

## The Revision of the EU General Product Safety Directive

The European Commission is in the process of reviewing Directive 2001/95/EC on General Product Safety (“GPSD”). A legislative proposal is anticipated for the second half of 2011.

As was evident from the 1 December 2010 stakeholder conference on the revision of the GPSD organized by the Commission as part of the International Product Safety Week, the review of the GPSD will be substantive and will have a real impact on the regulatory landscape affecting the safety of products manufactured and sold in the European Union (“EU”). In the meantime, companies should be careful to ensure they know which product safety and market surveillance provisions apply to their products.

### 1. A complex legal framework that requires revision

With the adoption of the legislative package on the Free Movement of Goods (also called the “Goods Package”), the EU regulatory landscape on product safety and market surveillance has become very complex and confusing. As part of this package, Regulation 765/2008/EC (“Regulation”) sets forth new rules for the market surveillance of products subject to harmonized EU legislation, and Decision 768/2008/EC provides rights and obligations on business operators related to product safety that can be used by the legislator in the adoption of legislation on specific products, as has been done recently in the new Directive on Toy Safety and the new Regulation on Cosmetic Products<sup>1</sup>.

In practice, this means that since the entry into force of the Regulation on 1 January 2010, products are subject to different regulatory regimes in the EU depending on whether or not they are (i) “consumer products” and (ii) subject to specific EU “harmonized rules”.

The relationship between the two different regimes can be illustrated as follows:

Products	Consumer Products	Non-Consumer Products
Subject to EU Harmonized rules	Regulation 765/2008 + GPSD + Specific EU harmonized rules	Regulation 765/2008 + Specific EU harmonized rules
Not subject to EU harmonized rules	GPSD	No horizontal Community rules on market surveillance

In view of the above, the GPSD still is the only legislation of reference for consumer products not subject to EU harmonized rules, such as baby high chairs, children’s products other than toys, clothing, textiles and fashion items for which some European and national standards exist. By contrast, only the Regulation applies to non-consumer

<sup>1</sup> Directive 2009/48/EC on toy safety and Regulation (EC) 1223/2009 on cosmetic products

products subject to harmonized legislation, such as most chemical products that are subject to REACH, for example. Products that are not destined for consumers and not subject to specific EU harmonized rules, such as ladders for professional use, are subject to no requirements other than possible European or national standards.

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

In addition, other products, such as foodstuffs, are subject to yet other sets of rules, and there is also confusion as regards products supplied or made available to consumers in the context of a service (such as tables and chairs in restaurants, bars, public transportation), which are subject to different rules depending upon whether the product is operated by the consumer or by the service provider, all this leads to a rather unsatisfactory situation.

One of the claimed objectives of the GPSD review is its alignment with the newer provisions of the “Goods Package”. However, the above demonstrates that it is the entire legal framework on the safety of products that requires streamlining. Not surprisingly, it has been suggested by different stakeholders and even within the European Parliament<sup>2</sup>, that the market surveillance provisions of the GPSD and the Regulation are consolidated within a single regulation, which would therefore affect all types of products.

## 2. Revision of the GPSD

The GPSD is indeed currently being reviewed by the European Commission. A report on the implementation of the GPSD was published by the Commission on January 2009, followed by a public consultation, the results of which were discussed among different stakeholders during the International Products Safety Week in early December 2010. The main objectives of the review are to (1) achieve better coordination of actions by market surveillance authorities; (2) ensure a level playing field for businesses; (3) establish simpler and clearer rules for more effective market surveillance activities; and (4) guarantee safer goods within the EU market. At least some of these objectives will be a challenge, considering the above.

Based on the 2009 report and public consultation, the following main areas for improvement have been identified by the European Commission, in addition to the need to align the GPSD and the “Goods Package”, as discussed above:

### (A) PROCEDURES FOR MANDATING STANDARDS

The procedure established in Article 4 of the GPSD for mandating standards is considered to be too long and cumbersome in a fast moving environment, therefore failing to suitably address emerging risks. Suggestions are made that safety requirements adopted in Commission Decisions on emergency measures become mandatory and directly applicable at least for certain products; to grant presumption of conformity with the GPSD also to non-European international standards (e.g. ISO) in some conditions; and to allow adoption of “standing” or “framework” mandates to the European Standard institutes on the basis of which more than one standard could be elaborated. Industry fears that this may diminish the checks and balances of the current system.

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<sup>2</sup> Draft Report for the Committee on the Internal Market and Consumer Protection, 12 November 2010 (PR\839238EN.doc).

## (B) HARMONIZING SAFETY EVALUATIONS AMONG MEMBER STATES

One of the problems in the implementation of the GPSD is the inconsistency in the application of the “emergency measures” adopted under Article 13 of the GPSD and their necessary renewal on a yearly basis. To avoid these divergences, several measures are being contemplated, such as the setting up of a European reference laboratory/agency for testing/risk assessment or the creation of a database for risk assessment. It is also proposed that EU “emergency measures” become directly applicable and valid for a longer period or until the realisation of an expected event (such as the adoption of a standard or legislation).

## (C) IMPROVE MARKET SURVEILLANCE COORDINATION AND COOPERATION AND THE FUNCTIONING OF RAPEX

The Commission also seeks to ensure a better coordination between national market surveillance authorities, notably through additional financial support for joint surveillance actions and exchanges of officials and establishing a coordination forum at the EU level.

The Commission is also considering that RAPEX notification procedures should be simplified to facilitate compliance by Member States in their notification and follow-up obligations. Notably, it considers making the notification criteria uniform for all products. Industry should in our view support simplification in this area but also make sure that the EU regulator understands the practical impact of the notification rules on business operators and that simplification of RAPEX procedures also brings more legal certainty to operators.

## (D) TRACEABILITY AND PRODUCTS SOLD ONLINE

Among the other issues discussed in the Review are the need to align the GPSD on the Goods package with respect to the traceability of products through the supply chain and the need to establish specific provisions on goods sold online. In respect to the later, it is suggested that enforcement can be improved if harmonized rules on market surveillance are introduced at the EU level for products sold online.

## 3. Next Steps

Further targeted stakeholder consultations will take place during the first quarter of 2011, leading to a Commission draft proposal for a new GPSD expected in the second half of 2011. The alignment of the GPSD with the Goods Package, possibly in one single coherent market surveillance regime, as discussed above, will likely be the key element of the reform. It is also the occasion for industry to ensure that, for instance, the new system will bring clarifications to the circumstances triggering notification obligations and to the relationship with sector specific legislation, and improvements in the management of RAPEX.

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