at the national supported the adoption of the same approach at the EU level whereas those which had not, opposed any EU legislative action with respect to the safety of services. Certain other Member States, such as Denmark proposed that the question the safety of services should be covered by other pieces of EU legislation, such as the Services Directive.[158]

In conclusion, for the reasons indicated the Commission decided not to include the issue of safety of services into the scope of this Product Safety Package.

12.3 General product safety requirements for professional products

The call of stakeholders for a uniform product safety framework for with the broadest possible scope raised the question whether the modernised harmonised product safety requirements which appeared well suited to apply also to non-harmonised consumer products should and could apply also to non-harmonised professional products. Due to its expected complexity this question was chosen to be left for a later exercise independent of this Product Safety and Market Surveillance Package. The Commission will, however, pursue its work and may come up with proposals on possible regulatory actions in this area at a later stage.

12.4. Safety of products marketed via the Internet

Under the existing product safety rules of the General Product Safety Directive products are subject to the same safety requirements regardless of the distribution channel through which they are marketed.[159] The study Future of Market Surveillance indicated that "*e-commerce is expanding rapidly and thus increasing cross-border trade.*"[160] Despite this fact, national market surveillance authorities of Member States have so far taken very limited action regarding safety of products sold via the

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157 See Annexes 2 and 3.

158 See Annexes 2 and 3.

159 Recital 7 of the General Product Safety Directive: "*This Directive should apply to products irrespective of the selling techniques, including distance and electronic selling*."

160 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).

Internet.[161] As a consequence, the level of protection of consumers and other users against health and safety risks posed by unsafe products sold on-line lags behind the level of protection provided in respect of other distribution channels. As a result, an unsafe product that has been withdrawn and recalled from the EU market may still be available to consumers via the Internet.

In the internet public consultation, economic operators and other stakeholders indicated that they did not think that national authorities pay as much attention to products sold online as they do to products sold through other distribution channels: A majority of economic operators think that dangerous consumer products are sold on the internet in the EU by operators based both in the EU and in third countries.[162] Only a minority thinks that attention given by market surveillance authorities to the safety of products sold online is equal (or higher) compared to that given to products sold through other distribution channels.[163] A strong majority of respondents confirmed that they were aware of dangerous consumer products being sold online in the EU.[164] An important majority of the respondents were also of the opinion that, with respect to safety, national market surveillance authorities do not treat products sold online in the same way as products sold in shops.[165]

The internet public consultation has shown that if national market surveillance authorities perform market surveillance on products marketed online, they do so in an incidental, fragmented and uncoordinated manner: only half of the national authorities have specifically monitored products sold online at a certain point of time during the last three years.[166] A large majority of those national market surveillance authorities which performed some monitoring products sold online had difficulties indicating the number of websites checked, the number of products targeted or the number of products sampled for further tests.[167] Certain national market surveillance authorities have, however, taken some preventive and/or restrictive measures against products

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161 See Annex 2, section 2.4.1.

162 Over 60% of economic operators pointed out that they are aware of dangerous consumer products are sold on the internet in the EU by operators based both in the EU and in third countries.

163 Only 28% of economic operators think that the attention given by market surveillance authorities to the safety of consumer products sold online is equal or higher compared to products sold through other distribution channels, while 35% pointed out that in fact the attention is significantly lower.

164 74% of the respondents confirmed being aware that dangerous consumer products are sold online in the EU.

165 Only 10% of the respondents think that the attention given by market surveillance authorities to these products sold online is equal (or higher) to the attention given to products sold via other distribution channels. Over two thirds of the respondents consider that national authorities do not treat products sold online the same way as products sold in shops.

166 53% of the responding national authorities monitored the safety of products at some point of time during the last three years.

167 About two thirds of these authorities pointed out that the number of websites checked was significant, but it was difficult to even estimate the numbers; only four NMSAs were able to quantify the number of potential unsafe products found on the internet and chosen for further tests. Only one NMSA was able to indicate the number of websites checked for the purpose of finding unsafe products; only four NMSAs were able to quantify the number of products found on the internet and sampled for further testing in order to assess their potential risks.

sold through online distribution channels.[168] The reasons for these shortcomings result from (i) a lack of explicit harmonised rules on the surveillance of the safety of *consumer products* sold via the Internet, (ii) a greater and more frequent presence of cross-border elements (including those going beyond EU borders) in on-line sales than in traditional sales, (iii) difficulties in tracking down *economic operators* responsible for selling unsafe products via the Internet, and (iv) the fact that many dangerous products are sold on the Internet by private individuals.[169] Although the General Product Safety Directive contains provisions which *de iure* could be applied to Internet transactions, their use by Member State market surveillance authorities has been rather limited, mainly due to the many uncertainties concerning their practical application.[170]

If no action with respect to safety of products sold on-line is taken, the exposure of consumers to dangerous products sold on the Internet will become higher than with respect to products sold through other distribution channels. This would lead to loss of consumer confidence in online consumer markets and could create barriers in the area of free movement of products sold online.

Since all products are already subject to the same requirements under the EU product safety legislation regardless of how they are sold, one of the possible options to address the issue of Internet sales would to clarify the practical application of the relevant provisions in a separate guidance document which would have a non-binding character. This document would build on the experience developed by some Member States and stakeholders in this field and its main goal would be the sharing and dissemination of best practices.

In case the adoption of guidelines for the application of the existing enforcement rules towards dangerous products sold on the Internet is not sufficient to effectively address the issue, a stronger regulatory action could be considered. Under this option, new specific provisions on market surveillance with regard to Internet sales would be introduced. These provisions would introduce obligations for economic operators selling products via Internet as well as specific enforcement powers for national enforcement authorities. More specifically, these provisions would address the categories of actions to be adopted by a responsible economic operator selling unsafe products via the Internet, such as the notification obligations, monitoring activities performed by national authorities, taking of samples, product and seller identification obligations etc.

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168 Three NMSAs were able to estimate the number of actions taken, while fifteen others confirmed that some measures were taken, without being able to quantify.

169 Annex 2, section 2.4.1; 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. 15).*

170 "*MSAs may struggle to prevent unsafe products reaching consumers when the location of stock is concentrated offshore or out of jurisdiction and for practical purposes "invisible to inspection". The most common form of inspection will not provide ready access to the products ready for distribution by e-commerce. This trend will also place an unequal burden on those MSAs in Member States that have territorial responsibility for large e-commerce operators or e-commerce supply depots*." ("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).

The position of stakeholders on the question of introducing specific measures to be taken against online distribution channels in cases of safety deficiencies of products sold through these channels were divided: whereas national market surveillance authorities pointed out that it would be easier to carry out market surveillance with regard to the products sold online if specific harmonised rules were introduced at EU level,[171] economic operators considered existing rules and enforcement means to sufficient for the purpose of tackling dangerous products sold via the Internet.[172]

The study "Future of Market Surveillance" indicated that *to* "*provide a more effective and efficient means of identifying and testing products that would otherwise slip past orthodox market surveillance inspectional activities,*" it is necessary to establish a pan-European task force which should be able to (i) "*harness accurate information with rapid intervention to succeed in identifying, intercepting and controlling the transit of dangerous products,"* and *(ii)* "*identify the locations of large supply depots and advise the relevant MSAs as appropriate.*"[173] The study therefore suggests that the most appropriate answer to the issue of distribution of unsafe product through the internet would consist in detection of the supply chains, in particular existing warehouses, which ensure distribution of products bought on-line by consumers and other users. Since the checks on products stored on business premises are a part of "standard" market surveillance authorities, adjustment of existing market surveillance tools, thus, seems to provide an appropriate and sufficient response to the problem of unsafe product marketed online.

Alternatively, special market surveillance measures for products marketed through on-line distribution channels helping to deal with dangerous products marketed on-line could be envisaged. However, the regulation of e-commerce is dealt with by existing EU legislative instrument.[174] Also, the main problem of safety of products sold on-line lies in the identification of the underlying distribution channels of physically existing products, the adoption of special market surveillance rules on-line distribution channels would not be able to provide desired tools for effectively eliminating from the market the products sold through the internet.

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171 When carrying out market surveillance of products sold online, market surveillance authorities were faced with difficulties with: a) identifying the economic operators (78%), b) enforcing restrictive measures on economic operators (70%), c) the cross-border nature of cases investigated (60%) or d) difficulties in taking product samples (50%). Over 90% of national authorities dealing with cross-border cases have had difficulties when investigating cases of products coming from third countries (outside EU/EEA). 64% of these national authorities also faced problems investigating cases related to products being sold inside the EU/EEA area. Three quarters of all national authorities would find it easier to carry out market surveillance with regard to dangerous consumer products sold on the internet if specific harmonised rules were introduced at EU level.

172 See Annex 3.

173 Study "The future of market surveillance in the area of non-food consumer product safety under the General Product Safety Directive", Final Report, Conclusions of the Workshop, BSI Development Solutions, May 2011, p. 26.

174 Directive 2000/31/EC 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market, OJ L 178, 17.7.2000, p. 1.

Apart from the high "cross-border" potential, the only difference between traditional and on-line distribution chain seems to be that the ends of on-line distribution chains cannot be found on the streets, but in the virtual internet environment. The only change to the current market surveillance practice necessitated by existence of these on-line distribution chains consists in finding the appropriate means for identification of the links between the ends of distribution chains appearing on the internet and the physically existing warehouses supplying potentially dangerous products. Given the fact that this task would be more effectively resolved in a non-regulatory way, for example, by the aforementioned pan-European task force, changing existing legislative rules does not seem to be necessary. However, the results of work of this pan-European task force should be reflected in operational guidelines in order to help national market surveillance authorities in identification of distribution chains supplying products to the on-line distribution channels.

In conclusion, it was chosen not to envisage legislative action with respect to the issue of the safety of products marketed through the Internet into this Product Safety Package. Instead, in line with the recommendations of the study “Future of Market Surveillance” it was preferred to include in the proposed Multiannual market surveillance plan actions aiming the establishment of a task force which should identify the most effective and efficient methods how to tackle the problem of unsafe product sold via the Internet. Once sufficient data on this issue are gathered and best methods identified, the Commission would consider the elaboration of guidelines for the application of general product safety rules sold on-line, inclusion of internet service providers among product safety actors.

13. ANNEX 13: COMPETITIVENESS ANALYSIS

13.1. Context

The General Product Safety Directive established a general obligation on economic operators to place only safe consumer products on the market. At the same time the Directive laid down requirements on the organisation and performance of market surveillance of health and safety aspects of consumer products. The Directive had as its goal to ensure that barriers to trade and distortions of competition within the internal market will be avoided. Therefore, the requirements on economic operators have the potential to impact on business competitiveness by influencing the following dimensions of competitiveness:

- Cost competitiveness: through compliance costs and costs necessary to produce and distribute the product, including for instance costs with labelling, packaging and traceability requirements.

- Capacity to innovate, by influencing the processes and requirements to develop and recognize a European standard and, therefore, having an impact on the speed by which they can place a product in the market.

- International competitiveness, by influencing the level playing field and the ability of operators (domestic and international) to place products on the EU market.

  At the moment, the co-existence of different legal instruments on European product safety, market surveillance and consumer protection creates a number of complexities and ambiguities.

  Following the steps proposed in the Operational guidance the following aspects will be assessed from the qualitative point of view: (i) the impact of costs for economic operators, (ii) adaptation of their methods in compliance with the law, (iii) the possible implications for companies' ability to innovate and the expected impact on international competitiveness.

13.2. Qualitative analysis

13.2.1 Availability of information

Consumer consumption represents 56% of the GDP of the European Union. Consumers' confidence is a key element for ensuring sustained level of consumer consumption which, in turn, is essential for generating economic growth and the proper functioning of the EU market. However, although there are no statistics that allow estimating the number or percentage of non-food dangerous products present on the EU market, there are indications – for example on the basis of the data from the RAPEX system - that unsafe products are being put on the internal EU market. Due to the absence of reliable statistics or even estimates about the number of unsafe and non-harmonised consumer products and the number of non-compliant harmonised products, the competitiveness proofing assessment is mainly qualitative.

13.2.2 Sectors affected

The measures resulting from the revision of the General Product Safety Directive and the measures concerning market surveillance for products can have an impact on different economic operators throughout the supply chain:

- Manufacturers have to comply with requirements concerning product safety and therefore have to considerer those requirements in the product development and manufacturing, including labelling and traceability. The ease of identification of manufacturers is key for the speed at which authorities can ensure that dangerous products for customers can be identified and withdrawn from the market.

- Importers act in many cases as representatives of the manufacturers and therefore become responsible for the introduction of the product in the market.

- Distributors (including online distributors) are the first contact point with consumers and have the responsibility to monitor the safety of products. Some retailers market own branded products for which they bear the manufacturers' responsibility.

  In terms of product sectors affected the General Product Safety Directive and Regulation (EC) No 765/2008 apply to a vast range of products as illustrated in Annex 7.

13.2.3 Cost competitiveness

13.2.3.1 Compliance costs

The current situation can be seen as non-optimal from the competitiveness point of view, since the business environment, in what concerns general product safety, can be characterised by:

- Costly conformity assessment and enforcement: The uncertainties as to the applicable safety requirements as well as the absence of referenced European standards for many products covered by the General Product Safety Directive makes conformity assessment and enforcement costly.

- Loss of synergies and unnecessary costs with 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 may have to be re-done in other Member States in order to make it possible to take action against such dangerous product in the other Member States.

  The current provisions on market surveillance in the EU internal market legislation can be a source of compliance costs for business, which can be optimised.

- Currently provisions on market surveillance are scattered over several directives and regulations. Besides certain market surveillance obligations set out in many harmonisation directives and regulations, market surveillance provisions for non-food products are contained in the General Product Safety Directive and Regulation (EC) No 765/2008.

- Inconsistent application of EU product measures by national market surveillance authorities was viewed as a problem by economic operators. Related compliance costs with the diverging national implementing measures were assessed as "non-negligible" by some of the operators.

- Failing traceability of manufacturers and importers is a problem for market surveillance authorities. Harmonisation of the obligations of economic operators in the non-harmonised area with those in the harmonised area, including traceability requirements and the obligation to establish certain technical documentation, would make enforcement activities more effective. In addition, economic operators and other stakeholders, including consumer organisations and a number of business associations, see more benefits than disadvantages if certain of these obligations of economic operators with regard to harmonised products were applied uniformly to all products.

- More demanding requirements on market surveillance activities of Member States (such as the need to check a minimum number of products of a certain kind) can impose additional costs to business.

13.2.3.2 Costs of production and distribution

Aligning the consumer product safety requirements with the harmonised products safety requirements would bring the desired clarity and legal certainty. Currently, there are differences between consumer product safety requirements and harmonised product safety requirements. Hence, stakeholders have to determine and then apply different sets of general requirements for products which often pose the same level of risk. There are also difficulties in particular for economic operators to determine which of the two inconsistent sets of requirements apply to a given product. Lack of coherence in the obligations of economic operators leads to confusion as to the applicable product safety rules which generates cost inefficiencies:

- Ambiguous legislation creates additional costs for economic operators resulting from the necessity of information research on applicable rules and legal advice on how to correctly apply these rules.

- Unnecessary additional legal costs for economic operators: Those arise from the absence of consistency between overlapping legislative instruments creates and has a negative impact on effectiveness of product safety rules.

- The coexistence without a substantive and practical alignment of the General Product Safety Directive with the New Legislative framework is likely to set up two separate legislative regimes – one for harmonised and one for non-harmonised products – with their own definitions and differing obligations for economic operators, and diverging competences of market surveillance authorities.

- Rules cannot be properly enforced and exert their full effect: this is the case when economic operators are not aware of which product safety requirements are prescribed or have doubts about their application.

- Legal uncertainty for both the economic operators as well as market surveillance authorities: Market surveillance authorities and economic operators are currently deprived of complete, up to date and efficient tools for determining the compliance of products on the market. Consequently, economic operators have to resort to alternatives which are sometimes costlier and which can be prone to inconsistency.

The preferred option "Option 1.C – Aligning consumer product safety requirements with harmonised product safety requirements" addressing Problem 1 will have the following expected qualitative impacts on cost competitiveness:

- Lower information-research costs and costs of legal advice to easily determine applicable product safety rules.

- Improve desired clarity and legal certainty by eliminating the existing overlap between inconsistent requirements under consumer product safety requirements and harmonised product safety requirements.

- Provide clear product safety requirements applying across the sectors and thereby 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 at lesser costs. Last but not least, it would contribute to the equal protection of consumers and other users against dangerous products.

- Enforcement of product safety rules would be easier if the obligations of economic operators in the harmonised and non-harmonised area were aligned.

The preferred option is expected facilitate marketing and ensure a fairer playing field across the internal market, having a positive impact for business production and distribution costs as well as for improved business environment with increased certainty.

13.2.4 Capacity to innovate

Unsafe consumer products constitute an immediate threat to the safety of consumers and undermine consumer confidence. They can become an obstacle for companies to launch new products and to generate new revenues by creating resistance in customers to accept new offerings. If consumers should have confidence in products available at the EU market, consumer products must be safe, irrespective of the place where they are produced.

Major shortcomings of the current General Product Safety Directive which can impact on companies' product cycles are:

- The unsatisfactory speed of standardisation procedures under the General Product Safety Directive is not satisfactory, and

- Confusion and uncertainty among economic operators about applicable product safety requirements.

  Measures to allow the rapid and easy identification of unsafe products can contribute to the adoption of new technologies. The application of track-and-trace technologies, and product authentication technologies, would be beneficial to consumer safety. The use of new technologies such as Radio Frequency Identification (RFID) technology tags and nano-printed intelligent packaging could aid traceability.

13.3. Competition in the internal market

The majority of products are increasing dependent on the globalisation supply chains which have become longer and more complex. Many products are regularly marketed in more than one Member State. Nevertheless, despite these developments market surveillance authorities undertake enforcement mainly along national lines, resulting in a fragmented enforcement effort and, hence, in unequal protection of European consumers and other users and little level playing field for economic operators.

Differences in the transposition of the General Product Safety Directive, and the limited powers of the Commission to introduce coordinated approaches, lead to:

- Unequal consumer protection. The lack of coherence of consumer product safety rules laid down in the General Product Safety Directive and other sector specific EU product safety legislation contributes to the unequal protection of consumers throughout the EU.

- Uneven playing field for economic operators across the EU with continuing existence of barriers on the internal market. Disparities in product safety legislation as well as the differences in enforcement practices between EU Member States create an uneven playing field for economic operators, in particular SMEs, which face distorted competition.

  Aligning consumer product safety requirements with harmonised product safety requirements" will have the following expected qualitative impacts on competition in the internal market:

- Reduction in information-research to certain economic operators: Clear rules relating to the identification of economic operators in the supply chain applying uniformly across consumer product sectors would bring a reduction in information-research to certain economic operators, in particular to those producing or marketing both products subject to the EU product safety legislation and consumer safety legislation, and selling their product in more than one Member State.

- 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 at lesser costs.

Providing tools for coordination of reactive market surveillance would would be expected to have the following impacts on competitiveness:

- It would help authorities to cope with the growing globalisation of product supply chains. Thus, 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 as well as it would provide more level playing field for compliant economic operators.

13.4. Competition with third countries

Imports from third countries are growing faster than domestic production and the EU is faced with an increasing number of non-conforming products arriving from third countries. The fact that market surveillance for products within the single market is fragmented, together with the globalization of value chains, can in some cases place European based manufacturers at disadvantages with EU importers that ignore European product safety rules:

- "Rogue" operators sell products cheaper than compliant economic operators. A low effectiveness of the sanction regime for breaches of product safety obligations contributes to the unlawful competition of "rogue" operators and generates health and safety risks for consumers and other users. The weakness of the current sanction gives to the "rogue" operators an incentive for costs savings on safety requirements and allows them to sell products cheaper than compliant economic operators. This gives to these "rogue" operators competitive advantage over the compliant operators and at the same time endangers the health and safety of consumers. "Rogue" operators save money by not investing in safety and 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. The situation “punishes” the law-abiding manufacturer, as compliance becomes a “competitive disadvantage”.

- Unequal treatment of economic operators and unequal protection of European consumers due to fragmented enforcement effort of EU product safety rules. Market surveillance authorities still undertake enforcement mainly along national lines despite the growing number of imports of non-food products from third countries to the EU – which also increasingly ends up in more than one Member State – and, more generally, the growing size of intra-EU trade in consumer products.

- Globalisation makes it difficult to determine how and by whom a product is manufactured or who has placed it on the market. For market surveillance to be efficient, collaboration with manufacturers is essential in order to rectify compliance, prevent the placing on the market, and, as a last resort, to

withdraw non-compliant products. In practice 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. They often cannot find a contact person who could provide them with the necessary information to evaluate the conformity of the product and who could help them to ensure that dangerous products are withdrawn from the market.

- Insufficient controls at external borders are exposing European producers to unfair competition: External borders are the best place to detect non-conforming products from third countries as they are the entry point for imported goods. However, resources are not always sufficient and have not kept pace with the increase in imports; therefore, external borders are not always sufficiently controlled. The differences in effectiveness of border controls between entry points once again create a problem for the whole Union. Experience has shown that where a shipment of non-compliant products is detected and destroyed at one entry point, importers will often look for another entry point into the Union which has less stringent controls for import of his product.

Examples: Non-conforming products arriving from third countries leading to unfair competition with EU producers.

EU electro-technical sector

The EU electro-technical sector is faced with an increasing number of non-conforming products arriving from third countries. The share of imported products in the total of non-compliant products detected by market surveillance authorities is between 70% and 99%. Most data on non-compliance is available in the electro-technical sector. It is also the sector in which stakeholders and in particular industry associations have been most active in pointing to the problem. The LVD market surveillance authorities have undertaken three cross border actions, on portable household lights, cord extension sets and Christmas lighting. Only 5% of the household lights tested showed no shortcomings (either administrative or technical). Whilst not causing immediate danger to consumers, the shortcomings were considered serious enough to require remedies. Only one in six cord extension sets fully complied with the requirements. 58% of the cord extension sets tested were considered sufficiently unsafe by the authorities to justify a sales ban. Similar findings were obtained in three market surveillance campaigns carried out by the EMC Administrative Cooperation group (ADCO) recently, which focused on Energy Saving Lamps, Power Tools and Consumer Entertainment Electronic Products. The results of these campaigns showed that the level of technical non-compliance was 23% for the Energy Saving Lamps, 20% for the Power Tools and 50% for the Consumer Entertainment Electronic Products. Further general conclusions drawn from the campaigns were that for the electro-technical sector, the share of non-compliant imported products was generally higher than the share of non-compliant products originating from EU countries, and that for a considerable part of non-compliant products the origin could not be determined.

Imported toys

A survey on the safety of imported toys in new Member States indicated that 55% of the imported products sample was non-compliant, and of those 12% had no indication of origin.

13.5. Conclusion

The proposal is expected to have a positive impact on the EU competitiveness since it has the potential to improve the detection of unsafe consumer products in the single

market and at the same time reducing compliance costs for business by creating a unified framework. This will translate into creating a more certain business environment and a level playing field which will be more demanding for "rogue" traders which distort the market.

14. ANNEX 14: SUMMARY OF JOINT MARKET SURVEILLANCE ACTIONS

NAME	DATE	PRODUCTS COVERED	MEMBER STATES
JOINT MARKET SURVEILLANCE ACTION ON HELMETS	1/12/2009 – 31/12/2010	HELMETS	Cyprus, Czech Republic, Germany, Iceland, Latvia, Lithuania, Norway, Slovenia, Spain, Sweden, The Netherlands (11 MS)
JOINT ACTION ON SUNBEDS 2008 2009	1/9/2008- 31/12/2009	SUNBEDS + SUNBED SERVICES	Belgium, Cyprus, Czech Republic, Denmark, Finland, Germany, Hungary, Latvia, The Netherlands, Poland (10 MS) And Switzerland
JOINT MARKET SURVEILLANCE ACTION ON TOYS	9/2008- 4/2010	TOYS FOR CHILDREN UNDER 3 YEARS OLD (small parts and magnets in toys; heavy metals)	Bulgaria, Czech republic, Denmark, Estonia, France, Greece, Germany, Italy, Lithuania, Latvia, Norway Slovakia, The Netherlands Other: Turkey, Canada (13 MS)
JOINT MARKET SURVEILLANCE ACTION ON CORDS AND DRAWSTRINGS ON CHILDREN'S CLOTHING	15/8/2008 – 15/2/2010	CHILDREN'S CLOTHING (cords and drawstrings)	Austria, Bulgaria, The Czech Republic, Denmark, Estonia, France, Greece, Ireland, Lithuania, The Netherlands and Portugal (11 MS) Also Turkey and Spain followed actively
"SAFE PLAY ON THE PLAYGROUND!"	9/2007- 11/2008	PLAYGROUNDS AND PLAYGROUND EQUIPMENT	Bulgaria, Denmark, Estonia, the Netherlands, Norway, Slovakia, Slovenia and Poland
JOINT MARKET SURVEILLANCE ACTION ON CHILD-RESISTANT	8/2007- 11/2009	CHILD-RESISTANT LIGHTERS AND NOVELTY	Austria, Bulgaria, Denmark, Estonia, Greece, Latvia, Malta, The Netherlands, Norway, Poland, Slovenia,

NAME	DATE	PRODUCTS COVERED	MEMBER STATES
LIGHTERS AND NOVELTY LIGHTERS		LIGHTERS	Slovak Republic and Sweden. (13 MS)
JOINT ACTION ON "ELECTRICAL SAFETY OF CORD EXTENSION SETS"	3/2007- 3/2008	MULTIPLE OUTLET EXTENSION CORDS	Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Germany, Denmark, Spain, Finland, Iceland, Lithuania, Luxembourg, the Netherlands, Norway, Malta, Poland, Sweden, Slovenia, Slovakia, and UK
SUSY SAFE PROJECT **(SURVEILLANCE SYSTEM ON SUFFOCATION INJURIES DUE TO FOREIGN BODIES IN EUROPEAN CHILDREN)**	2/2005- 8/2009	SUSYSAFE stands for Surveillance System on Suffocation Injuries due to Foreign Bodies in European children.	Italy, Austria, Germany, Cyprus, Greece, Czech Republic, France, Portugal, The Netherlands, Slovak Republic (Germany +Finland participated in the first phase of the project)
ICSMS2	1/1/2008-31/12/2008	The overall objective of the ICSMS2 project is to optimise ICSMS (a data exchange system on market surveillance) as a tool for the realisation of the network article 10 of the General Product Safety Directive (GPSD, 2001/95/EC).	Austria, Belgium, Estonia, Germany, Luxembourg
ENHANCING MARKET SURVEILLANCE THROUGH BEST PRACTICE (EMARS)	1/1/2006 - 31/12/2008	Aims to establish a common body of knowledge on market surveillance and to make this information and	Austria, Belgium, Denmark, Estonia, Finland, Germany, Greece, Hungary, Latvia, Lithuania, Malta, the Netherlands, Norway, Romania, Slovenia

NAME	DATE	PRODUCTS COVERED	MEMBER STATES
		expertise available to the Member States and the Commission for both strategic and tactical goals	
ENHANCING MARKET SURVEILLANCE THROUGH BEST PRACTICE II (EMARS II)	11/2008-12/2011	Continuation of EMARS I	Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Iceland, Ireland, Latvia, Lithuania, Malta, Norway, Poland, Romania, Slovenia, Sweden, The Netherlands, United Kingdom Participants outside the Financial Framework: Austria, Spain, Switzerland
JOINT MARKET SURVEILLANCE ACTION LIGHTING CHAINS	1/9/2007-31/3/2009	LIGHTING CHAINS	Hungary, Germany, Slovakia, Slovenia
JOINT MARKET SURVEILLANCE ACTION ON HOUSEHOLD APPLIANCES-CHILD APPEALING DESIGNS	12/2009 - 12/2010	HOUSEHOLD APPLIANCES-CHILD APPEALING DESIGNS	Belgium, Cyprus, Czech Republic, Denmark, Estonia, Germany, Latvia, Lithuania, Malta, Poland, Sweden, the Netherlands, United Kingdom
JOINT MARKET SURVEILLANCE ACTION ON BABY WALKERS	12/2009 - 12/2010	BABY WALKERS	Austria, Cyprus, Czech Republic, Denmark, Germany, Greece, Latvia, Lithuania, Malta, Portugal, Sweden, the Netherlands
JOINT MARKET SURVEILLANCE ACTION ON SUN	1/1/2010-31/12/2011	SUN BEDS AND SOLARIUM	Belgium, Cyprus, Czech Republic, Denmark, France, Germany, Hungary, Latvia,

NAME	DATE	PRODUCTS COVERED	MEMBER STATES
BEDS AND SOLARIUM SERVICES PART II		SERVICES	Norway, Portugal, the Netherlands, United Kingdom
JOINT FOLLOW UP MARKET SURVEILLANCE ACTION ON CHILD RESISTANT LIGHTERS AND NOVELTY LIGHTERS (LIGHTERS 2009)	1/1/2010-31/12/2012	CHILD RESISTANT LIGHTERS AND NOVELTY LIGHTERS	Austria, Cyprus, Czech Republic, Estonia, Greece, Iceland, Malta, Norway, Slovak Republic, Slovenia, Spain, Sweden, the Netherlands

15. ANNEX 15: LEGISLATIVE SIMPLIFICATION IN DETAIL

15.1. Problems with the existing legislative framework in the non-food product safety area

The current legislative framework can be described as complex and confusing.[175] Obligations of economic operators regarding consumer products are subject to the General Product Safety Directive and/or to the Union harmonisation legislation comprising sector specific New Approach and Old Approach Directives.[176]

Thus, the product safety requirements for consumer products which are not subject to any piece of the Union harmonisation legislation are governed by the General Product Safety Directive (square 2: so-called non-harmonised consumer products) whereas professional products[177] are subject to the respective piece(s) of the Union harmonisation legislation (square 3: so-called harmonised professional products). The consumer products which are at the same time subject to any piece of the Union harmonisation legislation have to comply with the requirements of both the General Product Safety Directive[178] and the relevant New Approach or Old Approach Directive(s).[179] The remaining products, i.e. professional products not subject to any

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175 "*With the adoption of the legislative package on the Free Movement of Goods (also called the "Goods Package"), the regulatory landscape on product safety and market surveillance has become very complex and confusing*." (Mayer Brown, The Revision of the EU General Product Safety Directive, Memorandum, January 2011).

176 Union harmonisation legislation is defined in Art. 2 (21) of regulation (EC) No 765/2008 as a any Union legislation harmonising the conditions for the marketing of products. Examples of of such legislations are in particular the so-called New Approach Directives, such as Recreational Crafts Directive (94/25/EC), Low Voltage Directive (2006/95/EC), Simple Pressure Vessels Directive (2009//105/EC), Non-automatic Weighing Instruments Directive (2009/23/EC), Civil Explosives Directive (93/15/EEC), ATEX Directive (94/9/EC), Lifts Directive (95/16/EC), Pressure Equipment Directive (97/23/EC), Measuring Instruments Directive (2004/22/EC), Pressure Equipment Directive (97/23/EC), Electromagnetic Compatibility Directive (2004/108/EC), Pyrotechnic Articles Directive (2007/23/EC), Personal Protective Equipment Directive (89/686/EEC), Radio and Telecommunications Terminal Equipment (1999/5/EC) etc.

177 Products not fulfilling the definition of a (consumer) product under the General Product Safety Directive.

178 The relationship between the General Product Safety Directive and sector-specific pieces of Union harmonisation legislation is governed by Art. 1 (2) of the General Product Safety Directive which provides that this Directive shall apply to all the products defined in Article 2 (a). Each of its provisions shall apply in so far as there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned. Where products are subject to specific safety requirements imposed by Community legislation, this Directive shall apply only to the aspects and risks or categories of risks not covered by those requirements. This means that: (a) Articles 2(b) and (c), 3 and 4 shall not apply to those products insofar as concerns the risks or categories of risks covered by the specific legislation; (b) Articles 5 to 18 shall apply except where there are specific provisions governing the aspects covered by the said Articles with the same objective. Concrete application of the General Product Safety Directive with respect to the sector-specific pieces of Union harmonisation legislation was detailed in a Guidance Document on the Relationship Between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety published by Directorate-General for Health & Consumers in 2003 and 2005.

179 "*The real confusion comes for consumer products that are subject to harmonized EU rules, such as toys and cosmetics products, which are subject to to both the GPSD and the Regulation as well as the*

piece of the Union harmonisation legislation, are subject to national laws of Member States subject to the rules of the Mutual Recognition Regulation[180] (square 4: so-called non-harmonised professional products).

Table 1: Overview of applicable legislation

Products	Consumer	Professional
Harmonised	1. Sector specific New and Old Approach Directives and the General Product Safety Directive	3. Sector specific New and Old Approach Directives
Non-harmonised	2. General Product Safety Directive	4. National product safety rules under the Mutual Recognition Regulation

Similar confusion as to the applicable rules exists at the level of market surveillance rules for consumer products.[181] If following an infringement of consumer product safety requirements and/or harmonised product safety requirements, the application of market surveillance rules comes into play, depending on the categorisation of the product in question either the rules on market surveillance laid down in (i) the General Product Safety Directive, or (ii) the Regulation (EC) No 765/2008, or (iii) both these instruments apply.[182] Adding to the complexity, many sector specific directives also have certain provisions relating to market surveillance which are supposed to apply. [183]

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specific provisions included in the specific (toys, cosmetic) regulations in place." (Mayer Brown, The Revision of the EU General Product Safety Directive, Memorandum, January 2011).

180 Regulation (EC) No 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State (OJ L 218, 13.8.2008, p. 11)

181 "*To determine which provisions of each of these three sets of rules apply [the General product safety Directive, Regulation (EC) No 765/2008 and sector-specific Union harmonisation legislation] […] 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 or recalls*." (Mayer Brown, The Revision of the EU General Product Safety Directive, Memorandum, January 2011).

182 The relationship between the General Product Safety Directive and Regulation (EC) No 765/2008 is governed by Art. 15 (3) of the latter instrument which stipulates that the application of this Regulation shall not prevent market surveillance authorities from taking more specific measures as provided for in Directive 2001/95/EC (the General product Safety Directive). The determination of which measures under the General Product Safety Directive are more specific in relation to Regulation (EC) No 765/2008 was specified by the Commission in the Working paper on the relationship between the General Product Safety Directive 2001/95/EC and the Regulation (EC) No 765/2008.

183 Those aligned to the reference provisions of Annex 1 of Decision (No) 768/2008/EC, in particular to the provisions of Articles R31 – R34 of this Annex.

Table 2: Overview of the EU regulatory framework in the area of non-foodproduct safety

<table>
<tr><th colspan="5">Overview of the 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>Professional</th><th colspan="2">Consumer</th><th>Professional</th></tr>
<tr><td>Obligations of economic operators</td><td rowspan="2">National law under the Mutual Recognition Regulation</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>Market surveillance on the internal market*</td><td rowspan="2">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>RAPEX*</td><td></td><td>Regulation 765/2008 referring to GPSD</td><td>Regulation 765/2008 referring to GPSD</td></tr>
<tr><td>Market surveillance on products imported to the EU*</td><td colspan="3">Regulation 765/2008</td></tr>
</table>

In addition to the described shortcomings of the existing legislative framework in terms of clarity and consistency, in the public consultation legal experts mentioned the lack of visibility of the market surveillance rules of Regulation (EC) No 765/2008 which further contributed to the confusion about the applicable product safety rules in the non-food area. They noted that it was extremely difficult for specialised lawyers and virtually impossible for economic operators to be able to ascertain which rules of which of the instruments apply, i.e. rules of the General Product Safety Directive, Regulation (EC) No 765/2008 or of the relevant piece of Union harmonisation legislation.[184]

In the view of the aforementioned problems, it is not surprising that in the public consultation all groups of stakeholders, including consumer organisations, business associations, national market surveillance authorities, [185] legal experts,[186] as well as the European Parliament,[187] called for the establishment of a uniform legislative market surveillance framework in the area of non-food products. The establishment of such framework was considered to be a necessary pre-condition for a more coherent

184 Fourth targeted stakeholder meeting "Legislative architecture of general and specific product safety rules (summary of the meeting is contained in Annex 4, section 2.4)

185 See the relevant sections of Annexes 2 and 3 summarising responses to the internet public consultation and the position papers of stakeholders.

186 "*However, the above demonstrates that it is the entire legal framework on the safety of products that requires streamlining […] [and] that the market surveillance provisions of the GPSD and the Regulation [(EC) No 765/2008] are consolidated within a single regulation, which would therefore affect all types of products*." (Mayer Brown, The Revision of the EU General Product Safety Directive, Memorandum, January 2011).

187 Schaldemose Report, points 1 and 2.

application of product safety rules by national market surveillance authorities of Member States.

15.2 The way forward: clarification of the legislative framework

Product safety rules can be effectively internalised by economic operators into their day-to day business if they are consistent, visible and easy to apply. If visibility helps economic operators to avoid information-research costs related to the existence of rules, consistency of legislation gives clarity and legal certainty about the contents of product safety requirements, and thus avoids additional legal costs of finding out which rules are actually applicable. Consequently, addressees of consistent rules should be able to determine easily which product safety requirements apply in which situations without incurring heavy information-research costs or running into interpretation difficulties. The simplification of the overall legislative framework in the non-food product safety area called for by all relevant stakeholders could entail three elements.

15.2.1 Splitting the General Product Safety Directive

The current General Product Safety Directive contains two parts:

- a part concerning the general product safety requirement of economic operators and related procedures for establishing mandates for development of European standards giving technical details of how the general product safety requirement can be applied in practice with respect to different products (Articles 3 – 5 of the current General Product Safety Directive) and

- a part on market surveillance, i.e. enforcement of non-food product safety requirements (Articles 6 – 18 of the current General Product Safety Directive).

  The former part of the General Product Safety Directive (i.e. the part containing the general safety requirement, procedures for mandating standards and the obligations of economic operators for non-harmonised products) would be modernised in a self-standing instrument in the form of a regulation (Consumer Product Safety Regulation), while the latter part would be improved in the single horizontal market surveillance regulation (Market Surveillance Regulation).

15.2.2. Merging market surveillance provisions into a single horizontal market surveillance Regulation

The second part of the General Product Safety Directive (Art. 6 – 18 of the current GPSD) concerning market surveillance and Chapter 3 of the Regulation (EC) No 765/2008 concerning market surveillance could both be improved and merged into a self-standing legal instrument, a "Market Surveillance Regulation". The consolidation of the market surveillance provisions of the two instruments would be performed by

"*taking into account the provisions developed more fully in the two existing legislative acts*."[188]

Regulation (EC) No 765/2008, without its market surveillance provisions, would remain an independent legal instrument dealing with specific technical issues, including (i) accreditation and conformity assessment bodies, (ii) CE marking, and (iii) EU financing of bodies pursuing the general European interest.

15.2.3 Relationship with sector-specific Union harmonisation legislation

Finally, the existing confusion which of the provisions of which instruments apply in which situations[189] would be resolved by moving all the provisions on market surveillance to the single market surveillance Regulation This avoids interpretation issues and different transpositions in different Member States.

15.3. The new simplified legislative framework in the non-food product safety area

The obligations of economic operators would be simplified by aligning the consumer product safety requirements contained in the current General Product Safety Directive with the harmonised product safety requirements laid down in the relevant provisions of Annex 1 of Decision No 768/2008/EC.[190] The overlaps and inconsistencies would be eliminated as the consumer product safety requirements would no longer (potentially) conflict nor overlap with the harmonised product safety requirements.

At the same time, the difficulties relating to the determination of the applicable set of rules for different categories of products (harmonised/non-harmonised/consumer/professional) would disappear since the elimination of overlaps between different sets of rules would render the *ex ante* determination of the applicable set of rules superfluous. Since these requirements would be aligned, economic operators would not have to perform any additional research or seek additional legal advice as to whether, for their products, additional safety requirements from the Consumer Product Safety Regulation apply or not.

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 (Consumer Product Safety 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.[191] A regulation is directly applicable in all Member States; there is therefore, no need for Member

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188 Schaldemose Report, point 12.

189 The relationship between Regulation (EC) No 765/2008 and sector specific market surveillance provisions contained in Annex 1 of the "alignment" (see for example, Articles 41 to 44 of the Toy Safety Directive which were "transposed" to this Directive from the aforementioned Annex) is governed by Art. 15 (2) of this Regulation which stipulates that Each of the provisions of Articles 16 to 26 shall apply in so far as there are no specific provisions with the same objective in Union harmonisation legislation.

190 Articles R1 to R7.

191 Article 296 TFEU

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.

Regarding market surveillance rules, both the inconsistencies between the market surveillance provisions of the current General Product Safety Directive as well as Regulation (EC) No 765/2008 as well as between these instruments and sector specific Union harmonisation legislation would be resolved since all the applicable market surveillance rules would be contained in a single horizontal market surveillance Regulation integrating all applicable market surveillance provisions for enforcement of any EU product safety rules.

Table 3: 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 in the area of non-food product safety</th></tr>
<tr><th rowspan="2">Products / Areas</th><th colspan="2">Non- Harmonised</th><th>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 rowspan="2">National law under the Mutual Recognition Regulation</td><td>Consumer Product Safety Regulation</td><td>Sector specific Union harmonisation legislation</td><td>Sector specific Union harmonisation legislation</td></tr>
<tr><td>Market surveillance on the internal market*</td><td colspan="3" rowspan="2"></td></tr>
<tr><td>RAPEX*</td><td>(Possibility of extension on the basis of a decision under Art. 11 of Mutual Recognition Regulation)</td><td colspan="3">Market Surveillance Regulation</td></tr>
<tr><td>Market surveillance on products imported to the EU*</td><td colspan="4"></td></tr>
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