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**WORKING PAPER ON THE RELATIONSHIP BETWEEN THE GENERAL PRODUCT SAFETY
DIRECTIVE 2001/95/EC AND THE MARKET SURVEILLANCE PROVISIONS OF
REGULATION (EC) No 765/2008**

1. OBJECTIVE AND SCOPE OF THIS DOCUMENT

The objective of this paper is to clarify the relationship between the Directive 2001/95/EC on general product safety (the "GPSD")¹ and Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance (the "Regulation").² It should help Member States to properly implement the Community legal framework on market surveillance of products.³

This paper only addresses the relationship between the two horizontal regimes on market surveillance, i.e. the GPSD and the Regulation. It does not deal with the relationship between these two pieces of Community legislation and sector specific Community legislation which contains specific market surveillance obligations for certain product sectors (e.g. the Medical Devices Directives⁴ or Cosmetics Directive⁵). The relationship with sector-specific legislation will be clarified in a separate step.

Chapter 2.2 of this document is not relevant for carrying out market surveillance with respect to legislation that does not have the objective of protecting the health and safety of consumers, but other objectives, e.g. the protection of health and safety at the work place, the protection of the environment or energy efficiency aspects. The measures listed in this chapter only concern market surveillance measures relating to products which present a risk to the health and safety of consumers. Chapter 2.3 however clarifies certain aspects of the use of the RAPEX system which are relevant for all areas of Community harmonisation legislation.

¹ OJ L 11, 15.1.2002, p. 4

² OJ L 218, 13.8.2008, p. 30

³ This document sets out the interpretation of the responsible Commission services. It does not in any way prejudge a possible formal position of the European Commission. Furthermore a binding interpretation of Community law is the sole competence of the European Court of Justice.

⁴ Directive 90/385/EEC relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17), Directive 93/42/EEC concerning medical devices (OJ L 169, 12.7.1993, p. 1) and Directive 98/79/EC on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1)

⁵ Directive 76/768/EEC relating to cosmetic products (OJ L 262, 27.9.1976, p. 169) (to be replaced as of 11 July 2013 by Regulation (EC) No 1223/2009 on cosmetic products, OJ L 342, 22.12.2009, p. 59)

2. RELATIONSHIP BETWEEN THE GPSD AND THE REGULATION

2.1. The scope of application of the GPSD and the Regulation

The GPSD first introduced requirements on the organisation and performance of market surveillance of health and safety aspects of (non-food) consumer products at the Community level. Since the adoption of the Regulation, there are two horizontal pieces of Community law containing requirements for market surveillance as regards the safety of products. The scope of application of the GPSD is, however, different from that of the Regulation.

The GPSD applies to all consumer products⁶ - regardless of whether they are covered by Community harmonisation legislation - provided that there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned; within this scope, it aims to protect the health and safety of consumers.

The Regulation applies to all products subject to Community harmonisation legislation (the "harmonised products")⁷ - regardless of whether they are consumer or non-consumer products – in so far as there are no specific provisions with the same objective, nature or effect in other existing or future rules of Community harmonisation legislation; within this scope, it protects not only the health and safety of consumers, but also other public interests, such as health and safety of users in the workplace, the environment, the sustainable use of energy, etc.

Hence, there are clearly defined areas with no overlap between the GPSD and the Regulation: the area of non-harmonised consumer products is subject to the rules of the GPSD, the area of harmonised non-consumer products is subject to the Regulation, and the area of non-harmonised non-consumer products is not subject to either of these two horizontal instruments. As regards the protection of the health and safety of consumers, however, the area of harmonised consumer products comes under the market surveillance provisions of both, the GPSD and the Regulation. This relationship between the GPSD and the Regulation is illustrated by Table 1.

⁶ Article 2(a) of the GPSD defines (consumer) product as "any product — including in the context of providing a service — which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned." This definition shall not apply to second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect;

⁷ Community harmonisation legislation is defined in Article 2 (21) of Regulation 765/2008 as "any Community legislation harmonising the conditions for the marketing of products". Examples of such legislation are the Toys Directive (Directive 88/378/EEC on the safety of toys, as amended (to be replaced by Directive 2009/48/EC on the safety of toys), the Low Voltage Directive (Directive 2006/95/EC on the electrical equipment designed for use within certain voltage limits), the Electromagnetic Compatibility Directive (Directive 2004/108/EC on electromagnetic compatibility), etc.

Table 1:

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

In order to clarify which market surveillance provisions of the GPSD and the Regulation are applicable to harmonised consumer products, Article 15 (3) has been integrated into the Regulation. It states that “[t]he application of Regulation 765/2008 shall not prevent market surveillance authorities from taking more specific measures as provided for in the GPSD”.

This means that all the market surveillance provisions of the Regulation, i.e. Articles 16 to 26, apply to harmonised consumer goods. In addition, the market surveillance provisions of the GPSD which contain "more specific measures" – when compared to the aforementioned market surveillance provisions of the Regulation – also apply to harmonised consumer products. Other market surveillance provisions of the GPSD, which do not entail "more specific measures", no longer apply to harmonised consumer products.

The market surveillance provisions of the GPSD which may entail such "more specific measures" are included in the Directive under *Chapter IV – Specific obligations and powers of the Member States* (Articles 6 to 9 of the GPSD), *Chapter V – Exchanges of information and rapid intervention situations* (Articles 11 and 12 of the GPSD) and *Chapter VII – Final provisions* (Articles 16 and 18 of the GPSD).

To determine which market surveillance measures contained in these Articles of the GPSD are more specific, they need to be compared in detail to the corresponding measures of the Regulation.

On the basis of such a comparison carried out by the Commission services, the market surveillance measures of the GPSD described in the following chapter have been identified to be more specific than those foreseen in the Regulation.

The consequences of Article 15 (3) of the Regulation for the exchange of information and the operation of the RAPEX system (Articles 11 and 12 of the GPSD) are explained in a specific chapter (chapter 2.3).

2.2. More specific GPSD measures which apply in addition to the Regulation

The market surveillance measures of the GPSD described in the following sections (2.2.1 – 2.2.8) have been identified as being more specific than those foreseen in the Regulation. As provided for in Article 15 (3) of the Regulation, they therefore apply, in addition to the provisions of the Regulation, to harmonised consumer products. The legal basis for their adoption is the GPSD that is, the legal acts transposing the GPSD into national law.

2.2.1. Measures under Article 8 (1) (b) GPSD (warnings and imposing prior conditions for marketing)

Article 8 (1) (b) of the GPSD foresees that for any products that could pose a risk in certain conditions, market surveillance authorities can require such products to be marked with specific warnings or make their marketing subject to prior conditions. The Regulation does not contain such a provision. Therefore, measures under Article 8 (1) (b) of the GPSD are more specific to those laid down in the Regulation and, consequently, they should be applied in the area of harmonised consumer products.

2.2.2. Measures under Article 8 (1) (c) of the GPSD (warnings for certain persons at risk)

According to Article 8 (1) (c) of the GPSD, market surveillance authorities can order that warnings be given to certain persons for whom products could pose risks. The provision in the Regulation on warnings (Article 19 (2)) is more general. Therefore, measures under Article 8 (1) (c) of the GPSD are more specific to those laid down in the Regulation, and, consequently, they should be applied in the area of harmonised consumer products in addition to Article 19 (2) of the Regulation.

2.2.3. Measures under Article 8 (1) (d) of the GPSD (temporary ban for period of evaluation)

Article 8 (1) (d) of the GPSD enables market surveillance authorities to impose a temporary ban on potentially dangerous products for the period needed for evaluation. The Regulation does not specifically foresee a temporary ban. Therefore, measures under Article 8 (1) (d) of the GPSD are more specific to those laid down in the Regulation, and consequently, they should be applied in the area of harmonised consumer products.

2.2.4. Accompanying measures required to ensure that a marketing ban is complied with, as provided for under Article 8 (1) (e) GPSD other than informing the public, the Commission and the other Member States

Article 8 (1) (e) GPSD foresees the possibility to adopt accompanying measures, alongside a marketing ban, which are required to ensure that the ban is complied with. The Regulation foresees that the public, the Commission and the other Member States must be informed of marketing bans (Articles 19 (2), 22 and 23) but it does not contain any other specific provisions on accompanying measures to ensure that the ban is respected. Hence, any other accompanying measure ensuring that a marketing ban is

complied with is a more specific measure of the GPSD and should, consequently, be applied in the area of harmonised consumer goods.

2.2.5. Measures under Article 8 (1) (f) (ii) of the GPSD (recall and destruction of products that are dangerous but do not present a serious risk)

Article 8 (1) (f) (ii) of the GPSD enables market surveillance authorities to order, coordinate or organise the recall of all dangerous products and their destruction. The Regulation only foresees recalls of products presenting *a serious risk* (Article 20) and enables authorities to destroy products which present a *serious risk* (Article 19 (1)).

Recalls and destruction of products which are dangerous but do not present a serious risk as foreseen under Article 8 (1) (f) (ii) GPSD are more specific measures than those foreseen in the Regulation and should, consequently, be applied in the area of harmonised consumer products.

2.2.6. Encouragement and promotion of voluntary action as provided for under Article 8(2), second sub-paragraph of the GPSD

The second subparagraph of Article 8 (2) of the GPSD requires market surveillance authorities to encourage and promote voluntary action, including the development of codes of good conduct. Such a requirement is not foreseen in the Regulation. Since this requirement is a more specific measure under the GPSD, it should consequently be applied, as appropriate, also in the area of harmonised consumer products.

2.2.7. Information for consumers on complaint procedures, as provided for under Article 9(2) of the GPSD

Article 18 (2) of the Regulation requires Member States to establish procedures to follow up complaints or reports on issues relating to risks arising in connection with products. Article 9 (2) GPSD contains a similar requirement on allowing consumers and other interested parties to submit complaints on product safety. Furthermore, it obliges authorities to actively inform consumers and interested parties about the procedures established to that end. This obligation to "*actively inform consumers and interested parties about the procedures established to that end*" goes beyond the Regulation and is therefore a specific measure of the GPSD which should be applied in the area of harmonised consumer products in addition to Article 18 (2) of the Regulation.

2.2.8. Information for consumers on products posing a risk as provided for under Article 16 (1) of the GPSD

Article 19 (5) of the Regulation stipulates that information must be made public to the fullest extent necessary in order to protect the interests of users in the Community. Article 16 (1) GPSD sets out the same principle. However, the first subparagraph of Art. 16 (1) of the GPSD further specifies that the public shall have access to information on product identification, the nature of the risk and the measures taken. Since this obligation to allow the public to have access to information on product identification, the nature of the risk and the measures taken is not spelled out in the Regulation, it is a more specific measure under the GPSD which applies in the area of harmonised consumer products in addition to Article 19 (5) of the Regulation.

2.2.9. General principles of the law of the European Union and good administration, as provided for under Articles 8 (2) and 18 of the GPSD

Articles 8 (2) and 18 of the GPSD make reference to a number of principles to be observed when carrying out market surveillance activities. The Regulation contains similar provisions in its Articles 19 and 21. The relevant GPSD provisions do not foresee any specific measures, which would apply in addition to the measures set out in the Regulation. These provisions are an expression of the general principles of the law of the European Union. In Article 8 (2), the GPSD explicitly mentions that recalls shall take place as a last resort. This principle is an important expression of the proportionality principle in the market surveillance context and it is fully applicable also to recalls adopted on the basis of the Regulation.

2.3. Consequences for the operation of the RAPEX system

Both the GPSD and the Regulation will use the RAPEX system for the notification of products presenting a serious risk. RAPEX will thus continue to function as a single system, and will operate as the rapid information exchange system for both the GPSD and the Regulation.

Article 22 (4) of the Regulation provides that paragraphs 2, 3 and 4 of Article 12 of the GPSD shall apply “*mutatis mutandis*” under the Regulation. The *mutatis mutandis* application means that the conditions of the GPSD also apply, in principle, to the functioning of RAPEX under the Regulation subject to certain adaptations necessary or inherent to the intention that RAPEX is to be used for notifications under the Regulation.

This means, inter alia, that:

- (a) the procedures for the functioning of RAPEX set out in Annex II of the GPSD and in the RAPEX Management Guidelines (Commission Decision 2010/15/EU⁸) also apply, *mutatis mutandis*, to notifications based on the Regulation;
- (b) the GPSD Committee has an advisory role in the adoption of any guidelines for notifications based on Article 22 of the Regulation; and
- (c) access of third countries to the RAPEX system is determined on the basis of, and under the conditions set out in, Article 12 (4) of the GPSD, also with regard to notifications made on the basis of the Regulation.

2.3.1. Notifications of measures concerning harmonised consumer products which present a serious risk to health and safety

Article 22 (1) of the Regulation obliges Member States to notify to the Commission through the RAPEX system measures taken in accordance with Article 20, i.e. *withdrawals, recalls and prohibitions of the marketing* of harmonised products presenting a serious risk, when it is considered that the reasons which prompted the measure or the effects of the measure go beyond the territory of the notifying Member State. This

⁸ OJ L 22, 26.1.2010, p. 1

obligation also includes notifications of measures recommended or agreed with economic operators. Furthermore voluntary measures taken by economic operators with respect to products presenting a serious risk have to be notified.

Article 12 (1) of the GPSD requires Member States to submit a RAPEX notification when they adopt or decide to adopt measures or actions to *prevent, restrict or impose specific conditions on the possible marketing or use* of harmonised consumer products presenting a serious risk and when it is considered that the effects of the risk are not limited to the national territory.

Hence, from the date of applicability of the Regulation on 1 January 2010, the legal basis for RAPEX notifications of *recalls, withdrawals and marketing prohibitions* of harmonised consumer products presenting a serious risk, including the accompanying measures, is no longer Article 12 of the GPSD but Article 22 of the Regulation. This means that the notification conditions set out in Article 22 (1) of the Regulation must be fulfilled and the information provided for in Article 22 (3) of the Regulation has to be provided with the notification.

However, Article 12 of the GPSD will still remain the legal basis for RAPEX notifications of *measures restricting or imposing specific conditions on the possible marketing or use of harmonised consumer products by reason of serious risk not amounting to a recall, withdrawal or prohibition*. Therefore, whenever market surveillance authorities adopt one of the more specific GPSD measures mentioned under points 2.2.1., 2.2.2 or 2.2.3 by reason of a serious risk they must notify them in accordance with Article 12 of the GPSD through the RAPEX system which determines the notification conditions and the information to be provided with the notification.

2.3.2. Notifications of measures concerning harmonised consumer products which present a non-serious risk to health and safety

Article 11 of the GPSD requires Member States to notify the Commission of measures taken which restrict the placing on the market of products, or require their withdrawal or recall unless a notification under Article 12 of the GPSD or any specific Community legislation is needed. Article 23 (2) of the Regulation obliges Member States to provide the Commission with information concerning products not already provided under Article 22. Hence, Article 23 of the Regulation serves as a basis for notification of any information on harmonised products posing a non-serious risk, including the measures adopted on the basis of the GPSD mentioned under points 2.2.1 - 2.2.5

2.3.3. Notification of measures concerning non-harmonised consumer products which present a risk to the health and safety of consumers

The applicability of the Regulation will not lead to any changes for RAPEX notifications concerning non-harmonised consumer products which present a risk to health and safety. Any market surveillance measures aimed at non-harmonised consumer products, i.e. all the measures listed in Article 8 (1) (b) – (f) (as well as other measures), continue to be notified on the basis of, and in accordance with, Article 11, in the case of a non-serious risk to the health and safety of consumers, or on the basis of and in accordance with Article 12, in the case of a serious risk to the health and safety of consumers.

2.3.4. Notification of measures concerning harmonised products which present other risks than a risk to the health and safety of consumers

For the sake of clarity and completeness it should be mentioned that measures taken against harmonised consumer and non-consumer products, which pose other risks than those affecting the health and safety of consumers, have to be notified on the basis of Article 22 of the Regulation through the RAPEX system. This concerns, for example, measures taken in view of a serious risk to the environment or to security.

NB: For an interim period pending the availability of the necessary informatics solutions notifications in this area should be made in accordance with the guidance issued on 14 December 2009 on "Interim lines of communication between the national authorities and the European Commission under Regulation No. 765/2008/EC".

3. GPSD PROVISIONS WHICH ARE NOT RELATED TO MARKET SURVEILLANCE

For the sake of clarity, it should be mentioned that the GPSD contains several provisions which do not concern market surveillance but other product safety related aspects, e.g. a general safety requirement in Article 3 or other obligations for economic operators in Article 5. These GPSD provisions are not affected by the Regulation and continue to apply to harmonised as well as non-harmonised consumer products in accordance with Article 1 (2) of the GPSD:

- Article 1: Objective and scope;
- Article 2: Definitions;
- Article 3: General safety requirement, conformity assessment criteria;
- Article 4: Procedure for mandating and drawing up European standards;
- Article 5: Other obligations for producers and obligations of distributors;
- Article 10: Network of the authorities promoted by the Commission⁹;
- Article 13: Specific decision-making procedure allowing the Commission to adopt decisions in urgent situations;
- Articles 14, 15: Comitology provisions;
- Article 17: Relationship to the Directive 85/374/EEC on liability for defective products¹⁰;
- Articles 19, 20: Reporting requirements for the Commission; and
- Articles 21-24: Final provisions.

⁹ This measure cannot be regarded as a market surveillance measure in the meaning of Article 15 (3) of the Regulation.

¹⁰ Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 307, 12.11.1988, p. 54