European Commission

COMBINED EVALUATION ROADMAP/INCEPTION IMPACT ASSESSMENT

This combined evaluation roadmap/Inception Impact Assessment aims to inform citizens and stakeholders about the Commission's work in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Citizens and stakeholders are, in particular, invited to provide views on the Commission's understanding of the current situation, problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options.

TITLE OF THE INITIATIVE	*Revision of Directive 2001/95/EC of the European Parliament and of the Council on general product safety*
LEAD DG – RESPONSIBLE UNIT – AP NUMBER	DG JUST (Unit JUST.E4 Product Safety and Rapid Alert System)
LIKELY TYPE OF INITIATIVE	*Legislative*
INDICATIVE PLANNING	*Q2 2021*
ADDITIONAL INFORMATION	*https://ec.europa.eu/info/policies/consumers_en*

This combined roadmap/Inception Impact Assessment is provided for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by this document, including its timing, are subject to change.

A. Context, Evaluation, Problem definition and Subsidiarity Check

Context

The General Product Safety Directive[1] (GPSD) provides the EU legal framework for the safety of non-food consumer products to the extent that there are no specific provisions with the same safety objective in other EU legislation, such as EU harmonised legislation for specific products. As such, it provides a "safety net" for consumers. The GPSD also establishes the EU Rapid Alert System, which enables quick exchange of information between EU/EEA Member States and the European Commission on measures taken on dangerous non-food products posing a risk to consumers and other users. This does not cover pharmaceuticals.

The Directive is nearly 20 years old and as such does not reflect any more the developments in products and markets. It does not explicitly address the fact that new technologies, in particular Artificial Intelligence (AI), can impact product safety. The Commission published a Report on safety and liability implications of AI, the Internet of Things and Robotics accompanying the White Paper on AI in February 2020. The report highlights the need to include clear provisions in the EU product safety legislation to explicitly address safety risks linked to products incorporating new technologies, such as connected products and AI. Furthermore, while the Directive applies to consumer products regardless if they are sold offline or online, e-commerce poses new challenges to the safety of consumers that need to be tackled.

In addition, the Directive's provisions on market surveillance are not fully in line with market surveillance rules for harmonised products, as recently updated through Regulation on market surveillance and compliance of products[2].

Finally, this initiative will also cover the Directive[3] concerning the safety of food-imitating products to address the existing safety issues linked to these products.

Evaluation

The revision will be based on an evaluation of the General Product Safety Directive to assess whether it is fit for purpose and fulfils its objective of ensuring safety of non-food consumer products. The evaluation will take into account the period from the Directive's adoption to today and cover all Member States and EEA countries. The evaluation will also cover the Directive on food imitating products.

The evaluation will assess the following criteria: relevance (whether the tools of the Directive correspond to current needs), effectiveness (whether the original objectives have been achieved), efficiency (the functioning of

[1] Directive 2001/95/EC

[2] Regulation (EU) 2019/1020

[3] Council Directive 87/357/EEC

the Directive from a simplification and burden reduction perspective), coherence (how the Directive works together with other legislation in the field of safety of consumer products), and the EU added value of the GPSD.

The evaluation's findings will feed into an Impact Assessment of the policy options, which would address the problems identified, including those related to food imitating products. Both the evaluation and the Impact Assessment will take into account extensive existing analysis and data collection efforts (studies, expert group meetings and workshops) as well as an underlying impact assessment study.

Finally, a report will also be prepared on the implementation of the General Product Safety Directive, as foreseen in its Article 19.

Problem the initiative aims to tackle

There are still too many dangerous products available to consumers on the EU market. In 2019, over 2200 dangerous products were notified in the EU Rapid Alert System. The actual number is even higher since not all consumer products on the EU market can be screened.

The specific problems to be tackled are the following:

1) **Product safety challenges linked to new technologies:** The GPSD dates from a period where connected devices were rare and the use of Artificial Intelligence (AI) in consumer products was very limited. This has significantly changed since. It is estimated that by 2020 the number of connected devices will reach 500 billion worldwide. These developments pose challenges to the current definition of products (to what extent does a product include software, whether it is sold with the product or downloaded later on). They also bring new risks or change the way existing risks could materialise (e.g. a product can become dangerous by not having sufficient cybersecurity protection, leaving it open to hacking, or a consumer's personal security can be endangered by third party accessing information). They also pose challenges related to the notion of placing products on the market (e.g. products can change via software updates).

2) **Product safety challenges in the online sales channels**: The increasing market share of online selling (in 2018, 69% of internet users in the EU made online purchases) creates new challenges. Member State authorities do not have sufficiently effective instruments for online market surveillance (e.g. powers to acquire product samples under covert identity). New online business models and actors (such as platforms hosting third party sellers) have become prevalent, and the product safety rules for these economic operators are unclear[4]. This affects consumer protection and creates an uneven level playing field between economic operators selling offline and online. Several online marketplaces have signed voluntary commitments to improve the safety of products online, e.g. to react within two days when a government informs about an unsafe product on the platform. As these commitments are voluntary and many economic operators do not join, safety concerns are not effectively addressed and competition between economic operators may be affected. Finally, consumers purchase products directly from operators located outside the EU more frequently, which renders it more complicated to control the safety of the product before it enters the EU market and to engage with the trader in case of safety concerns, if the trader is not represented in the EU market.

3) **Insufficient recall effectiveness:** The effectiveness of product recalls from consumers is low which means that too many dangerous products still remain in the hand of consumers. This may be because consumers are unaware that a product they own is being recalled or because the recall itself is unclear and burdensome, discouraging consumers from taking action. A third of EU consumers continue using a recalled product despite seeing a recall notice.

4) **Market surveillance rules are complex and not fully effective**: Market surveillance rules are not fully effective, which may lead to higher occurrence of dangerous products and risk of losing consumers' trust. Market surveillance and customs authorities lack appropriate instruments and resources to enforce product safety rules, including tools to impose effective sanctions. Products are difficult to trace throughout the supply chain. The legal framework on market surveillance is complex and uneven for different products. The recent adoption of Regulation on market surveillance and compliance of products covering products under EU harmonised rules, will lead to uneven obligations for the different actors based on whether they are dealing with products subject to such rules or not, the latter case being covered under the GPSD. In addition, the process for referencing voluntary standards under the GPSD is burdensome and could be simplified. There are discrepancies in the GPSD implementation across Member States (e.g. in the use of product safety test

[4] The responsibilities of online intermediaries are regulated under the E-Commerce Directive 200/31/EC The Commission also provided further guidance in its Recommendation C(2018) 117 final

reports as evidence). There is no arbitration mechanism between Member States, and the Commission lacks powers to intervene in case of divergence in the product safety risk assessment between national authorities, which causes a difference in consumer treatment inside the Single Market.

5) **Inconsistent application of product safety rules for food-imitating products:** The legal framework for food-imitating products is applied differently from country to country currently.

Basis for EU intervention (legal basis and subsidiarity check)

The legal basis for the present initiative will be Article 114, with due regard to Article 169, of the Treaty on the Functioning of the European Union TFEU[5].

The objective of this initiative 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 competent authorities in all Member States across the Single Market to ensure the protection of consumers. Because of its scale and effects, it can be better achieved at Union level. The Union may therefore adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union.

B. Objectives and Policy options

The main policy objective of the review of the GPSD is to ensure the safety of non-food consumer products on the EU market, while ensuring level playing field for businesses.

The initiative should: (1) ensure that the EU legal framework provides for general safety rules (lex generalis[6]) for all consumer products and risks, including product risks 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.

A preliminary set of general policy options to be considered have been identified as set out below but may be developed further in light of evidence collected. Coherence with other Commission initiatives, in particular with the planned proposal for a Digital Services Act[7] and the evolving approaches to Artificial Intelligence, will also have to be ensured.

Option 0 'Status quo': Baseline scenario not involving any new actions.

Options 1, 2, 3 and 4 will address the different specific objectives as outlined above.

Option 1: Improved implementation and enforcement of the existing legal framework – This option would include: (1) development of guidance on the safety of new technologies and exploring the use of European standards to address new risks ; (2) more support and promotion of the Product Safety Pledge; (3) development of guidance on product recalls; (4) increased funding for joint market surveillance activities among Member States; and (5) revision of the Food Imitating Products Directive to clarify its scope.

Option 2: Targeted revision of the Directive – This option would require a legal revision of the Directive, including: (1) making explicit how the scope of the legal framework and its definitions apply to risks posed by new technologies but without applying it to standalone software; (2) adding requirements for online marketplaces by making legally binding some provisions of the voluntary Product Safety Pledge; (3) adding requirements for enhancing the effectiveness of product recalls; (4) ensuring alignment with harmonised market surveillance rules while keeping different legal instruments and simplifying standardisation procedures; (5) integrating the provisions of the Food Imitating Products Directive into the risk assessment related provisions of the GPSD.

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT

[6] The GPSD acts as a lex generalis, being the EU legal framework for the safety of non-food consumer products to the extent that there are no specific provisions with the same safety objective in other EU legislation (lex specialis), such as EU harmonisation legislation.

[7] As announced in the Commission Work Programme for 2020, the Commission will clarify and harmonise the responsibilities of online platforms in the Digital Services Act (DSA), setting clear obligations to address illegal goods and illegal content disseminated by users of online platforms in the European single market.

Option 3: Full revision of the Directive – This option would repeal the Directive and ensure even application of its implementation through the choice of a Regulation. This option would build on all elements of Option 2 and, in addition, it would : (1) extend the definition of products to standalone software; (2) include new provisions for actors across the online supply chain, going further than integrating the elements of the Product Safety Pledge; (3) establish mandatory requirements for product recalls and registration; (4) give stronger enforcement powers to Member State authorities (for example on penalties and sanctions) and give arbitration powers to the Commission in case Member States have diverging product safety risk assessments; and (5) consider the ban of the marketing and sale of all food imitating products in the EU market.

Option 4: Integration of legal instruments – This option would provide for a new legal instrument including all elements described under option 3 and also merging the market surveillance provisions of the GPSD and Regulation on the market surveillance and compliance of products, so that one single set of rules would apply to harmonised and non -harmonised products.

Further alternative policy options could be envisaged by mixing the elements from options 1, 2, 3 and 4 taking into account the outcome of the evaluation and consultations and further analysis.

C. Preliminary Assessment of Expected Impacts

The expected impacts of all the options will be analysed in an impact assessment based on available evidence (such as data from the EU Rapid Alert System, trade statistics, market-monitoring surveys) and the findings of targeted studies carried out by an external contractor, workshops and expert group discussions.

Likely economic impacts

Addressing product safety is likely to have a positive impact on consumer trust, which will benefit the Single Market. Further efforts against unsafe products in the EU would also have a deterrent effect on rogue traders and create more level playing field with fair competition among businesses. The cost of additional obligations for economic operators should remain limited and largely offset by the above-mentioned efficiency gains. Addressing shortcomings in the regime for product safety would help prevent dangerous products being made available on the market for consumers, thus benefitting consumers' health. This will lead to lower costs for the society caused by unsafe products (e.g. public health expenditure due to treatment of injuries and accidents).

Likely social impacts

With options 2, 3 and 4, the level of product safety should gradually increase thus creating a positive impact on human health and wellbeing. Option 1 would also bring some positive effects but on a smaller scale.

Likely environmental impacts

Due to the close links between environmental and health issues, notably when dangerous chemicals are at stake, reducing the occurrence of products presenting health and safety risks in the single market is likely to ensure a higher level of protection of the environment.

Likely impacts on fundamental rights

Any legislative or non-legislative action will be in accordance with Article 38 of the Charter of Fundamental Rights of the European Union whereby the Union must ensure a high level of consumer protection

Likely impacts on simplification and/or administrative burden

Options 2, 3 and 4 will likely have benefits in terms of reducing unnecessary regulatory and administrative burdens in the sector through the alignment of market surveillance procedures for harmonised and non-harmonised products as well as the simplification of the standardisation procedure under the Directive. These burden reductions are likely to compensate for possible increased burdens brought by new provisions.

Legal certainty regarding the application of consumer product safety rules to new technologies will likely reduce the costs relating to businesses' (especially SMEs') efforts to design innovative, safe and cyber-secured products.

Since a coherent application of the provisions of the Directive across the EU is one of the main shortcomings of the GPSD, a Regulation would represent a common and directly applicable reference, likely to improve the situation and hereby reduce the administrative burden for businesses and authorities.

D. Evidence base, Data collection and Better Regulation Instruments

Impact assessment

A back-to-back evaluation and impact assessment will be carried out. The impact assessment report

accompanying any Commission proposal for revised EU legislation on general product safety will be supported by an impact assessment study, which will be carried out by an external contractor under the relevant Commission framework contract.

Evidence base and data collection

Information and data have started to be collected including for the implementation report of the GPSD under preparation and by other studies, expert group discussions and workshops.

Additional information and data are needed to assess the impacts of new possible measures. The Commission, supported by a contractor, will carry out further data collection and stakeholder consultations. Beyond the study supporting the evaluation and impact assessment, workshops and expert group meetings will also be organised. The Commission will make use of information gathered in the Consumer Safety Network and in other Commission groups, such as the Sub-Group on AI, connected products and other new challenges in product safety. Feedback on the AI product safety aspects has also been gathered via the public consultation on the White Paper on AI as well as on the accompanying Report on safety and liability implications of AI, the Internet of Things and Robotics.

Consultation strategy

The consultation strategy will involve gathering views and reliable key information from the general public and relevant stakeholders, including consumers and businesses. In particular, for the impact assessment, the consultation will collect feedback on the nature of the key problems, and the proposed options and their potential impacts. The following specific consultation activities will be carried out:

– all interested stakeholders will be able to provide feedback on this combined roadmap / inception impact assessment over a four-week period;

– a public consultation in all EU languages will be carried out. The Open Public Consultation will take place in the broader context of the New Consumer Agenda announced in the Commission Work Programme for 2020. The public consultation questionnaire will be made available on the Commission's central public consultation webpage ('Contribute to law-making') to consult the public, operators, Member States and other interested parties on the main issues and possible solutions. The Commission will publish a summary report of the public consultation shortly after the closure of the public consultation;

– targeted consultations will be carried out with the support of the consultants working on the evaluation and impact assessment study, in particular addressing Member State authorities and Europe-wide stakeholder organisations; and

– regular consultations with stakeholders, experts, consumers and other interested parties at EU level will be held.

In all these activities, particular consideration will be given to the views of SMEs likely to be affected by the possible revision (ensuring that they have access to them through the internet) and of the most representative European level organisations. The results of all the activities will be summarised in a synopsis report published on the consultation webpage.

Will an Implementation plan be established?

Yes. An implementation plan will help Member States to apply the new legislation consistently and effectively, in particular in the transition period. It will include specific information and communication activities, guidance documents and a public workshop.