AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

# Our position

# Product Liability Directive (PLD)



**American Chamber of Commerce to the European Union**
*Speaking for American business in Europe*

Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium • **T** +32 2 513 68 92
info@amchameu.eu • amchameu.eu • European Transparency Register: 5265780509-97

# Executive summary

In September 2022, the European Commission published a proposal to review the Directive on liability for defective products. The proposal aims to update the law for the digital age, the circular economy and the globalisation of value chains. However, the proposed broadened definitions and new concepts within the proposal are concerning, as they omit to consider existing liability rules – under tort or contract law – within domestic jurisdictions of Member States. The proposal, as it stands, risks introducing strict liability as a standard for all claims and alleged future challenges. The following recommendations provide guidance on how to best tackle identified challenges.

**Summary of comments and recommendations:**

| Topic | Recommendations |
|---|---|
| **Scope and definitions** | The definitions within the PLD should be clarified and aligned with existing product safety legislation, and the forthcoming General Product Safety Regulation, in order to provide legal certainty for all actors. |
| **Burden of proof** | The shift in the burden of proof described in the text is not technology-neutral and singles out AI systems and other 'complex' products, presuming their defectiveness. Terms like 'complexity' and 'opacity' need to be clearly defined. It is also important to clarify what the claimant must do and prove before alleviating the burden of proof. |
| **Protecting sensitive information subject to disclosure orders** | The drafting of article 8 should be tightened to better protect trade secrets in product liability proceedings. |
| **Thresholds** | Thresholds should be updated but not eliminated within the PLD. |
| **Liability chain and economic operators** | The Authorised Representative concept must be made meaningful and verifiable. |

# Introduction

The American Chamber of Commerce to the European Union (AmCham EU) welcomes the opportunity to provide feedback and recommendations on the proposal to review the Directive on liability for defective products. The PLD was adopted in 1985 and has since its introduction created a comprehensive harmonised system of no-fault liability for defective products. In its nearly 40 years of existence, the PLD has provided an effective compensation mechanism for those who suffer damages caused by defective products in the EU. The Commission has, however, expressed its intention to update the PLD to reflect the digital age, the circular economy and the globalisation of value chains.

The Commission proposal expands the scope of the Directive in several dimensions, extending the definition of a product and the types of harms that can be compensated as well as the scope of business entities with responsibilities or liabilities. It also changes the balance between the claimant and the economic operator. However, the way and extent in which these changes have been introduced lack predictability and distort the existing balanced approach that businesses and consumers have known and relied on since the introduction of the PLD. This will ultimately result in legal uncertainty and inconsistencies when implemented across EU Member States, which will hinder innovation of emerging technologies and other R&D-intensive industries.

AmCham EU members have identified five main areas with room for improvement. Under each area, we will provide an analysis, followed by recommendations on how to best address existing concerns in order to achieve a balanced result that protects consumers and is viable for businesses of all sizes.

1. **Scope and definitions**
2. **Burden of proof**
3. **Protecting sensitive information subject to disclosure orders**
4. **Thresholds**
5. **Liability chain and economic operators**

# Scope and definitions

The extended scope and new definitions within the proposal are unnecessarily broad and lack legal certainty. Given that the objective of the PLD is compensation for damage caused by defectiveness, there should be a clearer link to use cases/scenarios of defective software and AI (ie when software/AI is used).

## Definition of a product

The definition of a 'product' has been broadened from tangible goods to software – both embedded and standalone – and digital services necessary for the functioning of the product. The simplicity of the existing PLD ensures that rules apply to all physical products.

Strict liability should not be expanded to cover standalone software, as it does not represent the same type of risk to consumers as physical products. A defect in a physical product can lead to physical damage to consumers or property. This is not the case for standalone software, which can never be completely free of so-called 'bugs', but in which said 'bugs' can be fixed through updates, and cannot physically act upon persons or property. It also remains to be clarified whether any updates of standalone software would be considered as resetting the time-limitation period that the PLD provides for, as this risks excluding software developers from this important liability threshold.

It is generally recognised that the current definition of 'product' includes embedded software, which also encompasses Artificial Intelligence (AI) technology within that software. As with other products that operate in an automated fashion (eg microwave ovens, dryers), the allocation of liability is usually clear. Neither opacity nor complexity are specific to AI; they also apply to many other products. AI is always linked to the software as part of a product and simply relates to techniques that can be used to develop, offer and improve products and services. Standalone AI does not exist, as it is always linked to the software. Even in the case of an AI system that operates with a high degree of autonomy, there are always human actors involved – for example the developer, deployer or user – who could be held liable in case of defects that result in harm. Further, beyond EU level provisions, national tort and

contract laws apply. In the 1985 PLD, there seems to be no significant uncertainties, gaps or difficulties as to how the legislation can be applied to damages caused by software and AI. Jurisdiction has been clear for damages caused by products, including AI enabled products.

In addition, the European Commission's proposal also expands the scope of products covered to all AI systems, irrespective of the degree of risk classification. Given that the objective of the revised PLD is compensation for damage caused by a lack of safety, there should be a clearer link to safety-specific uses/scenarios of software and AI (ie when software/AI is used). Changes to the EU's product liability rules that expressly target AI-powered products and services without distinction of the degree of risk could create disincentives and deter producers from offering new AI-powered products and services that may be safer and more effective than their non-AI counterparts.

While introducing very limited benefits to consumers, these changes in the definition of a product represent a significant possibility of discouraging software developers from innovating as they would potentially be covered by a strict liability regime.

### Recommendation

The PLD is an ex-post instrument, intended to be used when a defective product has caused harm. It therefore does not seem appropriate to expand the definition of 'product' within the PLD beyond what is considered a 'product' under *ex-ante* product safety legislation. Instead, the PLD should apply to products as defined in existing EU product legislation such as the General Product Safety Regulation and vertical legislation under the New Legislative Framework. The fundamental difference in characteristics and risk to safety between physical products (containing embedded software or not) and standalone software has already been accepted in previous revisions of EU product safety laws, including the General Product Safety Regulations. Therefore, the proposal should avoid including stand-alone software in the scope of the PLD and subjecting it to a strict liability regime. At the very least, clarification is needed for many of the definitions under **article 4** to ensure that the new PLD is implementable and that risks are insurable.

## Open-source software and related services

Open-source software and software code should be excluded from the scope, as they are crucial for software innovation in the Single Market, especially in AI research and development. Many services and software systems, including AI systems, are the result of numerous entities building on top of other efforts, leveraging open-source libraries, tools and frameworks created by thousands of contributors – often in volunteer capacities.

The proposal also brings 'related services' in its scope, despite the widely understood and confirmed notion under Recital 15 that 'this Directive should not apply to services'. The current definition of related service is overly broad and could be understood to apply to almost all digital services that interact with the products. Further, the lack of a definition of software creates an additional uncertainty as to what extent the PLD would apply to digital services.

### Recommendation

For Europe not to discourage the development of open-source software, the exclusion for open-source software currently found in Recital 13 should be added directly to the binding articles of the

text. We would also welcome further clarity on the definition of software so that digital services such as SaaS solutions, hosting and online services, online platforms and search engines (as defined by the Digital Services Act) will not be considered as software within the scope of the revised PLD. The Digital Services Act and General Data Protection Regulation, among other laws, already implement the proper framework to address potential harm that may be caused by these services.

## Definition of damage

The definition of 'damage' has also been broadened to include the material losses resulting from medically recognised harm to psychological health (article 4[6a]) and data loss (article 4[6c]).

There is currently no clear definition of what 'medically recognized harm to psychological health' entails. While common definitions would refer to emotional health, wellbeing and behavioural change, these notions are difficult to quantify and will result in legal uncertainty for manufacturers and the industry at large. Unlike in cases of death or personal injury, whether a product is safe with regard to psychological health will vary greatly form one consumer to another based on their personal situation. This will also lead to difficulties to ascertain causality, as it is plausible that harm to psychological health is the result of combined myriads factors. This lack of clear definitions also risks resulting in the notion of damage being interpreted and transposed differently throughout the EU, ultimately resulting in consumers not receiving the same level of protection depending on the jurisdiction they find themselves in. These uncertainties will also make it extremely complex, if not impossible, to insure against this strict liability. A result of which will be increased product prices for consumers.

The European Commission's proposal also expands the notion of 'damage' to the 'loss or corruption of data'. While this inclusion should first and foremost be linked to the product's safety, clarifying the threshold of data loss/corruption that makes the loss material is also essential. Without clear definitions and thresholds, this extension of the scope could lead to waves of compensation claims against economic operators on illegitimate grounds. The General Data Protection Regulation already provides consumers with options for redress for many types of non-material damages.

### Recommendation

Strict liability is only appropriate in the cases of personal injury and damage to property that have direct and severe consequences for individuals. The existing definition of damages in the existing PLD has been working effectively, and there is no evidence that the definition is incomplete. This extension of strict liability does therefore not seem appropriate, especially when considering the challenges caused by remoteness of loss, quantification of damages and causation. As serious claims could be expected under additional categories of harm, it first needs to be defined how these (additional) damages could be quantified before including them in the legislation.

## Definition of defectiveness

The proposal further also expands the criteria to assess the **defectiveness of products**. The PLD states that 'a product shall be considered defective when it does not provide the safety which the public at large is entitled to expect'. It is unclear, however, how the defectiveness characteristics will apply to intangible products, in particular to software and AI systems, and to the loss or corruption of data. Defectiveness standards must be objective and clear to avoid overreaching into quality considerations.

It should be clarified how this factor weighs for/against liability of the developer when changes happen outside of the developer's control. In addition, a product should not be considered defective as a result of issues related to safety-relevant cybersecurity requirements. Malicious actors will continuously test the security and intend to find new loopholes to access programmes and products. The idea that a producer can be liable for an unknown vulnerability exploited by an evolving threat puts undue burden on those trying to stop malicious actors.

### Recommendation

The notion of defectiveness should be aligned with relevant existing and upcoming EU legislation. The current expansion of this notion within the proposal, coupled with the expanded scope and new definitions will make nearly all products potentially defective throughout their lifespan.

## Limitation periods

The limitation period of 10 years within the proposal does not grasp the realities of software development or AI applications. Products can have widely varying lifecycles, so requiring support for long periods will be very challenging for manufacturers. Under the revised PLD, software developers would have to provide updates for a period of 10 years which does not reflect the duration of software programs. In particular, the PLD would increase the period during which a producer must provide security updates to prevent data loss or corruption under the Sales of Goods Directive, from two to ten years from the placing in market. There are several difficulties associated with identifying security vulnerabilities as explained in the paragraph above.

### Recommendation

The liability limitation period for products should be aligned with existing EU legislation (Digital Content Directive, Sales of Good Directive, Ecodesign requirements, and the upcoming Cybersecurity Resilience Ac) in order to reflect the realities of software development and keep consistencies between these legislations.

## The burden of proof

The alleviation of the burden of proof within the proposal could lead to unintended consequences, including its *de facto* reversal.

While the proposal does not intend to reverse the burden of proof, the presumption of defectiveness and causality effectively amounts to a reversal of the burden of proof for products that are 'particularly technically or scientifically complex'. Many AI systems have a certain degree of complexity and opacity, while other types of particularly complex products are already subject to safeguards as they can only be placed on the market when having been approved for sales by regulatory authorities. The terms 'complexity' and 'opacity' are currently not legally defined and are overly vague. Without clearly defined thresholds, the presumption of defectiveness and causality would introduce far reaching evidence disclosure obligations for a wide variety of products where the defendant will have to prove that the product did not cause the harm. This places a disproportionate burden on companies that strict liability regimes and the existing PLD rightfully avoid. Further, in the context of emerging technologies and other complex products, there is a risk that companies simply do not have access to the required data that would absolve them from liability. Finally, as opposed to common law

jurisdictions, the introduction of broad new disclosure obligations will likely represent significant challenges, including procedural, for many legal systems in continental Europe.

The current wording broadens the scope of liability considerably and unintendedly carries the risk of resulting in excessive claims and potentially abusive litigation. This risk, coupled with the inclusion of the PLD under the scope of the Representative Actions Directive (Directive [EU] 2020/1828) could force companies to protect themselves by focusing on insurance premiums and defensive strategies to the detriment of innovation.

### Recommendation

The text of the Directive must be technology neutral and terms like 'complexity' and 'opacity' need to be clearly defined. It is also important to clarify what the claimant must do and prove before alleviating the burden of proof. This is essential to overcome excessive burden and potential non-legitimate claims.

## Protecting sensitive information subject to disclosure orders

The proposal does not adequately protect trade secrets in view of the new disclosure obligations.

Article 8 (2-4) contains certain protections for confidential information and trade secrets from disclosure in liability proceedings by injured claimants. Paragraphs 2 and 3 in particular are rather vague and limit disclosure to what is 'necessary and proportionate', which must consider 'the legitimate interests of all parties'. Paragraph 4 provides protective measures when confidential information/trade secrets are referred to in legal proceedings, which can either be invoked by the courts, or upon a reasoned request by a party. However, it does not refer explicitly to evidence that might have been shared with the plaintiff but, for whatever reason, has not been referred to in these proceedings.

The practical application of the provisions under article 8 during the course of proceedings is subject to changes in different national courts and under different laws. This creates uncertainty as notionally high-level concepts such as proportionality and legitimate interest, as well as courts willingness to apply protective measures on their own initiative, are not well harmonised across Member States.

### Recommendation

The drafting of the article should be tightened to better protect trade secrets in product liability proceedings. For example, the article could be clarified to state that, when determining whether to order the defendant to disclose information which is protectable as confidential information and/or trade secrets within the meaning of article 2(1) of Directive (EU) 2016/943, national courts must consider, *inter alia*, that the disclosure of such information is 'relevant and necessary' for the claimant to demonstrate, in the course of the legal proceedings, that the product is defective. This would ensure higher standards and more detailed consideration for disclosure than merely whether it is 'proportionate'. Disclosure should also be restricted to information required to assess whether the product was defective, who is liable or the causal link.

# Thresholds

The removal of the thresholds within the PLD could upset the careful balance of the current Directive.

The proposal removes both the €500 minimum value threshold and the possibility for Member States to impose a maximum limit of compensation (minimum €70 million). It also extends the longstop period from 10 to 15 years.

The combination of the removal of minimum (€500) and maximum (€70 million) thresholds with the new presumptions, types of damage and types of products (and therefore defects in these further product types) upsets the careful balance of the current Directive. The initial thresholds have changed overtime through inflation (the current €500 threshold for claims began at 500 ECU in 1985). This overall perspective needs to be addressed when weighing the individual extensions being proposed. The reasoning for having such thresholds remains true today; a minimum threshold prevents frivolous claims and maintains the back-stop nature of the regime, while an upper maximum allows for insurable risks. For SMEs and start-ups in particular, persuading retailers to carry their products will become increasingly difficult. These figures should be subject to maximum harmonisation to address the issues that the European Commission identifies with the current divergence across member states.

### Recommendation

Minimum and maximum thresholds should be maintained within the revised PLD. In case substantial evidence has been collected relating to these thresholds impeding legal remedy for consumers, they should be amended accordingly without being removed.

# Liability chain and economic operators

The hierarchy of liability among economic operators must be proportionate to their role in the chain.

The Directive appropriately emphasises that the Producers are the primary parties who should be considered liable in the case of damages caused by defective products they manufactured. Producers have the power over the manufacturing process of a product. The producer could appear in many ways under the current Directive and the definition should not necessarily be narrowed down.

Business entities which have no power over the manufacturing process (eg online marketplaces and retailers) should not be considered as having liability in cases of damage caused by defective products unless no other party in the EU can be identified within one month. The reference to the Digital Services Act liability exemption ensures coherence and consistency with product safety regulations. This should also be the case for fulfilment service providers, who should not be placed in a worse position than retailers. The proposal should remove article 7(3) and instead refer to article 7(5) for fulfilment service providers, as for retailers and as the marketplace provision in article 7(6) does.

The proposal includes new reference to the Authorised Representative concept (as one of the Responsible Persons [RSP] from the Market Surveillance Regulation and the nearly completed GPSR) as another potentially liable operator for defective products where there is no EU-based manufacturer

or importer. The Authorized Representative concept, however, must be made meaningful and verifiable (to support inclusion in this framework and the risks they take on must be insurable).

The first step to enhancing the Authorised Representative concept is to make them 'reliable' by professionalising the role of an Authorised Representative. We recommend establishing a minimum set of criteria for Authorised Representatives, accredited as the RSP, as an entity that is both legitimate (ie remove the ability to assign 'anyone' to act as an Authorised Representative) and possesses sufficient understanding of product compliance requirements to be responsible and potentially liable. The Authorised Representatives play a meaningful role in minimising the risk of having unsafe products sold to EU customers while assuming liability for these products in the event they are defective. The European Commission already has mechanisms for accrediting Notified Bodies, and such a mechanism could be used as a reference to create an accreditation program for Authorised Representatives. Similar for notified bodies, it is essential that the Authorised Representatives have access to personnel with sufficient and relevant knowledge and experience to be able to collect more compliance information, such as test reports and safety signals. They should also possess the necessary skills and expertise to verify those documents and ensure that they are not fraudulent. If documents are found to be fraudulent, the Authorised Representatives should be able to provide information to market surveillance authorities to enable investigation of bad actors.

The next step is to also enable verification of Authorised Representatives so that regulators, consumers, fulfilment service providers and marketplaces can confirm their status. A 'Registration Database' for Authorised Representatives (where there is no EU based manufacturer or importer) should be created for this purpose. This will enable interested parties to view all relevant and necessary information efficiently and at scale. Such a publicly accessible mechanism helps to incentivise a high standard for Authorised Representatives. At present, a rogue actor wishing to appoint a phantom Authorised Representatives can easily create fake contact details, which presents challenges to businesses or market surveillance authorities to confirm the presence of a valid Authorised Representatives. Having a centralised database would mean that this system of verification would be much more robust and also give the option of automating this verification.

### Recommendation

The Authorised Representative concept must be made meaningful and verifiable (to support inclusion in this framework and the risks they take on must be insurable). Product legislation also needs a mechanism to account for changing Authorised Representatives over the lifetime of the product and insurance for retailers, fulfilment service providers and marketplaces that are within the waterfall of potentially liable entities.

## Conclusion

AmCham EU members call on the co-legislators to consider the broader regulatory landscape, including national laws, harmonised standards and EU level safeguards that cover or will soon cover software and AI-systems, such as the AI Act and horizontal rules in the GPSR and Cyber Resilience Act. These EU laws provide *ex ante* safeguards that lower potential risks related to products and services which are placed on the market. Due to this lowered risk, additional strict liability rules at this time – before a body of evidence has had time to build up as to its necessity and the effectiveness of *ex ante* measures – risks resulting in overregulation and unintended consequences for law abiding businesses.

Strict liability is a 'hard' liability system that should remain reserved for situations that are especially hazardous and bear a risk of severe damage to persons or property. It should not be used as a blanket solution to solve perceived future challenges.

The PLD has been working effectively for nearly 40 years thanks to its simplicity and technology neutral language. We therefore respectfully urge policymakers to take a cautious approach when revising this Directive.