

## Our position

# General Product Safety Regulation



AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €3 trillion in 2020, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

## Executive Summary

The **American Chamber of Commerce to the European Union** (AmCham EU) welcomes the European Commission's proposal to review and modernise the General Product Safety Directive (GPSD). We share the objective to constantly improve and design a simplified, coherent and effective market surveillance and consumer safety legislation. However, certain provisions within the current proposal will not amount to the desired result, as they might generate disproportionate compliance obligations while missing the root causes of the issues identified by the Commission.

AmCham EU members have identified three key categories within the proposal, which would require fine tuning and additional discussions;

- **Definitions and general concepts:** Some of the new definitions within the proposal substantially increase the scope of the proposal or simply deviate from similar definitions in other pieces of legislation. Similarly, some new concepts within the proposal seem to be based on safety standards that are yet to be developed. Unless rectified and re-evaluated, this will lead to legal uncertainty in an already very technical and compliance-heavy field.
- **New obligations:** The proposal imposes substantial new obligations on economic operators and fulfilment service providers, some of which go beyond what is currently required for harmonised products (ie higher-risk products under the New Legislative Framework). By doing so, the General Product Safety Regulation (General Product Safety Regulation) risks losing its functionality as 'safety net' and baseline legislation for **all** products. It also imposes an unnecessarily burdensome compliance framework for businesses that will result in very limited benefits for consumers.
- **Enforcement and transition period:** The proposal contains enhanced enforcement tools and a very tight implementation timeline. Some of the enforcement tools seem unpractical and the current timeline for application seems impossible to comply with considering the nature of the proposal.

## Introduction

AmCham EU has long advocated for and supported the Commission's work to assess the European legislative framework on safety. There is a need to design and improve a simple, coherent and effective market surveillance and consumer safety legislation that can guarantee safe products and accurate product information to consumers, while enhancing competitiveness for businesses. For this, all relevant stakeholders must play under clear and consistent rules and should contribute to enhanced consumer protection with measures that are proportional to risks.

The proposal for a General Product Safety Regulation (GPSR), which seeks to reform the existing legal regime under the General Product Safety Directive (GPSD), contains a number of provisions that do not fully meet this purpose and would need improvement, given that they are unclear and/or risk generating a disproportionate burden for economic operators.

The following document highlights three key categories that should be tackled in the analysis of the proposal: 'Definitions and general concepts', 'New obligations' and 'Enforcement and transition period'. Each category includes several legal arguments and concrete examples of our position and the proposals for change.

## Definitions and general concepts

### Definition of ‘safe product’ and scope

The proposal introduces a new definition of **‘safe product’**. According to article 3(2), ‘safe product means any product which, under normal or reasonably foreseeable conditions of use or misuse, including the actual duration of use, does not present any risk or only the minimum risks compatible with the product's use, considered acceptable and consistent with a high level of protection of health and safety of consumers’.

While it is appropriate to require manufacturers to provide safety warnings and instructions to guide usage and prevent accidents resulting from misuse, misuse is primarily driven by **user behaviour, which manufacturers cannot control**. Manufacturers can, and should, only be held accountable for normal or reasonably foreseeable use of their products as intended, as under the existing GPSD, not its misuse nor use of products by consumers that were not intended for consumer use. Virtually all products can cause harm if misused, but this is not a valid reason to classify a product as ‘dangerous’, as the safety risk is attributable to the user, not to a lack of safety inherent to the product. The definition of ‘serious risk’ under article 3(5) more correctly refers to ‘the normal and foreseeable use of the product’, not to ‘misuse’. To avoid confusion, mistaken expectations and potential excessive liability for manufacturers, the term ‘misuse’ should be removed from the proposal, as well as the reference to ‘use by consumers even if not intended for them’.

Similarly, while the manufacturer can provide warnings and recommendations to the user about extended use, he cannot generally control the duration of use by the end users. This cannot be a basis for considering a product to be ‘dangerous’ within the meaning of the Regulation. Thus, the words ‘including the actual duration of use’ should be removed from the definition of ‘safe product’.

In the previous initiative to revise the GPSD, which was subsequently withdrawn, the legislators proposed to modify the definition of ‘safe product’ as follows: ‘means any **authentic** product which **is compliant with Union harmonisation legislation relating to health and safety. In the absence of such legislation it means any product which**, under normal or reasonably foreseeable conditions of use of the product concerned, including the duration of the use and, where applicable, its putting into service, installation and, maintenance, **training and supervision** requirements, does not present any risk or only the minimum risks compatible with the product's use, considered acceptable and consistent with a high level of protection of health and safety of persons;’ This would then imply that a presumption of safety is satisfied when:

- A product is authentic;
- A product is compliant with EU legislation.

In addition, it would be helpful to add a new definition of ‘accident’ to art. 3. Namely: ‘Accident means a user’s experience with a product arising during the intended or reasonably foreseeable use of the product, for which a possibility of a serious risk may exist’. It is necessary to tie a definition of ‘accidents’ to incidents where exists the possibility of a ‘serious risk’.

Finally, given the existence of horizontal rules on digital contracts and digital services as well as vertical regulation, standalone software should be excluded from the scope of the proposal and not be defined as a product.

### Combination with other products

Article 7(1)(b) and (c) makes it explicit that the safety assessment of products that are meant to be used in combination with other products (eg, detergent for dishwashers or laundry washing machines) needs to consider the interconnection among products and their effect on the product to be assessed. A manufacturer

can only execute his risk assessment toward other third-party products to the extent that he is aware of their nature and composition. The text should clarify that this co-assessment needs to be limited to those facts that are obvious and straightforward (eg, not design a highly flammable product to be used together with blow dryer).

## Cybersecurity and AI risks

When assessing a product's safety, authorities must consider:

- If a product has 'appropriate cybersecurity features necessary to protect the product'; and
- A product's 'evolving, learning, or predictive functionalities'.

However, **there are not yet agreed standards on what 'appropriate cybersecurity' entails and how distributors can check or confirm this feature. The same is true relative to AI embedded in products.**

## Targeting

Following case law (C-585/08 - Pammer and Hotel Alpenhof<sup>1</sup>), the concept of targeting is currently too broad to ensure legal certainty. The European Commission and the co-legislators should aim to clarify this concept. In any case, **the GPSR might not be the suitable framework for this purpose** (frameworks on applicable law/jurisdiction have been a topic of discussion for many years and the lack of clarity in this regard is generally acknowledged by experts).

## Presumption of conformity

**AmCham EU appreciates that the Commission's proposal makes a clear reference to harmonised standards as a way to demonstrate presumption of conformity with the general safety requirement of the GPSR** (as it was previously the case with the GPSD).

The possibility to develop standards in close collaboration between economic operators and national standardisation bodies greatly enhances the effectiveness of the GPSD/GPSR. The legal certainty provided by the presumption of conformity with the essential requirements of the GPSD/GPSR helps companies develop and market innovative products in a confident manner. The system is flexible enough to ensure that standards can be developed, revised or updated whenever necessary. Since the application of harmonised or other standards remains voluntary, it will not stifle innovation, as it gives manufacturers the freedom and flexibility to always apply other technical specifications to meet the requirements.

## New obligations

### Obligations of manufacturers

While there is value in most of the provisions included in the Commission's proposal, some of the changes proposed to the existing regulatory framework appear disproportionate and complex to implement for economic operators, in particular:

- **Manufacturers to keep actors in the supply chain informed of safety issues** (Article 8[3]) – Consumer feedback is essential, but the obligation to set up appropriate communication channels for consumer

<sup>1</sup> <https://curia.europa.eu/juris/liste.jsf?num=C-585/08&language=en>

complaints may be **unnecessarily burdensome in the eventuality that the company already has set up efficient customer service.**

- Technical documentation to be drawn up by manufacturer (Article 8[4]) – **Specific sectorial legislations already exist for products meant to be used in a situation that may cause harm to the user** (eg, Regulation 2016/425 on Personal Protective Equipment). In addition, Directive 85/374 on liability for defective products already covers damages to users caused by defective products. Therefore, the new requirement for manufacturers to draw up technical documentation for all its products appears disproportionate and unnecessary for most products. The approach taken by the Commission in its article 17 on traceability could be replicated to ensure that only products which are susceptible to bear a serious risk to the health and safety of consumers - based on accidents registered in the Safety Business Gateway, the Safety Gate statistics and the results of the joint activities on product safety - should be subject to technical documentation.
- Identification of products and manufacturer: Articles 8(6) and 8(7) contain requirements for the identification of the product as well as for the manufacturer's identification. Whenever possible, this information must be indicated on the product itself. Increasing regulatory requirements on mandatory consumer information has become a technical challenge for several companies in our membership. **Space on labels is limited, and in some cases, consumers will simply cut labels off as soon as the product has been purchased.** Digitalisation is a relevant and sustainable way to ensure information is up to date and understandable. Digital tools can engage with and inform consumers in an innovative, effective and efficient way, thus creating a culture of better-informed EU citizens, which is key for both the green and digital transformations. In addition, digital consumer information can support sustainability objectives by reducing packaging and packaging waste. We therefore recommend that mandatory consumer information can be either displayed on a physical label or electronically. Finally, article 5(1)a of the current GPSD provides that the identity and details of the producer and the product reference could be mentioned either on the product itself or on its packaging. This proposal is likely to create uncertainties and additional confusion as the possibility of adding extra information on the product can be subject to interpretation. We are not aware of any concerns raised about this information being provided on the packaging of some products. This **aspect of the current Directive should be left untouched.**

## Alerting consumers

Article 8(10) establishes that ‘manufacturers who consider or have reason to believe, on the basis of the information in their possession, that a product which they have placed on the market is not safe, shall **immediately take the corrective measures** necessary to bring the product into conformity, including a withdrawal or recall, as appropriate.’ Furthermore, according to article 8(11), ‘**manufacturers shall, via the Safety Business Gateway [...], immediately alert consumers of the risk to their health and safety** presented by a product they manufacture **and immediately inform the market surveillance authorities of the Member States** in which the product has been made available to that effect, giving details, in particular, of the risk to health and safety of consumers and of any corrective measure already taken.’ Article 8(3) adds that ‘Manufacturers shall also keep distributors, importers and online marketplaces in the concerned supply chain informed of any safety issue that they have identified.’

This contrasts with the provision under article 5(3) of the GPSD currently in force, which only imposes an obligation of immediate information to the authorities, not consumers. Moreover, article 5(3) of the GPSD is to be read in conjunction with Annex I, which provides for the adoption of a standard notification form to be submitted to the authorities after conducting a risk assessment in accordance with the risk assessment guidelines described in Part IV, 5 of COM Decision 2010/15 (RAPEX guidelines).

Considering the well-established practice required from manufacturers on conducting risk-assessments and the level of due diligence expected for the timing of risk notification to authorities and impacted consumers, **the**

**adverb ‘immediately’ should be replaced by ‘swiftly’ and the obligation to simultaneously alert consumers and authorities should be suppressed**, given its counterproductivity.

## Responsible person

AmCham EU members are reputable companies commercialising safe products. Consequently, the new requirement that the responsible person (RSP) shall periodically carry out sample testing of randomly chosen products made available on the market appears disproportionate and unnecessary for most products. In addition, there is also confusion around the terms ‘periodically and randomly’, which are not clearly defined and expose the implementation of this provision to multiple and contradictory interpretations. This said, we do support the implementation of such mechanism for products that are susceptible to bear a serious risk to the health and safety of consumers, as set forth in the second part of Article 15(2).

The GPSR expands the application of the responsible person from that outlined in article 4 of the 2019 Market Surveillance Regulation (MSR) to all products and adds responsibilities such as sample testing. As of July 2021 the MSR Article 4 applies to higher-risk product categories. The effects of the new rules should be understood before expanding the system to all products. The responsible person alone cannot be the solution to the product safety challenges. A general RSP requirement for all products, including those typically considered as very low risk (eg, books) will be too costly and present very few benefits, especially when balancing the perspectives of enforcement capacity, the resources available to smaller economic actors, the need for high product safety standards and the evaluated risk. **This obligation should be applied to high-risk products only.** The GPSR does not clarify on the basis of which standards or legislation should the sample testing take place, nor does it provide clarity on how much and what tests should be carried out. **The sample testing requirement should also be removed, as it would be very difficult to encompass all testing requirements in the GPSR.**

This provision will likely cause a disproportionate impact in its current form. There is no clear impact assessment to suggest whether this solution will ultimately solve the current perceived challenges.

This requirement also has significant implications for the EU, since it will make fully compliant products manufactured by a party outside the EU unavailable to EU consumers, whenever it is not feasible for that manufacturer to appoint a responsible person within the EU. This could again be mitigated by limiting the proposal to specific high-risk categories or product types, where a legitimate interest to protect customer safety is readily apparent.

There is also a high risk that other countries would see the responsible person provision as protectionist in nature and may explore reciprocal trade sanctions (copycat legislation) on EU imports, as we have seen with Turkey. **The high risk of copycat legislation from other countries and trade partners should be fully assessed in terms of the impact on European businesses of all sizes.**

Finally, as article 15(3) stresses, ‘the electronic address, of the economic operator (...) shall be indicated on the product or on its packaging, the parcel or an accompanying document’, the legislator should provide economic operators with the possibility to indicate a web address instead. This is less likely to become obsolete than an electronic address and the contact details of the company can easily be found (and updated) there.

## Displaying compliance information

The GPSR introduces the obligation to display:

- Manufacturer’s name and contact details.
- If the manufacturer is not based in the EU, then the name and contact details of the EU responsible person for compliance (RSP).
- The product’s batch/serial number.
- All safety warnings/information in the consumer’s language.

The new requirements should be channel-neutral, avoiding the imposition of higher costs on certain channels and ensuring these costs will not become barriers to innovation, preventing new market entrants or smaller players from launching new initiatives. A risk-based approach should be used to establish a level playing field in terms of safety for EU and non-EU based economic operators. E-labelling solutions could enable the flow of the data envisaged by the article. The European Parliament and the Council should consider narrowing the scope of the provisions, especially concerning batch/serial number. Building the necessary databases for such level of information will take significant time and resources. Indicating the serial and batch number for every product seems unnecessarily burdensome and would require listing every single serial and batch number in separate listings, which is not the case for offline sales.

## Obligations of economic operators in case of accidents

Article 19(1) introduces a mandatory obligation to notify the authorities if there is ‘an accident caused by a product’ within two working days ‘from the moment it knows about the accident’. This is a significant requirement and the timeframe for notifying the authorities appears highly challenging, especially when the decision-making and action-taking mechanisms of global companies are considered. The definition of ‘accident’ also lacks clarification. Economic operators can quickly get overloaded with information on presumed accidents, many of which will be irrelevant. The definition of ‘accident’ should be clarified so that economic operators are only required to inform the manufacturer in the event of verified accident reports. Additionally, **the time limit should be extended to at least 5 working days**, provided that the accident is not life-threatening.

## 2/5 days product removal

Product removal obligations should be aligned with the existing obligations under the Product Safety Pledge<sup>2</sup>; as laid out in article 20 of GPSR. The GPSR introduces a more stringent obligation for product removal. In practice, this will only be feasible if the obligation and removal requests are supported by clear and unambiguous information to help identify the products. The quality of the notice is crucial for effective and timely removal.<sup>3</sup> Moreover, the two- and five-days timeframe might be especially difficult for smaller online marketplaces. Therefore, the timeframe should only start once the online marketplace has processed the notice.

Additionally, references to ‘specific illegal content referring to a dangerous product’ referenced in article 20(2) and 20(3) require clearer definition, so online marketplaces understand specifically what is considered ‘illegal content’ that requires removal.

## Recalls

The Commission’s proposal should improve the framework for product recalls. Contacting affected consumers directly in the case of recalls whenever possible is crucial – regardless on whether the product has been sold in a brick-and-mortar store or online.

<sup>2</sup> [https://ec.europa.eu/info/files/product-safety-pledge\\_en](https://ec.europa.eu/info/files/product-safety-pledge_en)

<sup>3</sup> <https://ecipe.org/publications/combating-unsafe-products/>



## Enforcement and transition period

### Authority data scraping

The GPSR introduces the requirement for economic operators to consent to data scraping by authorities and to allow authorities to access the economic operator interface so that 'online tools' can be deployed to detect compliance issues. This is very concerning, as any access to such infrastructure would most likely expose business' sensitive information and may impact the integrity of the systems and the user experience. **Co-legislators should consider alternative approaches to this proposal, encouraging enhanced cooperation with market surveillance authorities and the development of mechanisms and communication channels building on the current EU Product Safety Pledge.**

### Penalties

The GPSR proposal requires country penalty law to have a maximum fine that is at least 4% of the company's Member State (or if multiple Member States, then EU) turnover. This will lead to fragmentation and increased compliance costs. The penalties mechanism will only be effective if the authorities are able to enforce the rules. However, there is an important opportunity to move beyond penalties and focus on building prevention capacity with market surveillance authorities.

### Transition of 6 months

The timeline foreseen in the proposal is unrealistic. There is an important educational aspect, and economic operators of all sizes will require the time to understand the rules and implement the necessary measures. Authorities will require time to prepare and ensure the resources are deployed. **At least 36 months should be allowed for businesses to plan, budget and develop the solutions needed.**

## Conclusions

AmCham EU welcomes the European Commission's initiative, but calls on the co-legislators to focus on practical solutions that will benefit consumers and law-abiding businesses while tackling unsafe products and rogue actors. Product safety is a complex environment and it is important to maintain legal certainty through a comprehensive framework based on a risk-based approach. The actual risk that certain product categories constitute is better mitigated through harmonised legislation, dealing exclusively with said product categories and therefore better suited to target the cause of the risk itself, as opposed to introducing a blanket approach to all products, irrespective of their risk level.