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EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council

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Executive Summary Sheet

Impact assessment on a Proposal to revise the General product safety directive

A. Need for action

What is the problem and why is it a problem at EU level?

This Impact Assessment follows the Evaluation of the General Product Safety Directive (GPSD), carried out in parallel. Evaluation results show that GPSD is a valid instrument and overall met its objectives, but still too many unsafe products circulate on the EU market, creating an **uneven playing field for businesses** and an **important cost for society and consumers**. The preventable detriment to EU consumers and society from injuries/death caused by unsafe products is estimated at **EUR 11.5 billion per year and the detriment to consumers** based on the value of unsafe products is estimated at **EUR 19.3 billion**. **Specific problems in the GPSD** relate to the following: the GPSD does not sufficiently address challenges linked to **new technologies** and the **online sales**; unsafe **product recalls from consumers** are not sufficiently effective, **market surveillance provisions** are not fully effective and coherent with rules relevant for harmonised products; and safety rules for **food-imitating products** are inconsistently applied across the EU. Main drivers of those problems are market and regulatory failures, in a context where online sales and new technologies are strongly growing. These problems are expected to increase over time, as consumer product sales will be more and more related to globalisation and digitalisation.

What should be achieved?

The initiative aims to achieve the **general objectives** of ensuring protection of EU consumers from unsafe products, while contributing to the proper functioning of the Single Market, in particular a level playing field for businesses. The **specific objectives** are to (1) ensure the EU legal framework provides for general safety rules for all consumer products and safety risks, including those linked to new technologies; (2) address product safety challenges in the online sales channels; (3) make product recalls more effective and efficient to keep unsafe products away from consumers; (4) enhance market surveillance and ensure better alignment of rules for harmonised and non-harmonised consumer products and (5) address safety issues related to food imitating products.

What is the value added of action at the EU level (subsidiarity)?

Product safety is a shared competence between Member States and the EU. The problems identified are widespread and have the same causes across the EU. The objective of product safety cannot be sufficiently achieved by the Member States acting alone, given the need for a very high degree of cooperation, interaction and coherent action of all the market surveillance authorities across the EU to ensure the same high level of protection of all EU consumers and enable level-playing field on the Single Market where goods circulate freely. Absence of EU action would also significantly increase the costs of market surveillance for Member States and administrative costs for businesses.

B. Solutions

What are the various options to achieve the objectives? Is there a preferred option or not? If not, why?

Beyond the baseline scenario, the following policy options have been identified to address the objectives:

Option 1: **Improved implementation** and **enforcement** of the existing legal framework, mainly through increased guidance and promotion of the current tools but without legal revision of the GPSD (only the Food-Imitating Product Directive would be revised);

Option 2: **Targeted revision** of the GPSD, as a Directive or Regulation, addressing the coverage of new risks linked to new technologies, making several provisions inspired by the Product Safety Pledge provisions legally binding, introducing mandatory requirements for product recalls, aligning with the

market surveillance rules for harmonised products and integrating rules for food-imitating products into the GPSD.

Option 3: **Full revision** of the GPSD in the form of a Regulation providing for, beyond Option 2, clarifications of safety rules linked to software, additional obligations related to online sales and product recalls, stronger enforcement powers to Member States, setting an arbitration mechanism for disputes between them in relation with divergent risk assessments, and enhancing product traceability.

Option 4: **Integration of the legal instruments on market surveillance,** beyond the provisions under Option 3.

The substantive provisions of the Food-imitating Product Directive were considered to be revised under all options 1 to 4 with two possible sub-options: (a) a full ban of food-imitating products *per se* and (b) application of the risk-assessment approach to this category of products.

The preferred option is Option 3 with the (b) sub-option for food imitating products.

What are different stakeholders' views? Who supports which option?

During the open consultation on the GPSD Roadmap/Inception Impact assessment, most of the stakeholders supported the GPSD legal revision, almost half of them being in favour of the full revision (Options 3+4). In the open public consultation, as well as other consultation activities, stakeholders provided clear support to specific measures under Option 3. **Consumer organisations** are generally in favour of Option 4. **Member States** are mostly supporting Option 3. **Businesses** highlight the need for clear definition of responsibilities, legal certainty and level-playing field and seem therefore to favour a legal revision of the GPSD (Option 2 and 3).

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise of main ones)?

Option 3 is expected to lead to major benefits to consumers and society. The consumer detriment is estimated **today,** based on the value of unsafe products, **to be around EUR 19.3 billion**. This should decrease by approximately **EUR 1.0 billion in the first year of implementation of the preferred option** and decrease by approximately **EUR 5.5 billion over the next decade**. Option 3 should also reduce consumer detriment related to ineffective recalls by more than EUR 400 million per year. Moreover, the current detriment suffered by EU consumers and society due to **preventable product-related accidents is estimated at EUR 11.5 billion per year.** The current **cost of health care** for product-related injuries in the EU is approximately **EUR 6.7 billion per year** (hospitalisation accounting for about EUR 6.1 billion). These costs should also be reduced by measures under Option 3 resulting in lower number of unsafe products (this impact could not be quantified due to lack of injury data to estimate trends). Estimated **savings of costs**, **caused by reducing the differences in the national implementation and legal fragmentation,** is estimated to amount to **EUR 59 million annually for businesses** and to **EUR 0.7 million per year** for **market surveillance authorities.** Reduced number of unsafe products, including those containing hazardous chemicals, would have also positive environmental impacts.

What are the costs of the preferred option (if any, otherwise of main ones)?

Total costs for businesses in the EU27 in the first year of implementation of Option 3 are estimated at **EUR 196.6 million** (one-off and recurrent costs), equivalent to **0.02% of turnover of EU companies** for manufacturing, wholesale and retail of non-harmonised products. In the following years, the recurrent costs would amount to **EUR 177.8 million for EU businesses.** These costs are linked to the increased obligations for businesses mainly for online sales, sales of new technology products and recalls of unsafe products and to the alignment of the market surveillance rules with those for harmonised products. **Market surveillance authorities** in Member States would face total additional recurrent costs under Option 3 of approximatively **EUR 6.7 million annually** due to the increased powers in the market

surveillance of unsafe products and only relatively moderate one-off adaptation and implementation costs. There are no negative environmental or social impacts.

What are the impacts on SMEs and competitiveness?

SMEs and micro-SMEs are not exempted from any of the obligations foreseen under the preferred option. EU product safety legislation does not allow for "lighter" regimes for SMEs since a consumer product must be safe whatever the characteristics of its supply chain, to meet the general objective of product safety and consumer protection. Total costs for EU SMEs in the first year of implementation of Option 3 are estimated at **EUR 111.1 million** (one-off and recurrent costs). In the following years, the recurrent costs would amount to **around EUR 100 million for EU SMEs.** Estimated **savings of costs**, **caused by reducing the differences in the national implementation and legal fragmentation,** would amount to **EUR 34 million for EU SMEs**. The most affected business sectors would be online sales, producers of some new technology sectors but without having a major impact on their competitiveness through harmonised EU requirements.

Will there be significant impacts on national budgets and administrations?

Member States would face total additional recurrent costs under Option 3 of around **EUR 6.7 million annually** but these should be compensated by **reduced health care costs** due to decrease of unsafe products on the market. Also, **cost savings** of around **EUR 0.7 million per year would arise due to harmonisation of market surveillance rules for Member States**. This harmonisation will also facilitate the implementation of the initiative by Member States, since they are already familiar with rules for harmonised products.

Will there be other significant impacts?

Option 3 would have positive impacts on fundamental rights by ensuring a higher level of the consumer protection and environmental protection due to a decrease of unsafe products on the EU market. Additional requirements for businesses do not affect the fundamental freedom to conduct a business and appear to be proportionate to the general objective pursued. Option 3 should also create simplification and reduction of administrative burden by streamlining the standardisation procedure and reducing legal uncertainty (lack of clarity of certain substantive rules) and fragmentation (diverging market surveillance rules for different categories of products).

Proportionality?

Option 3 appears conform to the principle of proportionality given that the size of the identified problem is significant (high presence of unsafe consumer products on the EU market and related high consumer detriment) and the costs associated with this option are limited. **Overall, the balance of this option is positive as it brings positive impacts for consumers and society and costs for business remain low in percentage of their turnover.** In addition, the choice of Regulation as Union action is coherent with satisfactory achievement of the objective to ensure level-playing field and effective and even enforcement at national level.

D. Follow up

When will the policy be reviewed?

In addition to regular monitoring, an evaluation of the effectiveness, efficiency, relevance, coherence and EU added value of this legislative intervention is proposed 5 years after implementation by Member States, based on predetermined core progress indicators.