

**Guidance Document**  
**on the Relationship Between**  
**the General Product Safety Directive (GPSD)**  
**and Certain Sector Directives with Provisions on Product Safety**

**Directorate General Health and Consumer Protection**

**(DG SANCO)**

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**ANNEX I: TABLE OVERVIEW**

## 1. Foreword

This document is intended as an informal guide to assist the public authorities of the Member States when implementing the directives covered, but it should also be of use for producers and distributors of products falling under the scope of sector directives and the GPSD.

The Guidance offered to the Member States in this document is also relevant for Iceland, Liechtenstein and Norway as signatories to the Agreement on the European Economic Area (EEA). References to the Community, Member States or the single/internal market should be understood as referring to the EEA, the EEA States and the EEA market.

**Only the text of the directives is authentic in law. The text of the directives is applicable where there are differences between the provisions of a directive and the contents of this Guide. The interpretation of Community law is ultimately the responsibility and privilege of the European Court of Justice. The analysis set out in this Guide does not in any way preclude a different interpretation by the ECJ in a particular case, and does not in any way commit the European Commission.**

Every effort has been made to ensure coherence with other guidance documents in the area; in particular guides on sector directives. Directorate General Health and Consumer Protection (DG SANCO) and Directorate General Enterprise (DG ENTR) have co-operated closely to achieve this aim. In addition a wide consultation of Member States and stakeholders has been carried out in preparing the guide. However it cannot be excluded that inconsistencies remain. Any such inconsistency should be accepted as such and notified to DG SANCO.

## 2. Introduction

### 2.1 Background

Over the last decades a substantial corpus of European legislation has been adopted in order to secure free movement of goods in the single market. Since the adoption of the Council Resolution of 1985 on the New Approach, the mechanisms put in place are based on prevention of new barriers to trade, mutual recognition, essential requirements in harmonised legislation, harmonised standards developed by European standardisation bodies and notification of draft technical regulations. A significant part of this legislation concerns safety aspects of products. According to the legal basis for legislation on the internal market, article 95, paragraph 3, proposals concerning consumer protection will take as a base a high level of protection. More information on the concept of the New Approach and the implementation of the Directives based on this approach can be found in the “Guide to the implementation of Directives based on the New Approach and the Global Approach”<sup>1</sup>. It should be noted that in some areas that were particularly well developed by 1985, older legislation still applies, for example for cosmetics.

In 1992 the Directive on General Product Safety was adopted (92/59/EC). The Directive has been revised (2001/95/EC) and this new General Product Safety Directive (GPSD) must be

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<sup>1</sup> <http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/legislation.htm>

transposed into national law by 15 January 2004. The GPSD is complementary to specific product safety legislation in two ways. First it applies in its *entirety* to consumer products falling outside the scope of sector Directives (for example lighters). Secondly it applies *partially* to consumer products covered by sector legislation (for example toys). In general specific sector provisions have priority over general provisions (*lex specialis* principle). It is noted that the GPSD for certain aspects is a more detailed Directive than the new approach sector directives covered. The consequences of this conceptual difference will be discussed below in relation to the applicability of each provision.

The aim of this guide is limited to facilitating the consistent application of the relevant provisions of the GPSD to consumer products that fall within the scope of sector Community legislation related to product safety. It only deals with the second aspect mentioned above, namely the borderline between different product safety regimes at EU level. Such guidance has explicitly been requested by Member States and by other stakeholders.

It is noted that this document is not intended as a global guide to the implementation of the GPSD. This would be too far reaching. However, at a later stage, the different guidance documents on the GPSD, including the guide on RAPEX notifications under article 12 of the GPSD, will be co-ordinated and made available together.

In several cases the legal applicability of the GPSD only implies in practical terms that systems and procedures under different directives that have already been put in place on an informal basis are now formalised and continued. This adds to the status of the practices and to legal certainty, since the relevant parties will be legally obliged to participate in the relevant procedures.

The Emergencies Committee established under article 10 of Directive 92/59/EEC on General Product Safety, as well as all expert Groups under sector directives, have been consulted in the preparation of this guidance document.

## **2.2 Use of this guide**

This guide has been structured around each of the relevant sector directives. Although this structure involves a repetition of the same issues for each directive, it ensures that sector authorities can easily find a complete guidance chapter for “their” sector directive. The analysis itself follows the structure of the chapters in the GPSD, focusing on a) obligations for producers, b) obligations for distributors, c) obligations and powers for Member States and d) exchange of information and rapid intervention situations. The introductory chapter of this document is relevant and important for all sector directives and must be read in connection with each sector specific chapter.

Annex I provides an overview of relationship between the GPSD and the different sector directives in table format. The table facilitates a comparison between different sector directives for each of the GPSD provisions.

The nature of the relationship between the GPSD and sector directives is dynamic. Changes in sector directives influence the applicability of the GPSD. This guide will be updated when appropriate, based on an assessment of the significance of the impact of such changes.

Reference to “products” in this guide should normally be understood as meaning “consumer products”. It should be emphasised that this is the general limitation of the scope of the GPSD defined in article 2 (a). “Consumer products” are products that are intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them. What are “reasonably foreseeable conditions” must be judged in the individual case and will change with market developments where consumers increasingly use complex products, for example medical devices and machinery. This is particularly relevant for the Directive on Personal Protective Equipment.

There is no legal definition of a “consumer” in the GPSD or in the EC Treaty as such. The essential concept is however widely accepted to be individuals acting in a personal capacity in the market as opposed to individuals or legal persons acting in their professional capacity. In other pieces of consumer legislation the term has been defined. For example a “consumer” in the Directive on Consumer Credit (87/102/EC) and the Directive on Doorstep Selling (85/577/EC) means “a natural person who, in transactions covered by this Directive, is acting for purposes which can be regarded as outside his trade or profession”. The definition is not directly applicable to the GPSD, but may be used as a basis for the interpretation.

The different sector directives are normally referred to only by their short title or abbreviation in this document, for example the Directive on Electrical Equipment Designed for Use Within Certain Voltage Limits is always referred to as the LVD.

## **2.3 The basis for assessment of the relationship**

### **2.3.1 Introduction**

GPSD article 1.2 is the starting point for an assessment of the relationship between the GPSD and sector directives. The application of the GPSD varies depending on which article of the GPSD is being considered.

### **2.3.2 Applicability of the general safety requirement etc. - GPSD articles 2 to 4**

According to GPSD article 1.2, “Articles 2(b) and (c), 3 and 4 shall not apply to those products [products subject to specific safety requirements imposed by Community law] insofar as concerns the *risks or categories of risks* [italics added] covered by the specific legislation”. In the preamble, paragraph 12 this is explained:

“If specific Community legislation sets out safety requirements covering only certain risks or categories of risks, with regard to the products concerned the obligations of economic operators in respect of these risks are those determined by the provisions of the specific legislation, while the general safety requirement of this Directive should apply to the other risks.”

There is no legal definition of what constitutes a certain “risk” or “category of risk” in this context, but it is clear from the ambit of the GPSD that only risks and categories of risk relevant for human health and safety are relevant, (GPSD article 2, paragraph (b)). Examples of types of risk that are covered include chemical risk, mechanical risk, thermal risk, electrical risk, noise and flammability. Environmental risks, risks to animal and plant health and financial risks, for example, are not included.

### **2.3.3 Applicability of other obligations for producers, obligations for distributors and Member States - GPSD articles 5 to 18**

According to GPSD article 1.2, “Articles 5 to 18 shall apply except where there are *specific provisions governing the aspects* covered by the said Articles *with the same objective* [italics added]”. In the preamble paragraph 13 this is further explained:

“The provisions of this Directive relating to the other obligations of producers and distributors, the obligations and powers of the Member States, the exchanges of information and rapid intervention situations and dissemination of information and confidentiality apply in the case of products covered by specific rules of Community law, if those rules do not already contain such obligations.”

It is noted that the test of applicability includes a) whether the sector directive has a *specific* provision, b) whether the provision governs the same *aspect* and c) whether the *objective* is the same. It is noted that the two last conditions allow for a considerable degree of flexibility in interpretation. The aim of securing a coherent level of consumer protection should guide this interpretation together with the need to respect the systems and particular features already established under sector directives and as interpreted by the European Court of Justice.

### **2.3.4 Specifically on the applicability of notification procedures in GPSD articles 11 and 12**

The relationship between GPSD article 11 on notification of national measures and the sector directives is defined in article 11 itself. According to article 11, Member States shall inform the Commission of “all measures [taken to ensure safety of the product] which restrict the placing on the market of products – or require their withdrawal or recall”. The obligation to notify such measures is waived if notification is already “*required under article 12* [RAPEX notification – requires serious, immediate danger/effects beyond own territory] or *any specific Community legislation* [italics added]”.

Thus the test of applicability of article 11 is related to the scope of the notification procedures in sector legislation (in most cases known as “safeguard clauses”) and the RAPEX system. It is only in the remaining cases that article 11 is applicable.

Article 12 contains a legal requirement for Member States to report to the Commission through a rapid alert system (RAPEX) on products causing serious risk. The notification should be made through the national RAPEX contact point to the RAPEX contact point in the Commission. This information is rapidly disseminated to the Commission services responsible for the relevant sector directive and to the Member States that are obliged to report back. According to article 12, Member States shall notify the relevant measures “immediately”. Further details on the procedure are included in Annex II to the GPSD, including the obligation for the Commission to act in the shortest time possible. In accordance with point 2.3.3 above, the test of applicability is related to whether the sector directives have specific provisions on rapid exchange of information.

In cases where RAPEX notifications are made for products falling under sector directives, a separate safeguard clause notification must be considered sent (to the service responsible for the sector directive) in addition to the RAPEX notification. The main reason for this is that the two different notification procedures serve different purposes.

**Important note! Each of the sector specific chapters 3-6 must be read in connection with the horizontal chapter 2.**

### **3. Toys Directive**

#### **3.1 Introduction**

Council Directive 88/378/EEC of 3 May 1988 on the Approximation of the Laws of the Member States Concerning the Safety of Toys (Toys Directive) is a New Approach Directive and it was amended by Council Directive 93/68/EEC of 22 July 1993.

#### **3.2 Producers' obligations - GPSD chapters II and III**

##### **3.2.1 The general safety obligation – GPSD articles 2 (b) and (c), 3 and 4**

GPSD articles 3 and 4 establish a general obligation to place only safe products on the market as well as a procedure for the adoption of standards covering risks and categories of risks. "Safe product" is defined in article 2 (b) while "dangerous product" is defined in article 2 (c). These GPSD provisions apply to the risks or categories of risks not covered by the sector Directive.

The Toys Directive article 2 refers to "safety and/or health of users" in general terms, not only to specific risks. Article 3 obliges the Member States to take all necessary steps to ensure that toys are only marketed if they meet the essential requirements set out in Annex II. Annex II consists of one part on "general principles" and another covering "particular risks". The latter include physical and mechanical risks, flammability, chemical properties, electrical properties, hygiene and radioactivity. The former includes "health hazards and risk of physical injury" in general. The Directive is thus intended to cover all foreseeable categories of risks. Although some risks (for example noise) are not explicitly included in the list on *particular* risks, they must be regarded as part of the general principles provided they are relevant to the safety and/or health of users. As a consequence any need for standards or further elaboration of legally binding safety requirements falls under the Toys Directive.

→ The general safety obligation in the GPSD articles 2 (b) and (c), 3 and 4 does not apply to toys because the scope of the Toys Directive covers all risks and categories of risk.

##### **3.2.2 Information to consumers on risks – GPSD article 5.1, subparagraph 1**

GPSD article 5.1, subparagraph 1 introduces an obligation for producers to provide consumers with relevant information on risks. The objective is to enable consumers to assess risks and to take precautions, thereby reducing risk.

In the Toys Directive the aspect of information from producers to consumers is covered by specific provisions, namely article 3, ref. Annex II, part I, paragraph 3 on labelling and information in instructions and article 11.5, ref. Annex IV on warnings and indications of precautions. The objective of these provisions is the same as the GPSD, namely to enable the consumer to take precautionary action.



→ The provision in the GPSD article 5.1, subparagraph 1 on producer's obligation to inform consumers does not apply to toys.

### **3.2.3 Identification of the producer – GPSD article 5.1, subparagraphs 3 and 4**

GPSD article 5.1, subparagraphs 3 and 4 introduce an obligation for producers to identify themselves in connection with the purchase of the product. The objective is to enable them to be informed of risks and to give consumers and others a point of reference.

The Toys Directive has a specific provision on this aspect in article 11.1 with the same objective. It requires the name or trademark of the manufacturer to be affixed to the product.

→ The obligation for producers to identify themselves in GPSD article 5.1, subparagraphs 3 and 4 does not apply to toys.

### **3.2.4 Identification of the product – GPSD article 5.1, subparagraphs 3 and 4**

GPSD article 5.1, subparagraphs 3 and 4 have a specific provision on identification of the product itself, for example by a product reference. The aspect and the objective is different from the above (point 3.2.3), namely to facilitate identification of the product concerned and to allow for action at the most appropriate level.

The Toys Directive article 8.1 (b) requires a manufacturer to have detailed information available concerning the design, manufacture and conformity of a toy. This does however not specifically require identification of the product.

→ The part of the GPSD provisions in article 5.1, subparagraphs 3 and 4 that concern identification of the product applies to toys.

### **3.2.5 Follow up of consumer safety after products are marketed – GPSD article 5.1, subparagraphs 3, 4 and 5**

GPSD article 5.1, subparagraphs 3, 4 and 5 require that producers take appropriate active steps after the product has been marketed. Examples include sample-testing, filing of complaints and information to distributors. The objective is to ensure preventive action and to detect risks.

The Toys Directive has no specific provision on the post-marketing activities of producers. Thus the provisions apply to producers of toys.

→ The obligations to follow up the safety of products after marketing in GPSD article 5.1, subparagraphs 3, 4 and 5 apply to toys.

### **3.2.6 Information from producers to the competent authorities about dangerous products – GPSD article 5.3**

GPSD article 5.3 requires producers to inform the competent authorities about dangerous products and actions taken to prevent risk. The objective is to ensure that the competent authorities can take appropriate steps to reduce risks and to ensure co-ordinated action.

The Toys Directive article 10.5 has a provision on information to competent authorities from notified bodies. This is not the same aspect and therefore not relevant here. Furthermore article 8 of the Toys Directive sets out an obligation for manufacturers to keep information available for inspection. This is not the same aspect, since it does not involve any action by the producer. Furthermore the objective is not so much to alert the competent authorities as to facilitate actions already initiated by the competent authorities. GPSD article 5.3 therefore applies when toys are not in conformity with the safety requirements of the Toys Directive.

→ The GPSD article 5.3 on information from producers to the competent authorities applies to toys.

### **3.2.7 Co-operation with public authorities – GPSD article 5.4**

GPSD article 5.4 requires producers to co-operate with the competent authorities upon request. The objective is to ensure that action to avoid risk is co-ordinated.

The Toys Directive does not cover the aspect of co-operation between producers and the competent authorities explicitly, although co-operation is implicitly foreseen as a pre-condition for the functioning of the Directive.

→ GPSD article 5.4 on co-operation with the competent authorities applies to toys. Co-operation in line with this article will be established by sector authorities in view of the provisions applicable to toys.

### **3.3 Distributors' obligations - GPSD chapter III**

There are several provisions in the GPSD articles 5.2, 5.3 and 5.4 dealing with distributors' obligations. The overall objective is to ensure that distributors do not supply dangerous products and that they participate in measures taken to reduce risk.

The Toys Directive does not cover these aspects and objectives.

→ Articles 5.2, 5.3 and 5.4 of the GPSD dealing with distributor's obligations apply to toys.

### **3.4 Member States' obligations and powers - GPSD chapter IV**

#### **3.4.1 Establishment of competent authorities – GPSD article 6, subparagraphs 1 and 2**

GPSD article 6, subparagraphs 1 and 2 requires Member States to establish and organise competent authorities. The objective is to have a clear point of responsibility and to ensure co-ordination of market surveillance and other public measures to improve product safety.

The Toys Directive article 3 requires Member States to take the necessary steps to ensure that toys are not placed on the market unless they meet the safety requirements. Article 7 concerns measures taken by Member States regarding toys jeopardising the safety and/or health of consumers. Although it is not stated explicitly anywhere in the Toys Directive that competent authorities shall be organised and designated, the above mentioned articles of the Toys Directive indicate that some kind of national competent authority is envisaged. These are specific provisions dealing with the market surveillance aspect and have the same objective.

However, because of the relatively limited scope of the sector directive provisions, the corresponding GPSD provisions should serve as an example and a model for market surveillance of toys.

→ GPSD article 6, subparagraphs 1 and 2 on the establishment of competent authorities does not apply to toys.

### **3.4.2 Adopting rules on penalties – GPSD article 7**

GPSD article 7 explicitly requires Member States to lay down rules on penalties. There is no obligation on how to operate the rules on penalties. The objective is to include penalties in the range of possible measures to ensure compliance at national level.

The Toys Directive has no specific provision on penalties.

→ GPSD article 7 on the adoption of rules on penalties applies to toys.

### **3.4.3 Attribution of powers to competent authorities – GPSD article 8**

GPSD article 8.1 sets out an extensive list of the powers Member States should have in order to take action in appropriate situations. According to article 8.3, the powers in article 8.1 (b) to (f) in particular must be available where products pose a serious risk. Article 8.2 and 8.4 deal with the exercise of powers in practice, for example to whom to address a measure and the obligation to take proportional actions. These are supplementary provisions to the powers listed in article 8.1, and not separate obligations. According to Article 8.2, subparagraph 2 the competent authorities of the Member States should encourage voluntary action in the relevant area of power.

The powers attributed in article 8.1 cover three different aspects. First article 8.1 (a) deals with information gathering (samples, checks, and information). The objective is to ensure that the competent authorities have the powers to obtain knowledge from the relevant organisation. Second, article 8.1 (b) and (c), covers the powers needed to make marketing conditional, for example requiring marking and warnings. The objective is to reduce risk. Third, article 8.1 (d) to (f) covers bans and recalls, including recall from consumers. The objective here is to prevent dangerous products from causing harm.

The Toys Directive deals with the aspect of powers for national authorities in articles 8.3, 12.1 and 12.1a (b). These provisions cover several of the aspects outlined above, but not the power to require recall of products. In this specific context the GPSD applies when the safety requirements in the Toys Directive are not fulfilled.

→ The provision on power to recall products in GPSD article 8.1 applies to toys. The application of this power is subject to the supplementary provisions of articles 8.2, 8.3 and 8.4 of the GPSD.

### 3.4.4 Approach to market surveillance – GPSD article 9

GPSD article 9 obliges Member States to adopt an approach on market surveillance based on measures such as surveillance programs and the follow-up and updating of scientific and technological safety knowledge. Interested parties must be given the opportunity to submit complaints and be informed about complaint proceedings.

The Toys Directive article 12 has a provision on market surveillance. However, the article does not cover an approach to market surveillance activities.

→ GPSD article 9 on the approach to market surveillance applies to toys.

### 3.4.5. European Network – GPSD article 10

GPSD article 10 establishes a European Network of the Member States authorities. The objective is to facilitate exchange of information, joint surveillance and improved co-operation.

Although not specifically mentioned in the Toys Directive, the Commission Services have established an informal Administrative Co-operation Group between Competent Authorities of Member States in order to ensure a consistent implementation of the Toys Directive.

→ GPSD article 10 on a European Network applies to toys. Administrative co-operation is carried out through the Administrative co-operation Group for toys already established.

## 3.5 Exchange of information and rapid intervention - GPSD chapter V

### 3.5.1 Notification – GPSD article 11

GPSD article 11 obliges Member States to inform the Commission of “all measures which restrict the placing on the market of products – or require their withdraw or recall”. Only measures such as those provided for in GPSD article 8.1 are to be covered, i.e. measures that are taken to ensure that products are safe, ref. article 6 and article 1. The obligation to notify such measures is waived if notification is already “**required under** article 12 [RAPEX notification – requires serious, immediate danger/effects beyond own territory] or **any specific Community legislation** [bold format added]”. The latter waiver refers for instance to notification under “safeguard clauses” in sector Directives.

Notification of national measures regarding products bearing the CE-marking is required under the safeguard clause of the Toys Directive. Furthermore notification is required under GPSD article 12 in the event of a serious danger (RAPEX-notification), see 3.5.2 below. Article 11 of the GPSD adds a formal obligation for Member States also to notify other national measures, but only insofar as these measures are taken to ensure that products are safe. Problems related only to documentation or non-safety related marking for instance, need not be notified.

→ GPSD article 11 on notifications applies to national measures that are taken to ensure safety of toys, except when safeguard clause notification under the Toys Directive or when RAPEX notification under the GPSD is required.

### **3.5.2 RAPEX – GPSD article 12**

GPSD article 12 provides the legal basis for an information exchange system for emergency situations (RAPEX system). The objective is to provide information to all Member States in order for them to take immediate actions when a serious risk from a product has been detected.

The Toys Directive has no specific provisions covering this objective. The provision on notification (safeguard clause) in article 7 has a different objective.

→ GPSD article 12 on RAPEX applies to toys, independently of the application of article 7 of the Toys Directive. The notification should be made through the national RAPEX contact point to the RAPEX contact point in the Commission.

### **3.5.3 Rapid intervention procedures – GPSD article 13**

GPSD article 13 introduces a basis for rapid intervention by the Commission in case of serious risk. The objective is to eliminate risk effectively.

The Toys Directive has no similar provision.

→ GPSD article 13 on rapid intervention applies to toys.

## **3.6 Committee procedures and final provisions - GPSD chapters VI and VII**

### **3.6.1 Committee procedures – GPSD articles 14 and 15**

GPSD articles 14 and 15 set out the basis for committee proceedings under the GPSD.

The articles only apply for procedures under the GPSD. It follows from point 3.5.3 above that such procedures can concern toys (rapid intervention).

→ GPSD committee procedures set out in articles 14–15 apply for proceedings under the GPSD such as under article 13.

### **3.6.2 Protection of confidentiality and motivation of measures – GPSD articles 16 and 18**

GSPD articles 16 and 18 deal with the administrative requirements when competent authorities in the Member States or the Commission adopt measures under the GPSD. Article 16 regulates access to information and protection of confidentiality while article 18 requires that where measures are taken, the appropriate reasons must be stated, that remedies available be quoted, that the opportunity to submit views be provided etc. The objective is to ensure that the interests of stakeholders are duly respected at the same time as the objectives of the Directive are being reached.

The Toys Directive in article 12.3 contains a specific provision dealing with confidentiality when the Commission or the Member States forward documents relating to the EC examination. The scope of this provision is much narrower than article 16 of the GPSD and the objective seems to be more focused on protection of certain technical documents obtained in relation to conformity assessment procedures and not on securing public access to information in general.

The Toys Directive under article 14 contains specific provisions on motivation of decisions and information to those concerned about remedies. The objective of the provision is the same as for the GPSD, namely to protect the interests of stakeholders. The provision only covers decisions involving restrictions on the placing on the market of toys, not recall situations. The provision does not cover access to justice or the relationship to the assessment of liability contained in GPSD articles 18.2 and 18.3.

→ GPSD article 16 on transparency and confidentiality applies to toys.

→ GPSD article 18.1 applies to toys for decisions on recall, but not for restrictions on the placing on the market or for withdrawal, since the Toys Directive has a specific provision governing the same aspect with the same objective. Articles 18.2 and 18.3 apply to toys.

### **3.6.3 Relationship with the Directive on Liability for Defective Products – GPSD article 17**

GSPD article 17 stipulates that the application of the GPSD shall be without prejudice to the application of the Directive on Liability for Defective Products (Council Directive 85/347/EC). This only confirms what follows from the general principles of Community law.

The Toys Directive has no specific provision setting out the relationship with the product liability Directive. Article 17 of the GPSD reflects a general principle which also applies to the Toys Directive.

→ As for the GPSD, the Toys Directive is to be applied without prejudice to the application of the Directive on liability for defective products.

### **3.7 Conclusions**

According to the analysis above the following provisions of the GPSD apply (other GPSD provisions do not apply because the Toys Directive itself contains specific provisions governing the same aspects with the same objective):

### GPSD Chapter III – Producer’s and distributor’s obligations

- Article 5.1, subparagraphs 3, 4 and 5 on identification of products and post-marketing obligations for producers
- Article 5.3 on the producers’ obligation to inform competent authorities about certain measures
- Article 5.4 on co-operation
- Articles 5.2, 5.3 and 5.4 on distributors’ obligations

### GPSD Chapter IV – Specific obligations and powers of the Member States

- Article 7 on adoption of rules on penalties
- Article 8.1 on the establishment of a power for competent authorities to require recall of products
- Article 9 on adoption of a strategy on market surveillance
- Article 10 on a Network of Member States authorities

### GPSD Chapter V – Exchange of information and rapid intervention situations

- Article 11 on notification of measures taken by Member States where the purpose of the measure is to ensure product safety, provided that notification is not required under the safeguard clause of the Toys Directive or article 12 of the GPSD (RAPEX).
- Article 12 on RAPEX
- Article 13 on the Commissions competence to carry out rapid intervention
- Articles 14 and 15 on committee procedures, but this only applies to procedures defined by the GPSD, such as article 13

### GPSD Chapter VII – Final provisions

- Article 16 on access to information and on confidentiality when carrying out actions
- Article 17 on the relationship with the Directive on Liability for Defective Products
- Article 18.1 on administrative requirements for recall
- Articles 18.2 and 18.3 on access to justice and the relationship to the assessment of liability

**Important note! Each of the sector specific chapters 3-6 must be read in connection with the horizontal chapter 2.**

## **4. Directive on Equipment with Voltage Limits (LVD)**

### **4.1 Introduction**

Council Directive 73/23/EEC on the Harmonisation of the Laws of Member States Relating to Electrical Equipment Designed for use Within Certain Voltage Limits (LVD) of 19 February 1973 was amended by Council Directive 93/68/EEC to introduce the CE mark and is a New Approach Directive.

### **4.2 Producers' obligations - GPSD chapters II and III**

#### **4.2.1 The general safety obligation – GPSD articles 2 (b) and (c), 3 and 4**

GPSD articles 3 and 4 establish a general obligation to place only safe products on the market as well as a procedure for the adoption of standards covering risks and categories of risks. “Safe product” is defined in article 2 (b) while “dangerous product” is defined in article 2 (c). These GPSD provisions apply to the risks or categories of risks not covered by the sector Directive.

LVD article 2 refers to “safety of persons” in general terms, not only certain risks. Article 2, paragraph 2 refers to Annex 1 for the “principal elements of the safety objectives”, while article 3 foresees that compliance with the Directive shall ensure that the free movement of LVD products are not impeded for safety reasons. Annex I, point 1 d) refers to the hazards in point 2. In addition to physical injury or other harm, which might be caused by electrical contact, temperatures, arcs and radiation, point 2 c) refers to protection against “non-electrical dangers”. The Directive is thus intended to cover all risks and/or categories of risk.

→ The general safety obligation in GPSD articles 2 (b) and (c), 3 and 4 does not apply to LVD, because the scope of the Directive covers all types of risks and/or categories of risk.

#### **4.2.2 Information to consumers on risks – GPSD article 5.1, subparagraph 1**

GPSD article 5.1, subparagraph 1 introduces an obligation for producers to provide consumers with relevant information on risks. The objective is to enable consumers to assess risks and to take precautions, thereby reducing risk.

LVD annex I, point 1 a) has a specific provision on marking of essential characteristics on the equipment, or where not possible, on the packaging. The objective is to “ensure that electrical equipment will be used safely”. Although this specific provision is limited to marking it governs the same aspect, namely information regarding risks, with the same objective - to enable consumers to use products safely.

→ GPSD article 5.1, subparagraph 1 does not apply to LVD.



#### **4.2.3 Identification of the producer – GPSD article 5.1, subparagraphs 3 and 4**

GPSD article 5.1, subparagraphs 3 and 4 introduce an obligation for producers to identify themselves in connection with the purchase of the product. The objective is to enable the producer to be informed of risks and to give consumers and others a point of reference.

The LVD in Annex I, point 1 b) has a specific provision requiring the producer to affix their details on the product.

→ The part of GPSD article 5.1, subparagraphs 3 and 4 on identification of the producer does not apply to LVD.

#### **4.2.4 Identification of the product – GPSD article 5.1, subparagraphs 3 and 4**

GPSD article 5.1, subparagraphs 3 and 4 have a specific provision on identification of the product itself, for example by a product reference. The aspect and the objective is different from the above (see point 4.2.3), namely to facilitate identification of the product concerned and to allow for action at the most appropriate level.

LVD Annex I has certain provisions on information requirements, but although electrical products would in most cases carry this kind of identification there are no specific provisions in the Directive dealing with this particular aspect.

→ GPSD article 5.1, subparagraphs 3 and 4 on identification of the product apply to LVD.

#### **4.2.5 Follow up of consumer safety after products are marketed – GPSD article 5.1, subparagraphs 3, 4 and 5**

GPSD article 5.1 subparagraphs 3, 4 and 5 require producers to take appropriate active steps after the product has been marketed. Examples include sample-testing, filing of complaints and information to distributors. The objective is to ensure preventive action and to detect risks.

The LVD does not introduce provisions on this aspect.

→ GPSD article 5.1, subparagraphs 3, 4 and 5 on follow up of product safety apply to LVD.

#### **4.2.6 Information from producers to the competent authorities about dangerous products – GPSD article 5.3**

GPSD article 5.3 requires producers to inform the competent authorities of dangerous products and action taken to prevent risk. The objective is to ensure that the competent authorities can take appropriate steps to reduce risks and to ensure co-ordinated action.

→ Since the LVD does not contain provisions on this aspect, GPSD article 5.3 on information from producers to the competent authorities applies when LVD products are not in conformity with the safety requirements of the LVD.

#### **4.2.7 Co-operation with the competent authorities – GPSD article 5.4**

GPSD article 5.4 requires producers to co-operate with the competent authorities upon request. The objective is to ensure that action to avoid risk is co-ordinated.

The LVD does not cover the aspect of co-operation between producers and the competent authorities explicitly, although co-operation is implicitly foreseen as a pre-condition for the functioning of the Directive.

→ GPSD article 5.4 on co-operation with the competent authorities applies to LVD. Co-operation under this article will be established by sector authorities in line with the provisions applicable to LVD.

#### **4.3 Distributors' obligations - GPSD chapter III**

There are several provisions in the GPSD articles 5.2, 5.3 and 5.4 dealing with distributors' obligations. The overall objective is to ensure that distributors do not supply dangerous products and that they participate in measures taken to reduce risk.

The LVD does not contain requirements affecting distributors.

→ GPSD articles 5.2, 5.3 and 5.4 regarding distributors' obligations apply to LVD.

#### **4.4 Member States' obligations and powers - GPSD chapter IV**

##### **4.4.1 Establish competent authorities – GPSD article 6, subparagraphs 1 and 2**

GPSD article 6, subparagraphs 1 and 2 requires that Member States establish and organise competent authorities. The objective is to have a clear point of responsibility and co-ordination of market surveillance and other public measures to improve product safety.

The LVD in several articles take the existence of a competent authority as a starting point and deals with the tasks of this competent authority, for example articles 7 and 10. These articles govern the same aspect as article 6, subparagraphs 1 and 2 of the GPSD with the same objective. Still, because of their quite limited scope, the corresponding GPSD provisions could also serve as an example and a model for market surveillance for LVD.

→ GPSD article 6, subparagraphs 1 and 2 on establishment of competent authorities does not apply to LVD.

##### **4.4.2 Adopting rules on penalties – GPSD article 7**

GPSD article 7 requires explicitly that Member States lay down rules on penalties. There is no obligation on how to operate the rules on penalties. The objective is to include penalties in the range of possible measures to ensure compliance at national level.

The LVD has no specific provision on this aspect.

→ GPSD article 7 on penalties applies to LVD.

#### **4.4.3 Attribute of powers to competent authorities – GPSD article 8**

GPSD article 8.1 sets out an extensive list of the powers Member States should have in order to take action in appropriate situations. According to article 8.3, the powers in article 8.1 (b) to (f) must in particular be available where products pose a serious risk. Article 8.2 and 8.4 deal with the exercise of these powers in practice, for example to whom to address a measure and the obligation to take proportionate actions. These are supplementary provisions to the powers listed in article 8.1, and not separate obligations. According to Article 8.2, subparagraph 2 the competent authorities of the Member States should encourage voluntary action in relation to the area of power.

The powers attributed in article 8.1 cover three different aspects. First article 8.1 (a) deals with information gathering (samples, checks, and information). The objective is to ensure that the competent authorities have the powers to obtain knowledge from the relevant organisation. Second, article 8.1 (b) and (c), includes powers necessary to make marketing conditional, for example marking and warnings. The objective is to reduce risk. Third, article 8.1 (d) to (f) covers bans and recall, including recall from consumers. The objective here is to prevent dangerous products from causing harm.

The LVD only indirectly mentions powers of the competent authorities in some articles, for example article 9. The provisions are much more limited than those under the GPSD. Thus article 8 applies when the safety requirements in the LVD are not fulfilled.

→ GPSD article 8 on powers of the competent authorities applies to LVD.

#### **4.4.4 Approach to market surveillance – GPSD article 9**

GPSD article 9 obliges Member States to adopt an approach on market surveillance which may include in particular surveillance programs and follow-up and updating of scientific and technological safety knowledge. Interested parties must be given the opportunity to submit complaints and must be informed about complaint proceedings.

The LVD has no provision on an approach to market surveillance activities.

→ GPSD article 9 on the approach to market surveillance applies to LVD.

#### **4.4.5 European Network – GPSD article 10**

GPSD in article 10 establishes a European Network of the Member States authorities. The objective is to facilitate exchange of information, joint surveillance and improved co-operation.

Co-operation between member states is inherent in the LVD. In particular, articles 9 and 11 of the LVD foresee a mechanism for the exchange of information, and the Commission Services have established an informal Administrative Co-operation Group between Competent Authorities of Member States in order to ensure a consistent implementation of LVD.

→ GPSD article 10 on a European Network applies to LVD. Administrative co-operation is carried out through the Administrative co-operation Group for LVD already established.

#### **4.5 Exchange of information and rapid intervention - GPSD chapter V**

##### **4.5.1 Notification – GPSD article 11**

GPSD article 11 obliges Member States to inform the Commission of “all measures which restrict the placing on the market of products – or require their withdraw or recall”. Only measures such as those provided for in GPSD article 8.1 are to be covered, i.e. measures that are taken to ensure that products are safe, ref. article 6 and article 1. The obligation to notify such measures is waived if notification is already “**required under** article 12 [RAPEX notification – requires serious, immediate danger/effects beyond own territory] or **any specific Community legislation** [bold form added]”. The latter waiver refers for instance to notification under “safeguard clauses” in sector Directives.

LVD article 9 requires notification of measures taken on safety grounds for all LVD products if the measure prohibits or “impedes” the marketing of “any electrical equipment”. The provisions foresee notification in all practical cases, i.e. it is not limited to measures regarding certain LVD products.

→ The GPSD notification procedure in article 11 does not apply to LVD.

##### **4.5.2 RAPEX – GPSD article 12**

GPSD article 12 provides a legal basis for an information exchange system for emergency situations (RAPEX system). The objective is to provide information to all Member States in order for them to take immediate action when a serious risk from a product has been detected.

The LVD does not cover this aspect.

→ GPSD article 12 applies to LVD. The notification should be made through the national RAPEX contact point to the RAPEX contact point in the Commission.

##### **4.5.3 Rapid intervention procedures – GPSD article 13**

GPSD article 13 introduces a basis for rapid intervention by the Commission in cases of serious risk. The objective is to eliminate risk effectively.

The LVD has no similar provision.

→ GPSD article 13 applies to LVD.

## **4.6 Committee procedures and final provisions - GPSD chapters VI and VII**

### **4.6.1 Committee procedures – GPSD articles 14 and 15**

The GPSD articles 14 and 15 set out the basis for committee proceedings under the GPSD.

The articles only apply for procedures under the GPSD. It follows from point 4.5.3 above that such procedures can concern LVD products (rapid intervention).

→ The GPSD committee procedures set out in articles 14 –15 apply to procedures under the GPSD, such as under article 13.

### **4.6.2 Protection of confidentiality and motivation of measures – GPSD articles 16 and 18**

GPSD articles 16 and 18 deal with administrative requirements when competent authorities in the Member States or the Commission adopt measures under the GPSD. Article 16 regulates access to information and protection of confidentiality while article 18 requires that measures taken must state the appropriate reasons, that remedies available shall be quoted, that opportunity to submit views is allowed etc. The objective is to ensure that the interests of stakeholders are being duly respected at the same time as the objectives of the Directive are being reached.

The LVD has no provision dealing with confidentiality. Thus the GPSD article 16 applies to LVD.

LVD article 9, paragraph 3 contains a provision on motivation of opinions from notified bodies. This is not the same aspect as motivation of decisions of competent authorities and the Commission.

→ GPSD articles 16 and 18 on transparency, confidentiality and other procedural requirements apply to LVD.

### **4.6.3 Relationship with the Directive on Liability for Defective Products – GPSD article 17**

GPSD article 17 stipulates that the application of the GPSD shall be without prejudice to the application of the Directive on Liability for Defective Products (Council Directive 85/347/EC). This only confirms what follows from the general principles of Community law.

The LVD has no specific provision setting out the relationship with the Product Liability Directive. Article 17 of the GPSD reflects a general principle which also applies to the LVD.

→ As for the GPSD, the LVD is to be applied without prejudice to the application of the Directive on Liability for Defective Products.

## 4.7 Conclusions

According to the analysis above the following provisions of the GPSD apply (other GPSD provisions do not apply because the LVD itself contains specific provisions governing the same aspects with the same objective):

### GPSD Chapter III – Producers’ and distributors’ obligations

- Article 5.1, subparagraphs 3, 4 and 5 on after-marketing obligations for producers and on producers’ obligation to identify products
- Article 5.3 on producers’ obligation to inform competent authorities about certain measures
- Article 5.4 on co-operation
- Article 5 regarding distributors’ obligations

### GPSD Chapter IV – Specific obligations and powers of the Member States

- Article 7 on adoption of rules on penalties
- Article 8.1 (a) to (f) on the establishment of powers for competent authorities to require information, to make marketing of products conditional or to ban or recall products
- Article 9 on adoption of a strategy for market surveillance
- Article 10 on a Network of Member States authorities

### GPSD Chapter V – Exchanges of information and rapid intervention situations

- Article 12 on RAPEX
- Article 13 on the Commission’s competence to ensure rapid intervention
- Articles 14 and 15 on the Committee procedures, but only for procedures under the GPSD, such as article 13

### GPSD Chapter VII – Final provisions

- Article 16 on access to information and on confidentiality when taking action
- Article 17 on the relationship to the Directive on liability for defective products
- Article 18 on motivation of decisions and other procedural requirements

**Important note! Each of the sector specific chapters 3-6 must be read in connection with the horizontal chapter 2.**

## **5. Directive on Personal Protective Equipment (PPE)**

### **5.1 Introduction**

The Council Directive on the approximation of laws relating to personal protective equipment (PPE) of 21 December 1989 has been amended several times, at the latest by Directive 96/58/EC. The PPE Directive is a New Approach Directive (i.e. a directive providing for the CE marking).

It is recalled that the applicability of the GPSD to “products” in this guide should be understood as meaning only to “consumer products”. These are products that are “intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them” according to GPSD article 2 (a). This is a general limitation of the scope of the GPSD. The application of the GPSD to PPE is therefore limited consumer products.

### **5.2 Producers’ obligations - GPSD chapters II and III**

#### **5.2.1 The general safety obligation – GPSD articles 2 (b) and (c), 3 and 4**

GPSD articles 3 and 4 establish a general obligation to place only safe products on the market as well as a procedure for the adoption of standards on risks and categories of risks. “Safe product” is defined in article 2 (b) while “dangerous product” is defined in article 2 (c). These GPSD provisions apply to the risks or categories of risks not covered by the sector Directive.

The PPE Directive in article 2 refers to the health and safety of users in general. Article 3 refers to basic health and safety requirements set out in annex II. Annex II has one part on general requirements, which in part 1 clearly states that all safety and health-related risk are covered. In addition specific safety and health related risks are dealt with in parts 2 and 3 of Annex II.

→ The general safety obligation in GPSD articles 2 (b) and (c), 3 and 4 does not apply to PPE since the PPE Directive covers all risks and categories of risk.

#### **5.2.2 Information to consumers on risks – GPSD article 5.1, subparagraph 1**

GPSD article 5.1, subparagraph 1 introduces an obligation for producers to provide consumers with relevant information on risks. The objective is to enable consumers to assess risks and to take precautions, thereby reducing risk.

The PPE Directive in article 3 refers to obligations imposed on the manufacturer in annex II. Annex II in points 1.4, 2.4, 2.8, 2.12, 3.5 etc. has specific provisions on information with the same objective as the GPSD.

→ The provision in GPSD article 5.1, subparagraph 1 on producers’ obligation to inform consumers does not apply to PPE.

### **5.2.3 Identification of the producer – GPSD article 5.1, subparagraphs 3 and 4**

GPSD article 5.1, subparagraphs 3 and 4 introduce an obligation for producers to identify themselves in relation to the purchase of the product. The objective is to enable the producer to be informed of risks and to give consumers and others a point of reference.

The PPE Directive in annex II point 1.4, subparagraph 1 has an obligation with the same objective.

→ The obligation in GPSD article 5.1, subparagraphs 3 and 4 for producers to identify themselves does not apply to PPE.

### **5.2.4 Identification of the product – GPSD article 5.1, subparagraphs 3 and 4**

GPSD article 5.1, subparagraphs 3 and 4 have a specific provision on identification of the product itself, for example by a product reference. The aspect and the objective is different from the above (see point 5.2.3), namely to facilitate identification of the product concerned and to allow for action at the most appropriate level.

The PPE Directive does not have a specific provision on this aspect. It should be noted that in practice PPE has such an identification based on the requirements in the PPE Directive article 12 ref. Annex VI on conformity declaration, whereby a product should be described precisely (make, type, serial number, etc).

→ The part of the GPSD provisions in article 5.1, subparagraphs 3 and 4 on identification of the product applies to PPE.

### **5.2.5 Follow up of consumer safety after products are marketed – GPSD article 5.1, subparagraphs 3, 4 and 5**

GPSD article 5.1 subparagraphs 3, 4 and 5 require producers to take appropriate active steps after the product has been marketed. Examples include sample testing, filing of complaints and information to distributors. The objective is to ensure preventive action and to detect risks.

The PPE Directive has no specific provisions on post-marketing obligations for producers although, in practice, some of the activities are carried out in order to comply with the other provisions of the Directive.

→ The obligations set out in GPSD article 5.1, subparagraphs 3, 4 and 5 to follow up safety of products after marketing apply to PPE.

### **5.2.6 Information from producers to the competent authorities about dangerous products – GPSD article 5.3**

GPSD article 5.3 requires producers to inform competent authorities of dangerous products and the actions taken to prevent risk. The objective is to ensure that the competent authorities can take appropriate steps to reduce risks and to ensure co-ordinated action.



The PPE Directive article 10.6 deals with information from inspection bodies, but this is another aspect. There are no provisions on information from producers to the competent authorities. Thus the obligation applies when PPE is not in conformity with the safety requirements of the PPE Directive.

→ GPSD article 5.3 on information from producers to the competent authorities applies to PPE.

### **5.2.7 Co-operation with the competent authorities – GPSD article 5.4**

GPSD article 5.4 requires producers to co-operate with the competent authorities upon request. The objective is to ensure that action to avoid risk is co-ordinated.

The PPE Directive article 11 has a provision on co-operation with the notified body, but this is another aspect of the Directive. The PPE does not explicitly cover the aspect of co-operation between producers and the competent authorities, although co-operation is implicitly envisaged as a pre-condition for the functioning of the Directive.

→ GPSD article 5.4 on co-operation with the competent authorities applies to PPE. Co-operation under this article will be established by sector authorities in view of the provisions applicable to PPE.

### **5.3 Distributors' obligations - GPSD chapter III**

There are several provisions in GPSD articles 5.2, 5.3 and 5.4 dealing with distributors' obligations. The overall objective is to ensure that distributors do not supply dangerous products and that they participate in measures taken to reduce risk.

The PPE Directive does not cover these aspects and objectives.

→ GPSD articles 5.2, 5.3 and 5.4 GPSD dealing with distributors' obligations apply to PPE.

### **5.4 Member States' obligations and powers - GPSD chapter IV**

#### **5.4.1 Establish competent authorities – GPSD article 6, subparagraphs 1 and 2**

GPSD article 6, subparagraphs 1 and 2 requires Member States to establish and organise competent authorities. The objective is to have a clear point of responsibility and to co-ordinate market surveillance and other public measures to improve product safety.

The PPE Directive articles 2, 6, 7 and 9 are drafted with a presumption of the existence of a competent authority. Although it is not stated explicitly in the PPE Directive anywhere that competent authorities must be organised and designated, the above mentioned articles of the PPE Directive indicate that a national competent authority is envisaged. These are specific provisions dealing with the aspect of market surveillance and have the same objective. However, given the relatively limited scope of these provisions, the corresponding GPSD provisions could serve as an example and a model for market surveillance also for PPE.

→ GPSD article 6, subparagraphs 1 and 2 on establishment and organisation of competent authorities does not apply to PPE.

#### **5.4.2 Adopting rules on penalties – GPSD article 7**

GPSD Article 7 explicitly requires Member States to lay down rules on penalties. There is no obligation on how to operate the rules on penalties. The objective is to include penalties in the range of possible measures to ensure compliance at national level.

The PPE Directive has no specific provision on penalties.

→ GPSD article 7 on adoption of rules on penalties applies to PPE.

#### **5.4.3 Attribution of powers to competent authorities – GPSD article 8**

GPSD article 8.1 sets out an extensive list of powers Member States should have in order to take action in appropriate situations. According to article 8.3, the powers in article 8.1 (b) to (f) must in particular be available where products pose a serious risk. Articles 8.2 and 8.4 deal with the exercise of powers in practice, for example to whom to address a measure and the obligation to take actions proportionally. These are supplementary provisions to the powers listed in article 8.1, and not separate obligations. Article 8.2, subparagraph 2 states that the competent authorities of the Member States should encourage voluntary action within their area of powers.

The powers attributed in article 8.1 cover three different aspects. First article 8.1 (a) deals with information gathering (samples, checks, and information). The objective is to ensure that the competent authorities have the powers to obtain information from the relevant organisation. Second, article 8.1 (b) and (c), includes powers necessary to make marketing conditional, for example by means of marking and warnings. The objective is to reduce risk. Third, article 8.1 (d) to (f) covers bans and recalls, including recall from consumers. The objective here is to prevent dangerous products from causing harm.

The PPE Directive deals with the aspect of powers for national competent authorities in articles 6, 7 and 13. These articles cover several of the aspects set out above, but the power to make marketing subject to conditions is only covered in part by article 13.4. Subparagraph (b) of article 13.4 includes the power to withdraw products but not to require recall. Therefore, for recall, the GPSD applies when the safety requirements in the PPE Directive are not fulfilled.

→ GPSD article 8.1(b), (c) and (f) on powers for competent authorities on marketing conditionality and recall of products apply to PPE as long as this is not covered by articles 7 and 13.4. The application is subject to the supplementary provisions of GPSD articles 8.2, 8.3 and 8.4.

#### 5.4.4 Approach to market surveillance – GPSD article 9

GPSD article 9 obliges Member States to adopt an approach to market surveillance based on surveillance programs and the follow-up and updating of scientific and technological safety knowledge. Interested parties must be given the opportunity to submit complaints and shall be informed about complaint proceedings.

The PPE Directive articles 2, 7 and 13 have substantive provisions on market surveillance. Although these provisions do not refer explicitly to the manner in which this is to be done in Member States, they have initiated such an approach in practice via the ‘Administrative Co-operation Group’ established under the PPE Directive. These practices must take into account that the Directive covers PPE for both professional and for private use.

→ GPSD article 9 on an approach to market surveillance applies to PPE. In practice the organisation of market surveillance is carried out through existing practices established in the context of the PPE Administrative Co-operation Group, based on the provisions applicable to PPE, reflecting that the Directive covers PPE for both professional as well as for private use.

#### 5.4.5. European Network – GPSD article 10

GPSD article 10 establishes a European Network of the Member States authorities. The objective is to facilitate the exchange of information, joint surveillance and improved co-operation.

PPE Directive article 6.2 designates the committee set up under Council Directive 89/392/EEC as the relevant body to discuss any matter regarding the implementation and practical application of the Directive. Although not mentioned in the Directive, the Commission Services have established informal administrative co-operation (bi-annual meetings, and a reserved Internet site) between competent authorities of the Member States in order to ensure a consistent implementation. However, there is no specific provision on this aspect.

→ GPSD article 10 on a European Network applies to PPE. Administrative co-operation is carried out through the administrative co-operation system already established.

### 5.5 Exchange of information and rapid intervention - GPSD chapter V

#### 5.5.1 Notification – GPSD article 11

GPSD article 11 obliges Member States to inform the Commission of “all measures which restrict the placing on the market of products – or require their withdraw or recall”. Only measures such as those provided for in GPSD article 8.1 are to be covered, i.e. measures that are taken to ensure that products are safe, ref. article 6 and article 1. The obligation to notify such measures is waived if notification is already “**required under** article 12 [RAPEX notification – requires serious, immediate danger/effects beyond own territory] or **any specific Community legislation** [bold form added]”. The latter waiver refers for instance to notification under “safeguard clauses” in sector directives.

Notification of national measures regarding products covered by the PPE is required under articles 7 and 13 of the PPE Directive. Article 11 of the GPSD adds a formal obligation for Member States to also notify remaining national measures, but only insofar as these measures are taken to ensure that products are safe. Measures concerning non-safety related marking should not be notified. Furthermore notification is required under article 12 of GPSD in the event of a serious danger (RAPEX-notification), see point 5.5.2 below.

→ GPSD article 11 on notifications applies to PPE products when national measures are taken to ensure safety except in cases where notification is not already required under PPE articles 7 and 13 or GPSD article 12 (RAPEX notification).

### **5.5.2 RAPEX – GPSD article 12**

GPSD article 12 provides a legal basis for an information exchange system for emergency situations (RAPEX system). The objective is to provide information to all Member States in order for them to take immediate action when a serious risk from a product is detected.

The PPE Directive contains no such provisions.

→ GPSD article 12 on RAPEX applies to PPE. The notification should be made through the national RAPEX contact point to the RAPEX contact point in the Commission.

### **5.5.3 Rapid intervention procedures – GPSD article 13**

GPSD article 13 introduces a basis for rapid intervention by the Commission in cases of serious risk. The objective is to eliminate risk effectively.

The PPE Directive has no similar provision.

→ GPSD article 13 on rapid intervention applies to PPE.

## **5.6 Committee procedures and final provisions - GPSD chapters VI and VII**

### **5.6.1 Committee procedures – GPSD articles 14 and 15**

GPSD articles 14 and 15 set out the basis for committee proceedings under the GPSD.

The articles only apply for procedures under the GPSD. It follows from point 5.5.3 above that such procedures may concern PPE (rapid intervention).

→ The application of the GPSD committee procedures set out in articles 14 –15 is limited to procedures under the GPSD, such as under article 13.

### **5.6.2 Protection of confidentiality and motivation of measures – GPSD articles 16 and 18**

GSPD articles 16 and 18 deal with the administrative requirements when competent authorities in the Member States or the Commission adopt measures under the GPSD. Article 16 regulates access to information and protection of confidentiality while article 18 requires that where measures are taken the appropriate reasons must be stated, that remedies available be quoted, that an opportunity to submit views be provided etc. The objective is to ensure that the interests of stakeholders are duly respected at the same time as the objectives of the Directive are being reached.

The PPE Directive article 15 contains a provision dealing with the access to data related to decisions made under the Directive. The objective is however not to secure confidentiality and does not appear to relate to public access to information. Thus the GPSD provision is applicable to PPE.

The PPE Directive in article 14 contains a specific provision on motivation of decisions as well as information on appeal possibilities etc. The objective of the provision is the same as for the GPSD, namely to protect the interests of stakeholders.

→ GPSD article 16 on transparency and confidentiality applies to PPE.

→ GPSD article 18 on motivation and other procedural requirements does not apply because the PPE Directive has a specific provision governing the same aspect with the same objective.

### **5.6.3 Relationship with the Directive on Liability for Defective Products – GPSD article 17**

GSPD article 17 stipulates that the application of the GPSD shall be without prejudice to the application of the Directive on Liability for Defective Products (Council Directive 85/347/EC). This only confirms what follows from the general principles of Community law.

The PPE Directive has no specific provision setting out the relationship with the Product Liability Directive. Article 17 of the GPSD reflects a general principle which also applies to PPE.

→ As for the GPSD, the PPE Directive is to be applied without prejudice to the application of the Directive on Liability for Defective Products.

## **5.7 Conclusions**

According to the analysis above the following provisions of the GPSD apply (other GPSD provisions do not apply because the PPE Directive itself contains specific provisions governing the same aspects with the same objective):

### GPSD Chapter III –Producers’ and distributors’ obligations

- Article 5.1, subparagraphs 3, 4 and 5 on producers’ after-marketing obligations and producers’ obligation to identify products
- Article 5.3 on producer’s obligation to inform competent authorities about certain measures
- Article 5.4 on co-operation

- Article 5 on distributors' obligations

#### GPSD Chapter IV – Specific obligations and powers of the Member States

- Article 7 on adoption of rules on penalties
- Article 8.1 (b), (c) and (f) on the establishment of powers for competent authorities to make marketing conditional (when this is not covered by PPE articles 7 and 13) and to recall products.
- Article 9 on an approach to market surveillance
- Article 10 on the establishment of a Network of Member States authorities

#### GPSD Chapter V – Exchange of information and rapid intervention situations

- Article 11 on notification of measures taken by Member States. The article applies if the measure is related to the health and safety of consumers and it is not notified under PPE articles 7 or 13 or under GPSD article 12 (the RAPEX system).
- Article 12 on RAPEX
- Article 13 on the Commission's competence to carry out rapid intervention
- Articles 14 and 15 on the Committee procedures, but only in relation to procedures under the GPSD, such as article 13

#### GPSD Chapter VII – Final provisions

- Article 16 on access to information and on confidentiality when carrying out actions
- Article 17 on the relationship to the Directive on Liability for Defective Products

**Important note! Each of the sector specific chapters 3-6 must be read in connection with the horizontal chapter 2.**

## **6. Directive on Cosmetics**

### **6.1 Introduction**

The Council Directive 76/768 of 27 July 1976 on the Approximation of the Laws of the Member States Relating to Cosmetic Products (Cosmetics Directive) has been amended several times, at the latest by European Parliament and Council Directive 2003/15/EC of 27 February 2003. The Directive is an old approach directive, thus it does not provide for the CE marking.

### **6.2 Producers' obligations - GPSD chapters II and III**

#### **6.2.1 The general safety obligation - GPSD article 2 (b) and (c), 3 and 4**

GPSD articles 3 and 4 establish a general obligation to place only safe products on the market and a procedure for the adoption of standards for risks and categories of risks. "Safe product" is defined in article 2 (b) while "dangerous product" is defined in article 2 (c). These GPSD provisions apply to the risks or categories of risks not covered by the sector Directive.

The objective of the Cosmetics Directive is to ensure that cosmetic products placed on the market are safe. However it is not global in scope. It contains requirements on the composition, labelling and packaging of cosmetics. Therefore for other risks, for example mechanical risks, the GPSD applies, provided that no other sector legislation is applicable.

→ The GPSD general safety obligation set out in GPSD articles 2 (b) and (c), 3 and 4 applies to cosmetics for risks not covered by the Cosmetics Directive itself, provided that no other sector legislation applies.

#### **6.2.2 Information to consumers on risks – GPSD article 5.1, subparagraph 1**

GPSD article 5.1, subparagraph 1 introduces an obligation for producers to provide consumers with relevant information on risks. The objective is to enable consumers to assess risks and to take precautions, thereby reducing risk.

The Cosmetics Directive articles 2, 6.1 (c), (d) and (f) and related annexes have specific provisions on information with the same objective.

→ The provision in the GPSD article 5.1, subparagraph 1 on producers' obligation to inform consumers does not apply to cosmetics.

#### **6.2.3 Identification of the producer – GPSD article 5.1, subparagraphs 3 and 4**

GPSD article 5.1, subparagraphs 3 and 4 introduce an obligation for producers to identify themselves in relation to the purchase of the product. The objective is to enable the producer to be informed of risks and to give consumers and others a point of reference.

The Cosmetics Directive article 6.1 (a) obliges producers to affix their details on the product. The objective is the same so the GPSD does not apply.

→ The obligation in GPSD article 5.1, subparagraphs 3 and 4 for producers to identify themselves does not apply to cosmetics.

#### **6.2.4 Identification of the product – GPSD article 5.1, subparagraphs 3 and 4**

GPSD article 5.1, subparagraphs 3 and 4 have a specific provision on identification of the product itself, for example by a product reference. The aspect and the objective is different from the above (see point 6.2.3), namely to facilitate identification of the product concerned and to allow for action at the most appropriate level.

The Cosmetics Directive article 6.1 (e) obliges producers to affix details on the product. The objective is the same, so the GPSD does not apply.

→ GPSD article 5.1, subparagraphs 3 and 4 on identification of the product do not apply to cosmetics.

#### **6.2.5 Follow up of consumer safety after products are marketed – GPSD article 5.1, subparagraphs 3, 4 and 5**

GPSD article 5.1 subparagraphs 3, 4 and 5 require producers to take appropriate active steps after the product has been marketed. Examples include sample testing, filing of complaints and information to distributors. The objective is to ensure preventive action and to detect risks.

The Cosmetics Directive has no specific provision on the active post-marketing activities to be carried out by producers (for example sample testing), although several provisions indirectly envisage such activities. In particular article 7a requires producers to keep detailed information available on the safety assessment of cosmetic products they place on the market, including data on undesirable effects. The source of these data on undesirable effects may vary, but generally comes from consumer complaints. These data must be kept to allow control by national competent authorities and, as of 11 September 2004, they will have to be made accessible to the public upon request when the 7<sup>th</sup> amendment to the Cosmetics Directive enters into force.

→ The obligations to follow up safety of products after marketing in GPSD article 5.1, subparagraphs 3, 4 and 5 apply to cosmetics when the aspects are not covered by the Directive itself.

#### **6.2.6 Information from producers to the competent authorities about dangerous products – GPSD article 5.3**

GPSD article 5.3 requires producers to inform the competent authorities of dangerous products and the actions taken to prevent risk. The objective is to ensure that the competent authorities can take appropriate steps to reduce risks and to ensure co-ordinated action.



The Cosmetics Directive article 7a has specific provisions on information to be kept available to the competent authorities, but the provisions do not cover the same aspect, namely active communication.

→ GPSD article 5.3 on information from producers to the competent authorities applies to cosmetics when the cosmetic is not in conformity with the safety requirements of the Cosmetics Directive or, for other risks, when the product does not meet the general safety requirement in GPSD article 3, ref. article 2b (see above under point 6.2.1).

### **6.2.7 Co-operation with the competent authorities – GPSD article 5.4**

GPSD article 5.4 requires producers to co-operate with the competent authorities upon request. The objective is to ensure that action to avoid risk is co-ordinated.

The Cosmetics Directive in articles 7.3 and 7a has provisions on information to the competent authorities, but the scope of the provisions is narrower than in the GPSD as they do not cover other forms of co-operation, for example in connection with warnings, recall and other measures to be taken. Co-operation is implicitly envisaged as a pre-condition for the functioning of the Directive, but not governed by a specific provision.

→ GPSD article 5.4 on co-operation with the competent authorities applies to cosmetics when the aspects are not covered by the Directive itself. Co-operation under this article will be established by sector authorities for the provisions applicable to cosmetics.

### **6.3 Distributors' obligations - GPSD chapter III**

There are several provisions in GPSD articles 5.2, 5.3 and 5.4 dealing with distributors' obligations. The overall objective is to ensure that distributors do not supply dangerous products and that they participate in measures taken to reduce risk.

The Cosmetics Directive does not cover these aspects and objectives.

→ GPSD articles 5.2, 5.3 and 5.4 dealing with distributors' obligations apply to cosmetics.

### **6.4 Member States' obligations and powers - GPSD chapter IV**

#### **6.4.1 Establish of competent authorities – GPSD article 6, subparagraphs 1 and 2**

GPSD article 6, subparagraphs 1 and 2 requires Member States to establish and organise competent authorities. The objective is to have a clear point of responsibility and co-ordination of market surveillance and other public measures to improve product safety.

The Cosmetics Directive articles 7.3 and 7a, paragraph 5, presuppose the establishment of competent authorities. These are specific provisions dealing with the aspect of market surveillance authorities and have the same objective. However, because of their quite limited scope, the corresponding GPSD provisions could serve as an example and a model for market surveillance also for cosmetics.

→ GPSD article 6, subparagraphs 1 and 2 on the establishment and organisation of competent authorities does not apply to cosmetics.

#### **6.4.2 Adopting rules on penalties – GPSD article 7**

GPSD article 7 explicitly requires Member States to lay down rules on penalties. There is no obligation on how to operate the rules on penalties. The objective is to include penalties in the range of possible measures to ensure compliance at national level.

The Cosmetics Directive has no specific provision on penalties.

→ GPSD article 7 on adoption of rules on penalties applies to cosmetics.

#### **6.4.3 Attribution of powers to competent authorities – GPSD article 8**

GPSD in article 8.1 sets out an extensive list of the powers Member States should have in order to take action in appropriate situations. According to article 8.3, the powers in article 8.1 (b) to (f) must in particular be available where products pose a serious risk. Article 8.2 and 8.4 deal with the exercise of powers in practice, for example to whom to address a measure and the obligation to take actions proportionally. These are supplementary provisions to the powers listed in article 8.1, and not separate obligations. According to article 8.2, subparagraph 2 the competent authorities of the Member States should encourage voluntary action.

The powers attributed in article 8.1 cover three different aspects. First article 8.1 (a) deals with information gathering (samples, checks, and information). The objective is to ensure that the competent authorities have the powers to obtain information from the relevant organisation. Second, article 8.1 (b) and (c), includes powers necessary to make marketing conditional, for example via marking and warnings. The objective is to reduce risk. Third, article 8.1 (d) to (f) covers bans and recall, including recall from consumers. The objective here is to prevent dangerous products from causing harm.

The Cosmetics Directive articles 7.3 and 12 set out provisions that cover the power to gather information and the power to ban products. These provisions have the same objective as GPSD article 8.1 (a), (d) and (e). One aspect however, the power to recall, is not addressed and here the GPSD applies when the cosmetic is not in conformity with the safety requirements of the Cosmetics Directive or, for other risks, when the product does not meet the general safety requirement in GPSD article 3, ref. article 2b (see above under point 6.2.1). The power to make marketing conditional is covered by article 12 of the Cosmetics Directive.

→ GPSD article 8.1 on powers for competent authorities applies to cosmetics for the recall of products. The application is subject to the supplementary provisions of GPSD articles 8.2, 8.3 and 8.4.

#### 6.4.4 Approach to market surveillance – GPSD article 9

GPSD article 9 obliges Member States to adopt an approach on market surveillance which may include in particular surveillance programs and follow-up and updating of scientific and technological safety knowledge. Interested parties must be given the opportunity to submit complaints and must be informed about complaint proceedings.

The Cosmetics Directive has no provisions on an approach to market surveillance activities.

→ GPSD article 9 on an approach to market surveillance applies to cosmetics.

#### 6.4.5. European Network – GPSD article 10

GPSD article 10 establishes a European Network of the Member States authorities. The objective is to facilitate exchange of information, joint surveillance and improved co-operation.

The Cosmetics Directive article 7a, paragraph 5 contains a specific provision governing co-operation between Member States.

→ GPSD article 10 on a European Network does not apply to cosmetics.

### 6.5 Exchanges of information and rapid intervention - GPSD chapter V

#### 6.5.1 Notification – GPSD article 11

GPSD article 11 obliges Member States to inform the Commission of “all measures which restrict the placing on the market of products – or require their withdraw or recall”. Only measures such as those provided for in GPSD article 8.1 are concerned, i.e. measures that are taken to ensure that products are safe, ref. article 6 and article 1. The obligation to notify such measures is waived if notification is already “**required under** article 12 [RAPEX notification – requires serious, immediate danger/effects beyond own territory] or **any specific Community legislation** [bold form added]”. The latter waiver refers for instance to notification under so-called “safeguard clauses” in sector directives.

The Cosmetics Directive article 12.1 refers to notification of measures where they concern products “complying with the directive”. Other measures taken, based on health and safety considerations, should be notified under GPSD article 11 except when they are notified under GPSD article 12 (RAPEX) - see point below.

→ GPSD article 11 on notification applies to cosmetics except when notification is required under the Cosmetics Directive or under the RAPEX procedure in GPSD article 12.

### **6.5.2 RAPEX – GPSD article 12**

GPSD article 12 provides a legal basis for an information exchange system for emergency situations (RAPEX system). The objective is to provide information to all Member States in order for them to take immediate actions when a serious risk from a product has been detected.

The Cosmetics Directive has no specific provisions with this objective. The provision on notification in article 12.1 has a different objective.

→ GPSD article 12 on RAPEX applies to cosmetics. The notification should be made through the national RAPEX contact point to the RAPEX contact point in the Commission.

### **6.5.3 Rapid intervention procedures – GPSD article 13**

GPSD article 13 introduces a basis for rapid intervention by the Commission in cases of serious risk. The objective is to eliminate risk effectively.

The Cosmetics Directive has a provision on adaptation of the Directive in article 10, but it does not cover intervention and rapid risk prevention.

→ GPSD Article 13 on rapid intervention applies to cosmetics.

## **6.6 Committee procedures and final provisions - GPSD chapters VI and VII**

### **6.6.1 Committee procedures – GPSD articles 14 and 15**

GPSD articles 14 and 15 set out the basis for committee proceedings under the GPSD.

The articles only apply for procedures under the GPSD. It follows from point 6.1.2 and 6.5.3 above that such procedures can concern cosmetics (rapid intervention).

→ The GPSD committee procedures set out in articles 14 –15 only apply to procedures under the GPSD, such as under article 13.

### **6.6.2 Protection of confidentiality and motivation of measures – GPSD articles 16 and 18**

Articles 16 and 18 of the GPSD deal with the administrative requirements when competent authorities in the Member States or the Commission adopt measures under the GPSD. Article 16 regulates access to information and protection of confidentiality while article 18 requires that where measures are taken the appropriate reasons must be stated, that remedies available be quoted, that an opportunity to submit views be provided etc. The objective is to ensure that the interests of stakeholders are duly respected at the same time as the objectives of the Directive are being reached.

The Cosmetics Directive does not contain any specific provision on access to information and confidentiality or motivation of measures that govern the same aspects with the same objective as the GPSD.

→ GPSD article 16 on transparency and confidentiality applies to cosmetics when the Cosmetics Directive itself does not cover this aspect.

→ GPSD article 18 concerning procedural requirements applies to cosmetic when the Cosmetics Directive itself does not cover the aspect.

### **6.6.3 Relationship with the Directive on Liability for Defective Products – GPSD article 17**

GPSD article 17 stipulates that the application of the GPSD shall be without prejudice to the application of the Directive on Liability for Defective Products (Council Directive 85/347/EC). This only confirms what follows from the general principles of Community law.

The Cosmetics Directive has no specific provision setting out the relationship with the Product Liability Directive. Article 17 of the GPSD reflects a general principle which also applies to the Cosmetics Directive.

→ As for the GPSD, the Cosmetics Directive is to be applied without prejudice to the application of the Directive on Liability for Defective Products.

## **6.7 Conclusions**

According to the analysis above the following provisions of the GPSD apply (other GPSD provisions do not apply because the Cosmetics Directive itself contains specific provisions governing the same aspects with the same objective):

### GPSD Chapter III – Producers’ and distributors’ obligations

- Articles 2 (b) and (c), 3 and 4 on a general safety obligation for risks not covered by the Cosmetics Directive itself, when no other sector legislation applies
- Article 5.1, subparagraphs 3, 4 and 5 on producers’ after-marketing obligations when the Directive itself does not cover the aspect
- Article 5.3 on producers’ obligation to inform competent authorities about certain measures
- Article 5.4 on co-operation
- Article 5 on distributors’ obligations

### GPSD Chapter IV – Specific obligations and powers of the Member States

- Article 7 on adoption of rules on penalties
- Article 8.1 on the establishment of powers for competent authorities for the recall of products
- Article 9 on adoption of a strategy on market surveillance

### GPSD Chapter V – Exchange of information and rapid intervention situations

- Article 11 on notification of measures taken by Member States. The article applies when the measure is not notified under the Cosmetics Directive article 12.1 or under GPSD article 12 (the RAPEX system).
- Article 12 on RAPEX
- Article 13 on the Commission’s competence to carry out rapid intervention

- Articles 14 and 15 on the Committee procedures, when procedures under the GPSD are applicable, such as article 13

GPSD Chapter VII – Final provisions

- Article 16 on access to information and on confidentiality when carrying out actions where as the Directive it self does not cover the aspect concerned.
- Article 17 on the relationship with the Directive on Liability for Defective Products
- Article 18 on motivation of decisions etc

## 7. Summary conclusions

The General Product Safety Directive (GPSD) is *complementary* to sector directives with safety provisions. The aim is to establish a coherent level of consumer protection for all consumer products in the internal market, without interfering or overlapping with sector-specific Community legislation or practices. The basis for the assessment is the GPSD article 1.2. The application of the GPSD can be divided into three parts:

**First**, GPSD articles 3 and 4 on a general safety obligation (together with the relevant definitions, in particular article 2 (b) and (c)) apply if a sector directive does not cover a risk or category of risk. The sector directives of the New Approach type included in this document have been found to cover all types of risks and the general safety obligation of the GPSD does indeed normally not apply to consumer products covered by these directives. However, in the case of the “Old Approach” Cosmetics Directive, the GPSD general safety obligation in articles 2 (b) and (c), 3 and 4 applies to the risks not covered, except when other directives cover the risks in question.

**Second**, the provisions in articles 5–18 apply as far as the *aspect* considered is not governed by a *specific* provision in a sector directive with the same *objective*. The analysis in this document shows that the application is similar for the Toys, LVD, PPE and Cosmetics Directives, although some minor differences have been identified. The articles of the GPSD set out in the following table apply (the other GPSD articles do not apply because sector directives have similar provisions covering the aspects with the same objective). In several cases existing informal practices are already in line with the GPSD requirements, particularly for administrative co-operation:

| GPSD article applicable               | Short description  | Who is concerned? |
|---------------------------------------|--|-------------------|
| Article 5.1, subparagraphs 3, 4 and 5 | Post-marketing obligations for producers (all directives) and obligation for producers to identify products (Toys, LVD and PPE)  | Producer          |
| Article 5.3                           | Obligation to inform competent authorities about certain measures  | Producer          |
| Article 5.4                           | Obligation to co-operate with the competent authorities.   | Producer          |
| Articles 5.2, 5.3 and 5.4             | Distributor’s obligations  | Distributor       |
| Article 7                             | Rules on penalties to be adopted   | Member States     |
| Article 8.1                           | Establishment of powers for competent authorities to require information, to make marketing of products conditional or to ban or recall products. Different applicability according to the specific directive. | Member States     |
| Article 9                             | Adopt approach on market surveillance  | Member States     |
| Article 10                            | Network of Member States authorities (except for cosmetics).   | Member States     |
| Article 13                            | Rapid intervention   | Member States     |
| Articles 14 and 15                    | Committee procedures for decisions taken   | Member States     |

|                        |  |               |
|------------------------|--|---------------|
|                        | under the GPSD.  |               |
| Article 16             | Access to information and confidentiality when carrying out actions. Some limitations apply under the specific directives. | Member States |
| Article 17             | Relationship with the Directive on Liability for Defective Products.   | ---           |
| Article 18.1           | Administrative requirements. Some limitations apply under the specific directives.   | Member States |
| Articles 18.2 and 18.3 | Access to justice and relationship to assessment of liability. Some limitations apply under the specific directives.       | Member States |

**Third**, notification procedures constitute a special case. Notification of national measures for products bearing CE marking is required under the safeguard clauses of the Toys and PPE Directives, while measures regarding all LVD products must be notified under the LVD Directive.

GPSD article 12 contains a legal requirement for Member States to notify the Commission through a rapid alert system (RAPEX) about consumer products presenting serious risk. It applies to all sector directives. The notification should be made through the national RAPEX contact point to the RAPEX contact point in the Commission. This information is rapidly disseminated to the Commission services responsible for the relevant sector directive and to the Member States that are obliged to report back.

In cases where RAPEX notifications are made for products falling under sector directives, a separate safeguard clause notification should be sent where required (to the service responsible for the sector directive) in addition to the RAPEX notification. The main reason for this is that the two different notification procedures serve different purposes.

GPSD article 11 adds a formal obligation for Member States to notify any additional national measures when these measures are taken to ensure product safety and notification is not already required under the safeguard clauses or under GPSD article 12 (RAPEX). This is relevant for toys, PPE and cosmetics.