U.S. Chamber of Commerce
Institute for Legal Reform

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Comments on the Proposed Product Liability Directive

1. Executive Summary

(1) The Product Liability Directive (**PLD**) is the foundation of the EU product liability regime. It was adopted nearly 40 years ago and during that time has provided a largely effective compensation mechanism for those who suffer damage caused by defective products in the EU.

(2) Maintaining a fair balance of interests between consumers and producers[1] has been viewed as the main objective of the PLD since the day of its adoption. However, the Commission's recent proposal for a new directive to replace the current PLD (the **Proposal**) risks undermining this balance, thereby increasing the risk that future EU policy could hamper producers' ability to innovate and develop new products and services.

(3) If adopted in its current form, the Proposal would introduce substantial changes to the existing regime and would create significant – and unjustified - imbalances between the rights of claimants and defendants.

(4) Indeed, as explained in more detail below, the Proposal tilts the playing field in the claimant's favour in several ways, including by:

- extending strict liability rules to cover intangible products (such as software and digital content) and new technologies (such as AI);
- extending the range of available damages to include also non-material damages (such as data loss and psychological harm);
- easing conditions for making consumer claims, in particular in relation to time limits and the minimum threshold for damage; and
- alleviating the burden of proof by applying a set of ambiguous claimant-friendly presumptions.

(5) The impact of these changes will be material, affecting broad swathes of consumers and industry. This paper identifies some areas where the Proposal should be reconsidered to maintain the right balance and preserve legal certainty for the ultimate benefit of European consumers.

[1] By 'producer', we refer to the manufacturer of a product or component, the provider of a related service, the authorised representative, the importer, the fulfilment service provider or the distributor.

2. Expansion of Scope #1: Types of Products Covered by the PLD

Commission Proposal

(6) The Commission has found that digital content, software, and data play a key role in the safe functioning of products, but it is not clear to what extent such intangible products can be classified as "products" under the current PLD. In particular, the Commission is concerned that claimants do not have adequate recourse under the current regime for damage caused by software.

(7) To address this problem, the Proposal expands the definition of "product" and, as such, the scope of the EU product liability regime, to include damage caused by electricity, digital manufacturing files (e.g., as used for 3D printing), software (which includes AI and AI-enabled products[2]) and so-called 'related services' (which include digital services that are "*integrated into, or inter-connected with*" a tangible or intangible product "*in such a way that its absence would prevent the product from performing one or more of its functions*").

Analysis

(8) The current PLD defines a "product" as any movable good. The definition has been interpreted broadly, applying to a wide range of products over several decades, including to digital products that did not exist when the PLD came into force in 1985. The current definition remains largely fit for purpose, and while some refinements may be necessary to ensure the PLD is able to encompass current technologies, an overly inclusive approach should be avoided[3].

(9) In addition, an excessively wide product definition could make it difficult to differentiate between various categories of products and applications. Rather than imposing a blanket strict liability approach with respect to standalone software and integrated services, more nuance is required to account for their wide range of applications. For instance, there is an important distinction to be made between a complex AI system and a less sophisticated algorithm that has been used safely by the public for many years.

(10) Importantly, standalone software is unlikely to cause physical harm in and of itself. The EU should engage in thorough fact-finding exercises and evidence-based risk assessments rather than reflexively responding to concerns by adjusting liability rules. The Proposal does not accurately reflect the challenges faced by consumers today in relation to new technologies but seems to focus on isolated cases. Nor do the case studies provided by the Commission in its Staff Working Document on liability for emerging digital technologies demonstrate that existing safeguards are inadequate. There does not appear to be sufficient evidence of harms arising that would justify the inclusion of whole new categories of products within the scope of the PLD.

Suggested Approach

(11) While integrated software applications and services that control how a device operates can reasonably fall within the scope of the PLD, it should be clarified that their scope excludes ancillary software (e.g., a gaming app or a digital map) or additional services which do not drive

[2] Article 4(1) of the Proposal.

[3] See the European Commission report, *Draft Report on Artificial Intelligence in a Digital Age,* 2 November 2021, available at: https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/AIDA/PR/2021/11-09/1224166EN.pdf, para. 120.

the device, but which provide only guidance to end users or are provided separately to the device (e.g., via download).

(12) The definition of 'software' should also account for the various applications and risk profiles of different software. While high-risk applications (to be clearly defined in the PLD) could be subject to a lower evidentiary standard, this approach is not appropriate for low-risk software that is not proven to be particularly dangerous to consumers.

3. Expansion of Scope #2: Forms of Damage Covered by the PLD

Commission Proposal

(13) The definition of 'damage' under the current PLD addresses harm caused by death, personal injuries and damage to property. The Commission claims that, in the interests of legal certainty, it should be clarified that 'personal injury' also includes medically recognised damage to psychological health. In addition, according to the Commission, to recognise the growing relevance and value of intangible assets, the loss or corruption of data should be compensated under the PLD.

(14) Therefore, the Commission proposes to explicitly expand the scope of the PLD to include damage in the form of (i) medically recognised harm to psychological health; and (ii) the loss or corruption of data[4].

(15) The Commission has also removed the minimum financial threshold of EUR 500, which means that a claim for damage of any value can be brought under the PLD. This is allegedly to prevent the excessive limitation of claims.

Analysis

(16) Strict liability under the PLD is not the right tool for determining compensation for such complex forms of damage as psychological harm and the loss or corruption of data. Psychological harm is particularly difficult to define and assess, with no harmonised definition at EU level, which will lead to a lack of legal certainty.

(17) As regards the loss or corruption of data, such infringements are already covered at EU level by the GDPR. Since the GDPR already provides the opportunity for redress, it is difficult to see why further options should be available under the PLD, particularly given that one of the objectives of the Proposal is to simplify the compensation process for consumers. As mentioned above, to have multiple overlapping consumer protection regimes gives rise to the risk of redundant or conflicting requirements, which undermines legal certainty and adds additional complexity and financial cost for producers.

(18) If the Proposal is adopted in its current form, it risks encouraging speculative claims. Without the certainty provided by the definition of 'damage' under the current PLD, there is a risk that claims could amount to punitive levels of compensation. It is also difficult for insurers to quantify 'non-material' risks, which means premiums could rise significantly.

(19) Finally, alternatives to court-based litigation should be prioritised for claims with a value of less than EUR 500 in the interests of the efficient administration of justice.

[4] Article 4(6) of the Proposal.

Suggested Approach

(20) The definition of 'damage' under the current PLD is already effective and sufficiently broad. The scope of the PLD should not be expanded to include nebulous concepts of non-material damage: to preserve legal certainty and to avoid encouraging speculative claims, damage should be provable, foreseeable, and quantifiable.

(21) Further, the minimum financial threshold should be retained. Since its inception, the current PLD has provided for monetary and temporal minimum thresholds, namely the 10-year limitation period for an injured party to issue a claim and the EUR 500 value threshold for damage. As is made clear in the PLD itself, these thresholds aim "*to avoid litigation in an excessive number of cases*"[5], a rationale which remains equally applicable today.

4. Expansion of Scope #3: Additional Factors for Establishing Defect

Commission Proposal

(22) The Proposal expands the list of factors to be considered when assessing whether a product is "defective''. These adjustments are intended to reflect the "*legitimate expectation*" that a product's software and underlying algorithms are designed to prevent *"hazardous product behaviour*"[6]. Specifically, the Proposal requires that product defects be assessed in a way that takes account of connectivity and cybersecurity risks, the ability of a product to learn after deployment, and the content of software upgrades or updates, or the lack thereof.

(23) According to the Commission, to reflect the relevance of product safety and market surveillance legislation, safety requirements, including safety-relevant cybersecurity requirements, should also be considered in the assessment of whether a product is defective, as well as interventions by regulatory authorities (e.g., product recalls) and economic operators themselves[7].

(24) In addition, the Proposal expands the concept of 'defect' to encompass both reasonably foreseeable use *and misuse* of a product[8].

Analysis

(25) Under EU consumer law, manufacturers already need to comply with a whole suite of regulatory and safety requirements. The Proposal appears to add to these rules, in effect placing new liability concepts and presumptions on top of existing regulatory requirements, which risks exposing manufacturers to parallel and overlapping regimes. This may lead to overlapping and contradictory obligations in areas as diverse as financial services, healthcare, transportation, and data protection.

(26) It is particularly concerning that manufacturers could be liable for the misuse of a product. This places a significant burden on producers to anticipate and mitigate the risks of potential misuses while already complying with safety requirements that relate to a product's intended use cases. Provided producers have taken reasonable steps (e.g., with appropriate instructions or warnings if merited), liability should be excluded (or at least not presumed) for misuse which is the responsibility of the consumer, especially intentional misuse.

[5] Recital 9 of the Proposal.
[6] Article 6(1), Recital 23 of the Proposal.
[7] Article 6(1), Recital 24 of the Proposal.
[8] Article 6(1) of the Proposal.

(27) Finally, including a product's self-learning function as a factor for assessing defectiveness could lead to AI software developers being penalised for matters that are genuinely outside their control. This is because the solutions and effects developed by AI cannot always be foreseen, which is in essence the intrinsic purpose of AI (i.e., autonomous decision-making). As a result, producers will likely be reluctant to enable autonomous decision-making capability where liability is expanded to beyond what is reasonably foreseeable at the time of development and commercialisation. As such, if the Proposal is adopted in its current form, it will deter manufacturers from enabling such functions in the first instance.

Suggested Approach

(28) To ensure that producers are not exposed to the threat of excessive or frivolous litigation, the concept of 'defect' under the Proposal should not include the misuse of a product. At the very least, the Proposal should include detailed guidance on the extent to which liability could arise for 'reasonably foreseeable' misuse.

(29) What is more, the concept of 'defect' should reflect the nuance and complexities of AI systems, with a flexible approach that turns on the extent to which the AI serves part of a human-driven decision-making process or functions autonomously. The fact that damage arises from the use of AI does not necessarily mean that the product is defective, nor that liability should rest with the manufacturer of the AI system.

5. Expansion of Scope #4: New Concept of "Manufacturers' Control"

Commission Proposal

(30) The Commission has rightfully retained the exemption from liability under the current PLD, which provides that a manufacturer will not be liable if it can prove it is probable that the product in question was not defective when it was placed on the market or put into service[9].

(31) However, the Proposal states that this exemption should *not* apply where a product remains within the control of the manufacturer after this moment, which includes circumstances in which the manufacturer has (i) supplied software (including software updates and machine-learning algorithms)[10] or related digital services, or (ii) failed to supply a software update necessary to maintain the safety of a product. This idea of a manufacturer continuing to have control is also a relevant factor to be considered when assessing a product's defectiveness[11].

(32) The Commission has introduced this change arguing that in the digital age many products remain within a manufacturer's control beyond the moment at which they are placed on the market (e.g., where the manufacturer provides software updates).

Analysis

(33) The Proposal simply provides for an exemption from liability where it is probable that the defect "*did not exist when the product was placed on the market [or] put into service [or] came into being after that moment*" but Article 10(2) of the Proposal and the accompanying Recitals essentially introduce an exemption to the exemption: e.g., where a manufacturer has supplied software (such as a machine learning algorithm) or failed to issue a software update, the

[9] Article 10(1)(c) of the Proposal.
[10] Recital 37 of the Proposal.
[11] Recital 23 of the Proposal.

manufacturer could still be liable after a product has been placed on the market or put into service.

(34) This seems to ignore the intrinsic characteristics of software and related digital services: they can be deployed in various ways, they continue to be further developed over time, and their features are contingent on the way in which they are used. The potential liability for failure to issue a software update or upgrade is particularly problematic as it is not clear in which circumstances a legal duty to issue an update might be triggered – i.e., when such an update will be deemed "*necessary to maintain safety*" or how to ensure an update is sufficient to effectively discharge this legal duty.

(35) Producers have their own market-based incentives to ensure their products are safe and adapted to known risks but they should not be held accountable for matters that are genuinely outside their control.

Suggested Approach

(36) Article 10(2) and the Recitals to the Proposal should be amended to clarify that a software manufacturer is equally exempt from liability where (i) it is probable that the product in question was not defective when it was placed on the market or put into service, or (ii) with respect to safety-related software updates, where the producer could not reasonably foresee the risk to the product's safety.

6. Expansion of Scope #5: Enabling Representative Actions

Commission Proposal

(37) In line with the new Representative Actions Directive (**RAD**)[12], the Proposal clarifies that claimants can bring representative or collective actions under the PLD.

Analysis

(38) The new PLD will sit alongside parallel policy initiatives that are set to significantly increase liability risks for all product manufacturers and suppliers who place products on the EU market. Of these initiatives, perhaps the most significant are the EU representative actions laws. The changes envisaged in the Proposal (such as strict disclosure requirements and easing of the burden of proof) are likely to embolden litigation funders to support representative actions in injury, property damage and loss of data claims. Indeed, this was anticipated in the Commission's accompanying impact assessment, which predicts a rise in product liability insurance premiums because of increased liability exposure.

(39) According to the Proposal, claimants will be able to bring representative actions under the PLD via the Representative Actions Directive (**RAD**) or national collective redress schemes. It is important to ensure consistency across the single market to the extent possible: while the RAD provides Member States with a common legal mechanism for representative actions, it leaves broad discretion to Member States to implement the mechanism in practice, as well as leaving open the possibility that Member States can, in many important respects, maintain or create separate mechanisms that differ from the process set out in the RAD.

[12] Directive (EU) 2020/1828.

(40) The EU must also ensure that Member States find an appropriate balance between facilitating legitimate actions and safeguarding against opportunism and abusive litigation. Abuse can rise where claimants have financial incentives to file weak (or even entirely meritless) claims. The expansion in scope of the PLD and lower evidentiary burden for claimants increases the risk of such litigation[13].

Suggested Approach

(41) The EU should take steps to ensure consistency and legal certainty for producers with respect to representative actions. The EU should also implement harmonised measures to protect producers from abusive litigation.

7. Expansion of Scope #6: Extending Liability Down the Supply Chain

Commission Proposal

(42) The Commission aims to ensure that injured parties have an enforceable claim under the PLD even where a manufacturer is established outside of the EU. While the current PLD already extends liability to importers of products, the Commission's proposed changes go significantly further and extend liability in turn to authorised representatives, fulfilment service providers, distributors, and (in certain circumstances) online marketplaces where the EU establishment of an economic operator further up the supply chain cannot be identified.

Analysis

(43) The Commission's approach constitutes a radical extension of the scope of liability under the current PLD. Indeed, the Proposal represents a substantial broadening of the list of potential defendants, going far beyond the entities found in a traditional supply chain.

(44) Crucially, producers should not be required to account for, or accept, liability in circumstances where they are not in control of the risk or where the risk has properly shifted to another party. The effect of the Proposal would be to hold EU-based economic operators, e.g., distributors, liable for products manufactured outside the EU even where those distributors had no control over the manufacturing process and have not subsequently modified the products. To impose such burdensome liability requirements on parties further down the supply chain will stifle the import of products into the EU and, in turn, reduce options available to consumers.

Suggested Approach

(45) To maintain sufficient legal certainty while ensuring effective redress for injured parties, the Proposal should be revised to clarify that liability rests with those able to control the risk. The EU should refrain from extending liability to parties who do not control the risk in question.

[13] For more information, see *12 Recommendations for the Implementation of the EU Directive on Representative Actions*, dated November 2020, available at: https://instituteforlegalreform.com/wp-content/uploads/2020/11/Implementation-Guideline-for-EU-Representative-Actions-Directive.pdf.

8. Expansion of Scope #7: Weakening the Longstop Period

Commission Proposal

(46) While the PLD has retained the 10-year longstop period in most circumstances, this time limit restarts where the product has been 'substantially modified' after being placed on the market or put into service (e.g., because of remanufacturing in such a way that its compliance with applicable safety requirements may be affected). 'Substantially modified' could be interpreted to include a software update.

(47) The longstop period has also been extended to 15 years in cases where the symptoms of personal injury or disease are, according to medical evidence, slow to emerge.

(48) According to the Commission, these changes seek to facilitate the right to an effective remedy and avoid unreasonably denying the possibility of compensation.

Analysis

(49) The longstop period should strike an appropriate balance between providing potential claimants with adequate time to launch a claim and preserving legal certainty. Indeed, this was acknowledged by the Commission in its recent appraisal of the current PLD: "*the time-limits aim at creating a balance between the interests of producers and those of injured parties … to give legal certainty and reduce financial burdens for producers*"[14]. The time limits provided under the current PLD effectively manage this balance of interests.

(50) Extending the longstop period undermines legal certainty, placing a significant burden on producers, including potential conflicts with data processing and retention obligations under the GDPR. In practice, it would be difficult to comply with these rules. Insurance premiums are also likely to increase as producers will be exposed to liability risks for longer periods of time.

Suggested Approach

(51) The PLD should maintain the longstop periods provided under the current PLD.

9. Burden of Proof: New Rebuttable Presumptions and Disclosure Requirements

Commission Proposal

(52) The Commission has concluded that the complexity of certain products, for example pharmaceuticals and products that use emerging digital technologies, make it unduly difficult for claimants to prove the causal link between a product's defect and any damage suffered. The Commission has also identified obstacles in proving causation with respect to AI systems, given the specific characteristics of AI (e.g., their autonomous behaviour and opacity), which is compounded by a perceived lack of sufficient technical information about AI products and services.

[14] SWD (2018) 157 Final, *Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Application of the Council Directive on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products (85/374/EEC),* available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2018:157:FIN, page 9.

(53) In response to these concerns, the Proposal sets out new disclosure requirements (notably, an obligation for a defendant to disclose relevant evidence to the extent necessary and proportionate to support a claim) and two new rebuttable presumptions:

a. a presumption of defectiveness[15] – according to which the defectiveness of a product shall be presumed where:

i. the defendant fails to comply with an obligation to disclose relevant evidence;

ii. the claimant is able to prove that the product does not comply with mandatory relevant safety requirements;

iii. the claimant can prove that the damage was caused by an obvious malfunction of the product during normal use or circumstances, or

iv. the claimant faces excessive difficulties, due to technical or scientific complexity, to prove the defectiveness of the product and can demonstrate that (i) the product contributed to the damage, and (ii) it is likely that the product was defective.

b. a presumption of causality[16] – under which the causal link between the defectiveness of a product and the damage shall be presumed where:

i. the claimant is able to provide that the product is defective, and the damage caused is of a kind typically consistent with the defect in question, or

ii. the claimant faces excessive difficulties, due to technical or scientific complexity, to prove the causal link and can demonstrate that (i) the product contributed to the damage, and (ii) it is likely that its defectiveness is a cause of the damage.

Analysis

(54) Appropriate risk allocation through the burden of proof is the foundation for achieving a fair balance of interests in a product liability framework. If the Proposal is accepted in its current form, it would mean a *de facto* reversal of the burden of proof from claimant to defendant.

(55) Indeed, the new disclosure requirements and rebuttable presumptions would make it sufficient for a claimant only to allege a hypothetical complaint in order to shift the burden to a defendant. In turn, defendants will be required to "*prove a negative*" by submitting sufficient technical information to establish that the product in question did not cause the alleged harm[17].

(56) The new presumptions give rise to significant legal uncertainty. For instance, the concept of 'technical or scientific complexity' has not been defined, and nor is it clear how courts should assess the 'likelihood' of defectiveness or causality. Such uncertainty will further hinder innovation and likely lead to costly legal test cases. A defendant will only be able to reverse this presumption if it can demonstrate the lack of 'excessive [evidential] difficulties' faced by the

[15] Article 9(2),(4) of the Proposal.
[16] Article 9(3)-(4) of the Proposal.
[17] See the response by ITI to the Commission's public consultation on liability rules for AI, dated 10 January 2022, available at: https://www.itic.org/documents/europe/1001ITIResponsetoEULiabilityRulesConsultiation.pdf.

claimant, which may prove an impossible task: the defendant would have to prove that a claim is not complex whilst also seeking to establish an effective defence.

(57) It is important that the key principles embedded in the PLD, such as causation and fair apportionment of risk, must be preserved going forward. These principles are fundamental founding blocks of any liability regime and are essential to maintaining the balance between producers' and consumers' interests.

(58) By setting aside well-established procedural guarantees and shifting the burden of proof to defendants, the Proposal risks undermining legal certainty, significantly reducing incentives on producers to innovate and hampering economic growth: producers will be deterred from investing where they face significant risks of product liability pay-outs based on assumptions, rather than proof, of harm. The increased threat of frivolous, excessive, and expensive litigation will ultimately reduce consumer choice by frustrating efforts to foster innovation.

(59) Finally, with respect to disclosure requirements, a defendant may simply not have access to the data it requires to rightfully absolve itself of liability. The disruption to the usual legal process could be due to a lack of information altogether, as opposed to an information imbalance. As such, the proposed changes will be particularly burdensome for SMEs and start-ups, who lack both the capacity to prove that they had no responsibility for any harm and are least able to afford compensation costs. The complexity of products from a consumer perspective is not a valid reason to reverse the burden of proof on defendants.

<u>Suggested Approach</u>

(60) The Proposal should reflect the evidentiary processes under the current PLD, which strikes a fair balance of interests between consumers and producers. To that end, in order to shield producers from spurious and opportunistic claims and to maintain fair apportionment of risk, the Proposal should preserve basic burden of proof protections, in particular the requirement for an injured party to prove the damage, the defect and the causal relationship between the two.

(61) If the presumptions of defectiveness and causality are introduced, clear rules should be established to provide for better legal certainty. For example, the PLD should set down explicit standards for a claimant to demonstrate evidential issues arising from the 'technical or scientific complexity' of a product. In addition, to establish that a defect or causal link is 'likely', the clamant should have to refer to objective criteria, e.g., an assessment of benefits and risks or other relevant information at their disposal.

(62) Where the burden of proof is reversed, there should be a corresponding requirement on claimants to disclose relevant evidence that may support the defence, e.g., it will be challenging for a defendant to prove an alternative explanation for a medical condition unless it has access to the claimant's medical records.

(63) Moreover, where the claimant faces evidential difficulties with respect to AI, the Proposal should introduce a 'sliding scale' approach to the burden of proof which depends on the extent to which the AI serves part of a human-driven decision-making process (in which case the usual evidentiary processes should apply) or functions autonomously. In the latter case, liability should turn on the degree of the AI's transparency, the constraints its creators or users place on it, and the vigilance used to monitor its conduct. Strict liability should lie with the person who is most in control of the risk connected with the operation of AI and who benefits economically from its operation.

The EU should account for distinctions between the types of risk presented by different AI applications and tailor the rules on a case-by-case basis. This would allow those who develop and employ AI to implement risk management practices in ways that are best fitted to the use case and risk profile.

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