

## ROADMAP

Title of the initiative: **Review of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (GPSD)**

Type of initiative (CWP/Catalogue/Comitology): Legislative Proposal / Directive

Lead DG/contact person/details: DG SANCO

Expected date of adoption of the initiative (month/year): June 2011

Date of modification: 25 March 2010

Version No:

### Initial IA screening & planning of further work

#### A. Context and problem definition

*(i) What is the political context of the initiative?*

The legislative framework set up by the two successive General Product Safety Directives<sup>1</sup> (GPSD) has established over almost two decades, a market surveillance system that fosters a general culture that all consumer products must be safe and integrates the role of harmonised standards for otherwise non-harmonised products. However, recurrent product safety alerts have made clear the need for a system that delivers more rapidly, efficiently and consistently throughout the EU and which is also flexible enough to adapt to the challenges of globalisation. In addition, the New Legislative Framework for harmonised products requires that certain alignments are made also in the General Product Safety legislation, to ensure efficient practical compliance and market surveillance including enforcement. Various forms of cooperation among the Member States must be facilitated to allow them also to make the best use of the RAPEX system and thereby effectively protect consumer health and safety. Finally, it must be considered if there are grounds to follow some recent examples and recast the Directive into a Regulation for more clarity and more level implementation.

*(ii) How does this initiative relate to past and possible future initiatives, and to other EU policies?*

This initiative relates to the New Legislative Framework<sup>2</sup> (NLF) which is in force as from 1<sup>st</sup> January 2010. Therefore, market surveillance in the field of consumer product safety will be covered by two pieces of Community legislation:

- Products subject to Community harmonisation legislation (so called "harmonised products") will be covered by both by the NLF Regulation<sup>2</sup> and by the GPSD;
- Consumer products not subject to Community harmonisation legislation (so-called "non-harmonised products") will continue to be governed by the GPSD only.

In the area of "harmonised products", the interaction between the "NLF Regulation and the GPSD is not defined unambiguously. Also, the legal set up which will be in place as from 1st January 2010 does not offer a thorough consistency for market surveillance of all consumer products (harmonised and non-harmonised). The risk of confusion amongst market surveillance authorities as regards the practical enforcement of relevant legislation is real and this should be addressed.

Furthermore, the NLF Decision contains some modern elements which have become general principles meant for all Community legislation governing marketing of goods. Their addition to specific instruments will reinforce their effectiveness.

The GPSD is also a flexible gap-filling tool, providing emergency measures to cope with serious risks, also for products regulated in other sector specific legislation (e.g. toys, chemicals). Making such measures under the GPSD more powerful (e.g. by including provisions for permanent bans, possibly subject to revision clauses) would increase the effectiveness of several product safety-related pieces of law with just one revision.

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<sup>1</sup> Directive 92/59/EC and 2001/95/EC

<sup>2</sup> Decision 768/2008/EC on a common framework for the marketing of products and, Regulation 765/2008/EC.

*What are the main problems identified?*

**Need of alignment of the GPSD with the principles of the NLF:**

The practical implementation of the NLF, as mentioned above, is likely to bring about two main problems. First, in the area of harmonised consumer products, to which both the NLF Regulation and the GPSD apply, the complexity of determining whether in a given case it is the GPSD or the NLF Regulation that should apply is likely to affect the coherence across Member States, the effectiveness of market surveillance actions and, ultimately, the level of consumers' health and safety protection. Second, the coexistence without a substantive and practical alignment of the GPSD with the NLF is likely to set up two separate legislative regimes – one for harmonised and one for non-harmonised products – with their own definitions and differing obligations for economic operators, diverging competences of market surveillance authorities, different conditions for notification of measures targeting unsafe products, etc. The scope of the guidelines on the functioning of the RAPEX system is also bound to divergences in their implementation. This is not in the interest of consumers and economic operators.

**Product traceability:**

Although the GPSD contains provisions regarding product traceability, these are somewhat ambiguous, resulting in different obligations stipulated for economic operators in different Member States thereby causing obstacles to the internal market. The lack of effective and clear product traceability requirements fragments the internal market, harms the interests of reputable businesses and is to the detriment of a high level of consumer protection throughout the EU. If market surveillance authorities cannot trace the manufacturer or importer of a product that is found to be unsafe, they are not in a position to adopt effective measures to prevent or restrict the marketing of such products (for example, to order a withdrawal from the market or a recall). Furthermore, the authorities are not able to monitor any voluntary actions taken by economic operators against such products.

Article 5(1) of the Directive contains general obligations for producers to provide consumers with the necessary information for tracing the origin of a product or to display the identity of the producer or details of the production batch on the packaging of the product. Nevertheless, it is up to the Member States to adopt concrete measures to implement such obligations. The number of notifications in which the product was untraceable has decreased in comparison with previous years. However, as products that pose a serious risk and whose country of origin is unknown account for 10% of notifications, there is still room for improvement.

**Standardisation procedures:**

Standardisation procedures under the GPSD are longer and more complex than those in the harmonised area. The average time for setting up safety requirements and publishing standards under the GPSD is significantly longer than in the harmonised area. The procedures under the GPSD foresee voting by comitology and scrutiny by the EP which do not apply to the harmonised area. This is not conducive to a satisfactory level of consumer protection, especially when a solution is already available to cope with certain risks (ex. fire-safer cigarettes). Furthermore, the current provisions increase the costs for economic operators as they are deprived of regularly updated EU-wide referenced standards which would grant their products, quickly and easily, with the presumption of conformity. In the absence of such standards, the conformity assessment has to be sought via more costly certification procedures.

**Problems with the temporary character of emergency Community measures:**

Community emergency measures (adopted under comitology) restricting the marketing of dangerous products cause uncertainty due to their temporary nature, even where a permanent solution is in sight but cannot be achieved within the limited one-year period of the Community measure. Also, there are no provisions to permanently ban a product when it is found to be dangerous.

**Inclusion of the provisions of the Food-Imitating Products Directive into the general rules on product safety:**

The Food Imitating Products Directive 87/357/EC causes confusion, as it is currently unclear whether food imitating products are subject to the GPSD or whether they have their own specific regime under the Food Imitating Products Directive. The inclusion of the provisions of the Food-Imitating Products Directive into the general rules on product safety will contribute to the simplification of the product safety framework in the EU.

**Need for coordinated market surveillance actions:**

There is a need for more coordinated market surveillance considering the number of consumer products sold in more than one Member State.

**RAPEX:**

There are reasonable grounds to assume that Member States do not notify all preventive and restrictive measures taken in relation to dangerous consumer products, despite the fact that all notification criteria are fulfilled. Member States also do not ensure appropriate follow-up actions to all RAPEX notifications.

**Different risk management and risk assessment approaches fragment the internal market:**

Economic operators complain that a product may be prohibited as dangerous in one Member State but continues circulating freely in another. Moreover, different measures may be adopted for a product with the same risk level, and there is no clear mechanism foreseen to address such issues.

**Problem of on-line selling of unsafe products:**

Some MS raised the issue that it is difficult to take action against products sold online. Currently, the directive does not specifically address this increasingly important area. Also products notified on RAPEX as dangerous find alternative and convenient distribution channels online

**Safety of services:**

Although the GPSD covers consumer products made available to consumers in the context of the provision of a service (such as rented equipment), products operated by service providers when supplying a service to the consumer are excluded from the scope of the GPSD (and if non-harmonised, also from the scope of the NLF market surveillance). Consequently, the general safety requirement applies to a product located at the premises of the service provider handled directly by the consumer, but not to the same product if handled by the service provider, even despite the fact that the danger in both situations stems from the product itself.

*Who is affected?*

Member States, economic operators, consumers, etc.

*(i) Is EU action justified on grounds of subsidiarity?*

This initiative concerns the revision of existing Community legislation that prevents barriers to trade and distortion of competition within the internal market associated with disparities between horizontal product safety legislation of the Member States. Action at Community level (in the form of harmonised rules and coordinated surveillance activities) would deliver better results than a series of individual actions by Member States because: i) a harmonised approach across Member States lowers the administrative burden on companies operating either trans-nationally or Community wide, and ii) uniform action ensures Community wide minimum standards for consumers, thereby reducing inequity for citizens across the EU.

*(ii) Why can the objectives of the proposed action not be achieved sufficiently by Member States (necessity test)?*

The scope of the revision imply between others: (i) the enforcement of the market surveillance, (ii) the improvement of system of standards' adoption, (iii) the improvement of the safety of products sold online, (iv) the reduction of the costs stemming from diverging risk assessment and/or test results and etc. These objectives cannot be easily achieved by Member States.

. Additionally, institutional framework for enforcing safety rules is very different in MS: identical product can be banned in one MS and allowed in another one, or market surveillance powers can be different and place economic operators in different situations in different MS, thus creating an internal market barrier and distortion.

*(iii) As a result of this, can objectives be better achieved by action by the Community (test of EU Value Added)?*

Yes, the objectives of the GPSD revision can be better achieved through an EU action allowing to avoid disparities in the internal market and to prevent barriers to trade.

## **B. Objectives of EU initiative**

*What are the main policy objectives?*

### ***Relating to the high level of consumer protection:***

- To ensure more consistent and more effective market surveillance in the EU, including consistent follow-up, both in the field of risk assessment and risk management actions to remove unsafe products from the market (with particular attention to the e-commerce environment);
- To improve product traceability, also in view of the need for further international cooperation and if possible convergence in the interest of (legitimate) businesses and consumers alike;
- To make more efficient the adoption of European standards;
- To provide EU product safety 'emergency' measures with a more permanent and direct effect.
- To monitor more consistently and on a regular basis accidents and injuries caused by products and services.

### ***Relating to the strengthening of the internal market:***

- To provide a more uniform and level playing field for EU economic operators;
- To make the rules for marketing of (consumer) products clear and consistent;
- To reduce unnecessary administrative costs;
- To guarantee a harmonised approach to economic operators across Member States;
- To facilitate conformity assessment for economic operators by efficiently providing referenced standards.
- To create a coordinated approach and a consensus mechanism for risk assessment and management;
- To assess the need to extend the general safety requirement to products handled by service providers when supplying a service to consumers
- To introduce a mechanism for collecting data allowing the Commission to better monitor the market surveillance activities undertaken by the Member States in relation to consumer products and, in parallel, to more accurately and correctly assess their participation in the RAPEX system.

*Do the objectives imply developing EU policy in new areas or in areas of strategic importance?*

No, the objectives do not imply developing EU policy in new areas or in areas of strategic importance.

## **C. Options**

*(i) What are the policy options?*

At the level of content, options have not yet been identified. Options for the type of intervention could range from non-binding measures i.e. Recommendations or Guidelines to either revised Directive or even Regulation.

*(ii) What legislative or 'soft law' instruments could be considered?*

Non-binding measures i.e. Recommendations or Guidelines could be adopted.

*(iii) Would any legislative initiatives go beyond routine up-date of existing legislation?*

The GPSD revision would not be limited to a simple recast of the current Directive but aims at increasing the level of consumer protection by simplifying and improving the current system (i.e. enforcing market surveillance, making standards adoption more efficient, improving the safety of products sold online, reducing the costs stemming from diverging risk assessment and/or test results, etc.).

*Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?*

Yes, DG ENTR

*Explain how the options respect the proportionality principle*

For each issue we have foreseen a no EU Action scenario. We will assess the impact of this scenario and envisage action based on the scope and the depth of problems with consumer safety on the internal market.

#### **D. Initial assessment of impacts**

*What are the significant impacts likely to result from each policy option (cf. list of impacts in the Impact Assessment Guidelines pages 32-37), even if these impacts would materialise only after subsequent Commission initiatives?*

All options are likely to improve the safety of products sold through traditional channel and online and to increase the protection of consumers.

The measures aim at reducing administrative burden for economic operators stemming from differing risk assessment and resulting from unequal level of enforcement in Member States.

*Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?*

No impact on budget.

*Could the options have significant impacts on (i) simplification, (ii) administrative burden or on (iii) relations with third countries?*

Yes. The main objective of the GPSD review is the simplification based on the experience with the administrative burdens of the current rules and the alignment with other relevant, recent legislation. Between the key elements of the simplification are: i) modernising and make more efficient the standardisation machinery within the GPSD ii) moving the food imitating products Directive under the GPSD iii) reducing the level of legal uncertainty related to the implementation measures under art. 13 of the GPSD.

#### **E. Planning of further impact assessment work**

*When will the impact assessment work start?*

The impact assessment work started in September 2009.

*(i) What information and data are already available?*

Data already collected by DG SANCO in the framework of monitoring of consumer market. Targeted studies in standardisation exist already.

*(ii) Will this impact assessment build on already existing impact assessment work or evaluations carried out?*

NLF impact assessment on the (omnibus) alignment of the new approach directive and the IA on the revision of the 98/34 Directive.

*(iii) What further information needs to be gathered?*

Data and views, to complement the existing information, on the impact of the options and in some areas on the precise scope of the problem. Given that one of the stated objectives is the reduction of administrative costs, EU Standard Cost Model is planned to be used where possible.

*(iv) How will this be done (e.g. internally or by an external contractor) and by when?*

Terms of reference will be finalised in order to launch some targeted studies for the areas where we would still be missing key information after having analysed the information provided by stakeholders in the Internet based questionnaire ( the Interactive Policy Making consultation) or acquired by other means.

*(v) What type and level of analysis will be carried out (cf. principle of proportionate analysis)?*

*Which stakeholders & experts have been/will be consulted, how and at what stage?*

Member States have been informed throughout the GPSD Committee from the beginning. Economic operators and consumers association have also been informed during the ECCG and

Business Europe meetings and some consultation documents, mainly concentrated on the problem definition, have also been sent to them.

An Inter-Service Steering Group (ISSG) has been created and has so far met two times to discuss problem definition and progress on the Directive's revision.

A public consultation will be launched in March-April through the IPM.

Furthermore, consultations on the options are foreseen over the year.

Finally, a Stakeholder Workshop on the GPSD revision is under preparation and will be held in the beginning of December 2010. This event, which is a milestone of the GPSD revision process and of the Stakeholder consultation strategy, aims at wrapping-up the impact assessment work. About 120 participants coming from different environments (industries, Member States, Consumers associations, International organisations, etc.) will take part.