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Product Safety and Market Surveillance Package

COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

PRODUCT SAFETY AND MARKET SURVEILLANCE PACKAGE

A proposal for a Regulation of the European Parliament and the Council on consumer product safety and a proposal for a Regulation of the European Parliament and of the Council on market surveillance for products

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1. SUMMARY OF THE PROBLEM DESCRIPTION, SUBSIDIARITY AND OBJECTIVES

1.1. Policy context

The free movement of safe and compliant products is one of the cornerstones of the European Union. This principle constitutes an important pillar of the single market and allows consumers and enterprises to purchase or sell products in another Member State.

The impact assessment concerns manufactured non-food products which are either subject to EU harmonisation rules for specific categories of products, or to Directive 2001/95/EC on general product safety (the "General Product Safety Directive"), applicable to consumer products. This set of EU rules has put in place product safety requirements for a large number of products, while the free movement provisions of the Treaty and the mutual recognition principle govern the remaining product categories.

Effective market surveillance should enable unsafe, or otherwise harmful, products to be identified and kept or taken off the market and allow for the penalisation of unscrupulous or even criminal operators. It should also act as a powerful deterrent. In a single market in which products circulate freely, market surveillance needs to be highly coordinated and capable of reacting rapidly over a huge area.

However, market surveillance has not kept pace with developments in the Union's regulatory framework. Advances have been made over the last decade with the implementation of the General Product Safety Directive, which had to be transposed by 15 January 2004, and with the coming into application of Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products on 1 January 2010. These legal instruments, together with market surveillance rules for certain sector-specific Union harmonisation legislation, provide today an EU legal basis for the market surveillance of all consumer products (both harmonised and non-harmonised) and for all harmonised products (for consumers and professional users). However, the market surveillance rules are fragmented and spread over different pieces of Union legislation (Regulation 765/2008, the General Product Safety Directive and sector-specific Union harmonisation legislation) which creates confusion on the part of both operators and national authorities.

Overall architecture of Union product safety and compliance rules

Products	Consumer	Professional
Harmonised	Sector specific Directives and Regulations and the General Product Safety Directive	Sector specific Directives and Regulations
Non-harmonised	General Product Safety Directive	National product safety rules under the 'Mutual Recognition Regulation' Article 34-36 TFEU

This initiative is one of the important actions of the European Consumer Agenda[1] and the Single Market Act II[2], both adopted by the Commission in 2012.

1.2. Problem definition - Unsafe and non-compliant products in the single market

The internal market for products is enormous. In 2010, intra-EU trade of harmonised and non-harmonised consumer products amounted to almost EUR 1 trillion. The value of harmonised sectors (including both consumer and professional goods) in the EU-27 is estimated to be no less than EUR 2,100 billion.

An internal EU market should be a place where safe products circulate freely. Effective application of the free movement principle in the product safety area requires that the assessment of whether a product is safe or not - and thus, whether it should stay on the market or not - be performed in the same way in all Member States. Free circulation of safe products should be promoted and unsafe products effectively tracked down and removed from the single EU market.

1.2.1. Problem 1: Difficulties in compliance with EU product safety requirements

Compliance with the EU product safety requirements is often difficult for economic operators since, in general, requirements in the area of so-called non-harmonised products are not consistent with those in the harmonised area. Furthermore, in the non-harmonised area, the EU product safety requirements are often ambiguous and lack detailed benchmarks for safety evaluation, while, in the harmonised area, different and overlapping layers of product safety undermine legal certainty.

Unsafe and non-compliant products not only pose risks to consumers and other users, they also have important economic consequences: they lead to unfair competition. Operators not adhering to the rules can make significant savings on compliance costs. They can consequently offer their products at lower prices than their competitors who respect the law. In sectors where there is tough competition from imported, low-price products, European industry is at a disadvantage. The situation therefore "punishes" the law-abiding manufacturer, as compliance becomes a "competitive disadvantage".

With the intensification of trade globalisation, the problem of unsafe and non-compliant products concerns increasingly (but not exclusively) those goods imported from third countries.

1.2.2. Problem 2: Market surveillance for products within the single market is fragmented

Despite the widespread harmonisation of safety standards and other requirements for products (e.g. environmental) across the Union, and the fact that many products are regularly marketed in more than one Member State, the Single Market is regulated through 27 separate systems of enforcement.

A major reason for the considerable number of non-compliant products on the market is that market surveillance does not operate effectively within the European Union. The principal causes of ineffective and inefficient market surveillance on the single EU market are: weak coordination of the market surveillance authorities of different Member States, poor functioning of EU procedures for the exchange of information on product risks and inconsistent enforcement of EU-wide product safety action.

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1 COM(2012)225 final.

2 COM(2012)573 final.

Where action is needed beyond the border, authorities must rely on their colleagues in other Member States. However, in contrast to other areas, for example the Consumer Protection Cooperation Regulation or the Services Directive, in the area of product safety, market surveillance authorities do not benefit from procedures for effective cross-border enforcement. Thus, significant resources are wasted and important synergies are lost.

1.3. EU right to act

The single market for products is a key achievement of the European Union. Yet the elimination of national barriers for consumer and other products offers plenty of opportunities to less scrupulous traders who do not apply the consumer safety rules or refuse to implement the EU legislation on products. The EU therefore has the right to act on the basis of Article 114 TFEU in order to ensure the proper functioning of the single market for consumer products and to increase the efficiency of cross-border market surveillance. Article 168(1) and Article 169(1) TFEU complement this right to act. The first stipulates that a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities; the latter provides that in order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall, amongst others, contribute to protecting the health, safety and economic interests of consumers.

Despite the existence of the single EU market, the enforcement of product safety requirements is the responsibility of the Member States. According to the principle of subsidiarity actions against products posing risks are carried out by Member States. However, the way in which market surveillance is performed and organised significantly varies from one Member State to another.

Differences in the organisation of market surveillance at national level cause problems when viewed in a framework where controls at national borders have practically disappeared. To ensure that only safe and compliant products circulate on the market, every Member State depends on the market surveillance of its neighbours. Consequently, weaknesses in the organisation of market surveillance in one Member State can seriously undermine the efforts taken by other Member States. This justifies EU action to address this issue.

1.4. Objectives

1.4.1. General policy objectives

The general objective of this initiative is to improve the functioning of the internal market and to achieve a high level of protection of consumers and other product users through the reduction of the number of unsafe or non-compliant products on the market.

1.4.2. Specific policy objectives

- Consolidation and reinforcement of EU product safety requirements;
- Better coordination and increased effectiveness of market surveillance activities on the single EU market for goods;
- Simplification of the EU legislative framework.

1.4.3. Operational policy objectives

- Ensuring consistency of EU product safety requirements;

- Reducing ambiguity of product safety requirements for non-harmonised consumer products;
- Reinforcing EU cooperation mechanisms;
- Making EU product safety procedures more coherent;
- More effective EU-wide product safety action.

2. POLICY OPTIONS

The presented policy options were established by the Commission in close cooperation with all groups of stakeholders. Certain policy options were, however, discarded at an early stage, including regulating the safety of services, adopting product safety requirements for non-harmonised professional products[3], adopting specific rules concerning products marketed via the internet and abolishing the general requirement that all consumer products must be safe.

2.1. Specific policy objective 1: Consolidation and reinforcement of EU product safety rules

2.1.1. Operational policy objective: Ensuring consistency of EU product safety requirements

Option 1.A – Baseline scenario: Keeping differences between consumer product safety requirements and harmonised product safety requirements

Option 1.B – Aligning consumer product safety requirements with harmonised product safety requirements

Option 1.C – Consumer product safety requirements to be defined less strictly then harmonised product safety requirements

Option 1.D – Consumer product safety requirements to be defined more strictly than harmonised product safety requirements

2.1.2. Operational policy objective: Reducing ambiguity of product safety requirements for non-harmonised consumer products

Option 2.A – Baseline scenario: Existence of pre-standardisation procedures for non-harmonised consumer products that are not aligned with the new European standardisation regime

Option 2.B – Direct applicability of ad-hoc safety requirements

Option 2.C – Abolition of formal adoption of the non-binding ad-hoc safety requirements (alignment with the new European standardisation regime)

Option 2.D – Fast-track procedure for adopting already existing European standards without mandates

[3] Professional products mean those products which are only used by professionals and not by consumers, such as industrial machines, raw materials or semi-finished products.

2.2. Specific policy objective 2: Better coordination and increased effectiveness of market surveillance activities on the single EU market for goods

2.2.1. Operational policy objective: Reinforcing EU cooperation mechanisms

Option 3.A – Baseline scenario: keep status quo based mostly on voluntary market surveillance coordination

Option 3.B – Coordination of cross-border enforcement of measures resulting from "on the-field" market surveillance

Option 3.C – Overall rationalisation of coordination of market surveillance activities

Option 3.D – Centralisation of EU market surveillance in the area of non-food products (EU Market surveillance agency)

2.2.2. Operational policy objective: Making EU product safety procedures more coherent

Option 4.A – Baseline scenario: Keeping the parallel notifications under RAPEX procedure and safeguard procedure

Option 4.B – Simplification of the RAPEX procedure

Option 4.C – Simplification of the RAPEX procedure and streamlining of that procedure with the safeguard procedure

2.2.3. Operational policy objective: More effective EU-wide product safety action

Option 5.A – Baseline scenario: Keeping EU-wide product safety measures indirectly applicable for a period of one year only

Option 5.B – Extension of the scope of EU-wide product safety measures to harmonised non-consumer products

Option 5.C - Making EU-wide product safety measures directly applicable

Option 5.D – Removal of the limited validity of EU-wide product safety measures

Option 5.E – Combination of options 5.B, 5.C and 5.D

2.3. Specific policy objective 3: Simplification of the EU legislative framework

The two other specific policy objectives are complemented by the objective to simplify the legislative framework regarding product safety and market surveillance. The simplification consists in (1) merging the market surveillance rules of different pieces of legislation into a single horizontal market surveillance regulation, (2) the transformation of the revised General Product Safety Directive into a regulation and (3) the repeal of Directive 87/357/EEC and the transfer of its concept, that food-imitating products must not endanger the health and safety of consumers, into the new Consumer Product Safety Regulation replacing the General Product Safety Directive.

3. ANALYSIS OF IMPACTS AND COMPARISON OF ENVISAGED POLICY OPTIONS

Due to the absence of reliable statistics or even estimates regarding the number of unsafe and non-harmonised consumer products, and the number of non-compliant harmonised products, the assessment of the options is mainly qualitative.

3.1. Specific policy objective 1: Consolidation and reinforcement of EU product safety rules

3.1.1. Operational policy objective: Ensuring consistency of EU product safety requirements

In order to provide consumers and other users with an equally high level of protection against unsafe products throughout the EU, as well as to prevent barriers on the EU internal market, the EU product safety rules must be clear and compatible across different product sectors.

Comparison of the options against the baseline scenario

Options / Issues	Option 1.B	Option 1.C	Option 1.D
Safety of consumers	++	-	++
Legal clarity and certainty	++	+	-
Market surveillance effectiveness and efficiency	++	--	+

Comparison of the change in costs for economic operators compared to the baseline scenario

Options / Cost types	Option 1.B	Option 1.C	Option 1.D
Information research costs/legal costs	Decrease	Slight decrease	0
Production costs	0*	0	Increase

* slight increase except for a very small group of producers

Preferred option: Option 1.B - Alignment of consumer product safety requirements with harmonised product safety requirements

3.1.2. Operational policy objective: Reducing ambiguity of product safety requirements for non-harmonised consumer products

Policy options aimed at reducing the ambiguity of product safety requirements for non-harmonised consumer products are assessed according to the ease in which they can lead to the development of European standards under the general product safety rules, the coherence of procedures with the general regime under the new Standardisation Regulation (EU) No 1025/2012 and the costs for public administration.

In terms of timeliness and reduced administrative burden, Options 2.C and 2.D. can both be considered to be superior to Option 2.B. Between Options 2.C and 2.D the criterion of coherence of procedures for requesting standards favours Option 2.C to Option 2.D.

Comparison of options against the pre-defined criteria

Options / Criteria	Option 2.B	Option 2.C	Option 2.D
Rapidity	-	+	++
Coherence	-	+	-

Costs for authorities (including national authorities and EU)	Unchanged	Decrease	Decrease

Preferred option: Option 2.C – Abolition of formal adoption of the non-binding ad-hoc safety requirements (alignment with the new European standardisation regime)

3.2. Specific policy objective 2: Better coordination and the increased effectiveness of market surveillance activities on the single EU market for goods

3.2.1. Operational policy objective: Reinforcing EU cooperation mechanisms

The impact of the different policy options is assessed and compared according to the criteria of effectiveness and efficiency of market surveillance in accordance with the resources available and the aim of ensuring seamless market surveillance for the single EU market.

In contrast to Options 3.B and 3.C, which aim to do more with the same amount of resources, Option 3.D would likely lead to higher benefits for the single EU market and for consumer safety but it would require substantial investment to build a centralised EU framework for market surveillance in the area of non-food product safety. However, even under option 3.D, only certain activities (such as system inspections, peer reviews of the quality of the functioning of market surveillance authorities in Member States, monitoring of the coordination between enforcement authorities and national RAPEX contact points), could be moved to the central EU level. By contrast, core market surveillance actions, such as on-site inspection of manufacturers, importers and distributors, testing of products, risk assessment and risk management would have to stay at national level.

Thus Option 3.C seems to be the most appropriate for fulfilling the objective of achieving a coherent and seamless framework for decentralised market surveillance for the single EU market. In terms of benefits, it is superior to Option 3.B, although potentially inferior to Option 3.D; in terms of costs it is equal to Option 3.B, but superior to Option 3.D.

Comparison of the options against the baseline scenario

Options / Issues	Option 3.B	Option 3.C	Option 3.D
Safety of consumers/users	+	++	++
Competitiveness of compliant economic operators	+	++	++
Effectiveness of market surveillance	+	++	+++
Efficiency of market surveillance	+	++	+
Potential of harmonisation of enforcement approaches on the	+	++	+++

internal market			

Comparison of the change in costs for public authorities compared to the baseline scenario

Options / Cost types	Option 3.B	Option 3.C	Option 3.D
Costs for national market surveillance authorities	Slight increase	Slight increase	Increase
Costs for the EU	Slight increase	Slight increase	High increase

Preferred option: Option 3.C – Rationalisation of the overall coordination of decentralised market surveillance on the single EU market.

3.2.2. Operational policy objective: Making EU product safety procedures more coherent

The options are assessed and compared according to the criteria of effectiveness in tracking dangerous products and the efficiency of managing the EU notification procedures for Member States and the Commission.

Option 4.A would not eliminate or mitigate any shortcomings of the existing EU notification procedures and is therefore not appropriate to achieve the pursued objective. Options 4.B and 4.C would both offer effective means to track unsafe products on the internal EU market since with both options the RAPEX notification conditions would be simplified and the objective of a better functioning of the alert procedures for dangerous non-food products would be achieved. Option 4.C appears to be superior to Option 4.B because it would have the additional advantage of streamlining various procedures, thus making their application more user-friendly.

Comparison of the change compared to the baseline scenario in relation to public authorities

Options / Criteria	Option 4.B	Option 4.C
Effectiveness in tracking down unsafe products	Increase	Increase
Costs for national market surveillance authorities	Slight decrease	Decrease
Costs for the EU	0	Decrease

Preferred option: Option 4.C – Simplification of the RAPEX procedure and streamlining of that procedure with the safeguard procedure

3.2.3. Operational policy objective: More effective EU-wide product safety action

To fulfil the objective of making action at EU-level against products presenting a risk more effective, especially in situations where individual action by Member States fails to provide a coherent response, EU measures concerning product safety need to be timely, predictable and effectively implemented by national market surveillance authorities.

Making EU product safety measures directly applicable - combined with the possibility of adopting these measures either for a period specified on a case-by-case

basis or without limitation of their validity - is the best way to achieve a timely response to safety issues that is both effective and predictable. EU product safety measures could be made directly applicable so that market surveillance authorities could take enforcement measures without any additional delays or uncertainties related to the transposition into national legislation by each individual Member State.

Comparison of options 5.B, 5.C and 5.D against pre-defined criteria

Options / Criteria	Option 5.B	Option 5.C	Option 5.D	Option 5.E
Rapidity	0	+	+	++
Predictability	0	0	+	++
Effective application	+	++	0	+++

Preferred option: Option 5.E – Combination of options 5.B, 5.C and 5.D

4. FORM OF THE LEGISLATIVE INSTRUMENTS

It is suggested that the selected options are reflected in two different legal instruments:

Problem 1 would be solved through the adoption of the Consumer Product Safety Regulation replacing the General Product Safety Directive, which would maintain the general requirement that all consumer products must be safe and, in respect of the obligations of economic operators, would be aligned with the respective provisions of Annex 1 of Decision (No) 768/2008/EC[4]. Problem 2 would be addressed by a new Regulation on market surveillance of products that would constitute the main instrument for market surveillance in the area of non-food goods. Provisions on market surveillance in the EU internal market legislation, which are currently scattered over several pieces of sector-specific EU legislation, Regulation (EC) No 765/2008 and the General Product Safety Directive, would be replaced by the provisions of this new Regulation.

A Regulation, being directly applicable in all Member States, would achieve a very high degree of harmonisation of the rules on consumer product safety and market surveillance. The Consumer Product Safety Regulation would impose obligations on economic operators that would be directly enforceable (thus creating a level playing field) and would empower market surveillance authorities to act immediately in case of unsafe consumer products or non-compliance, without the need for transposition of these rules into different national laws.

5. MONITORING AND EVALUATION

In addition to the evaluation of the legislative instruments five years after their entry into force, the monitoring of the application of EU product safety rules will be performed through the collection of relevant information from (i) the Eurobarometer surveys relating to consumer safety, (ii) the GRAS-RAPEX information system, (iii) the general information support system (ICSMS) and (iv) the Enforcement Indicators

[4] Articles R1 – R7.

monitoring activity which surveys certain parameters of market surveillance in Member States.

Eurobarometer surveys can measure how consumers and economic operators perceive the safety of products on the market. This perception is relevant to assess whether the initiative has contributed to an increased level of safety of consumer products as well as increased consumer confidence in the market and the regulatory framework.

The contribution of the future legislation to the reduction of compliance costs of economic operators and benefit gains due to fairer competition and the elimination of non-complaint market players could be assessed through ad-hoc studies performed, in particular, by the industry.

Finally, better coordination and effectiveness of market surveillance activities in the single market could be demonstrated by means of the Enforcement Indicators monitoring activity and the data notified and exchanged through the IT systems that will be further developed under the new legislation.