AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Feedback on Product Liability Directive proposal

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Executive summary

In September 2022, the European Commission published a proposal to review the Directive on liability for defective products (Product Liability Directive [PLD]). The proposal aims to tackle challenges linked to the digital age, the circular economy and the globalisation of value chains. However, the broadened definitions and new concepts within the proposal are concerning and we are worried that the proposal omits to consider existing liability rules, being under tort or contract law, within domestic jurisdictions of Member States and risks introducing strict liability as a standard for all claims and alleged future challenges.

AmCham EU members are therefore grateful for the opportunity to bring the following concerns to the attention of the Commission:

1. Unnecessarily broad scope and definitions
2. Unintended consequences of the 'alleviation' of the burden of proof
3. Removal of the thresholds
4. Adequately protecting sensitive information subject to disclosure orders
5. Extending the Economic Operator to include fulfilment service providers and marketplaces

Introduction

The American Chamber of Commerce to the European Union (AmCham EU) welcomes the opportunity to provide feedback to the Commission's proposal to review the Product Liability Directive. 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 damage caused by defective products in the EU, and the Commission has expressed its intention to tackle the alleged challenges arising from the digital age, the circular economy and the globalisation of value chains.

The 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.

1. Unnecessarily broad scope and definitions

Product definition

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. 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, rather, 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, 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.

Strict liability should not be expanded to cover standalone software. Standalone software, inherently, does not represent the same level of risk to consumers as physical products, for which strict liability is justified. A defect in a physical product can lead to physical damage to consumers or property, and it cannot be repaired at a distance. This is not the case for standalone software, which can never be completely free of 'bugs', but said 'bugs' can be fixed through updates, and cannot physically act upon persons or property. It is also to be clarified whether any updates of standalone software would be considered as resetting the time-limitation period that the PLD provides for. Considering this risk excluding software developers from this important liability threshold. This 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 revision of the General Product Safety Directive. Therefore, the proposal should avoid including stand-alone software in the scope of the PLD and subjecting it to a strict liability regime.

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.

Open-source software

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. This exclusion should be added directly into the article of the text in addition of the recital 13. 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, while it is widely understood and confirmed by 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 extend the PLD would apply to digital services.

Definition of damage

The definition of 'damage' has also been broadened to include the material losses resulting from personal injury, including medically recognised harm to psychological health. 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. 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.

The European Commission's proposal is also expanding 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.

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

Finally, the European Commission's proposal 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 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. Cybersecurity is an ongoing struggle against existing and evolving threats and cybersecurity professionals constantly strive to stop malicious actors. 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.

2. Unintended consequences of the 'alleviation' of the burden of proof

While the proposal does not intend to reverse the burden of proof, the presumption of defectiveness and causality effectively amount 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 risk to be 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 a negative by demonstrating that the product did not cause the relevant harm. This thus 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. Clarifying what the claimant must do and prove before alleviating the burden of proof is essential to overcome excessive burden and potential non legitimate claims.

The current wording broadens the scope of liability considerably and unintendedly caries 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[1] could force companies to protect themselves by focusing on insurance premiums and defensive strategies to the detriment of innovation.

3. Adequately protect sensitive information subject to disclosure orders

Article 8 (2-4) contains certain protections for confidential information and trade secrets from disclosure in liability proceedings by injured claimants. Paragraphs 2-3 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 for 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.

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, which creates a significant degree of 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.

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

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020L1828

trade secrets within the meaning of article 2, point 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.

4. Removal of thresholds

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 (€70m) 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 overtime changed 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 becomes increasingly difficult. These figures should be subject to maximum harmonisation to address the issues that the Commission identifies with the current divergence across member states.

The extension of the longstop period further increases legal uncertainty and places a significant burden on companies. This extension is not in line with the reality of software development and AI and further creates complexities regarding data retention and processing laws, where some companies are restricted under the General Data Protection Regulation.

5. Extending the Economic Operator to include fulfilment service providers and marketplaces

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, 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 the marketplace provision in article 7.6 does.

The proposal includes new reference to the Authorized Representative concept (as one of the Responsible Persons or RSP from the Market Surveillance Regulation and the draft GPSR) as another potentially liable operator for defective products where there is no EU-based manufacturer or importer. This is a proportionate allocation of liability, but the Authorized Representative concept must be made meaningful and verifiable (to support inclusion in this framework and the risks they take on must be insurable). The proposal also needs a mechanism to account for changing Authorized 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. The availability of insurance is closely connected to retaining the liability thresholds in particular.

The first step to enhancing the Authorized Representative concept is to make them 'reliable' by professionalising the role of an Authorized Representatives. We recommend establishing a minimum set of criteria for Authorized Representatives, accredited as the RSP, as an entity that is both legitimate (ie remove the ability to assign 'anyone' to act as an Authorized Representative) and possesses sufficient understanding of product compliance requirements to be responsible and potentially liable. The Authorized 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[2], and such a mechanism could be used as a reference to create an accreditation program for Authorized Representatives[3]. Similar for notified bodies, it is essential that the Authorized 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 be able to verify those documents and ensure they are not fraudulent; if documents are found to be fraudulent, the Authorized 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 Authorized Representatives so that regulators, consumers, fulfilment service providers and marketplaces can confirm the status of an Authorized Representative. A 'Registration Database' for Authorised Representatives (where there is no EU based manufacturer or importer) should be created for this purpose, which 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 the Authorized Representatives. At present, a rogue actor wishing to appoint a phantom Authorized Representatives can easily create fake contact details, which presents challenges to businesses or market surveillance authorities to confirm the presence of a valid Authorized 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.

Conclusion

Policymakers should 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

[2] P75-8 Blue Guide https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726(02)&from=DE.

[3] Section 5.2.2. of the 'Blue Guide' on the implementation of EU products rules 2016 (2016/C 272/01) which outlines the roles and responsibilities of notified bodies.

AI Act and horizontal rules in the GPSD/R and Cyber Security Regulation. These EU laws provide *ex-ante* safeguards that lower potential risks related to products and services that 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 should remain reserved for situations that are especially hazardous and bear a risk of severe damage to persons or property. We agree that consumer trust is an important prerequisite for the use of new technologies. AmCham EU members, however, do not experience a general lack of customer trust concerning digital products and emerging technologies. This experience is in line with the Commission's Expert Group's findings, which only refer to potential future challenges, which the technology neutral language of the existing PLD is already able to address if they arise.

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.