EUROPEAN PARLIAMENT

DIRECTORATE-GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT A
ECONOMIC AND SCIENTIFIC POLICY

Economic and Monetary Affairs

Employment and Social Affairs

Environment, Public Health and Food Safety

Industry, Research and Energy

Internal Market and Consumer Protection

Market Surveillance and revision of GPS Directive

IMCO

EN

2010

DIRECTORATE GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICIES

INTERNAL POLICIES

Market Surveillance and revision of GPS Directive

Abstract

The study examines the relationship between the General Product Safety Directive and the New Legislative Framework from the point of view of market surveillance, looking in particular at definitions and interpretations of concepts. It also looks at joint market surveillance actions, market surveillance of consumer products and of dangerous products bought online.

IP/A/IMCO/ST/2010-03 September 2010

PE 447.505 EN

This document was requested by the European Parliament's Committee on Internal Market and Consumer Protection.

AUTHORS

Ms Hanna-Maija Kuhn
Ms Janne Sylvest
Rambøll Management Consulting

RESPONSIBLE ADMINISTRATOR

Mr Balazs Mellar
Policy Department Economic and Scientific Policies
European Parliament
B-1047 Brussels
E-mail: poldep-esc@europarl.europa.eu

LINGUISTIC VERSIONS

Original: EN

ABOUT THE EDITOR

To contact the Policy Department or to subscribe to its monthly newsletter please write to: poldep-esc@europarl.europa.eu

Manuscript completed in September 2010.
Brussels, © European Parliament, 2010.

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LIST OF ABBREVIATIONS

ADCO	Administrative Cooperation Group in Market Surveillance
ANEC	The European Consumer Voice in Standardisation
BEUC	The European Consumers' Organisation
DG ENTR	European Commission Directorate General for Enterprise and Industry
DG SANCO	European Commission Directorate General for Health and Consumers
DG TAXUD	European Commission Directorate General for Taxation and Customs Union
DMF	Dimethylfumarate
EEA	European Economic Area
EMARS	Enhancing Market Surveillance Through Best Practice
EMC	Electromagnetic Compatibility
EMOTA	European E-Commerce and Mail Order Trade Association
ESA	European Sunbed Association
EUROSAFE	European Association for Injury Prevention and Safety Promotion
GPSD	General Product Safety Directive
IMCO	Committee on Internal Market and Consumer Protection
LVD	Low Voltage Directive
MSA	Market Surveillance Authority
NLF	New Legislative Framework
PROSAFE	Product Safety Enforcement Forum of Europe
R&TTE	Radio and Telecommunications Terminal Equipment

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EXECUTIVE SUMMARY

The current EU level legislative framework for the market surveillance of products consists of three legislative elements: **The General Product Safety Directive** (Directive 2001/95/EC); **the New Legislative Framework** (NLF) for the marketing of products, and in particular Regulation 765/2008; as well as relevant **sector harmonisation directives**. While the General Product Safety Directive (GPSD) is applicable to all consumer products, the Regulation 765/2008 applies to all products covered by sector harmonisation directives, including both consumer and non-consumer products. Since the Regulation 765/2008 came into force on 1 January 2010, the harmonised consumer products are covered by both the GPSD and the NLF. The objective of this study is to provide an overview of possible divergences between the GPSD and the NLF in order to assess whether there is a need for alignment between the two instruments. Furthermore, the study includes more specific questions concerning joint market surveillance actions, market surveillance specific to consumer products, and market surveillance of products purchased online. The main conclusions of the study can be summarised in the following points:

1. While several stakeholders acknowledge that some definitions of the GPSD and the NLF differ from each other, the main message is that **the divergences in the definitions do not cause any important challenges to market surveillance and consumer safety.** The differences are mainly considered to be subtle and rather issues of terminology than content. On a general level it can be said that the definitions in the NLF are somewhat more specific and updated than those in the GPSD. Even though only limited challenges were identified, the predominant view among the stakeholders is that it is relevant to update the definitions in the GPSD and thus to align them with the NLF in order to avoid any possible confusions.

2. The definitions of **economic operators** differ from the GPSD to the NLF. According to the interviewees this divergence does not have any direct implications on market surveillance, but it does have a direct impact on how the obligations of the economic operators are defined and these differing definitions can cause some confusion concerning the obligations of the economic operators. In order to avoid confusion, some Member States have gone over to only applying the definitions used in the NLF.

3. The definition of **"product"** is directly connected to the scope of both the GPSD and the NLF, and the way in which "product" is defined, indicates what products are covered by the two legislative instruments. The difference in the definition is not as such considered to have any negative implications on market surveillance or consumer safety.

4. Whereas the NLF includes definitions of **"making available on the market"** and **"placing on the market"**, the GPSD does not provide for a clear definition of either. The interviews and the desk research have not revealed any concerns related to the lack of definition of the two in the GPSD. The inclusion of the definitions in the NLF has however been welcomed by several stakeholders, indicating their importance to market surveillance and product safety. Moreover, it is considered that a clear definition of the two can also clarify the obligations of the economic

operators responsible for making a product available on the market and for placing a product on the market.

5. The definitions of **recall and withdrawal** are almost the same in both the GPSD and the NLF, with the difference that the GPSD is more specific in determining the characteristics of the products to be recalled or withdrawn from the market. Neither of these definitions seem to have any negative implications for the functioning of the internal market. None of the interviewees refer to the small divergences in the definitions as something that would cause challenges for the market surveillance of products.

6. The issues regarding the concept of "**serious risk**" in the GPSD, the NLF and the sector legislation lie not in the definition of serious risk as such, but rather in how serious risk is identified and assessed. In the context of GPSD, the RAPEX Guidelines provide a method for risk assessment, but the stakeholders hold differing views concerning the usefulness of these Guidelines. Whereas some consider the Guidelines to be very useful and practical, others see them as too general in scope, making it difficult to apply the method to specific products. Moreover, no clear Guidelines exist for conducting risk assessment on harmonised products that are not covered by GPSD and the RAPEX Guidelines. In the case of these products, the Member States are used to operating with the compliance testing, which can be checked against the technical annex in the sector directives. Hence, some stakeholders express concerns about the ability of the RAPEX Guidelines to warrant a consistent interpretation of "serious risk" in the Member States. Guidelines that are not specific enough can, together with the personal assessment of the Market surveillance authorities (MSA) lead to risk assessment being carried out differently across Member States and authorities, and result in products being placed on the market in one Member State, while they are banned in another Member State.

7. With regards to **the obligations of economic operators**, the GPSD is on some points more developed than the NLF, including the requirement to provide information to the consumers, and the requirement to keep a register of complaints. On other points, the GPSD is less clear, for instance with regards to traceability, which is an issue that could be improved. Likewise, it is pointed out that provisions concerning the safety documentation and the declaration of conformity could also be included in the revised version of the GPSD, in order to ensure that the products covered only by the GPSD are also covered by these provisions. As some Member States have already included traceability requirements in their national legislation transposing the GPSD, making the provisions obligatory in the revised version of GPSD would only change the situation in some Member States. This should be taken into account when considering the need to align the provisions of traceability.

8. There are indications that **the obligations and powers of the Member States** are not stringent enough in the GPSD, partly because of transposition issues. The NLF, for its part, is very specific in its way of presenting the obligations and powers of the national authorities. For example the right to enter the premises of economic operators, if necessary, is a provision found in the NLF but lacking in the GPSD. Thus, in effect, two different market surveillance systems now exist for harmonised and non-harmonised products, where the system for harmonised products (NLF) in a number of cases provides more wide-ranging powers and obligations to the MSAs. Whether, and to what extent, this has effects on market surveillance and on the safety of products in practice is not quite clear; in some Member States, it appears that there is no real difference in practice, whereas others point to specific issues

where there are disparities that may potentially have a negative effect. In order to avoid uncertainties and differing practices in Member States it may thus be advisable to align the rights and powers of national authorities in the GPSD along those of the NLF.

9. With regard to **the options for alignment**, there is general agreement between the respondents that at least some level of alignment is needed between the two instruments. The interviews point to two preferred ways to go about: Including the market surveillance provisions of the GPSD into the NLF, or having two separate documents, where the GPSD is updated in such a way that it takes into account the relevant provisions in the NLF. The documents would not be identical, as the GPSD would still be a legislative act for general product safety. Which option is chosen is a political decision and no recommendations are provided in this study to this end. Instead, some specific needs for alignment can be pointed out. These include for example the following:

   - The definitions should be aligned between the GPSD and the NLF and follow the definitions as presented in the NLF.
   - In particular the definition of economic operators should be aligned, as differing definitions have a direct implication on the obligations of the economic operators. These will become easier to understand if the definitions used are the same in both the GPSD and the NLF.
   - There is a need to clarify the risk assessment method and the definition of serious risk in the harmonised non-consumer area.
   - An important difference between the GPSD and the NLF is the obligation in the NLF to draw up market surveillance programmes. This means that market surveillance programmes are only required for the harmonised area and there seems to be a need for alignment so that similar programmes will be drawn up in the non-harmonised area as well.

10. The experiences of joint actions show that the **factors determining the success of a joint action** include for example: shared objectives and ambitions; cooperation between the MSA and the industry organisations; training of market surveillance authority staff in order to align inspections and measurements; as well as cost-cutting in the form of joint investments and economies of scale through joint testing of products. The main **limitations and barriers to Member State participation in joint market surveillance actions** are closely linked to the need for financing. Firstly, the limited resources of the national market surveillance authorities (MSA) can lead to some Member States not participating in joint actions as their resources are needed on the national level, or to prioritise between joint actions. Secondly, while the Commission is an important source of funding for the joint actions, the respondents point to an unreasonable administrative workload associated with applying and receiving EU funding for joint actions. Moreover, problems associated with EU funding include cash flow problems and lengthy procedures. Other limitations and barriers mentioned by Member States include lack of human resources, difficulty to coordinate between national tasks and joint actions, as well as linguistic shortcomings. Some Member States also mention that one of the reasons for non-participation is that the topics chosen for joint actions are not always relevant for each Member State.

11. With regards to **the need for market surveillance specific to consumer products**, the views of the stakeholders are somewhat mixed. Interviewees agree that the main characteristic or specificity of consumer products is the role of the **user** – the consumer – which, as opposed to the professional user, cannot be expected to be able to assess the safety of a product. Some interviewees point out that most of the market surveillance activities are already now directed at consumer products, but it is not possible to conclude whether there is a general need for market surveillance that is specific to consumer products.

12. With regards to **products bought online**, the existing legislation focuses on the unsuitable and dangerous characteristics of a product, not the means through which it is acquired and how it reaches the consumer. The importance of the role of customs and the need to strengthen the degree of cooperation with MSA was a particularly recurrent point. However, there is considerable difficulty in defining exactly which type of power is necessary to act online. Among the key issues specific to products sold online are the problems of traceability (including the location of the seller), and the sheer volume of small but numerous imports by private individuals which amplify the difficulty of detecting non-compliant products. However, the issue seems less one of changing the current legislation but more one related with improving the way market surveillance works, and not least the co-operation between MSAs and customs.

1. INTRODUCTION

The General Product Safety Directive (GPSD)[1], which was adopted in its amended form in December 2001[2], aims to protect consumer health and safety and to ensure the proper functioning of the internal market. The GPSD applies to all consumer products, both those not covered by sector specific harmonisation legislation and those covered by it, insofar as no specific provisions with the same objective exist in the Community legislation. The GPSD was to be transposed into the national legislation of the Member States by 15 January 2004.[3]

In addition to the GPSD, more specific provisions of product safety exist for a number of products, for which a piece of sector specific harmonisation legislation exists. The sector specific legislation covers both consumer and non-consumer products, and consists mainly of Directives that follow the New Approach[4] (i.e. they provide for CE marking). The sector specific legislation covers, among others, such product groups as toys, construction products, personal protective equipment, lifts and pressure equipment.[5]

In July 2008 the New Legislative Framework (NLF) was adopted. The NLF, which is a modernisation of the New Approach for marketing of products, consists of three legislative instruments:

- Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC.
- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
- 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

The Regulation 765/2008 came into force on 1 January 2010[6] and it covers all harmonised products (consumer and non-consumer[7]), meaning that consumer products subject to sector specific harmonisation legislation are now covered by both the NLF and the GPSD (as illustrated in Figure 1, below). While the GPSD covers several provisions not included in the

[1] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. OJ L11, 15.1.2002.

[2] The original Directive being the Council Directive 92/59/EEC of 29 June 1992.

[3] Directive 2001/95/EC, Art. 21(1).

[4] The New Approach is a regulatory technique whereby product legislation is restricted to the requirements necessary to protect the public goals of health and safety. In addition it provides for the essential requirements to be combined with technical specifications agreed by stakeholders and experts in the field, usually harmonised European standards. See: http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/index_en.htm. The New Approach has not been applied in sectors where Community legislation was well advanced prior to 1985, or where provisions for finished products and hazards related to such products cannot be laid down. See: Guide to the implementation of directives based on the New Approach and the Global Approach. European Commission, 2000.

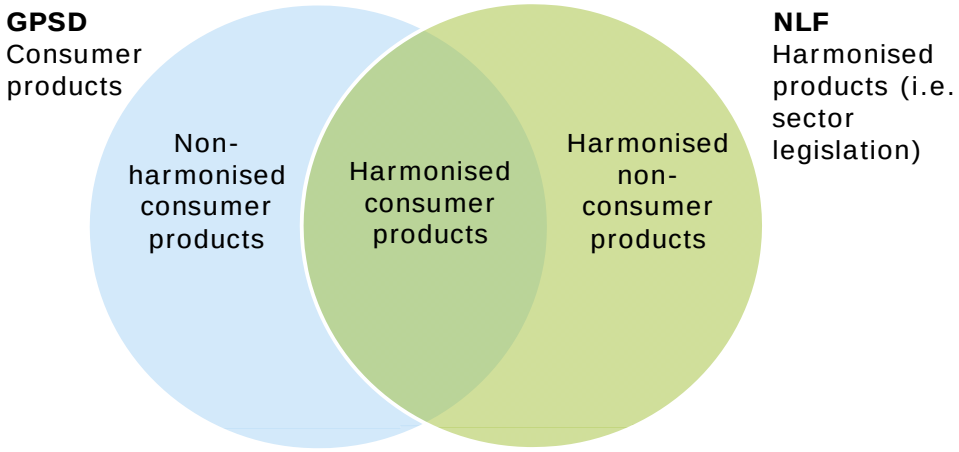
[5] See List of references of harmonized standards: http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/.

[6] The provisions in Decision 768/2008 can be used immediately, but in order to be operational, they have to be fed into existing Directives when they are revised. See: http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/.

[7] NLF excludes however food, feed, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction. See Regulation 765/2008, Art. 15(4).

NLF (such as those on standardization), especially Regulation 765/2008 setting out requirements for accreditation and market surveillance (hereinafter "the Regulation") contains provisions related to market surveillance of products that may cause some uncertainty concerning which piece of legislation is to be applied.

Figure 1: The coverage of the GPSD and the NLF



In the Roadmap document explaining the backgrounds for the revision of the GPSD, the Commission warns that without a substantive and practical alignment of the GPSD with the NLF there is a risk that two separate legislative regimes are set up for harmonised and non-harmonised products.[8] Moreover, as specified by the Commission, "recurrent product safety alerts, either of global or regional relevance, have made it clear that we need a system that delivers more rapidly, efficiently and consistently throughout the EU and which, at the same time, is flexible enough to adapt to the challenges of globalisation and continue to contribute to the EU internal market of safe products."[9] Hence, there may be a need to revise the GPSD. The Commission (DG SANCO) is currently preparing this revision, among others by organising a public consultation for all relevant stakeholders with a view to adopting the initiative in June 2011.

[8] Roadmap on the Review of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, http://ec.europa.eu/consumers/safety/prod_legis/GPSD_consultation/docs/GPSD_roadmap_en.pdf.
[9] Ibid.

1.1. Objective of the study

This study on Market Surveillance and revision of the GPSD has been commissioned by the European Parliament's Committee on Internal Market and Consumer Protection. The objective of the study is to provide an overview of possible divergences between the General Product Safety Directive and the New Legislative Framework, and in particular Regulation 765/2008, in order to assess whether there is a need for alignment between the two instruments. In this way the study should provide the European Parliament with background knowledge that it can refer to during the revision process of the GPSD. Furthermore, the study aims to outline the existing experiences in the field of joint market surveillance activities, examine the need for market surveillance specific to consumer products and assess the suitability of current legislation on market surveillance for detecting dangerous products bought online. To this end, the following questions will be covered in this study:

The relationship between the NLF and the GPSD

- Which definitions and obligations of economic operators are divergent and what are the implications thereof? (e.g. serious risk, economic operator, placing on the market, product)
- How is 'serious risk' interpreted in GPSD compared to NLF? What are the consequences for the level of consumer protection, if there are any differences? Are there any diversions concerning the definitions of 'serious risk' in sector legislation, and if yes, does it pose a problem? Do the RAPEX Guidelines warrant a consistent interpretation of 'serious risk' in the different Member States?
- Which obligations and powers for national authorities are divergent in the GPSD and the NLF respectively and what are the implications thereof?
- What other alignments between GPSD and NLF might be necessary in the light of the experiences in the area of enforcement in a selected number of Member States and with which implications?

Market surveillance

- Which are the main limitations for Member States that prevent their participation in joint market surveillance actions?
- Is there a need for market surveillance specific to consumer products? Would it be possible to identify any specificity of consumer products and take them into account in a more general market surveillance framework geared on the enforcement of EU legislation on safety requirements?
- Is the current legislation on market surveillance suitable for detecting dangerous products bought online?

1.2. Structure of the study

The study is structured along the following lines: following this introductory chapter, Chapter 2 describes the relationship between the GPSD and the NLF in particular with regard to definitions and obligations, touching upon sector legislation and the RAPEX guidelines. Chapter 3 concentrates on market surveillance, looking firstly at joint market surveillance actions, secondly at market surveillance specific to consumer products, and finally at market surveillance of dangerous products purchased online. Chapter 4 concludes the study.

Different types of sources have been used for this study. The main body of data is formed by interviews with key stakeholders in selected Member States, in the European institutions and in European consumer and interest organisations. These include the European Commission (DG ENTR, DG SANCO, DG TAXUD), the Product Safety Enforcement Forum of Europe (PROSAFE), the consumer organisations ANEC and BEUC, the European Engineering Association (Orgalime), and the European Association for Injury Prevention and Safety Promotion (Eurosafe). Moreover, two national distance selling organisations (DK and FI) were interviewed. With respect to selecting the Member States represented in the study, criteria such as geographical coverage, the size of the Member State and whether the Member State is one of the older or the newer Member States were used. Furthermore, the study team looked at criteria specific to the market surveillance system (centralised/decentralised), participation in cooperation between Member States (for example in Prosafe, AdCo, Nordic Council, Baltic cooperation), specificities or other special needs for market surveillance, such as big harbours or external land borders, and finally whether the Member States have participated in joint market surveillance actions. Based on these criteria, the following Member States were selected:

- Denmark
- Finland
- Germany
- Hungary
- Lithuania
- Poland
- Portugal
- Slovenia
- Spain
- UK

Key relevant characteristics of these Member States are described in more detail in Table 1 below. It should be noted that neither the sample of stakeholders nor the selection of Member States is necessarily representative. This is why the conclusions of the study should be treated with caution.

Table 1: Overview of Member States consulted in the study[10]

Member State	Characteristics – reason for choosing the Member State					
	Large / mid-size / small	**Old / New**	**System**	**Cooperation among Member States**	**Specificities / other special need for market surveillance**	**Participation in joint market surveillance[11]**
Denmark	Small	Old	Decentralised	Baltic Area, Prosafe, AdCo, Nordic Council	No	Active
Finland	Small	Old	Decentralised	Baltic Area, Prosafe, AdCo, Nordic Council	External land border	No participation in 2009 (and in general low participation)
Germany	Large	Old	Decentralised (federal).	Prosafe, AdCo, Baltic Area	Yes, important ports (Hamburg)	Active
Hungary	Mid-size	New	Decentralised	Prosafe, AdCo	External land border; previously a relatively high number of RAPEX notifications	Participates, but less actively
Lithuania	Small	New	Decentralised	Prosafe, Baltic Area, AdCo, bilateral cooperation with Russia	External land border	Participates, but less actively
Poland	Large	New	Semi-centralised	Prosafe, Baltic Area, AdCo	External land border	Participates, but less actively
Portugal	Mid-size	Old	Centralised	Prosafe, AdCo	No	Participates, but less actively
Slovenia	Small	New	Decentralised	Prosafe, AdCo	External land border	Participates, but less actively
Spain	Large	Old	Regional	Prosafe, AdCo	Yes, important ports (Algeciras and Valencia)	Participates, but less actively
UK	Large	Old	Sectoral with national co-ordination	Prosafe, AdCo	Sea border Important ports (Grimsby & Immingham, London)	Participates, but less actively

[10] The information is partly based on the European Parliament study "Market Surveillance in the Member State", October 2009.

[11] Based on participation in Prosafe joint actions in 2009. Source: Prosafe.

2. THE RELATIONSHIP BETWEEN THE NLF AND THE GPSD

2.1. The GPSD, the NLF, and sector legislation

In 1984 a Council Decision[12] introduced a common system for the European Community to exchange information on products liable to endanger the health or safety of persons – the "rapid exchange of information system" known as RAPEX. The Decision stated that Member States, who identify serious or immediate risks in products and decide to prevent, restrict or attach particular conditions to the marketing, use or the potential marketing of these products must inform the Commission, who will then forward the notification to the other Member States. This Decision was one of the first steps towards cooperation among the Member States in the field of product safety.[13]

2.1.1. General Product Safety Directive

In 1992, the Decision in its amended form was replaced by the General Product Safety Directive[14]. The Directive had as its goal to ensure that barriers to trade and distortions of competition within the internal market will be avoided when introducing the general obligation on economic operators to market safe products only. Furthermore, as stated in the preamble to the Directive, adopting Community legislation for every product is not possible, which is why there is a need for a broadly-based legislative framework of a horizontal nature that deals with the non-harmonised products and that can cover lacunae in existing or forthcoming specific legislation. The Directive thus introduced a general safety requirement for all consumer products (products intended for consumers or likely to be used by consumers) placed on the market.[15]

The original General Product Safety Directive was revised through the adoption of Directive 2001/95/EC. The Directive was the first Community instrument presenting requirements on the organisation and performance of market surveillance of health and safety aspects of consumer products.[16] The Directive applies, as mentioned above, to non-food consumer products and leaves out the safety of services. The Directive does however cover products that are supplied or made available to consumers in the context of service provision for use by them. While products used by the consumer (such as hairdryers in hotels etc.) are included, equipment used by service providers to supply a service to consumers is excluded from the scope of the Directive.[17]

One of the most important aspects of the Directive is the general obligation for economic operators to place only safe products on the market and to provide information to the consumers and the Member State authorities. Simultaneously, Member States authorities have the obligation to ensure that the products that have been placed on the market are

[12] Decision 84/133/EEC of the Council of 2 March 1984 introducing a Community system for the rapid exchange of information on dangers arising from the use of consumer products.

[13] The first step in this direction was the Preliminary programme of the European Economic Community for consumer protection and information policy, adopted in 1975, which stated that protection of health and safety is one of the fundamental rights of consumers. OJ No C 92, 25. 4. 1975, p. 1.

[14] Council Directive 92/59/EEC of 29 June 1992 on General Product Safety.

[15] Ibid. preamble.

[16] Working paper on the relationship between the General Product Safety Directive 2001/95/EC and the market surveillance provisions of Regulation (EC) No 765/2008.

[17] Directive 2001/95/EC, preamble, recital 9.

safe. To this end, the Member State authorities are obliged to monitor that the producers and distributor comply with the provisions in the Directive.[18]

Another important measure included in the GPSD is the possibility to introduce emergency measures to cope with serious risks by adopting a decision which can require the Member State to ban the marketing of the unsafe product, to recall it from consumers or to withdraw it from the market. This possibility has to date been used four times, most recently in March 2009, when the Commission issued a Decision, requiring all Member States to ban products that contain dimethylfumarate (DMF).[19]

2.1.2. New Legislative Framework

In 2003, the Commission presented a Communication on how the New Approach Directives could be further enhanced.[20] In the Communication, the Commission concluded that while the New Approach had become an effective instrument for ensuring the free movement of goods on the internal market, the implementation of the directives could be further improved. The Commission stated for example that it is necessary to introduce a horizontal piece of legislation defining the basic rules for market surveillance with which the Member States will be obliged to comply. Moreover, the Commission stated that whereas the safety requirements of the GPSD do not apply to the products covered by the New Approach (only the enforcement provisions of the GPSD apply to the products covered by New Approach legislation), it is necessary to introduce provisions into the New Approach Directives for exchanging information on industrial products that present a serious or immediate risk to users. The Communication was the starting point for the development of the New Legislative Framework, which was adopted in July 2008.

The New Legislative Framework is a package consisting of three legislative instruments modernising the New Approach for marketing of products: Regulation 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State; Regulation 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products; and Decision 768/2008 on a common framework for the marketing of products.

Overall, the NLF aims to "facilitate the functioning of the internal market for goods and to modernise the conditions for placing a wide range of industrial products on the EU market".[21] More specifically, and directly relevant to this study, Regulation 765/2008 aims to reinforce the market surveillance framework for harmonised products, i.e. products that are covered by Community harmonisation legislation among others by introducing the obligation for the Member States to carry out market surveillance.

2.1.3. Sector legislation

In addition to the General Product Safety Directive and the New Legislative Framework, the EU Acquis includes a number of sector specific harmonisation directives that contain provisions for product safety. Most of this legislation falls under the concept of the New Approach, based on the Council Resolution of 1985[22], which introduced a new regulatory

[18] Report from the Commission to the European Parliament and to the Council on the implementation of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety. COM(2008)905 final, p. 4.

[19] See: http://ec.europa.eu/consumers/safety/prod_legis/index_en.htm#sect.

[20] Communication from the Commission of 7 May 2003 to the Council and the European Parliament "Enhancing the implementation of the New Approach Directives". COM(2003) 240 final.

[21] http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/.

[22] Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards. OJ C 136, 4.6.1985.

technique for technical harmonisation, ensuring that product legislation does not extend further than to the requirements that are necessary in order to protect the public goals of health and safety.[23]

In relation to consumer safety and the General Product Safety Directive, the main corpus of sector legislation consists of, among others, the Directives governing the fields of toy safety[24], safety of equipment with voltage limits[25], of personal protective equipment[26], of cosmetics[27], of medical devices[28], of construction products[29], of machinery[30], of medicinal products[31], liability for defective products[32], and safety of recreational crafts[33].

2.1.4. The relationship between the NLF, the GPSD, and sector legislation

While the relationship between the NLF, the GPSD and the sector legislation is not explicit in all aspects, the general differences between the three levels of legislation are however relatively clear and they are explained in more detail below.

NLF and GPSD

One of the main differences between the NLF Regulation 765/2008 and the GPSD is that while the Member States are free to transpose the Directive (GPSD) into their national legislation in a way best suitable for the Member State, as long as the essential safety requirements in the Directive are taken into account, the Member States are obliged to incorporate the Regulation into the national legislation as a whole. This means that the provisions in the GPSD may be transposed somewhat differently from one Member State to another, while the provisions in the Regulation should have a harmonising effect in the field of market surveillance in the Member States.

The GPSD has the role of a safety net, ensuring that consumer products that are not covered by more specific Community legislation are covered by product safety legislation. According to an interviewee representing DG ENTR, at the time of the preparation of

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[23] See: http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-approach/index_en.htm.

[24] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys. OJ L170, 30.6.2009; and Council Directive of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys.

[25] Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits. OJ L374, 27.12.2006.

[26] Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment. OJ L 399, 30.12.1989.

[27] Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products. OJ L66, 11.3.2003. The Cosmetics Directive follows a traditional approach and does thus not belong to the New Approach Directives, meaning that it does not include specifications on CE marking.

[28] Medical devices are regulated by three Directives: Council Directive 90/385/EC, Council Directive 93/42/EEC, and the Council Directive 98/79/EC.

[29] Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products. OJ L040 , 11.2.1989.

[30] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast). OJ L157, 9.6.2006.

[31] Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use. OJ L136, 30.4.2003.

[32] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. OJ L210, 7.8.1985.

[33] Directive 2003/44/EC of the European Parliament and of the Council of 16 June 2003 amending Directive 94/25/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft. OJ L214, 26.8.2003.

Regulation 765/2008, it was decided to introduce a specific framework for market surveillance of harmonised products, as market surveillance over time had become all the more important. The Member States were also calling for a clear, strong and comprehensive market surveillance framework for harmonised products.

Several interviewees point to the fact that the GPSD is already several years old, which is why the Regulation 765/2008 is more updated and suitable to the current market surveillance needs of the Member States. With the adoption of the Regulation, the GPSD ceased to apply to the harmonised products in the areas where the lex specialis principle (cf. below) does not apply. According to DG ENTR, together with the Decision 768/2008, the Regulation provides an adequate and comprehensive framework for market surveillance.

As mentioned above, the main difference between the scopes of the NLF and the GPSD is that the NLF covers all Community harmonisation legislation harmonising the conditions for the marketing of products, while the GPSD only covers the safety of *consumer* products. The European Commission illustrates this in their working paper as follows[34]:

Table 2: Relationship between the GPSD and Regulation 765/2008

Products	Consumer	Non-consumer
Harmonised	Regulation 765/2008 GPSD	Regulation 765/2008
Non-harmonised	GPSD	No horizontal Community rules on market surveillance

As pointed out earlier in this report, this means that both pieces of legislation include provisions on consumer products covered by Community harmonisation legislation. Article 15 of the Regulation specifies the main rules to be followed when assessing which piece of legislation is to be applied in which case. It states in particular that the application of the Regulation should not prevent market surveillance authorities from taking more specific measures as provided for in the GPSD. Thus, the market surveillance provisions in the GPSD containing more specific measures than those included in the Regulation, apply to harmonised consumer products. The market surveillance measures in the GPSD that cannot be considered more specific than those in the Regulation are however no longer valid in case of harmonised consumer products. The Commission working paper[35] defines the market surveillance measures in the GPSD that have been identified as being more specific than the relevant measures in the Regulation. These include for example the measures in Art. 8(1) (b and c) on warnings and imposing prior conditions for marketing, and warnings for certain persons at risk.[36]

The question is thus, how the overlapping of the two instruments in the field of harmonised consumer products affects the market surveillance in the Member States and whether an

[34] Working paper on the relationship between the General Product Safety Directive 2001/95/EC and the market surveillance provisions of Regulation (EC) No 765/2008.
[35] Ibid.
[36] The implementation of the Regulation had also other impacts on the functioning of the GPSD as the Regulation (art. 42) also amended the wording in Article 8(3) of the GPSD in order to strengthen the obligations of the Member State authorities.

alignment is needed in order to avoid possible confusion among market surveillance authorities. This will be discussed more thoroughly in chapter 2.4.

GPSD and sector legislation

In general it can be said that the sector legislation has priority over the provisions in legislation that is of more general nature, such as the GPSD. This principle is called lex specialis, which means that a law governing a specific subject matter (*lex specialis*) overrides a law which only governs general matters (*lex generalis*). The role of the GPSD is to complement the sector legislation in situations where gaps may exist. The General Product Safety Directive complements the sector legislation in two different ways: firstly, the GPSD applies not only to the harmonised sector legislation, but also to consumer products that are not covered by a sector directive. Secondly, the GPSD is in some parts more detailed than the sector directives. The extent to which the GPSD applies to each harmonised consumer product sector depends on the sector directive and its specificities. For this reason, guidelines have been created by the European Commission on the relationship between the GPSD and selected sector directives.[37] Taking the Low Voltage Directive (LVD)[38] as an example, it can be seen that e.g. Distributors' obligations, as defined in GPSD art. 5(2-4), apply to the LVD as it does not contain requirements affecting distributors. The same is true for GPSD art. 7 on adopting rules on penalties, where the LCD does not have any specific provisions on this matter. However, the general safety obligation specified in GPSD art. 2(b) and (c), 3 and 4, does not apply to LVD due to the scope of the Directive, which already covers all types of risks and/or categories of risk.[39]

NLF and sector legislation

As mentioned in the fifth recital in the preamble of Regulation 765/2008, the Regulation only applies in so far as no specific provisions exist with the same objective, nature or effect in other existing or future rules of Community harmonisation legislation. Moreover, the Regulation (Art. 2(21)) states that Community harmonisation legislation shall mean "any Community legislation harmonising the conditions for the marketing of products".

Regulation 765/2008 and Decision 768/2008 both aim to bring more consistency into the regulatory framework for products and to simplify its application so as to limit the number of unsafe products that enter the European market. The Decision 768/2008 is as such not legally binding for enterprises, individuals or Member States, but it is “designed to work as a toolbox containing those provisions which are common elements of technical harmonisation legislation.”[40] The Decision thus provides a set of clear, general definitions, a reference list of obligations on economic operators and an exhaustive register of conformity assessment procedures, which together lay down “a coherent basis for revision or recasts of [New Approach Directives]”.[41]

In order that the Decision achieves its purpose, it would need to be transposed into the existing, or future, harmonisation directives. The Commission is currently in the process of

[37] Guidance Document on the Relationship Between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety. DG SANCO, November 2003.

[38] Council Directive 73/23/EEC.

[39] Guidance Document on the Relationship Between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety. DG SANCO, November 2003, pp. 16-22.

[40] http://ec.europa.eu/enterprise/newsroom/cf/itemlongdetail.cfm?item_id=4289.

[41] Decision 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.

carrying out a public consultation on the possible alignment with a set of ten directives (including for example the Low Voltage Directive 2006/95/EEC; the Simple Pressure Vessels Directive 2009/105/EC and the Lifts Directive 95/16/EC). If such an alignment were to take place, it would introduce a common vocabulary and consistent compliance assessment procedures for all products covered by New Approach legislation by:

- aligning definitions and terminology;
- aligning conformity assessment procedures;
- imposing clear product compliance requirements on importers and distributors;
- imposing traceability requirements on the actors in the supply chain, including manufacturers.[42]

It is envisioned that such an alignment would have a smoothing effect on the internal market, ensuring that all economic operators abide by a uniform set of requirements and are therefore treated equally by national authorities. Also, operators that do not play by the rules, finding loopholes in overlapping compliance requirements and national authorities who do not interpret the sector directives in a consistent manner, should be less successful in a market where everybody speaks the same language. However, rather than modifying the directives, there are also the options of encouraging the economic operators to step up efforts to ensure compliance and traceability on a voluntary basis, or taking no action at all.[43]

The need for alignment between the NLF and sector legislation was expressed for example by the UK interviewees, who pointed out that even though one often speaks of New Approach concepts, they are used in many different ways in the sector legislation. The interviewees also mentioned that it is possible to find a product that is subject to three different directives that all use concepts in different ways. It is thus relevant to try and bring the concepts completely in line with each other.

2.1.5. Key findings: The GPSD, the NLF and sector legislation

Several interviewees point out that the NLF is more suitable to the current market surveillance needs of the Member States as it is newer than the GPSD. The two instruments overlap to some extent, because the harmonised consumer products are included within the scope of both instruments. In general it can be said that the GPSD is applicable where more specific provisions concerning harmonised consumer products can be found in the GPSD, compared to NLF.

[42] European Commission: Roadmap - Alignment to the New Legislative Framework (Decision 768/2008).
[43] Ibid.

2.2. Definitions

One of the areas where the GPSD and the NLF differ from each other to some extent is that of definitions and concepts. Generally speaking the list of definitions and concepts provided in the GPSD is somewhat narrower in scope and less specific than the one included in the Regulation 765/2008 and Decision 768/2008.

Most Member State interviewees see the clarity of the NLF in terms of definitions positively. For example the Danish interviewee mentions that having a clear definition of the economic operators as well as of their obligations has a positive impact on market surveillance in Denmark. The Finnish interviewee points out that the NLF definitions have had a positive effect on the communication between the Finnish authorities and economic operators, as the Finnish authorities are now only using the definitions used in the NLF.

In order to get a clear overview of the divergences between the GPSD and the NLF in terms of definitions and concepts, and the potential implications of these divergences, the most important definitions will be discussed below.

2.2.1. Economic operators

One of the divergences between the GPSD and the NLF concerns the way in which economic operators are defined. While the GPSD uses the term "producer"[44], in NLF the term used is "manufacturer".[45] The scope of the terms used is also somewhat different: while the GPSD differentiates only between "the producer" (including the manufacturer, the manufacturer's representative and other professionals in the supply chain, insofar as their activities may affect the safety properties of a product) and the "distributor" (any professional in the supply chain whose activity does not affect the safety properties of a product), the NLF introduces the overall concept of "economic operators". These include the manufacturer, who is 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; the authorised representative[46]; the importer[47] and the distributor[48]. In this way the NLF makes a clear distinction between the manufacturer and the other economic operators in the supply chain and it is thus easier to define the obligations of the different economic operators. The UK interviewees however point out that when looking more specifically at what is meant by the definitions of a producer and economic operators, the GPSD and the NLF are very much along the same line.

Some Member States have implemented the GPSD into their national legislation in such a way, that the terms used for the economic operators are similar to those presented in the NLF. For example in Lithuania, the national legislation transposing the GPSD uses the terms of manufacturer, importer, authorised representative, and distributor.

Whereas the GPSD does not include any provisions on authorised representatives, in the context of the NLF an authorised representative is defined as "any natural or legal person

[44] Art. 2(e).

[45] Regulation 765/2008, Art. 2(3).

[46] Any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under the relevant Community legislation.

[47] Any natural or legal person established within the Community who places a product from a third country on the Community market.

[48] Any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.

established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under the relevant Community legislation"[49]. It can be said that the role of the authorised representatives has however become all the more important during the past years, for example following the increase in online shopping, and their role is also more pronounced in market surveillance. The NLF assigns responsibilities to the authorised representatives for example in relation to placing a product on the EU market (such as affixing the CE-marking on a product).

The general view among the interviewees is that the divergences in the definitions of economic operators do not have any negative implications on the level of market surveillance in the Member States as such. The differences in the definitions of economic operators are however directly connected to *the obligations* of the economic operators that are divergent due to the differing understanding of who the economic operators are (cf. Section 2.3.1). According to the German interviewee, these differences in wording hinder coherent, easily understandable product safety legislation from being in place.

2.2.2. Product

Another definition that is different between the GPSD and the NLF is that of a 'product'. The definition is central to both legislative instruments, as it specifies what kind of products each piece of legislation covers. The GPSD, Art. 2(a), defines a product in the following way:

"'Product' shall mean 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"[50].

In the NLF (Regulation 765/2008, Art. 15(4), a 'product' is described to be "a substance, preparation or good produced through a manufacturing process other than food, feed, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction".

The difference in the definition is directly related to the difference in the scope of the two legislative instruments. The product, as described in the GPSD, is a consumer product, or a product likely to be used by consumers, while the product, as described in the NLF, can be any kind of a good, apart from those listed as goods excluded from the scope of the NLF. A discussion concerning the implications of this divergence is thus simultaneously a discussion on the scope of the legislative instruments.

Whereas the scope of the legislative instruments was discussed in more detail above (cf. section 2.1.4), it can be mentioned that the majority of the interviewees did not consider that the definition of 'product' would have any direct implications on the level of market surveillance. The German interviewee mentioned however that certain confusions can arise, because the GPSD applies to both new and used products, while the NLF only applies to new products.

[49] Art. 2(4).

[50] This definition shall however not apply to second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect.

2.2.3. Making available on the market and placing on the market

The definitions "making available on the market" and "placing on the market" are not specified as such in GPSD. In the NLF, on the other hand, a specific definition is provided (Art 2 (2) and (3)):

"'Making available on the market' shall mean any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge".

"'Placing on the market' shall mean the first making available of a product on the Community market.

The inclusion of these two definitions in the NLF responded to the requests by several stakeholders for a simplification in the internal market.[51] They specify the point in time in the product cycle at which different measures need to be undertaken by different economic operators. This is emphasised for example by the representative of the Portuguese authorities, who states that the clarity that these two definitions have brought to the obligations of different economic operators has been important for the work carried out by the market surveillance authorities.

The GPSD only discusses the "placing on the market" of products. The concept is not defined in the Directive, but can be understood as both making available and placing on the market of products. The most important reference to the concept can be found in Art. 3(1) of GPSD, which states that the producers shall be obliged to "place only safe products on the market". In the context of the NLF, products are placed on the market by the manufacturer or the importer (when the product is from a third country) and made available on the market by the distributor. This differentiation is not directly specified in the GPSD. The GPSD does mention products that "have been *supplied* or *made available to consumers* by the producer or distributor"[52], without specifying what is understood by supplying a product or making a product available to consumers. As discussed earlier in this report, the GPSD only differentiates between the producer and the distributor, which can also lead to some confusion in terms of assessing what is meant by "placing on the market" and which economic operator is responsible.

The interviews and the desk research have not revealed any concerns related to the lack of definition of the two in the GPSD. The inclusion of the definitions in the NLF has however been welcomed by several stakeholders, indicating their importance to market surveillance and product safety.

2.2.4. Recall and withdrawal

'Recall' and 'Withdrawal' are definitions included in both the GPSD and the NLF. The definitions are also very close to each other, as can be seen in the table below:

[51] See for example Orgalime Position Paper on "Placing a product on the Community Market" – Making things simpler in the Internal Market. 24 July 2006.
[52] Art. 2(g). Italics added by author.

Table 3: Definitions of "recall" and "withdrawal" in the GPSD and the NLF

	GPSD	NLF
Recall	Any measure aimed at achieving the return of a *dangerous* product that has been *supplied* or made available to consumers *by the producer or distributor.*	Any measure aimed at achieving the return of a product that has already been made available to the end user.
Withdrawal	Any measure aimed at preventing the *distribution, display and offer* of a product dangerous to the consumer.	Any measure aimed at preventing a product in the supply chain from being made available on the market.

The difference in the definition of "recall" is mainly that the GPSD states that the product must be "dangerous" before it can be recalled. In the NLF, the dangerousness of a product is not included in the definition, but rather in the provisions stating in what situations products can be recalled. Moreover, whereas the GPSD defines the consumers as the users of the products, the NLF is, according to its scope, less specific on who the end-users of the products are.

The differences in the definition of "withdrawal" are similar to those seen in the case of "recall". The GPSD is more specific in stating the different measures that should be prevented (distribution, display, offer), while in the NLF withdrawal refers to measures that aim to prevent the making available on the market of a product. Similarly, the GPSD specifies that the product should be dangerous to the consumer, whereas the definition in the NLF does not specify what kind of products are to be withdrawn.

Neither of these definitions seems to have any negative implications for the functioning of the internal market. None of the interviewees refer to the small divergences in the definitions as something that would cause challenges for the market surveillance of products.

2.2.5. Serious risk

An important part of product safety and of the assessment of whether a product is dangerous is the risk assessment, determining the level of risk of products. Currently there are three different sources for the identification of "serious risk" in product safety legislation: the GPSD, the NLF and the sector legislation.

a) GPSD

In the GPSD, "serious risk" is defined as "any serious risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities".[53] In the context of GPSD the assessment of a risk as being serious can have important consequences. On the one hand, the GPSD (Art. 12(1)) states that in the case of adopting specific measures on a product "by reason of serious risk, it [the Member State] shall immediately notify the Commission thereof through RAPEX". This means that when a product is considered to entail serious risk, the use of the RAPEX system (cf. below) is triggered. On the other hand, Art. 13 of GPSD provides the Commission with the possibility to adopt an emergency action in the form of a decision requiring Member States to

[53] Art. 2(d).

immediately stop the retail of products presenting a serious risk on the European market. As mentioned previously, this measure has to date been used at four different occasions, namely in the cases of lighters, phthalates, magnetic toys and dimethylfumarate. This kind of emergency measure does not exist in the NLF and thus it only covers consumer products.

b) RAPEX

As mentioned above, the GPSD includes an obligation for the Member State authorities to inform the Commission of actions taken on products by reason of serious risk. For this purpose, the European Union is using RAPEX, which is the EU rapid alert system for dangerous consumer products established by Art. 12 of GPSD. Annex II of the GPSD states that "RAPEX covers products as defined in Art. 2(a) that pose a serious risk to the health and safety of consumers". The Commission has adopted a Decision[54] which lays down the guidelines for ensuring that both RAPEX and the notification procedure, as specified in Art. 11 of GPSD (relevant for products posing a non-serious risk only), are properly applied. The guidelines set out a risk assessment method and, in particular, **specific criteria for identifying serious risks**. As the RAPEX is not intended for the exchange of information on non-serious risks, the Member State authorities always have to perform the appropriate risk assessment in order to assess whether the product in question in fact poses a serious risk to the health and safety of consumers.[55]

Annex 5 to the updated RAPEX guidelines adopted in December 2009, specifies the risk assessment method that the Member States should use when assessing the level of risk posed by a non-food consumer product. The guidelines include four different levels of risk (serious, high, medium, low), and the level of risk is calculated by looking both at the *severity of the injury* and the *probability of the injury scenario occurring*. Whether a risk is serious, depends on the severity of the injury (1-4) and the probability of damage during the foreseeable lifetime of the product (in combination with high severity, 1/10,000 and in combination with low severity, >50%). This is illustrated in the figure below:

[54] Commission Decision of 16 December 2009 laying down 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 (the General Product Safety Directive). OJ L22, 26.1.2010.
[55] Commission Decision 2010/15/EU, p. 12.

Figure 2: Risk level from the combination of the severity of injury and probability[56]

Probability of damage during the foreseeable lifetime of the product		Severity of injury			
		1	2	3	4
High	> 50 %	H	S	S	S
	> 1/10	M	S	S	S
	> 1/100	M	S	S	S
	> 1/1 000	L	H	S	S
	> 1/10 000	L	M	H	S
	> 1/100 000	L	L	M	H
	> 1/1 000 000	L	L	L	M
Low	< 1/1 000 000	L	L	L	L

S — Serious Risk
H — High risk
M — Medium risk
L — Low risk

The guidelines aim to take into account the personal aspect of risk assessment, i.e. the decisions taken by individual risk assessors. The guidelines emphasise the need for experience in risk assessment, and recommend that experienced risk assessors be consulted in particular when conducting the probability assessment and checking for its plausibility.[57]

Even though RAPEX was established by the GPSD, it has also been included in the NLF, where Art. 22 of Regulation 765/2008 states that RAPEX is to be used for informing about products presenting a serious risk. However, the RAPEX guidelines, and the risk assessment procedures presented in the Annex, are specifically directed at non-food consumer products and only cover the products for which the GPSD applies. The RAPEX guidelines specify nevertheless that "the structure and content of the Guidelines allow them to be adapted, if and as appropriate, to include provisions relating to the notification procedure established under Article 22 of Regulation (EC) No 765/2008 [...]".[58] This means that it is in principle possible to adapt the Guidelines in such a way that they would also include guidelines for the risk assessment of harmonized non-consumer products, if it is decided that such guidelines are necessary.

This means that the definition of "serious risk" presented in the RAPEX guidelines is not applicable for the Community harmonisation legislation not covered by GPSD. No guidelines such as the RAPEX guidelines exist in the field of NLF and for example the Polish authorities pointed out that assessing the seriousness of risk for industrial products is harder than for consumer goods, e.g. what level of noise should be considered as serious infringement (the

[56] Commission Decision 2010/15/EU, p.64.
[57] Ibid. p. 46.
[58] Ibid, p. 6.

Directive on Environmental Noise[59]) or what level of EMC[60] radiation should be considered as serious infringement (EMC[61] and R&TTE Directives[62]). This can often lead to diverging risk assessments in the Member States.

Some interviewees view the Guidelines very positively and consider the risk assessment method, presented in Figure 2, to be practical. For example the Danish authorities have taken the method into systematic use when conducting risk assessment. The interviewee emphasises that a learning process is needed in order to become better at setting up exposure scenarios and conducting probability assessments.

Several interviewees state however that the RAPEX guidelines are very general and thus difficult to use when faced with assessing the risk of a specific product. This means that there is a risk that the Member States will overdo surveillance and put on more precautions that might be necessary. Moreover, it is possible that risk assessment is done differently from one Member State to another.

ANEC agrees with this, and provides examples of cases, where Member States have had difficulties in interpreting the Guidelines in a consistent way:

- Child appealing products: There is no definition at EU level for what is "child appealing", leading to difficulties in evaluating such products.
- Baby walkers and bath seats: The Member States' views differ from each other on whether these should be banned from the European market or not.
- Some years ago, 'flashy soothers' for teenagers were widespread on the European market. They contained a battery which sometimes exploded. Some Member States took them off the market while others did not.

The Spanish authorities are of the opinion that the risk assessment method of the RAPEX Guidelines is too subjective. The Guidelines include a table presenting examples of types of injuries and their severities. While the Spanish interviewee mentions this table to be especially useful, other aspects, such as calculation of probability, are considered to be challenging. Including several categories of risk into a risk assessment may lead to a lower level of assessed risk. According to the interviewee, when more than three scales of risk are taken into account, the assessment rarely points to serious risk. This is challenging in cases, where all the other elements point towards serious risk. The Spanish authorities take however the view that when a serious risk, such as electrical shock or asphyxiation, is possible, the low probability should not decrease the level of risk.

From the point of view of Orgalime, the risk assessment approach in the RAPEX Guidelines may be too simplistic for assessing the level of risk in technically complex consumer products, such as IT and electrical products, or machine tools. The interviewee fears that the lack of specificity may lead to authorities missing important elements that are necessary for determining the level of risk in these products that are covered by harmonisation legislation. Such elements are often documented in standards, which is why authorities should know and make use of the same reference documents (including standards) that are used by manufacturers. If this is not done, the benchmark for

[59] Directive 2002/49/EC of the European Parliament and of the Council of 25 June 2002 relating to the assessment and management of environmental noise - Declaration by the Commission in the Conciliation Committee on the Directive relating to the assessment and management of environmental noise.

[60] Electromagnetic Compatibility.

[61] Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC.

[62] Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity.

assessing risk by authorities and manufacturers is not the same. The interviewee proposes that GPSD is reduced in scope so that it only covers non-harmonised products, in which case the problem would be solved.

Eurosafe considers the RAPEX Guidelines to be an excellent starting point, but emphasises that they have to be constantly developed in order to follow the developments in the market.

The Hungarian authorities point out that the risk assessment method presented in the RAPEX Guidelines is not suitable for cases of chemical risks, where the classification of the level of injuries and the estimation of their probability require specific skills and education, which market surveillance specialists do not usually possess. The interviewee is calling for a specific guideline for cases of chemical risks, similar to the guidelines existing for phthalates (cf. above).

A number of Member State representatives express concerns about the ability of the RAPEX Guidelines **warranting a consistent interpretation of "serious risk" in the different Member States**, and even between individual authorities. While this can not only be claimed to be the fault of the Guidelines, which are very useful according to several Member States, the problem is still in the way in which the market surveillance authorities interpret the Guidelines and assess risks.

For example the German authorities indicate that whereas the RAPEX Guidelines do not, in their view, warrant a consistent interpretation of serious risk, they do support the process and bring more transparency to the process of risk assessment. Their view is that there are no scientific methods to exactly determine the severity of possible injuries and the probability of the injury occurring, but that these estimates depend strongly on the cultural background and the experience of the risk assessor. Statistical data on products and/or injuries could, according to the interviewee, provide help in finding a more consistent approach for risk assessment. The Hungarian authorities agree to the extent that the RAPEX Guidelines contain subjective factors and that the different cultural backgrounds of the risk assessment specialists can have an impact on the assessment. Their view is, however, that the risk assessment method in the RAPEX Guidelines ensures there are no longer sharp divergences between the Member States with regard to the classification of a specific product. The Slovenian authorities, on the other hand, consider that the RAPEX Guidelines do warrant a consistent interpretation of serious risk.

The Portuguese authorities state that while a consistent interpretation of "serious risk" is needed, it is possible that a product represents "serious risk" in one Member State, and not in another due to weather conditions, such as very low or very high temperatures.

Orgalime points out that the Guidelines are not suitable for being used in the framework of Regulation 765/2008, as they do not incorporate the risk assessment method, which is currently used under New Approach legislation. In particular, due consideration for conducting the compliance test on products is currently missing from the Guidelines, according to Orgalime. Moreover, the interviewee states that the formulation used in the Guidelines is often misleading (whether the guidelines are to be used when identifying the lack of safety of a product already placed on the consumer market, or whether they are intended to help assess the intrinsic risk of a product).

c) NLF

Regulation 765/2008, Art. 20 uses the definition of "products presenting serious risk". According to the Article, the products "which present a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate [...]" should be recalled, withdrawn or prohibited from the market.

In general the GPSD and the NLF are on the same lines when it comes to specifying how serious risk is identified and assessed. In the NLF, serious risk is to be identified based on appropriate risk assessment, which takes account of the nature of the hazard and the likelihood of its occurrence.[63] Moreover, Recital 29 of the preamble describes that risk assessment should take into account all relevant data and any measures that may have been taken by the economic operators to alleviate the risks. According to interviewees from DG ENTR, this general way of assessing serious risk is a good starting point for elaborating more specific guidelines. The same method of looking at the nature of the hazard and the likelihood of its occurrence is also used in the RAPEX Guidelines under GPSD. As explained above, the RAPEX notification system is used for informing the Commission of products causing a serious risk also in the case of products to which Regulation 765/2008 applies, but the RAPEX Guidelines are not applicable to products regulated by the NLF, apart from the harmonised consumer products, which are covered both by the NLF and the GPSD. An interviewee points out that the inclusion of the concept of serious risk in the NLF was inspired by the GPSD. Previously there has been no need for developing this concept further in the context of the New Approach legislation, where the main goal has been to check the products for compliance with essential safety requirements. The requirement to report any products (all harmonised products) presenting serious risk to RAPEX has however made it necessary to provide a clear and useable definition of serious risk also in the context of harmonised non-consumer legislation. Nevertheless, most interviewees do not mention any specific issues related to the current way of defining serious risk in the context of NLF.

d) Sector legislation

When looking into the definition of "serious risk" in sector legislation, it is important to remember that the NLF applies to the harmonisation legislation, meaning that the provisions on risk assessment in the field of market surveillance, covered by Regulation 765/2008 (as presented above), are applicable to the harmonisation legislation where there are no provisions that are more specific than those in the NLF. The sector legislation has as its emphasis to indicate essential health and safety requirements, but the more specific definitions of what makes a safe product can be found in the harmonised European standards, with which products have to be in conformity.

In general it can be said that sector legislation does not provide a definition of serious risk. In fact, the Toy Safety Directive (Directive 2009/48/EC) is the only one mentioning the concept at all. However, even in the Toy Safety Directive, serious risk is not defined as such. Risk is defined as being "the probable rate of occurrence of a hazard causing harm and the degree of severity of the harm".[64] The different levels of risk however are not defined and thus it is not specified what level and combination of probability and hazard is understood to be "serious risk". The only reference to a serious risk is provided when discussing the right of market surveillance authorities to request technical documentation or translations related to a product in the case of serious or immediate risk.

In other examples of sector legislation, the Directive on personal protective equipment (Directive 89/686/EEC) covers several types of risks and different levels of risk. The level of risk should result in an appropriate class of protection and the Directive gives examples of different types of risks and the protection that these types of risk entail. Nevertheless, no definition of the different levels of severity of risks is provided and thus no clear definition of a serious risk exists.

[63] Art. 20(2).
[64] Directive 2009/48/EC Art. 3(28).

e) Additional issues related to the definition of serious risk and risk assessment

In general it can be said that while the definition of serious risk is a central part of the GPSD, in particular in relation to triggering the RAPEX method and the Art. 13 emergency procedure, it is only included in the harmonised legislation through Regulation 765/2008, which presents a definition of serious risk. The main issue does however not seem to be the concrete definition of "serious risk", but rather the way in which the level of risk is assessed.

A number of Member States stress that the differences in the definition of serious risk in the GPSD and the NLF are very small and do not have an impact on the practical work conducted in the Member States. In general the same principles can be applied to products covered by both legislations. One difference which is mentioned by the Finnish interviewee is that the NLF includes a broader range of risks, such as environmental risks, which are neither covered by the GPSD nor by the RAPEX Guidelines. The German authorities emphasise that there should be no difference in the interpretation of "serious risk" as far as safety and health of persons is concerned. The interviewee is concerned that there may be a lower level of protection in the case of products providing other hazards than for safety and health, as no guidelines currently exist for market surveillance authorities in this field.

According to an interviewee representing DG ENTR, in the cases where the Community legislation does not apply, the Member State authorities use the principle of precaution when assessing the level of risk of each product. This means that in many cases the market surveillance will be overdone in order to ensure the safety of the products where no guidelines exist. When a piece of legislation exists, there is an indication of what represents a risk. Because the GPSD provides a general definition of serious risk, it does not present the Member States with proper guidelines. This analysis is supplemented by an interviewee representing Orgalime, who holds the view that the assessment of whether a risk is serious or not should not be carried out from scratch on all suspicious products by Member State authorities, as suggested in the GPSD guidelines, but should rather take into consideration the risk assessment (self-assessment) procedure carried out by manufacturers to comply with sector directives. For that reason, the GPSD Risk assessment guidelines need to be revised in order to take into account the NLF “compliance approach” (cf. above) for assessing the seriousness of the risk.

According to the representative of Prosafe, the definitions of serious risk in existing legislation are in general useable, but the practical way to perform risk assessment differs from one person to another. This causes divergences from one Member State to another, even in the case of the same product. The experience, competence and technical knowledge of the market surveillance inspectors is the main component and this should be supported by legislation that does not create confusion. This view is strongly shared by the representative of Eurosafe, according to whom the Commission should better ensure a more consistent application of the tools that are available to the Member States and to foster further exchange and development of these tools.

The consumer organisations emphasise the importance of including in the definition of serious risk the specification that the effects of a risk might not be immediate. This is important for example in the case of chemicals, which can have a very serious impact that many not be immediately detectable. Currently, this is covered in both GPSD, Art. 2 and Regulation 765/2008, Art. 20(1).

Some concerns are expressed by the representative of Orgalime, according to whom the concept of serious risk was imported into Regulation 765/2008 without clarifying how it should be handled by authorities who are used to checking the non-compliance of products against the technical annex of the New Approach directives. There are currently different

procedures in place for assessing the level of non-compliance that entails unacceptable risks, and for assessing the seriousness of risks in products. The interviewee states that having divergent approaches to risk assessment and enforcement, depending on whether the authorities apply GPSD, NLF or sector legislation first, is problematic.

An interviewee representing DG ENTR states that the need to update the definitions of serious risk is indeed acknowledged by the Commission. To this end a consultation is planned to be held in the autumn of 2010.

2.2.6. Key findings: Definitions

When looking at the definitions one by one, only a limited number of stakeholders express views on the need for alignment between the GPSD and the NLF. However, when discussing the definitions in general, there are some stakeholders who consider that the diverging definitions cause confusion and would thus need to be aligned.

The definitions of economic operators differ from the GPSD to the NLF. According to the interviewees this divergence does not have any direct implications on market surveillance, but it does have a direct impact on how the obligations of the economic operators are defined. The differing definitions can cause some confusion concerning the obligations of the economic operators. In order to avoid confusion, some Member States have gone over to only applying the definitions used in the NLF.

The definition of "product" is directly connected to the scope of both the GPSD and the NLF, and the way in which "product" is defined, indicates what products are covered by the two legislative instruments. The difference in the definition is not as such considered to have any negative implications on market surveillance or consumer safety.

Whereas the NLF includes definitions of "making available on the market" and "placing on the market", the GPSD does not provide for a clear definition of either. The interviews and the desk research have not revealed any concerns related to the lack of definition of the two in the GPSD. The inclusion of the definitions in the NLF has however been welcomed by several stakeholders, indicating their importance to market surveillance and product safety.

The definitions of recall and withdrawal are almost the same in both the GPSD and the NLF, with the difference that the GPSD is more specific in determining the characteristics of the products to be recalled or withdrawn from the market. Neither of these definitions seems to have any negative implications for the functioning of the internal market. None of the interviewees refer to the small divergences in the definitions as something that would cause challenges for the market surveillance of products.

The issues regarding the concept of “serious risk” in the GPSD, the NLF and the sector legislation lie not in the definition as such (serious risk is not defined in sector legislation), but rather in how serious risk is identified and assessed. In the context of GPSD, the RAPEX Guidelines provide a method for risk assessment, but the stakeholders hold differing views concerning the usefulness of these Guidelines. Whereas some consider the Guidelines to be very useful and practical, others see them as too general in scope, making it difficult to apply the method to specific products. Moreover, no clear Guidelines exist for conducting risk assessment on harmonised products, not covered by GPSD and the RAPEX Guidelines. In the case of these products, the Member States are used to operating with compliance testing, which can be checked against the technical annex in the sector directives. Hence, some stakeholders express concerns about the ability of the RAPEX Guidelines to warrant a consistent interpretation of "serious risk" in the Member States. These issues, among others, can lead to risk assessment being carried out differently across Member States and

authorities, and result in products being placed on the market in one Member State, while they are banned in another Member State.

To conclude, it can be said that while several stakeholders acknowledge that some definitions of the GPSD and the NLF differ from each other, the main message is that the divergences in the definitions do not cause any important challenges. No concerns were expressed with regards to the implications of the divergences on consumer safety. The differences are mainly considered to be subtle and rather issues of terminology than content. Most stakeholders acknowledge however that it is relevant to update the definitions in the GPSD and thus to align them with the NLF. Several interviewees point out that while NLF has looked for inspiration for the definitions in the GPSD, NLF is more advanced in terms of definitions than the GPSD. The only clear concerns expressed by the interviewees are related to the risk assessment procedures that are used in order to determine the level of risk that products present. Currently there is still the possibility that risk assessment is conducted in different ways by different Member States and authorities. This can lead to diverging levels of consumer protection from one Member State to another.

2.3. Obligations

2.3.1. Obligations of economic operators

As presented above, the GPSD was the first legislative act establishing a general obligation on economic operators to place only safe products on the market. It also requests the producers to provide consumers with relevant information to enable them to assess the risks inherent in a product. More specifically, the obligations of the producers include[65]:

- To adopt measures that make it possible for the consumers to be informed of risks that products might pose. This can take the form of an indication of the identity and details of the producer and the product reference in the product or its packaging, i.e. the product's traceability.
- To take appropriate action, such as withdrawal from the market, warning the consumers or recall from consumers, for example by carrying out sample testing of marketed products, keeping register of complaints and keeping distributors informed of these.

A couple of the interviewees representing Member State authorities consider that the GPSD on some points is more developed than the NLF. The examples mentioned include the requirement to provide information to the consumers, both in relation to the marketing of the product and attached to the product, which is considered to be a provision that is more developed in the GPSD than it is in the NLF. The requirement should thus be kept also in a revised version of the Directive. Similarly, it is pointed out that the provisions in the GPSD requiring the producer to keep a register of complaints related to a product are not reflected to a sufficient extent in the NLF. Even though this provision is not generally used very often, it has proven to be an efficient tool in some cases where authorities have used it. The provision is especially useful in cases where the risk is very high and the product has been distributed widely and to many different types of user groups. In these cases it is important to have the possibility to oblige the producer to collect the accident/complaint statistics.[66]

According to the Commission report on the implementation of the GPSD[67], the Member States have transposed the Directive in different ways for example with respect to the provisions on traceability. In some Member States it is obligatory to indicate the identity and details of the producer or importer on the product or its packaging, but in other Member States this is optional. Another difference between the Member States can be found concerning the notification by producer. Some Member States request the notification by producers only in the case of a known risk and no obligation exists to notify when the producer "ought to know" the risk based on available information.[68]

Apart from the general obligation to ensure that the product is safe, and to notify when this is not the case, the GPSD does not include specific provisions about the obligations of economic operators when placing a product on the market. An interviewee representing DG SANCO also points out that looking at GPSD, Art. 5(1), the wording "for example" is used in

[65] GPSD, Art. 5.

[66] In Denmark the provision has been applied for example in the case of electric meters installed at private homes. The products belong to the service provider (the electronic company), but they are rented to private users.

[67] Report from the Commission to the European Parliament and to the Council on the implementation of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety. COM(2008)905 final.

[68] Ibid, p. 5.

combination with the measures ensuring traceability of the products. According to the Commission representative, this undermines the legal certainty of the GPSD. For this reason the interviewee considers that the revision of the GPSD should address this issue in the light of the provisions of Decision 768/2008 (cf. below). Several Member State representatives also point to the question of traceability as an issue that would need to be improved in the context of GPSD and in particular in the context of the products that are not covered by the Community harmonisation legislation (and thus the NLF). Moreover, it is mentioned that the provisions concerning the safety documentation and the declaration of conformity could also be included in the revised version of the GPSD, in order to ensure that the products covered only by GPSD would also be covered by these provisions.

With respect to the NLF, the obligations of the economic operators are included in the Decision 768/2008. Art. 1 of Decision 768/2008 describes the general obligations of the economic operators by stating that "When placing products on the Community market, economic operators shall, in relation to their respective roles in the supply chain, be responsible for the compliance of their products with all applicable legislation". Moreover, the economic operators have the responsibility for ensuring that all information they provide with regard to their products is accurate, complete and in compliance with Community rules. The issue of traceability is included in Article R2 (5 and 6) of Annex I in the Decision, which states that

- 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.[69]

For example the Spanish interviewee describes the inclusion of the traceability provisions in the NLF as "a step forward".

The Regulation 765/2008 only specifies a limited number of obligations, as the focus is rather on the role of the national authorities in market surveillance.

However, one of the key provisions concerning the obligation of economic operators and included in Regulation 765/2008 concerns CE marking of products. As the NLF covers the New Approach Directives, it also includes the obligation for the economic operators to affix the CE marking on their products. Art. 30 in Regulation 765/2008 defines more specifically that CE marking shall be fixed only by the manufacturer or his authorised representative. By affixing the CE marking the manufacturer or his authorised representative states (and takes responsibility for) that the product is in conformity with the applicable requirements of the relevant Community harmonisation legislation. This differs to an important extent from the GPSD, where the market surveillance authorities have to prove that the product is dangerous and to assess the level of risk they pose.

As mentioned in chapter 2.2.6, several of the interviewed Member States indicate that there is a need for alignment between the GPSD and the NLF, in particular as regards the wording and definitions of economic operators and their roles. Orgalime agrees that the

[69] The specific obligations, divided between the different economic operators are detailed in Chapters R2-R5 of Annex I of the Decision. The Annex contains the reference provisions for Community harmonisation legislation for products.

definitions should be aligned, but states that this does not necessary imply that the *obligations* of economic operators need to be aligned.

Summing up, a key issue relating to a possible need for alignment with respect to the obligations of economic operators is that of traceability, where the NLF is more specific than the GPSD. In principle, this could have implications on successful tracing of dangerous products already on the market. As some Member States have already included traceability requirements in their national legislation transposing the GPSD, making the provisions obligatory in the revised version of GPSD would only change the situation in some Member States. This should be taken into account when considering the need to align the provisions of traceability.

2.3.2. Obligations and powers of the national authorities

The general difference between the NLF and the GPSD concerning the obligations and powers of the national authorities is that while the NLF (and in particular Regulation 765/2008) sets up obligations for Member States regarding market surveillance, the GPSD is a product safety directive, which sets up requirements for business.

The GPSD does however contain some provisions concerning the obligations and powers of national authorities. As mentioned above, the GPSD assigns the responsibility for ensuring that only safe products are placed on the market to the Member State authorities. This obligation must be fulfilled by monitoring the compliance of the producers and distributors with the obligations stated in the GPSD.[70] More specifically, the obligations and powers of the national authorities specified in the GPSD are the following:

Table 4: Obligations and powers of national authorities according to the GPSD

The role of the national authorities in relation to the GPSD consists of the following:
• The obligation to ensure that producers and distributors comply with their obligations in such a way that products placed on the market are safe (Art. 6, par.1). • The obligation to establish or nominate competent authorities that will monitor the compliance of products with general safety requirements and that have powers to take appropriate measures (Art. 6, par.2); define the tasks, powers, organisation and cooperation arrangements of these competent authorities (Art. 6, par.3). • The obligation to lay down the rules on penalties applicable to when the national legislation transposing the GPSD is not followed, and the obligation to make sure that the penalties are implemented (Art. 7). • The obligation and right to take measures to order warnings, ban the supply, marketing, withdrawal, recall or destruction of products (Art. 8, par.1). • The obligation to ensure that the market surveillance approaches include appropriate means and procedures (Art. 9, par.1) and to ensure that consumers and other interested parties are given an opportunity to submit complaints on product safety and on surveillance and control activities (Art. 9, par.2).

However, as the GPSD is a Directive, the text is not directly applicable. This causes, according to an interviewee at DG ENTR, a problem as the requirements in Articles 6-8 laying down the obligations and powers of the Member States are not stringent enough. While the NLF is very specific in its way of presenting the obligations and powers of the

[70] Report from the Commission to the European Parliament and to the Council on the implementation of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety. COM(2008)905 final, p. 4.

national authorities this causes, in effect, two different market surveillance systems to exist for harmonised and non-harmonised products. The obligations and powers of national authorities specified in Regulation 765/2008 are presented below.

Table 5: Obligations and powers of national authorities according to Regulation 765/2008

The role of the national authorities in relation to the NLF (Regulation 765/2008) consists of both obligations and rights (powers), including:

- The obligation to establish procedures to a) follow up complaints or reports on issues relating to risks arising in connection with products subject to Community harmonisation legislation; (b) monitor accidents and harm to health which are suspected to have been caused by those products; (c) verify that corrective action has been taken; and (d) follow up scientific and technical knowledge concerning safety issues (Art. 18, par. 2)
- The obligation to "establish, implement and periodically update" market surveillance programmes (Art. 18, par. 5)
- The obligation of MSAs to "perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples" (Art. 19, par. 1), before those products are released for free circulation (Art. 27, par. 1)
- The right to "require economic operators to make such documentation and information available", and if necessary to enter the premises of economic operators to take the necessary samples of products. MSAs are also given the right to destroy products presenting a serious risk (Art. 19, par. 1, Art. 30)
- The obligation to alert users of identified hazards relating to a product (Art. 19, par. 2)
- The obligation of the market surveillance authorities, when they decide to withdraw a product manufactured in another Member State, to inform the economic operator concerned at the address indicated on the product in question or in the documentation accompanying that product (Art. 19, par. 3).
- The obligation to ensure that products which present a serious risk are recalled, withdrawn or prohibited (Art. 20, par. 1)
- The obligation, when a product presents a serious risk or does not comply with Community harmonisation legislation and that product is subsequently prohibited from being placed on the market, to involve the customs authorities (Art. 29); and to notify the Commission, when the Member State takes a measure against a product that presents a serious risk (Art. 22)
- The obligation to provide the Commission with information on products that present a risk, but that are not included under Art. 22 measures (Art. 23).

The Finnish authorities are worried about the provisions in NLF requiring exchange of information between the Member States (Art. 23), also in other cases than products causing serious risk. According to the interviewee the current tasks of translating the RAPEX warnings into English, sending safeguard clause-notifications and conducting other reporting required on the national level takes up a considerable time of the MSA. This is why it is important that any system or database that is built for exchanging general information among the Member States should be merged with the RAPEX notification system and the system of sending safeguard clause-notifications. Having one common interface would facilitate the work of the national authorities (i.e. the same starting page for all notifications and information, where you can choose in which database you want to add the information).

The Polish and Slovenian authorities refer to the difficulty in implementing the Art. 19(3) of Regulation 765/2008 on the obligation to inform the economic operators about the decision

to withdraw a product in the cases where the economic operator is situated in another Member State. Similar issues have been experienced by the Danish authorities. The Danish authorities tend to primarily rely on the provisions in the NLF and sector directives, and only use the GPSD in situations, where sector requirements do not cover all the issues (lex specialis principle). Some problems have arisen in relation to importers. The interviewee mentions situations, where the sector legislation refers to manufacturers or their representatives in the EU, but where the authorised representative or the EU importer is in fact situated in another Member State than Denmark. The older sector directives do not accommodate for this situation, but the NLF now provides the authorities with the possibility to deal with the "first in line" importer or distributor in the country where the national authority is situated. This provision is included in Decision 768/2008 (Art. R5(5)), which states that "Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have made available on the market". In order to take effect, the provision has to be included in a new or revised piece of sector legislation. This supports the need for alignment between the NLF and sector legislation, which is currently being planned by DG ENTR.

The Hungarian authorities mention that the identification of the manufacturer or the importer of harmonised products causes difficulties for the Hungarian authorities while conducting market surveillance, because the Hungarian legislation does currently not dispose of the compulsory indication of the names and addresses of manufacturers and importers. Similarly to the issue of obligation to inform the economic operators situated in another Member States (cf. above) the Decision 768/2008 contains provisions to this end (Art. R2 and R4 of Decision 768/2008), but as this Decision has not yet been transposed into the Hungarian legislation, the question of traceability remains difficult. The Decision 768/2008 provides also some support for the issue of obligation to inform the economic operators in Article R5(5), according to which the distributors shall cooperate with the national authorities on any action taken to eliminate risks posed by products which they have made available on the market. This provision is however only applicable for products, where the provision is included in the specific sector directive.

According to a representative of DG SANCO, the question of obligations of national authorities is one of the main issues for the alignment of the GPSD with the NLF. For example the drawing up of market surveillance plans is an *obligation* in the NLF (cf. the list of obligations in Table 5 above), while it is not in the GPSD. Thus, in the GPSD the Member States are required to ensure that approaches employing appropriate means and procedures are put in place, which *may* include *sectoral* market surveillance programmes (general programmes are not mentioned). As the NLF only covers harmonised products, a paradoxical situation arises, where the market surveillance authorities have the obligation to present market surveillance plans for harmonised products only. Moreover, a representative of Prosafe states that the Member States have different ways of understanding what is meant by a national market surveillance programme.

As regards the obligation of market surveillance authorities of a Member State to inform the economic operator concerned when they decide to withdraw a product manufactured in another Member State, this obligation does not exist in the GPSD.

The provisions allowing the Member State authorities to enter the premises of the economic operators are not included in the GPSD either.

The NLF also includes provisions concerning the role of border control in market surveillance. The Regulation 765/2008 specifies that the authorities "in charge of the control of products entering the Community market shall have the powers and resources

necessary for the proper performance of their tasks".[71] The Regulation also requests adequate cooperation mechanisms to be established between market surveillance authorities and external border controls. This pronounced role of the border control authorities is not included in the provisions of the GPSD.[72] This role also entails the active involvement of DG TAXUD in the discussions on market surveillance, and a working group has been established to discuss the market surveillance activities under articles 27, 28 and 29 of Regulation 765/2008. The representative of the Finnish authorities states that while these new provisions have led to an increased cooperation between the Finnish authorities, customs have always had a pronounced role in the Finnish market surveillance activities, including the mandate to take decisions to refuse products to enter the Community market. This is however not necessarily the case in most other Member States.

While in the GPSD the producers are obliged to keep a register of complaints, the NLF specifies that the Member State authorities have to monitor accidents and harm to health which are suspected to have been caused by products that are subject to Community harmonisation legislation. The requirement to monitor injury statistics is as such not included in the GPSD. The representative of the Finnish authorities does consider this to be a problem, as on the GPSD side the economic operators have the requirement to notify the authorities of products that can cause danger. According to the interviewee some pieces of sector legislation include the obligation to notify of potentially dangerous products.

While some Member States argue that obligations and rights should be the same in the two pieces of legislation, other Member States do not see the differences between the powers and obligations of the national authorities as important. For instance, both Slovenia and Germany state that any divergences do not affect the effectiveness of the market surveillance. In Germany, the GPSD and 13 New Approach Directives were transposed in one single German law. According to the interviewee, this results in coherent market surveillance with coherent obligations and powers. One of the interviewees states that the authorities seem to have similar powers to carry out market surveillance both in case of products covered by the GPSD and those covered by the NLF.

2.3.3. Key findings: Obligations

Overall, the key difference between the NLF and the GPSD concerning obligations and powers is that while the NLF (and in particular Regulation 765/2008) lays down obligations for Member States regarding market surveillance, the GPSD is a product safety directive, which mainly lays down requirements towards businesses.

With regards to the **obligations of economic operators**, the GPSD is on some points more developed than the NLF, including the requirement to provide information to the consumers, and the requirement to keep a register of complaints. On other points, the GPSD is less clear, for instance with regards to traceability, which is an issue that could be improved. Likewise, it is pointed out that provisions concerning the safety documentation and the declaration of conformity could also be included in the revised version of the GPSD, in order to ensure that the products covered only by the GPSD are also covered by these provisions. Some Member States have however already included traceability provisions in their national legislation. This means that an alignment between the GPSD and the NLF with this respect would ensure the alignment of procedures not only between harmonised and non-harmonised products, but also between the Member States.

[71] Art. 27.

[72] It should however be mentioned that this is not necessarily a problem, since the provisions in Regulation 765/2008, Art. 27, 28 and 29 cover both the harmonised and the non-harmonised area.

The NLF includes the obligation for the manufacturer/authorised representative to affix the CE marking to the product, thus taking responsibility for product's conformity with the applicable requirements whereas in the GPSD, market surveillance authorities have to prove that the product is dangerous and to assess the level of risk they pose. There are indications that the **obligations and powers of the Member States** are not stringent enough in the GPSD, partly because of transposition issues, whereas the NLF is very specific (and, as a Regulation, directly applicable) in its way of presenting the obligations and powers of the national authorities.

In some cases, the same issues are covered, but as obligations in the NLF and as rights in the GPSD, whereas some rights and obligations which are included in the NLF (such as the right to enter the premises of economic operators if necessary) are not at all included in the GPSD. Thus, in effect, two different market surveillance systems now exist for harmonised and non-harmonised products, where the system for harmonised products (NLF) in a number of cases provides more wide-ranging powers and obligations to the MSAs.

Whether, and to what extent, this has effects on market surveillance and on the safety of products *in practice* is not quite clear; in some Member States, it appears that there is no real difference in practice, whereas others point to specific issues where there are disparities that may potentially have a negative effect. In order to avoid uncertainties and differing practices in Member States it may thus be advisable to align the rights and powers of national authorities in the GPSD along those of the NLF.

2.4. Options for alignments

As presented in the introductory chapter to this report, one of the aims of this study is to find out in what ways the GPSD and the NLF overlap, and what alignments may be needed between the two in order to ensure a coherent internal market and market surveillance for both harmonised and non-harmonised products. This chapter concentrates on the options for alignment. Firstly, the views of the stakeholders concerning options for alignment are presented, and secondly, recommendations are given for alignments between the GPSD and NLF, based on the previous chapters on definitions and obligations.

In addition to the divergences in definitions and obligations presented in the above chapters, there are also other issues that deserve to be mentioned when considering the potential need for alignment between the GPSD and the NLF. These are presented below. Several interviewees mention however that it should be kept in mind that the General Product Safety Directive consists of several provisions that do not entail a need for alignment with the NLF; hence, the emphasis is kept on the market surveillance provisions, which to a different extent are included in both the GPSD and the NLF.

Regulation 765/2008 presents a comprehensive framework for market surveillance. When this is supported by the Decision 768/2008 provisions on the obligation of economic operators, the new safeguard mechanism and the information procedure that has to be followed by national authorities in case of non-compliance or unsafe products, the market surveillance framework is relatively complete. Some interviewees representing DG ENTR consider that the market surveillance measures of GPSD should be included in the NLF. They do not consider it to be justified that there are two different legislations for harmonised and non-harmonised products. An alignment of the GPSD and the NLF would help the situation to some extent, but it would not make the work of the national authorities any easier, especially if the revision of the GPSD leads into it becoming a regulation.

Currently, Art. 15(5) of the Regulation 765/2008 states that the provisions concerning the controls of products entering the Community market (Art. 27, 28 and 29) shall apply to all products covered by Community legislation. This means that the provisions in the NLF apply also to products covered by the GPSD, insofar as they enter the European Union at its external borders. According to an interviewee representing the Commission, in cases such as these there would be no need to duplicate the measures in the GPSD, when the scope of the NLF could be increased. Moreover, there are some provisions in the GPSD, such as the standardisation procedure or the Art. 13 emergency measures, which are considered by a representative of DG ENTR to be very important specific measures for non-harmonised products and remain relevant for the scope of the GPSD.

According to an interviewee representing DG SANCO, the goal of DG SANCO for the revision of the GPSD is to have genuinely one, coherent regime for market surveillance, which is clear and streamlined. DG SANCO would like to ensure an alignment with the provisions of Decision 768/2008 and full consistency of the market surveillance regime for all consumer products, be they harmonised or not. The objectives concerning market surveillance are the same both in GPSD and in NLF. The fact that there has been a need to draw a working paper explaining the relationship between the GPSD and Regulation 765/2008 shows that there is indeed a need for better consistency. Regulation 765/2008, Art. 40, recognises the need to consider the consistency of Community rules in the field of market surveillance. The interviewee states that one of the main issues identified by DG SANCO in terms of alignment is that concerning the obligations of the national authorities,

where for instance market surveillance plans are now only drawn up in the harmonised area.

From the point of view of customs authorities, the simpler legislation, the better. The customs authorities have to implement a large number of legislative acts, which is why it is important that the market surveillance provisions are very clear and easy to understand. DG TAXUD is also calling for the harmonisation of enforcement provisions so that you can only use one set of rules with respect to the enforcement of market surveillance legislation.

The UK authorities emphasise that in the decentralised market surveillance system of the UK, the market surveillance authorities use both the GPSD and the NLF and take the action that is most appropriate for each product. The GPSD is considered to be an umbrella piece of legislation and the everyday market surveillance is conducted very pragmatically. There is a need for flexibility, where, such as in the case of toys containing magnets, the umbrella legislation "kicks in" when the sector legislation (in this case the Toys Directive) does not deal with a problem to a sufficient extent. The Danish authorities agree that the GPSD should be aligned to the NLF to the extent possible. The point is that there are some aspects of consumer protection that are not adequately covered by the NLF. There is thus a need for umbrella legislation on product safety. The Danish authorities would like to see provisions similar to those on sector legislation in NLF also in the GPSD.

The main concern of Prosafe in relation to market surveillance is the lack of uniformity in the way in which market surveillance is carried out in the European countries. In their view one way of leading to a more uniform approach is the active implementation of joint market surveillance actions (see section 3.1). The goal is not to harmonise the practices to 100%, but to support a more harmonised way of looking at market surveillance. The interviewee points out, however, that there are still challenges in getting the Member States to see the European Union as one market with only one border, one policy, one methodology and one market surveillance competence. With a combination of both the NLF and the GPSD you would cover all the possible ways to conduct market surveillance and thus support the harmonisation of the procedures. An alignment would also lead to one set of principles, and the same basis for the training of market surveillance officers. This would also make it possible to use the same reference documents for the Member State activities.

The Prosafe interviewee does however not think that the small divergences between the GPSD and the NLF constitute a real problem for the implementation of market surveillance. One of the challenges is also to get the economic operators to understand the way in which the MSA work. Informing the industry about the market surveillance provisions is thus a key task.

The consumer organisations point to the importance of the precautionary principle included in the GPSD, Art. 8(2), which is currently not included in the NLF. The interviewee representing ANEC states that the precautionary principle can have direct implications for standardisation efforts: often a manufacturer will claim that there is no need to change existing standards because there have not been any serious accidents involving the product in question. This might not be the case if the precautionary principle were upheld. The absence of accidents does not mean that the risk is low. This is why ANEC considers that it is better to prevent rather than to act after an accident has taken place. This is particularly true for products containing dangerous chemicals where the harmful effects may not materialise immediately.

Orgalime is of the opinion that little alignment is actually necessary, except perhaps for a minor recast to ensure that the GPSD complements and does not supplement the existing legislative framework of safety legislation, avoiding overlaps and legal uncertainties. They point to the fact that the GPSD is in practice narrow in application, since according to

Orgalime's own calculation, the majority of consumer products are in fact covered by specific safety legislation (sector legislation). What is needed instead is efficient enforcement of NLF and all related sector legislation. On a more specific note, Orgalime considers that the application of the precautionary principle is unfit for use by authorities and/or the Commission in the enforcement of the GPSD, because it leaves too much room for interpretation. Instead, product safety should be determined from a list of essential requirements.

2.4.1. Options for alignments in text

The divergences between the GPSD and the NLF, and their implications presented in the previous chapters have led to a number of possible alignments that can be proposed. These are presented below.

General comments

Based on the research conducted in the context of this study, it seems that there are two main options for the alignment between the GPSD and the NLF: Including the market surveillance provisions of the GPSD into the NLF, or having two separate documents, where the GPSD is updated in such a way that it takes into account the relevant provisions in the NLF. The documents would not be identical, as the GPSD would still be a legislative act for general product safety. While other options are also possible, these two have been identified as the two most feasible options due to the predominant view among the stakeholders that at least the definitions used in the GPSD should be aligned with those presented in the NLF. This is why it is not considered feasible *not* to take into account the provisions in the NLF when updating the GPSD. Considering that there is an agreement among the stakeholders concerning the need for alignment between the two instruments, the question is rather *to what extent* the instruments should be aligned. Which option is chosen is a political decision and no recommendations are provided in this study to this end.

For the interviewees representing DG ENTR, the most attractive option is to include the market surveillance provisions in a single piece of legislation. The main challenge is thus not to align definitions or small divergences in the GPSD and the NLF, but to decide upon the number of legislative acts that are needed. In the question of GPSD the task is, according to an interviewee representing DG ENTR, that of small updates and making the text more coherent. The main question in this respect is related to the obligations (cf. section 2.3.2 above) of the national authorities and the authority of the Commission, as well as that of looking at where the national authorities get their authority to carry out their activities.

As mentioned above, the goal of DG SANCO is to arrive at genuine streamlining of market surveillance. According to the interviewee representing DG SANCO, the GPSD is a suitable instrument for ensuring the safety of non-harmonised consumer products for aspects such as standardisation. The aim is however to have a single set of rules for market surveillance, which is why there is a need to ensure full consistency between the provisions of the GPSD and those in Regulation 765/2008.

The Member States mention some areas where alignment is in their view necessary. The German authorities propose that the GPSD takes into use the definitions and the obligations for economic operators from Decision 768/2008. Moreover, the interviewee sees a need for the RAPEX Guidelines to be amended so as to fit the needs of the NLF and to cover non-consumer products as well as risks other than those to safety and health of consumers.

While the Slovenian interviewee request that both instruments are aligned to the extent possible as regards definitions, the Hungarian authorities refer to the need to provide an adequate definition of serious risk in the NLF.

The representative of the Finnish authorities mentions that the main provisions in NLF, missing currently in the GPSD, are those concerning the traceability of the products and concerning safety documentation. The UK representatives point out that while there are parts of the NLF not existing in the GPSD (such as CE marking), they are not necessarily relevant to be included in the revision of the GPSD.

Orgalime is emphasising the need to keep emergency measures decided by Comitology temporary in nature and leave possible permanent requirements for placing a product group on the consumer market up to the decision of policy makers under the normal legislative procedure.

Specific options for alignment

On the basis of the findings in this report, the following alignments can be proposed:

1. Alignment of the definitions in general

The majority of the stakeholders consider it to be relevant to align the definitions used in the GPSD and the NLF. The general view is that the definitions in the NLF are more modern than those in the GPSD and some Member States have begun to use the NLF definitions only. This is why it is recommended that the definitions in the NLF be used also in the context of GPSD.

2. Definition of economic operators

As the definitions of economic operators used in the GPSD and the NLF differ from each other, confusion can arise concerning the obligations of economic operators. In order to enable a better understanding and clarity of the obligations of economic operators within the two legislative frameworks, it is recommended that the definitions of economic operators be aligned so that the GPSD takes into account the different operators in the supply chain.

3. Definition of "making available on the market" and "placing on the market"

Directly related to the alignment in the definition of economic operators is also the definition of "making available on the market" and "placing on the market". While these are both specified in the NLF, the definitions are not clarified in the GPSD. In order to bring further clarity into the obligations of economic operators, it is also recommended to align these definitions.

4. Clarifying the risk assessment method for non-consumer area

The inclusion of the definition of serious risk in the NLF and the use of RAPEX for harmonised non-consumer products have led to the need for a clear understanding of the risk assessment method to be used in order to define the level of risk in non-consumer products. In the field of consumer products, the RAPEX Guidelines offer at least some level of coherence for conducting risk assessment. It is thus recommended that the definition of serious risk be clarified in the field of non-consumer products and guidelines be developed for conducting risk assessment on products that are not covered by the RAPEX Guidelines.

5. Obligations of economic operators

On obligations of economic operators, the issue of traceability was put forward by some stakeholders as one that is better specified in the NLF than in the GPSD. Traceability is already included in the national legislation of some Member States, making an alignment between the NLF and the GPSD relevant not only due to a difference between harmonised and non-harmonised products, but also due to differences in Member States' national provisions.

6. Rights and obligations of national authorities

The rights and obligations of national authorities are in general more wide-ranging in the NLF than in the GPSD. An important difference is the obligation in the NLF to draw up market surveillance programmes while this is put forward as an option in the GPSD (but only for sector programmes), meaning that market surveillance programmes are only required for the harmonised area. This is a very clear option for alignment. Other areas where alignment seems warranted is the right of the MSAs to enter the premises of economic operators, and the obligation to inform economic operators in other Member States if their product is withdrawn from the market – both included in the NLF but not in the GPSD.

7. Principle of precaution

The views of the stakeholders differ concerning the importance of the principle of precaution, included in GPSD, Art. 8(2). This is currently not included in the NLF. While the consumer organisations point out the need for including the precautionary principle in the NLF, in particular in cases dealing with chemicals, both representatives of DG ENTR and Orgalime consider the principle to lead to overdoing of market surveillance, especially where guidelines do not exist. If the principle of precaution is not included in the NLF, it should be ensured that proper guidelines exist for conducting risk assessment in the field of non-consumer products.

8. Joint Market Surveillance Actions

Joint market surveillance actions are currently mainly carried out under the auspices of the GPSD and coordinated by Prosafe. In order to create complementarity between the cooperation activities under the GPSD and the NLF, it is proposed that the principles for conducting joint actions are aligned between the two instruments.

2.4.2. Key findings: Options for alignment

Based on the findings of this report, the two main options for alignment between the GPSD and the NLF seem to be to include the market surveillance provisions of the GPSD into the NLF, or to have two separate documents, where the GPSD is updated in such a way that it takes into account the relevant provisions in the NLF. Needs for alignment have been identified at least in the following areas: definitions (and in particular those of economic operators); and risk assessment guidelines for harmonised products;

2.5. Summary

While several stakeholders acknowledge that some **definitions** of the GPSD and the NLF differ from each other, the main message is that the divergences in the definitions do not cause any important challenges. The differences are mainly considered to be subtle and rather issues of terminology than content. Most stakeholders acknowledge however also that it is relevant to update the definitions in the GPSD and thus to align them with the NLF. Several interviewees point out that while NLF has looked for inspiration for the definitions in the GPSD, NLF is more advanced in terms of definitions than the GPSD.

The issues regarding the concept of "serious risk" in the GPSD, the NLF and the sector legislation lie not in the definition as such (serious risk is not defined in sector legislation), but rather in how serious risk is identified and assessed. In the context of GPSD, the RAPEX Guidelines provide a method for risk assessment, but the stakeholders hold differing views concerning the usefulness of these Guidelines. Whereas some consider the Guidelines to be very useful and practical, others see them as too general in scope, making it difficult to apply the method to specific products. Moreover, no clear Guidelines exist for conducting risk assessment on harmonised products, not covered by GPSD and the RAPEX Guidelines. In the case of these products, the Member States are used to operating with the compliance testing, which can be checked against the technical annex in the sector directives. Hence, some stakeholders express concerns about the ability of the RAPEX Guidelines to warrant a consistent interpretation of "serious risk" in the Member States. These issues, among others, can lead to risk assessment being carried out differently across Member States and authorities, and result in products being placed on the market in one Member State, while they are banned in another Member State.

Overall, the key difference between the NLF and the GPSD concerning **obligations and powers** is that while the NLF (and in particular Regulation 765/2008) lays down obligations for Member States regarding market surveillance, the GPSD is a product safety directive, which mainly lays down requirements towards businesses.

With regards to the **obligations of economic operators**, the GPSD is on some points more developed than the NLF, including the requirement to provide information to the consumers, and the requirement to keep a register of complaints. On other points, the GPSD is less clear, for instance with regards to traceability, which is an issue that could be improved. Likewise, it is pointed out that provisions concerning the safety documentation and the declaration of conformity could also be included in the revised version of the GPSD, in order to ensure that the products covered only by the GPSD are also covered by these provisions.

As to the **obligations and powers of the Member States**, there are indications that these are not stringent enough in the GPSD, partly because of transposition issues, whereas the NLF is very specific (and, as a Regulation, directly applicable) in its way of presenting the obligations and powers of the national authorities.

In effect, two different market surveillance systems now exist for harmonised and non-harmonised products, where the system for harmonised products (NLF) in a number of cases provides more wide-ranging powers and obligations to the MSAs.

Whether, and to what extent, this has effects on market surveillance and on the safety of products *in practice* is not quite clear; in some Member States, it appears that there is no

real difference in practice, whereas others point to specific issues where there are disparities that may potentially have a negative effect. In order to avoid uncertainties and differing practices in Member States it may thus be advisable to align the rights and powers of national authorities in the GPSD along those of the NLF.

With regard to the options for alignment, the study points to two feasible ways to go about: Including the market surveillance provisions of the GPSD into the NLF, or having two separate documents, where the GPSD is updated in such a way that it takes into account the relevant provisions in the NLF. The documents would not be identical, as the GPSD would still be a legislative act for general product safety. Which option is chosen is a political decision and no recommendations are provided in this study to this end. Instead, some specific needs for alignment can be pointed out. These include for example the following:

- The definitions should be aligned between the GPSD and the NLF and follow the definitions as presented in the NLF.
- In particular the definition of economic operators should be aligned, as differing definitions have a direct implication on the obligations of the economic operators. These will become easier to understand if the definitions used are the same in both the GPSD and the NLF
- There is a need to clarify the risk assessment method and the definition of serious risk in the harmonised non-consumer area.
- An important difference between the GPSD and the NLF is the obligation in the NLF to draw up market surveillance programmes. This means that market surveillance programmes are only required for the harmonised area and there seems to be a need for alignment so that similar programmes will be drawn up in the non-harmonised area as well.

3. MARKET SURVEILLANCE

3.1. Joint market surveillance

3.1.1. Joint market surveillance actions

The establishment of joint actions between the Member States and respective enforcement authorities constitutes an important aspect in the effective enforcement of product safety. The importance of joint initiatives is enhanced by the fact that market surveillance typically has been an exclusive, national prerogative of the Member States. As a way to create a legislative framework conducive to joint actions, both the GPSD and the NLF encourage the MSA to enhance the degree of cross-country collaboration at the operational level. As such, the role of market surveillance networks is related to the promotion of mutual learning mechanisms as well as the sharing and the optimisation of resources – particularly relevant when considering the financial issues national enforcement authorities have to deal with.

According to GPSD the execution of joint market surveillance projects contributes to enhance the degree of collaboration between different national enforcement authorities. To this end, it is considered "appropriate to promote the operation of a European network of the enforcement authorities of the Member States"[73]. In line with Article 10 of the GPSD, the European Commission takes upon itself the responsibility of promoting and taking part in the operation of a European network which gathers the authorities competent for product safety, "in particular in the form of administrative cooperation."[74]

Furthermore, the Member States are reminded of the need to coordinate joint operations developed by this network with existing Community procedures such as the RAPEX. The purpose of this network rests upon four key objectives informing the joint efforts which the Member States shall develop under the auspices of the GPSD. This network intends to facilitate:

a) the exchange of information on risk assessment, dangerous products, test methods and results, recent scientific developments as well as other aspects relevant for control activities;

b) the establishment and execution of joint surveillance and testing projects;

c) the exchange of expertise and best practices and cooperation in training activities;

d) improved cooperation at Community level with regard to the tracing, withdrawal and recall of dangerous products.[75]

On what concerns the NLF, and in particular Regulation 765/2008, the development of joint market surveillance activities is seen as a way of better sharing resources and knowledge. According to this legislative act, such initiatives are "designed to share resources and expertise between the competent authorities of the Member States"[76]. Much like in the GPSD, the European Commission takes upon itself the responsibility of coordinating the development of cross-border joint market surveillance initiatives and enforcement activities. However, there is a change of tone in Regulation 765/2008 which stresses the role of the Member States, and the sharing of the duty of setting up and organising cross-

[73] Recital to the GPSD, Paragraph 25.
[74] Art. 10(1).
[75] GPSD, Art. 10(2).
[76] Art. 25 (2).

border joint market surveillance activities. As such, either "the Commission or the Member States concerned" should:

a) develop and organise training programmes and exchanges of national officials;

b) develop, organise and set up programmes for the exchange of experience, information and best practice, programmes and actions for common projects, information campaigns, joint visit programmes and the consequent sharing of resources.[77]

3.1.2. Examples of Joint Actions

In this section, examples of joint actions will be presented. These joint actions are considered to be representative of the efforts developed by the Commission and the Member States. The cases were selected based on their contribution to what is considered best practice in joint actions. Moreover, the cases provide an idea of the main problems faced by Member States when participating in joint actions and respectively, of areas where there is room for improvement.

EMARS I

Starting in 2006, EMARS I was the first major project backed by European Union funds and coordinated by Prosafe[78]. The project "aimed to achieve a basic level of expertise and practical experience throughout most of the market surveillance organisations within Member States of the EEA"[79]. In order to achieve this objective, EMARS was broken down into diverse focal points such as: the setting up of an informal first assessment Rapid Advice Forum; a documental Knowledge Base; a book on Best Practice Techniques in Market Surveillance; development of risk assessment guidelines; development of a Training Strategy for market surveillance officials, and lastly the definition of a future strategy based on the discussion and forecasting of further market surveillance challenges and developments.

According to the handbook of Best Practice Techniques in Market Surveillance, developed during EMARS I, cross-border joint actions constitute a proactive form of cooperation in surveillance programmes. Cross-border market surveillance was structured along the lines of seven levels of coordinated activities:

1. Exchange of product information and test results
2. Coordinated sampling of follow-up
3. Coordinated information activity
4. Coordinated testing
5. Joint testing
6. Cross-border market surveillance action
7. Joint action under GPSD Article 10

A specific example of such a Prosafe joint action is Lighters I. This joint action was developed between 2007 and 2009 under the full title of: *Joint market surveillance Action on Child-Resistant Lighters and Novelty Lighters*[80]. According to Prosafe, thirteen Member

[77] Art. 25 (2).

[78] Product Safety Enforcement Forum of Europe, an organisation established by market surveillance officers from across Europe. Since 2006, PROSAFE has coordinated a number of Joint Actions which are all financially supported by the EU Commission

[79] http://www.prosafe.org/default.asp?itemid=10

[80] Other examples of EMARS I joint actions concern: Playground equipment; Cords and drawstrings on children clothing; Toys; Sun beds and solarium services.

States participated actively in the execution of this joint action. Subsequently, the joint action Lighters II was initiated as a follow-up activity under the framework of EMARS II. The planning and carrying out of the Lighters II, which is still being undertaken, incorporated the main lessons extracted from the implementation of Lighters I, and further developed those areas where room for improvement had been identified in the discussions held by the participants.

The development of this action was based on the results achieved by the 2005 Working Group for lighters which gathered members of the European Commission, Member States and relevant stakeholders. The activities developed included both market surveillance authorities and customs authorities. In order to establish a minimum common denominator in the operationalisation of the project, a set of common monitoring indicators was established[81]. Additionally, the implementation of the action included several aspects regarded as best practice:

a. The sharing of common and ambitious objectives among the participants (i.e. less than 2% of unsafe lighters by 2008)

b. Use of coordinated sampling plans

c. The involvement of industry and consumer representatives as a form to optimise the knowledge they possess about the product, respective market, pit-falls, and associated risks, etc.

d. Better coordination of cross-border cooperation activities

e. Resource to the Rapid Advice Forum, as a way to expedite sharing of knowledge and avoid the bureaucratic burden of formal procedures.

f. Joint testing of products

EMARS II

The implementation of EMARS II by Prosafe started in November 2008 and it is meant to be concluded in late 2011. EMARS II builds on the experience and success of EMARS I, but also seeks to further advance the degree of cooperation and coordination in the field of market surveillance. Therefore, EMARS II does not only follow-up on some of the joint actions developed by EMARS I and respective best practice identified, but moves beyond by incorporating some of the elements identified by the future strategic discussions held as part of EMARS I.

The implementation of EMARS II seeks to take forward the results achieved by using the same tools upon which EMARS I was founded (Rapid Advice Forum; knowledge base, etc.). The tone set in the phasing of EMARS II objectives, clearly articulates the need to address those main areas where room for improvement had been identified[82]:

1. Developing a *more rigorous* and systematic approach to the identification and execution of joint actions"

2. Promoting a *more consistent* approach to market surveillance through the development of best practice and a training programme for market surveillance officials in the field of consumer product safety;

3. Ensuring adequate liaison between market surveillance authorities and standards development;

[81] i.e. The share of non-compliant lighters that are found on the European market; The share of non-compliant lighters that are imported to Europe; The share of non-compliant lighters that are produced in Europe

[82] http://www.emars.eu/

4. *Improving* collaboration with Customs officials through networking opportunities and the identification of best practice ;

5. *Improving* operational level collaboration with relevant enforcement authorities outside the EEA

In addition, the implementation of EMARS II was also distributed among different thematic areas which correspond to Core Coordination Tasks. Among these, Task B is focused particularly on the *Management and Planning of Future Joint Actions and Coordinated Market Surveillance Activities*. The activities of task B counted with the active participation of seven Member States (BG, CZ, FR, DE, IE, LT, NL).

The specific joint actions organised have mainly followed up on EMARS I projects, and much in line with the rationale of EMARS II, the joint actions have attempted to carry results forward based on identified successes and gaps. Up until this point, these joint actions focused on: a) Playground equipment; b) Lighting chains; c) Lighters; d) Sunbeds; e) Toys; f) Cords and draw strings.

At a general level these activities have aimed at developing and implementing management procedures and instruments that permit a daily execution of all joint projects. At a more specific level, the task has intended to identify best practices emerging from the operationalisation of joint actions or other coordinated market surveillance projects. Based on this procedure, participants in task B should prepare a deliverable exposing the main findings. Additionally, there have been other deliverables that have focused on a generic model for joint actions and respective phases of operationalisation, necessary procedures and instructions pertaining on how to apply this model.

Task B has intended to develop a platform for more informed decision-making and a better planning of future joint actions, progressively better tailored to the needs of the Member States. To achieve this it was considered necessary to gather all national market surveillance programmes[83] which eventually would create a dynamic database with previous and current national market surveillance programmes, including information on projects carried out by the MSA. The fields included in this database comprise the scope and aim of the project, period of implementation, a summary of most relevant results and respective contact person. The concept of collecting annual plans from all the Member States was originally developed under EMARS I, but only effectively carried out and improved during the course of EMARS II. Through this initiative Prosafe has been able to gather information from 20 countries, which represent app. 75% of EU Member States. This platform could not only provide an overview of product safety in different countries, but also assist in the planning and identification of common problems and potential synergies. For instance, the Prosafe interviewee responsible for the overseeing of Task B mentioned that MSA mainly resort to this database in order to find projects with similar specificities, which other MSA have carried out. The same interviewee added that this process often leads to bilateral contacts between MSA or the development of cooperation channels between neighbouring countries and the consequent sharing of experiences and knowledge.

The idea of collecting the annual market surveillance plans of the Member States has subsequently been included also in Regulation 765/2008. According to an interviewee representing Prosafe, the database developed by the European Commission (DG ENTR) for collecting the annual market surveillance plans of the Member States in the field of harmonised products is based on the format devised and used by Prosafe under EMARS. The two databases differ from each other in scope, as the Prosafe activities are conducted

[83] The requirement for all the Member States to have a national market surveillance programme was introduced in Regulation 765/2008.

within the scope of the GPSD (consumer products), while the market surveillance plans collected by the Commission only cover the scope of the NLF (harmonised products). The Prosafe task manager for joint actions expressed that two overlapping systems which employ the same database format are currently in use. That is, the Prosafe annual market surveillance plans database (GPSD) and the database used by the SOGs working group on market surveillance (NLF). The interviewee was of the opinion that improvements could be attained by aligning both instruments and resorting to a single database.

In addition to the development of a more tailored approach to the design of joint actions, it has also been considered important to identify different levels of engagement in joint actions. This more flexible approach has intended to encourage the participation of a greater number of participants by accommodating the possibility of adapting the degree of commitment to the joint action to its specific circumstances (financial, staff, relevance of the joint action).

Joint Action on Sunbeds

The Sunbeds I joint action was developed under the framework of EMARS II joint actions and had the participation of 10 Member States[84]. This joint action was implemented between 2008 and 2009 and enabled the inspection of more than 300 locations and the investigation of more than 500 sunbeds. The great majority of these inspections targeted service providers (i.e. tanning salons, wellness centres) and focused on providing appropriate safety information to consumers, labelling of the products, UV radiation exposure and availability of eye protection. Subsequently focus on this product area was continued through the Sunbeds II joint action, which is currently under implementation and will continue until 2011 with the participation of the Netherlands, the Czech Republic, Norway, Germany, the UK, Belgium, France, Denmark, Hungary, Lithuania, and Portugal.

Several interviewees referred to this joint action as a successful example of cross-country cooperation. According to the Prosafe interviewee, part of this success is based on the cooperation established between the MSA and the European Sunbed Association (ESA). This collaboration was based on the realisation made by both sides regarding the shared interest in assuring legislative conformity. From the viewpoint of the MSA, compliance is crucial to enforce safety requirements and assure the protection of consumers and from the industry standpoint, compliance is an important form of avoiding negative publicity and asserting the credibility of the branch.

The set-up of this joint action had some unique features determined by the need to combine both a service and a product approach. This is explained by the fact that sunbeds can both constitute a product available to consumers for direct purchase from the producer/distributor or alternatively, they can be a service available to consumers via a service provider (i.e. sunbed studio). In order to address this complexity, it was crucial to establish channels of cooperation linking MSAs from different Member States to industry representatives such as the ESA, and eventually reaching business operators and consumers. A particular example of collaboration between MSA and the ESA was the work developed towards the elaboration of new standards for sunbeds. In this context, both actors joined efforts in awareness raising initiatives with the purpose of informing sunbed studio owners of the newly established standards and the importance of complying with its requirements. The rationale conveyed by the Prosafe interviewee was that if sunbed studio owners are aware of the new legislation and convinced by the arguments presented regarding the importance of compliance, they will in fact conform to the rules. Reducing the

[84] Belgium, Cyprus, the Czech Republic, Denmark, Finland, Germany, Hungary, Latvia, Netherlands, Poland.

incidence of non-compliance due to mere lack of awareness would allow MSAs to focus on identifying economic agents who consciously do not respect the new standards.

The Prosafe Task B manager interviewed also stated that important technical and methodological accomplishments were made with respect to the alignment of inspections and measurements between the countries participating. Partly, this entailed the undertaking of a two-day long training session, in which the participating inspectors exchanged practices and knowledge concerning how non-compliance is viewed in each country and possible solutions and resources available. Lastly, another successful aspect outlined by the interviewee concerned the exchange of professional measuring equipment. Since the unit cost of a specific measurement instrument was approximately €35,000, Prosafe opted to make this investment and place it at the disposal of the countries participating in the joint action. Consequently, Dutch experts travelled with this equipment and conducted several measurements of sunbeds in a number of countries. As such, equipment which many MSA would not be able to afford or which constituted a burdensome investment was accessible via a cooperation mechanism and at a lower cost (enabling MSAs to redirect these resources elsewhere). In fact, the Lithuanian interviewee identified the lack of appropriate testing infrastructures for some product categories, in addition to the financial expenses associated with the testing of products as the main factor hindering the participation in joint actions. In line with this, the Portuguese interviewee stated that participation in joint actions was advantageous because community financing supported the testing of products thus discharging the national MSA from having to cover such costs.

Baltic Sea Market Surveillance Network[85]

The Baltic Sea Network-Product Safety gathers all the consumer protection agencies of the Baltic Sea Countries since 2004. The enhancement of the level of cooperation in the Baltic area was important to expedite the flow of information among the agencies concerned and consequently prevent the import and re-import of unsafe products. Focused on non-food products, the work of the network implies a great deal of cooperation with custom authorities (assessed as best practice in the Prosafe Handbook of Best Practice). The network is also both supported by DG SANCO and DG ENTR, and uses RAPEX as an important source of information.

Based primarily in the port of Hamburg (the second largest in Europe), the regional focus of this market surveillance network takes into consideration both the degree of integration of the Baltic States economies, as well as the main distribution chains and trading connections in the area. Operationally speaking the focus is mainly placed on early detection processed via exchanges of information. Working in network not only avoids double testing and allows the optimisation of resources, but also enhances the probability of detecting non-compliant products all throughout the distribution chain. As such, enforcement authorities in cooperation with customs focused on identifying importers and direct importers in order to map trading routes and account for the fact "that a recall must be conducted from the top of the distribution chain"[86]. This factor is both relevant in terms of consumer safety, but also in terms of the protection of the Baltic Sea area economies from distorted competition. The balance between product safety and economic fairness is seen to guarantee a level playing field for all the compliant economic operators and producers.

Since its inception, concrete actions have primarily taken place in the area of electric household appliances, since this was a common problem for all the participant countries. Work developed focused on this issue took into particular consideration the low cost

[85] http://www.hamburg.de/baltic-sea-network/

[86] http://www.hamburg.de/contentblob/125206/data/kooperationsbericht-zweiter-2006.pdf, Second Report, 2006, p.22.

segment of consumer products – and within this group, especially products imported from the Far East (incl. China). Another product area that has been given considerable focus throughout the years was toys.

3.1.1. Limitations experienced by the Member States

In general terms the Member State interviewees were pleased with the effect of participation in joint actions. One aspect emphasized by several interviewees was the input in terms of enhancing the knowledge of market surveillance officials and the strengthening of interpersonal relations and informal contacts. Further to this, the Prosafe interviewee identified the possibility of providing MSAs in different Member States with connecting channels as the main result of both EMARS I and EMARS II. It was further added that joint actions constituted an important forum for discussions among officials about market surveillance as a profession. These discussions subsequently allow MSAs to acquire a better overview of the variety of problems affecting different countries as well as of the variety of methodological approaches and technical solutions employed to solve them. EMARS I and II joint actions have thus helped in providing a systematic and structured framework for the MSA to exchange views and experiences. The Finnish interviewee emphasised the importance of the media exposure and contribution to the awareness-raising of consumers.

One of the main limitations identified by the interviewees was fundamentally of a financial nature. The degree of participation in joint actions is impacted by the fact that many MSA do not possess enough human and financial resources. This is corroborated by the Polish interviewee as well as the European Commission. Due to these national budgetary limitations (which can be particularly acute in the case of smaller Member States) European funds become vital for the enforcement of market surveillance and engagement in joint actions.

The impact of burdensome bureaucratic procedures was mentioned by a number of interviewees as an important factor limiting the participation in joint actions. The amount of red tape necessary to obtain Community financial backing, the lengthy procedures associated with it and the disparity between the timing of the implementation and the effective transfer of funds to the organisations involved were all mentioned as major factors by Prosafe. In fact, the Finnish authorities mentioned that the load of administrative burdens was considered so great that the MSA felt this could have a negative impact on the primary purpose of enforcing product safety and further compromise nationally defined implementation timings. The interviewee further added that when Finland did participate in joint actions, it even opted to do so without receiving Community funding simply because of the bureaucratic load implied.

Furthermore, the bureaucratic weight of formal procedures also impacts the swiftness of the exchange of information and knowledge among the participants. In this sense the informal set-up of the Rapid Advice Forum established by EMARS I provides an interesting solution. This platform constitutes an informal network connecting market surveillance officials for the purpose of rapid first assessment advice and feedback from fellow officials in other Member States

Another important financial aspect has to do with the cost associated with the preparation of joint actions. Besides the investment made by Prosafe in specialised staff qualified to prepare and monitor the applications, the overall length of time necessary to complete an application is mentioned as an important cost factor which may reduce the amount of countries partaking in the action. Following the approval of an application, another factor which can reduce the efficiency and degree of participation in a joint action has to do with the source of financing for the start-up phase. Fundamentally this problem is related to the

fact that Prosafe – and subsequently the participant countries – have to cover all the start-up costs since instalments from the Commission may take up to six months.

As a consequence of the time-span that the processing of reimbursements may take, Prosafe is not able to cover the travel costs of the MSAs participating in the joint action. This means that travel costs are in some cases only covered several months subsequent to the conclusion of the joint action and only after the financial report is completed. In fact, this issue was identified by the German and Portuguese interviewees as a factor limiting the participation of these Member States in joint actions. It was further added that in addition to Prosafe joint actions, the national MSA also has to exclusively cover all travel cost of Administrative Co-operation Group (ADCO)[87] members, and that this leads to an accumulation of expenses which limits the capacity of participation in joint actions.

Furthermore, there is also a risk associated with the fact that the Commission may actually not approve the joint action, in which case the resources used for the preparation of the application cannot be reimbursed. This situation places Prosafe under financial pressure and seriously limits its cash flow. The issue is especially important since Prosafe is concerned with losing (in particular) the smaller countries if a membership fee was to be introduced strictly to tackle this challenge. To limit its impact, the Prosafe representative refers to the importance of introducing a more precise and regularly timed system of financial transfers from the Commission to Prosafe, and as much as possible to avoid ad hoc funding. Instead, different alternatives could be considered, such as the possibility of developing a funding mechanism similar to that used by EFSA in the food area[88]. Another possibility mentioned by the same Prosafe interviewee consisted of conferring more autonomy over budgetary decisions to Prosafe – or any other coordinating body. This would convert the organisation of joint actions into a more flexible process by allowing the coordinating body to provide separate yearly budgets and determine the most appropriate budgetary allocation. The last possibility put forward consisted of distributing the total budget to the coordinating body in the start-up phase of the project and only reimburse unused funds back to the financing body after the project has been completed and its effective cost calculated.

Partly due to the problem related to financing, the effective inception of the activities can prove very lengthy and rigorous calendar planning can be compromised. In line with this, a Member State representative mentioned that participation in Prosafe joint actions often occurred under a rather irregular implementation calendar (i.e. actions planned for 2009 which effectively run in 2010). The interviewee mentioned this as a ground for non-participation, since the irregular timing in the implementation of the activities included in the national programme could be compromised. A Prosafe representative acknowledges this problem and points out that while the Member States plan their national budgets relatively early in the previous year, the financing mechanism makes it impossible for Prosafe to apply for funding from the Commission that far in advance.

In addition, other Member State interviewees pointed out that due to the limitations in human resources available there were difficulties in allocating personnel to work on joint

[87] Several ADCO (Administrative Cooperation Group in Market Surveillance) groups have been established such as the European market surveillance group instituted in 1996 for the area of Electromagnetic compatibility (EMC-ADCO), in 1997 for the area of the Low Voltage Directive (LVD-ADCO); and in 1998 in the area of recreational crafts (RCD-ADCO).

[88] According to article 36 of the Founding Regulation of EFSA, a list of competent organisations with the capacity to assist this agency was approved in 2006 by EFSA's Management Board. This list is based on nominations made by Member States and includes all competent organisations approved to undertake work on behalf of EFSA. Accounting for the fact that organisations evolve and needs can change as a result of scientific and policy developments, this list is constantly updated and subject to additions and alterations (last version is from December 2008). Based on its Annual Work Programme, EFSA allocates financial support for tasks entrusted in the form of grants and via calls for proposals. This enables the establishment of a networking platform between ESFA and different Member States. http://www.efsa.europa.eu/en/networks/art36.htm

actions. Linguistic shortcomings also act as a barrier. Moreover, the disclosure of information regarding income was identified as another problematic issue since some Member States are not willing or do not find it appropriate to disclose this information, and consequently this hampers their participation in a joint action.

Another limiting factor was identified by another Member State representative who emphasised the importance of the financial role of the European Commission, in terms both of the joint activities developed under the Framework of the GPSD and the NLF. However, the interviewee advocated transferring the responsibility for the coordination of these actions from the Commission to Prosafe. This transformation would not only convert Prosafe into the network mentioned in article 10 of the GPSD, but also grant a more formal role in the field of European market surveillance. Furthermore, it could reduce the number of market surveillance fora that Member States participate in, help in the harmonisation of practices and strengthen the network. The existence of multiple fora further limits the participation of Member States in joint actions because not all Member States have the financial capacity to be able to afford the travel costs that need to be covered (a stance corroborated by the Portuguese and German officials).

The fact that the projects last at least two years may also impose some limitations on the Member States in terms of the degree of commitment necessary (and the fading of this commitment towards the end). Even if a Member State does decide to take part in a joint action, Prosafe identified the existence of serious management limitations which hinder the successful implementation of a joint initiative. This issue partly concerns the national management of market surveillance which often prioritises national projects in detriment of joint actions, and despite the agreement to participate in the Prosafe joint action.

This issue emphasises the need for a more flexible approach, based on different levels of engagement and the preoccupation on having results which can be used by all the Member States. In addition to this aspect, an interviewee representing DG ENTR further mentioned that the group of countries participating in joint actions is relatively stable in its composition. This is explained both by national financial constraints as well as the fact that the countries participating receive the benefits from the system of joint actions, while others are waiting for the final conclusions. Additionally, this interviewee mentions that actions organised under the framework of the NLF are financially more constrained than those organised under the legislative framework of the GPSD..

In addition to financial issues, several Member States mention the relevance of the area of focus of joint actions as a factor which constrains the choice to participate in a specific joint action. The incidence of product safety issues can differ across Member States, and can be determined by factors such as the market share of a particular product in a country, the climate, food habits, etc. In Spain, the main issue hindering participation is, according to the interviewee, the administrative structure of the Spanish state, where the Autonomous communities are responsible for market surveillance. Difficulties in communication and coordination between the different stakeholders have led to problems in relation to meeting deadlines.

Lastly, both the German and Portuguese officials stated that improvements could be achieved by having more cross-border actions linked to and promoted by the ADCO groups. Partly, the rationale behind this statement refers to the fact that Prosafe's strength is the administrative part of a joint action (assisting with applications, supporting participants with consultants, managing financial issues and reporting), but according to the German

interviewee, joint action proposals often lack technical depth[89]. To address this issue, a possible suggestion includes the setting up an expert group composed of officials from different Member States who volunteer on the basis of specific technical know-how and skills. As such, joint actions would continue to be prepared on the basis on Member States proposals[90], but would include a more refined and comprehensive set of technical specifications. Additionally, in order to increase the organisational efficiency, all technical issues should be decided ahead of the submission of the proposal and the kick-off of the joint action (i.e. which products, how many samples to collect, testing criteria, production of checklists, decide on testing methods and laboratories). To this end, instead of creating a new group or institution, the interviewee suggest drawing from existing sources of technical expertise such as, experts within Prosafe, national experts which prepared the joint action proposal, ADCO group experts and/or a small and permanent group of national experts. Representatives of other Member States did not specifically mention any need for increased cooperation within the scope of the ADCO groups.

3.1.2. Key findings: Joint Market Surveillance Actions

In general terms the Member States officials interviewed concurred in a positive assessment of their participation in the Prosafe joint actions. The reasons for this were fundamentally of a financial nature but additionally, benefits in terms of capacity development of market surveillance officials and the possibility for mutual learning were emphasised. From a financial perspective, a more coordinated joint approach to specific product categories has enabled MSA to increase the amount of samples tested, support the costs of laboratory tests and also allowed more MSA to make use of expensive technical equipment.

These forms of financial optimisation are particularly important when taking into consideration that limited financial resources was the major cause for non-participation in joint actions identified by the Member States. Another reason which was also widely quoted by many interviewees is related to the administrative liabilities associated with the granting of Community financial support and the delayed processing of reimbursements. Consequently, MSA and Prosafe have to exclusively support the start-up phase of joint actions and cover a wide range of costs, among which the burden of travel costs was particularly emphasised. Other limitations mentioned by the officials interviewed concerned human resources, coordination difficulties between national and joint projects such as mismatch in terms of timing concerning national budgets, planning and allocation of inspectors. Lastly, issues concerning knowledge of languages and the relevance of the area for the Member State were also identified as aspects limiting the participation in joint actions.

A possible alignment between the NLF and the GPSD was identified in terms of merging the Prosafe database with the SOGs database for market surveillance plans, drawing on the advantage that both are based on the same model developed by Prosafe.

[89] In fact, the ADCO group is composed by Member States representatives who specialise on certain product groups, and therefore are able to provide with the technical information necessary to organise a joint action (i.e. joint action on Simple Pressure Vessels).

[90] In this context, Member State participation would be limited to the submission of proposals, checking of products and their collection for the purpose of testing.

3.2. Market surveillance specific to consumer products

With regards to the need for market surveillance specific to consumer products, there are arguments both for and against. When it comes to identifying specificities in consumer products, several interviews point to the main difference between consumer and business products being the user, and more specifically the ability of the user to understand the risks attached to the product. While a professional will more easily notice gaps in the safety of a product and decide not to use the product, a "normal" consumer cannot in general be assumed to have this ability. Interviewees emphasise that the question is to a high extent the way in which the product takes the user into account. This is not necessarily a question specific to consumer products, as all products should be safe. In addition, there are a number of products, such as sunbeds, where the border between consumer products and professional products is somewhat blurred, as they can be bought by consumers for their own use (consumer products) or be offered for use by service providers. The safety of the product has to be ensured in both cases.

Poland considers that market surveillance of consumer products should be one, coherent system which ensures that all products which create any potential risk for consumers should be checked. The Finnish interviewee points out that clearly the majority of all market surveillance is already directed at consumer products. It is also highlighted that the requirements in the GPSD concerning safety and conformity assessment are not as elaborate and extensive as they are in the New Approach Directives. This points to a gap, where non-harmonised consumer products are not subject to equally high criteria on safety and conformity assessment, as harmonised consumer products are.

Both Lithuania and the UK already conduct market surveillance specific to consumer products. In the UK, market surveillance is divided between different market surveillance authorities, and while the Local Authorities have the responsibility for the surveillance of most products on the market (such as consumer products), the Health and Safety Executive conducts the surveillance of business products. Concerning the specificities of consumer products, the interviewees consider that the current level of market surveillance is sufficient in this respect. While consumer products that are used by vulnerable consumers are of interest, the interviewees do not see a need to make important changes to the practices or legislation.

The Portuguese authorities do not see a need for market surveillance specific to consumer products. It is according to the Portuguese authorities sufficient that the NLF covers all the harmonised non-food products, but the possibility to take more specific measures available to them under the GPSD should however be withheld. This view is shared partly by the Spanish authorities, according to whom common basic procedures are needed for market surveillance of consumer products, with the possibility of determining complementary specific procedures for concrete product groups, but that in general the legislative framework is sufficient as it is, in the form of GPSD and NLF.

Prosafe supports the idea of conducting market surveillance that is specific to consumer products. Their view is however that this is already clearly indicated in the GPSD and NLF has further emphasised the role of border controls and market surveillance in the Member States. It is however important to train economic operators to conduct their own market surveillance activities so that products would be pre-checked before they enter the market. The communication between importers and producers should be increased. While Prosafe does not see any specificity in consumer products that would need to be taken into account in a more general market surveillance framework, but instead the role of GPSD Art. 13

should be increased as a method that can be used in situations where extremely dangerous products are found.

Among the consumer organisations, BEUC agrees that there is a need for market surveillance specific to consumer products. While a number of dangerous products posing a risk to the health and safety of consumers are still found in the market, EU treaties and legislation aim at the protection of the consumer. An adequate level of market surveillance of consumer products is also very important for the fairness and transparency of the internal market. It is important how the supply chains of consumer products are managed and that the authorities can intervene before a product enters the shelves. As for the specificity of consumer products, BEUC emphasises that it is important to protect certain vulnerable groups. What is however essential is to ensure a sufficient level of control at the external borders of the EU. By doing this, and by exchanging information between the Member States it should be made impossible for a manufacturer to get their product to the market if it has been rejected at one of the entry points to the Union.

ANEC calls for a more general market surveillance framework. While product safety is now based on harmonised legislation and harmonised standards, market surveillance, which can be seen as the enforcement of these, is currently not harmonised. This can lead to a situation where a product is banned in one Member State, while it is still allowed in another Member State. This is why ANEC calls for a pan-European market surveillance system in Europe.[91] ANEC notes that, although Regulation 765/2008 of the NLF calls on the Member States to provide adequate resources, it doubts this will happen, with reference to the 2009 study on "Market Surveillance in the Member States" for the IMCO Committee which concludes that most Member States do not intend to commit more resources to market surveillance, either because they believe they already meet the requirements of the Regulation or because they do not have the resources. Although the Member States cite the recent financial crisis, ANEC believes the low electoral priority of market surveillance will prevent adequate resources from ever being made available. Moreover, adequate resourcing alone does not solve the problem of different definitions at national level and inconsistent actions. Hence ANEC repeats the need for the pan-European framework.

Eurosafe supports the possibility to establish EU-wide coordination for consumer safety and services. As food safety questions are already the responsibility of an agency, it would be reasonable, in the view of Eurosafe, to establish a similar structure for consumer safety and services. According to the interviewee, equal emphasis should be given to the safety of non-food products as is already given to the food products. However, the special expertise that is needed in the field of enforcement of both legislations differs from non-food to the food sector. Concerning the specificity of consumer products Eurosafe emphasises the additional need to concentrate on products with vulnerable users. These include in particular children's products where there is an interest in entrapment hazards, while suffocation risks are to some extent neglected. Many initiatives are currently undertaken based on perceived risk, but Eurosafe emphasises the need to look more at injury statistics.

Orgalime does not see a need for market surveillance specific to consumer products. According to the interviewee this could lead to such market surveillance being carried out separately from the enforcement of other legislation that is applicable to the same consumer products. The interviewee considers that the consumer interests are already sufficiently covered by sector specific legislation. Both the consumer and professional products deserve, according to the interviewee, the same level of market surveillance.

[91] ANEC has together with Orgalime issued a joint paper: ANEC & Orgalime: Common position paper – Call for an effective pan-European market surveillance system. 22 April 2009 – ANEC-SC-2009-G-014.

Emphasising specific types of products (i.e. consumer products) could lead to less attention being given to other products.

3.2.1. Key findings: Market surveillance specific to consumer products

According to the interviewees, the main difference between consumer and business products is the user, and more specifically the ability of the user to understand the risks attached to the product. Most interviewed Member States do not see a need for specific provisions concerning market surveillance specific to consumer products. In many Member States this kind of market surveillance is already conducted, either officially or in practice, meaning that an important part of market surveillance activities are directed at consumer products. Some interviewees point however out that it is important to train the market surveillance authorities to understand the specificities of consumer products.

3.3. Market surveillance of products bought online

Increased possibilities for purchasing products on the internet have brought along the question of how to ensure product safety and how to enforce market surveillance of products bought online. The question is whether the current legislation is suitable for detecting dangerous products on the internet or what might be done to improve e-commerce market surveillance.

3.3.1. Online trade in the legislation

The safety of products purchased online is a concern manifested in the GPSD. In the preamble (recital 7) it is specified that the Directive applies to products irrespective of the selling techniques, including distance and electronic selling. This implies that the provisions in the Directive also apply to products sold online.

With respect to the NLF no specific provisions were articulated with a clear reference to e-commerce. However, Regulation 765/2008 is applicable to product safety regardless of by whom and how products are made available and placed on the market. The Regulation focuses on the obligations and procedures necessary to uphold the safety requirements of products, including harmonised consumer products, and these safety obligations are the same for all economic operators irrespective of the channels used to sell the products.

The Electronic Commerce Directive was adopted in 2000 for the purpose of facilitating the free movement of information society services in the internal market.[92] Information society services signify the retail of most goods and services by electronic means and at a distance. The E-Commerce Directive thus covers, but is not limited to, the selling of products online. For example, online financial services would be covered by the E-Commerce Directive, but not the GPSD.

The E-Commerce Directive does not include provisions on the safety of products sold online. It does, however, specify certain obligations on information society service providers and Member States to assure the smooth functioning of the internal market, including:

- Service providers may freely market information society services in any Member State as long as they comply with the total legal framework of their country of establishment.[93]
- Member States may not require prior authorisation from a provider wanting to engage in provision of information society services.[94]
- Service providers shall make sure that the recipients of their services are presented with certain information, including the name, address and contact details of the provider.[95] Moreover, the provider shall see to it that the recipient of the service is guided through the transaction process with ease and transparency.[96]

[92] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce). OJ L178, 17.7.2000.

[93] Art. 3(1-2).

[94] Art. 4(1).

[95] Art. 5(1).

[96] Art. 10(1-3) and art. 11(1-2).

The Commission is currently undertaking a consultation on e-commerce to establish the impact of the E-Commerce Directive and identify possible means to improve the functioning of the internal market for information society services even more.[97]

3.3.2. The European e-commerce market

Though the absolute size of the European e-commerce market is still comparative small, it is growing at a steady pace. In 2009, 13% of the total turnover of EU-based businesses came from online sales, up from 9% in 2004.[98] At the same time, 51% of all European retailers now make their products available for purchase online. That is still 24% less than the share of retailers who sell their products in shops. However, online retail has overtaken telephone sales and mail order which are used by 43% and 29%, respectively, of the retailers.[99]

Not all enterprises who engage in online sales offer their goods for sale to customers in other EU countries. In fact, only 25% of all retailers do any kind of cross-border trade. The figures vary considerably between the Member States, however, with 46% of all retailers based in Luxembourg trading across borders compared to just 8% in Romania.

The share of European consumers who buy products online is also on the rise. In 2009, 38% of all EU citizens placed one or more orders online.[100] This amounts to a rise of 5 percentage points in just one year. Again, there is great variation between the Member States. For instance, a majority of the UK consumers (57%) went shopping online while only 11% did the same in Bulgaria.

There is no consistent pattern in the types of non-food products that European consumers look for when they go online (see Figure 3). Only one class of products, i.e. clothes and sporting goods, really stands out from the crowd at 17%.[101] A handful of other goods were bought online by just about one in ten consumers in 2009, including household goods (13%), books and magazines (12%) and electronic equipment (10%).[102]

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[97] http://ec.europa.eu/internal_market/consultations/2010/e-commerce_en.htm.

[98] Eurostat: Industry, trade and services - Information society statistics. Extracted 22 September 2010.

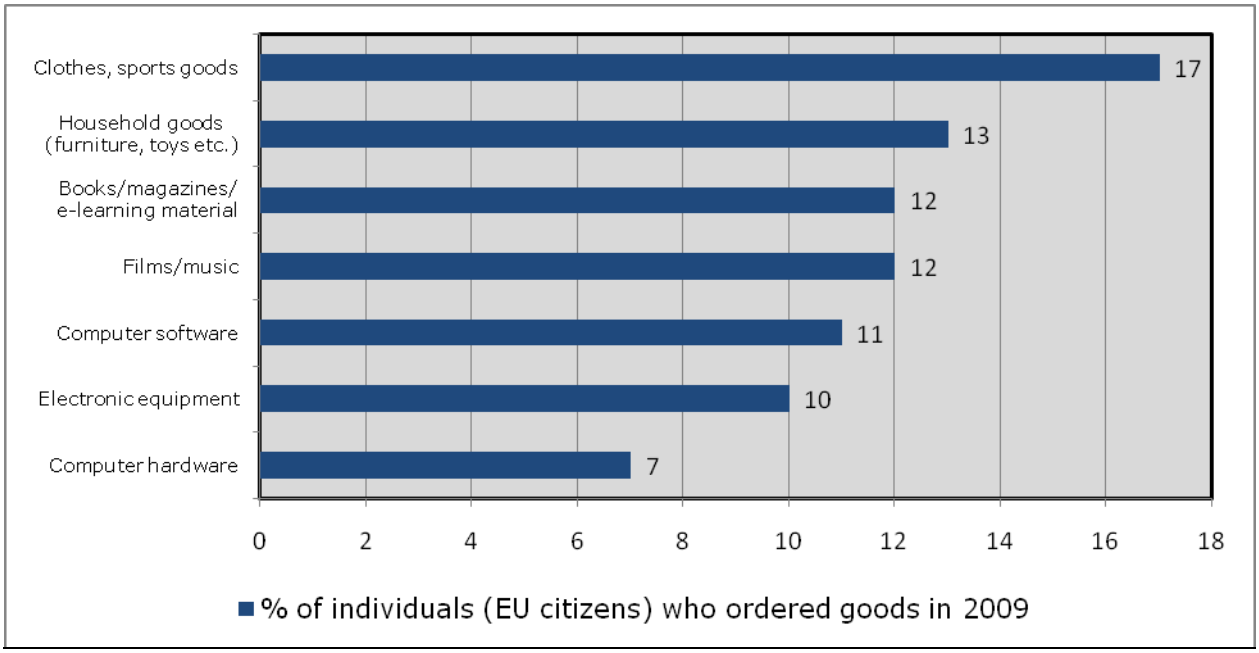
[99] Flash Eurobarometer 278: Business attitudes towards enforcement and redress in the internal market. Analytical report. Brussels, November 2009.

[100] Flash Eurobarometer 282: Attitudes towards cross-border sales and consumer protection. Analytical report. Brussels, March 2010.

[101] Eurostat: Industry, trade and services - Information society statistics. Extracted 22 September 2010.

[102] Statistics on the safety of products bought online compared to products sold in shops were not located.

Figure 3: Goods ordered over the Internet for private use in 2009, by product class[103]



The 38% of European consumers who engage in e-commerce today is a sharp increase on previous years. In 2004, for instance, just 15% bought any kind of products online. It should be noted, however, that only 8% bought something via the internet from another Member State in 2009 while a mere 4% made a purchase from a retailer based outside the EU. In other words, of all the goods that were bought online by European consumers in 2009, 9.5% were imported from a non-EU country.

Qualitatively, the European e-commerce market may be characterized as follows, according to an ACSEL study[104]:

- A mature market in Northern Europe. 60-80% of all internet users buy products online (about 40-60% of the general population).
- A growing market in Southern Europe. The share of internet users who engage in e-commerce is low but rising quickly.
- An emerging market in Eastern Europe. E-commerce figures have remained fairly low for some years.

3.3.3. Market surveillance of online trade

The Member States' market surveillance activities do include some level of supervision, inspection and testing of products that are offered for sale on the internet. In general, the national authorities have not developed specialised tools and methodologies for the market surveillance of online trade. Instead, they extend known and tested practices from regular market surveillance to the area of internet sales.

In Germany for instance, when a certain group of products is subjected to the scrutiny of market surveillance officials, it automatically triggers a complementary procedure to check whether the products in question are available online. This mirrors the approach taken by

[103] Eurostat: Industry, trade and services - Information society statistics. Extracted 22 September 2010.

[104] Association de l'économie numérique: Europe, An opportunity for e-Commerce. Paris 2008. Cited in SEC(2009) 283 final.

the Polish authorities who, whenever they receive a complaint about a potentially hazardous product, will survey the internet to see if the product is readily available to Polish consumers.

In the same vein, market surveillance authorities in Slovenia and Portugal will from time to time initiate internet surveys at their own initiative in order to assess the safety and availability of certain consumer and non-consumer goods, e.g. non-domestic household air-conditioners.

In Lithuania, on the other hand, the authorities do not carry out regular preventive control of products sold online. Yet they do undertake rapid controls on products such as laser pointers, cigarettes and some drugs.

Finally, online retail of consumer products has yet to be formally integrated in the market surveillance activities in Spain. Inspections of services sold online are however carried out.

The national market surveillance authorities have come together once a year since 2007 to undertake a so-called "EU Sweep". The EU Sweep is a comprehensive inspection of several hundred websites within a certain sector. It is carried out by the national authorities under the direction of the Commission in order to identify online retailers who do not respect the law and protect consumer rights and safety. So far, Sweeps have checked websites selling airline tickets, mobile phone content, electronic goods and online tickets. In the case of airline ticket vendors, more than half the websites inspected did not observe the law in every respect. Corrective actions were subsequently enforced and today 94% of the websites are in full compliance.[105]

3.3.4. Problems specific to market surveillance of products bought online

Most of the problems with market surveillance of products bought online relate to the fact that internet trade evades traditional and well-known distribution chains, allowing European consumers and businesses to purchase almost any kind of goods directly from a source anywhere in the world.

According to Commission officials representing DG TAXUD, the enhanced access to e-commerce brings about a difficulty in terms of the increasing number of importers as well as third countries whose products enter and circulate in the internal market. In particular, the kind of direct transactions that take place via the internet escape the concept of placing a product on the market. It is not clear, in other words, who is ultimately responsible for the safety and general condition of the product and the authorities' power to intervene in case of a violation is limited accordingly.

This relates to the broader challenge of establishing the origin of a product. Both Prosafe and an official from DG ENTR emphasised that the traceability of products bought on the internet may often be limited. With online purchases there is both a clear problem in determining the specific location of the manufacturer as well as in controlling and mapping the distribution chain of the product in order to assure the undertaking of necessary legal action. This task becomes particularly strenuous if the relevant economic operators are based in a third country.

Such sentiments are shared by German and British market surveillance authorities. They point to the fact that when a website is offering dangerous goods to European businesses and consumers from a third country locality, it is first of all often difficult to ascertain the ownership of the website and secondly, the powers of the authorities to act against such extraterritorial ventures are very limited. For instance, the UK authorities attempted to

[105] http://ec.europa.eu/consumers/enforcement/sweeps_en.htm.

prohibit import of a small yet powerful laser which is produced in China. However, despite appeals to the Chinese authorities, the product is still to be found on the internet and easily imported to the EU.

Additionally, the representative from Prosafe highlighted the problem that some of the internet sites that sell dangerous products remain active for very short periods of time only. Notification and test procedures take time, especially if the seller is located outside the EU, and when market surveillance authorities finally establish a case for shutting down a website in breach of the law, it might have moved to a different address.

At the same time, business-to-consumer e-commerce represents an unusually individualised form of retailing. Goods are imported on a reduced scale and often across borders directly from the producer to the home address of the consumer. Due to their negligible individual volume, such goods will easily escape custom checks. Cumulatively speaking, however, the individual units of online purchases amount to an enormous volume. The products cross the external and internal borders of the EU in small quantities and are easily spread to numerous locations via the postal system. In sum, personal import of products from other Member States and elsewhere has reached a level where, according to Commission officials from DG ENTR and DG TAXUD, adequately checking if individual purchases represent a safety hazard is an massive task which has yet to be accomplished.

As far as the European consumers are concerned, ANEC and BEUC consider that online trade constitute a bigger safety risk to the individual consumer than regular retail products. Often consumers are not aware that products imported from outside the external borders of the EU do not necessarily conform to European standards and they shop for virtually any kind of product online with little afterthought.

The Danish Distance Selling and E-business Association (DDSEA) offers a less disturbing view of the current situation with regards to surveillance of products purchased online. As the online vendor is in most cases based within the EU, the European consumers can be reasonably sure that the products they buy are in conformity with EU standards and legislation.

This view is echoed by the Finnish Direct Marketing Association (FDMA) which considers that the basic structure of the framework for detecting dangerous products is suitable. Moreover, according to the FDMA, cases involving consumers who have bought a hazardous product online rarely occur, indicating that the scale of the problem is rather insignificant.

Finally, the counterfeiting of legitimate brands may also be considered in the context of safety of online purchases. Counterfeiting is a problem which affects member states differently. Therefore, while some national enforcement authorities have led campaigns to tackle this issue, others do not see it as a priority. However, as the Commission representative from DG SANCO pointed out, it is important to note that counterfeiting does not necessarily constitute a specific problem of product safety but rather one of fair competition and value for money. In effect, unsafe products may be placed on the market by legitimate as well illegitimate brands.

In summary, online trade has reached considerable proportions in recent years and consumers have access to virtually any kind of product they could possible want through the internet. Yet while the large majority of goods bought online are safe and conform to EU standards, an unknown but non-negligible amount of dangerous goods are allowed to slip through the hands of EU customs officials, dodging the market surveillance authorities in turn. For obvious reasons there is no fixed inventory of the kind and amount of dangerous products which manage to escape the inspections but the list certainly includes everything from unapproved drugs and chemically loaded toys and appliances to eye-damaging lasers and combustible electronic equipment. The reason that such products are

not withheld by the authorities has to do with the nature of e-commerce. In effect, each individual consumer becomes an importer when he or she buys a product from abroad over the internet. Authorities simply do not have the capacity to control such an amount of petty imports, and at the same time they are fighting rogue traders who continue to make dangerous products available to European consumers from bases outside the EU.

3.3.5. An option to strengthen market surveillance of online trade: Revise the legislation

The first option for improving the performance of the Member States market surveillance systems is to revise the legal framework in a way that restricts online sale of dangerous products or provides the enforcing officers with a more effective set of tools to survey and control internet trade.

Of all the stakeholders who were interviewed for this report, only national market surveillance authorities support the idea that amending the legislation will help identifying dangerous products bought online before they reach European consumers and businesses. Yet of the ten national authorities interviewed, six do consider it expedient to revise the existing legal framework.

Their main recommendation is to introduce specific obligations for economic operators who engage in e-commerce, such as operators of web-portals, in order that they do not place any potentially dangerous products on the market or even distribute such. To achieve the broadest scope possible, the provisions would be added to both the GPSD and the NLF. The representatives do not address the question, however, whether or not this particular group of economic operators are in principle already covered by the provisions in the GPSD and Regulation 765/2008 that extend to all economic operators. Similarly, it is not specified exactly what such obligations would consist of.

Only the representative from Poland goes a step further, suggesting that the legislation is revised in such a way as to allow customs authorities to expand their activity considerably, effectively inspecting most of the individual imports that arrive at the borders of the Member States. Again it is not made clear if the powers and responsibilities of customs officials might be expanded without resorting to a revision of the law.

3.3.6. Strengthening market surveillance of online trade: Other options

A number of interviewees, including Orgalime and Prosafe, Commission officials from DG ENTR and DG SANCO and market surveillance officials from the UK and Finland, strongly emphasise that the current regulatory framework is not to be blamed for the fact that dangerous products from inside and outside the EU end up in the hands of European consumers via online sales. They in fact consider the legislation quite adequate for the purpose of tracking and banning rogue economic operators. In other words, online trade does not in itself constitute a reason for revising the GPSD and Regulation 765/2008. Orgalime also notes that the Commission is carrying out a review of the Distance Selling Directive that will in any case render a revision of the aforementioned legislative acts redundant..[106]

Whereas the option of revising the existing European legislation is thus clearly rejected, Orgalime does suggest that the Member States introduce certain provisions in national legislation to facilitate stronger penalties for economic operators who knowingly market hazardous goods on the internet.

[106] Orgalime Position Paper: Envisaged Review of the General Product Safety Directive (2001/95/EC). Brussels, 29 July 2010.

A number of other possible solutions to the problems surrounding internet trade of dangerous products are put forward. Most of them imply a more efficient use of delegated powers and resources so that the existing legislative acts may be enforced with more tenacity.

The solution that draws most support among the stakeholders is to enhance the role of customs authorities. Products which are imported by individual consumers from non-EU countries via an online sale are potentially much more dangerous than EU-manufactured goods. At some point along the route to their end destination, such products have to pass through customs. Customs officials thus occupy an absolutely essential role in the Member States' efforts to limit the trade of dangerous goods..

BEUC, the FDMA and a Commission official from DG ENTR all agree that expanding and optimising the role and procedures of Member State customs officials in such a way that the number of unsafe products that are bought online within the EU diminishes dramatically is possible and achievable. Likewise, the practical solution that they advance is identical: In order to increase the effectiveness of European customs, the sheer number of controls on imported goods must also rise. This implies that the resources that are currently allocated to these activities are inadequate.

Other possibilities for effective enforcement of product safety in the area of e-commerce are related to the development of practical methodologies designed to help agents working in the field, as pointed out by Prosafe. Research into these matters and sharing of experiences may well take place at the European level as suggested by ANEC and BEUC who further highlight how the benefits of international cooperation activities and exchange of data and experience on the enforcement of online trade product safety requirements might trickle down to market surveillance officials and customs agents on the ground, helping them optimise practical approaches to limit the availability of dangerous products on the internet.[107]

While the stakeholders generally agree that there is ample room for improvement in the way customs checks are carried on consumer imported goods, Orgalime and the Finnish market surveillance representative suggest that the consumers themselves may contribute as much to the solution as the problem. Because of the individualised nature of this form of retail, both the degree of awareness and precautions taken by consumers buying products online are of crucial importance. The consumers must be made to see that they and no one else are responsible for the option of buying products online and need to be aware of the possible risks associated with this form of retail, particularly when third countries are concerned. Devising campaigns that enhance the consumer purchasing proficiency is therefore an obvious strategy.

3.3.7. Key findings: Market surveillance of products bought online

Online trade is covered by the same product safety legislation as regular retail, and the E-Commerce Directive places additional restrictions on online vendors. The size of the European e-commerce market is growing, with 38% of European consumers making an online purchase in 2009, but only a fraction of those products crosses the borders of the Member States, not to mention the EU's external borders. Still, adequate market surveillance of websites based outside the EU is difficult to achieve. The majority of the stakeholders interviewed suggest that the role and resources of customs authorities are expanded so that they may cope with the growing number of petty imports. A minority

[107] ANEC and BEUC joint paper: Consultation on the General Product Safety Legislative Initiative: Replies from ANEC and BEUC. Brussels, 22 July 2010.

argues that the current legislative framework ought to be amended to prevent retailers from marketing unsafe products to European consumers.

3.4. Summary

The main **limitations and barriers to Member State participation in joint market surveillance actions** are all closely linked to the need for financing. Firstly, national market surveillance authorities have limited funds and need to prioritise their efforts. This may lead to some Member States not participating in joint actions, as the resources are rather needed on the national level. In order to assess the effective capacity to partake in a joint action the MSA can, for instance, take into account its ability to cover all necessary travel costs. Secondly, and as a consequence of the abovementioned limited national funds, the Commission is an important source of funding for the joint actions. However, applying for and receiving Commission funding is associated with significant administrative workload, cash flow problems (due to costs related to application procedure and in the first phases of a project), and lengthy procedures. A combination of these factors is generally referred to by both Prosafe and the interviewed national MSAs as the main limitations. Some Member States also identified staff related limitations such as, lack of human resources, difficulty to coordinate the planning of national tasks and joint actions, as well as linguistic shortcomings. Lastly, some MSA stated that at times, non-participation was explained by the lack of relevance of the product area and the issue at stake in their Member State.

Views among stakeholders as to whether there is a **need for market surveillance specific to consumer products** are somewhat mixed. While some Member States already conduct market surveillance specific to consumer products, there are also several interviewees who consider that there is indeed a need to improve market surveillance of consumer products. Interviewees agree that the main characteristic or specificity of consumer products is the role of the **user** – the consumer – which, as opposed to the professional user, cannot be expected to be able to assess the safety of a product. It is however not possible to conclude whether there is in general a need for market surveillance specific to consumer products.

With regards to **products bought online**, the existing legislation focuses on the unsuitable and dangerous characteristics of a product, not the means through which it is acquired and how it reaches the consumer. The importance of the role of customs and the need to strengthen the degree of cooperation with MSA was a particularly recurrent point. However, there is considerable difficulty in defining exactly which type of power is necessary to act online. Among the key issues specific to products sold online are the problems of traceability (including the location of the seller), and the sheer volume of small but numerous imports by private individuals which amplify the difficulty of detecting non-compliant products. However, the issue seems less one of changing the current legislation but more one related with improving the way market surveillance works, and not least the co-operation between MSAs and customs.

Most MSA interviewed said that to a greater or lesser degree, some level of supervision of products sold online was maintained in their Member State. Some referred to the use of a database where information was shared internally among different MSA and which permitted to systematise information concerning i.e. testing of products, inspections undertaken and in some cases the simulation of acquisitions. Still consumer complaints constituted the main source of information for MSA and the methods employed essentially emulated regular market surveillance techniques. In addition, MSA stressed that the majority of non-compliant products bought online entering the internal market were produced in third-countries. MSA suggested that this fact added further problems in terms of assuring that the product was made inaccessible to consumers and appropriate legal

action against the economic operators involved was undertaken. Lastly, the importance of consumer awareness, particularly when third counties are involved, was also cited by MSA.

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ANNEX: List of interviews

Name	Position	Organisation	Country	Interview date
European Commission Officials				
Rita l'Abbate	Policy Officer	DG Enterprise and Industry, Unit C.1: Regulatory approach for the free movement of goods and market surveillance	EU	20.07.2010
Caroline Edery	Head of Unit	DG Taxation and Customs Union, Unit B.1: Protection of citizens and enforcement of IPR	EU	23.07.2010
Jacques McMillan	Head of Unit	DG Enterprise and Industry, Unit C.1: Regulatory approach for the free movement of goods and market surveillance	EU	19.09.2010
Stefano Soro	Head of Unit	DG Health and Consumers, Unit B.3: Product and service safety	EU	23.07.2010
EU Organisations				
Marijn Colijn	Treasurer	PROSAFE – the Product Safety Enforcement Forum of Europe	EU	17.08.2010
Silvia Maurer	Senior Policy Officer	BEUC – The European Consumers' Organisation	EU	26.07.2010
Philippe Portalier	Senior Adviser	Orgalime – The European Engineering Industries Association	EU	18.08.2010
Wim Rogmans	Secretary General	EuroSafe – the European Association for Injury Prevention and Safety Promotion	EU	26.07.2010
Tania Vandenberghe	Senior Programme Manager	ANEC – the European consumer voice in standardisation	EU	09.08.2010
Gunnar Wold	Secretary	Prosafe – the Product Safety Enforcement Forum of Europe	EU	10.08.2010
Member State Officials				
Jozsef Boldizs	Professional Chief Adviser	Ministry of Social Affairs and Labour	Hungary	13.08.2010

Paloma Deleuze	RAPEX contact point	Instituto Nacional del Consumo	Spain	15.09.2010
Marian Dias	Technical Officer	Autoridade de Segurança Alimentar e Económica (ASAE) Food and Economic Safety Authority	Portugal	08.09.2010
Virginijus Jusys	Chief State Inspector	Products control department, The State Non Food Products Inspectorate under the Ministry of Economy of the Republic of Lithuania	Lithuania	09.09.2010
Richard Lawson	Head	Environmental and Technical Regulation Directorate, Department for Business, Innovation and Skills, Technical Regulation	United Kingdom	29.07.2010 (Interviewed together with David Southerland)
Hannu Mattila	Head of Consumer Safety	Finnish Safety Technology Authority	Finland	13.08.2010
Anna Mazurak	Director	Office for Competition and Consumer Protection, Department of Market Surveillance	Poland	10.08.2010
Dirk Moritz	Deputy Head of Unit	Equipment and Product Safety Federal Ministry of Labour and Social Affairs	Germany	01.09.2010
Janez Novak	Inspector – Senior Counsellor	Department for surveillance of Technical Products, Market Inspectorate of the Republic of Slovenia	Slovenia	25.08.2010
Jan Roed	Head of Section	The Danish Safety Technology Authority	Denmark	23.07.2010
David Southerland	Head	Consumer and Competition Policy, Department for Business, Innovation and Skills, Consumer Product and Services Safety	United Kingdom	29.07.2010 (interviewed together with Richard Lawson)
National Organisations				
Jari Perko	Managing Director	ASML – The Finnish Direct Marketing Association	Finland	08.09.2010
Henrik Theil	Chief of Communications	FDIH – The Danish Distance Selling and E-Business Association	Denmark	01.09.2010

NOTES

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