

Key messages on the European Commission's proposal for a revision of the Product Liability Directive (PLD)

Insurance Europe's position in a nutshell

Insurance Europe appreciates the European Commission's intention to create a liability regime suitable for the digital age by revising the Product Liability Directive (PLD). However, the proposal, as currently drafted, would negatively impact the availability of insurance and would therefore not meet its intended purpose of enhancing consumer protection while encouraging innovation.

In summary, the insurance industry's concerns are:

- The proposed changes would, if adopted in their current form, compromise insurers' ability to price risk, most notably the risk of personal injuries, including "medically recognised damage to psychological health" and the proposed extended liability risks for producers.
- The proposal to extend liability risks for producers to include cyber risks is problematic from an insurance point of view, primarily because cyber risks are difficult to insure for a number of reasons, including the fact that they are evolving. Consequently, the extent to which cyber insurance can, in practice, be integrated into product liability policies remains to be seen.
- The EU's proposed adjustments to the PLD increase the liability placed on the producer, which will thus result in increased litigation risks and, ultimately, costs for consumers. In other words, the Commission has opted to alter the careful balance between consumers and producers that has existed and worked well for decades and that has supported innovation. The insurance industry is concerned that the proposed amendments to the PLD will harm, rather than support, innovation.

This paper identifies the areas of the proposal that should be reconsidered to achieve the right balance and preserve legal certainty, to the ultimate benefit of European consumers.

Definition of product and its placement in the market

European Commission's proposal

The text of the PLD extends the scope to all movables that have been made available on the market, including embedded and stand-alone software, AI products and related services.

Insurance Europe's assessment

- Broadening the scope could make it difficult to differentiate between various categories of products, some of which should not fall within the scope of the Directive. For instance, drugs and medical devices that are in a phase of clinical trial should be excluded from the liability framework.
- Inconsistencies could be created with other pieces of legislation such as the Digital Services Act, the Medical Devices Regulation or the AI Liability Directive.

Key messages

- For insurers to be able to provide insurance coverage tailored to policyholders' needs, the scope of the Directive should be clarified by including provisions that clearly refer to the products that fall under the liability framework.
- Products that are already covered by other pieces of legislation should be clearly excluded to avoid overlaps with other regulation.

Definition of damage

European Commission's proposal

The PLD would cover damage in the form of (i) medically recognised harm to psychological health and (ii) the loss or corruption of data.

Insurance Europe's assessment

- Without a harmonised definition of psychological harm, it will be very hard for insurers to assess damage, inevitably leading to litigation.
- Loss or corruption of data will probably be difficult to insure. Additionally, such losses are already covered by the General Data Protection Regulation (GDPR), which includes the opportunity for redress. Having overlapping regimes could give rise to conflicting requirements.
- European businesses would face a lowering of the bar for litigation as well as very granular and prescriptive conduct rules and documentation requirements.

Key messages

- The future PLD should include a clear definition of psychological harm to avoid inconsistencies in the assessment of damages. The assessment of distress needs to be carried out at an individual level, as is the case for bodily injury claims, which require medical evidence.
- The PLD should not cover damages that are already subject to compensation under other regulation. Having overlapping regimes would add complexity and financial costs for producers as well as undermine legal certainty.

Definition of defectiveness

European Commission's proposal

The revised PLD introduces a list of factors to consider when assessing the defectiveness of a product. Notably, the proposal requires to be taken into account: the reasonably foreseeable use and misuse of the product; connectivity and cybersecurity risks; the ability of a product to learn after development; and the content of software upgrades and updates, or the lack thereof.

Insurance Europe's assessment

- Requiring producers to foresee all possible misuses of a product places a significant burden on them, as they are asked to anticipate and mitigate all possible risk scenarios, even though manufacturers are already complying with product safety legislation.
- Some criteria such as the "specific expectations of the end users for whom the product is intended" are too broad and subjective. This could lead to divergent case law and fragmented interpretations at national level.
- The text is not clear about the extent of the coverage of cybersecurity vulnerabilities.
 - For instance, if this factor includes the threat of a product being vulnerable to cyber attacks, it could lead to excessive litigation which would reduce a producer's incentive to innovate and, ultimately, reduce consumer choice.
 - Furthermore, there is already legislation in place that provides compensation in cases of cyber attacks. For instance, under the Cyber Resilient Act, manufacturers are bound by cybersecurity obligations for five years after the product has entered circulation/service. Broadening the scope of the liability framework to include these types of risks will therefore create legal inconsistencies.
 - In the case of loss of data due to a cybersecurity incident, it is not clear whether insurers would bear the cost both of the damages resulting from the data loss and of management of the crisis.

Key messages

- To ensure that producers are not exposed to the threat of excessive or unfounded litigation, the PLD should include detailed guidance on the extent to which liability could arise from “reasonably foreseeable” misuse. Similarly, to avoid fragmentation and ensure legal certainty, the Directive should include specific criteria to frame the expectations of the end-user.
- The revised PLD should also clarify what is expected in terms of cybersecurity vulnerability to avoid having a negative impact on the insurability of cyber risks and ensure legal certainty. Insurance is, by definition, not available for inevitable losses and insurers fear that, in this case, if cyber vulnerability is considered a defect, then insurers will be unable to insure the liability burden placed on the producer.

Substantially modified products

European Commission’s proposal

The current wording of the proposal extends the liability framework to manufacturers that substantially modify products already on the market. A modification will be defined as substantial on the basis of relevant EU or national rules.

As substantially modified products will be considered new products, the limitation period of 10 years will also apply to refurbishers.

Insurance Europe’s assessment

- The reference to a plurality of normative texts at European or national level may create confusion and is likely to lead to differences in interpretation between member states. This could, in turn, be a source of litigation and distort competition.
- Applying a 10-year limit significantly increases the burden of responsibility on participants in the circular economy and could slow the development of more sustainable models.

Key messages

- The notion of “substantial modification” should be assessed on the basis of EU rules and only on the absence of those, on the basis of national legislation applicable to product safety.
- The limitation period for refurbished products should be reduced to a more reasonable period that reflects the reality of the products that have been modified.

Disclosure of relevant evidence

European Commission’s proposal

The revised text of the PLD introduces new disclosure requirements, notably an obligation for a defendant to disclose relevant evidence to the extent necessary and proportionate to support a claim.

Insurance Europe’s assessment

- The proposal does not take into account the interests of all the parties involved. For instance, the manufacturer may simply not have access to the data it requires to absolve itself of liability or may also benefit from receiving evidence from the injured party, for example, to prove an alternative explanation for a medical condition.
- The threshold to order the disclosure of the evidence is too broad and could establish a de facto discovery framework.

Key messages

- The PLD should contain specific requirements or criteria that limit the recourse to the disclosure of evidence tool to avoid opportunistic claims and maintain a fair apportionment of the risk. For instance, the financial effort involved in determining the relevant evidence should be considered. Only claims over €500 should have recourse to this evidentiary tool.
- To ensure a fair balance between the producers' and consumers' interests, the PLD should also require claimants to disclose evidence when the burden of proof is reversed.

Burden of proof

European Commission's proposal

The proposal sets out a rebuttable presumption of defectiveness and of causality to help claimants prove the causal link between a product defect and the damage suffered.

Insurance Europe's assessment

- In its current form, the proposed text could be understood as introducing a de facto reversal of the burden of proof. Indeed, the current wording of the provision would allow claimants to shift the burden of proof with only a hypothetical complaint, placing all the evidentiary burden on the defendant.
- The new presumptions also give rise to legal uncertainty, as it is unclear how courts should assess "technical or scientific complexity" or the "likelihood" of defectiveness or causality.

Key messages

- The disclosure of evidence should be limited to high-risk AI systems as defined in the proposed AI Act.
- To reduce liability and litigation costs, the PLD should include 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 claimant should have to refer to objective criteria.

Limitation periods

European Commission's proposal

Under the proposal, software updates could be considered as substantially modifying a product, which would restart the liability period for the manufacturer.

Insurance Europe's assessment

- Producers will be exposed to liability risks for a very long time, especially in the case of software updates, for which the liability and financial burden are placed fully on manufacturers.
- There could be inconsistencies with other pieces of legislation, such as the retention requirement under the GDPR.

Key messages

- The PLD should limit the types of software updates that can be considered as substantially modifying a product. Otherwise, insurers may need to revisit existing coverage, introduce exclusions or increase premiums in order to cover the extended liability.
- The text of the PLD should not have overlapping obligations, as this would increase the financial burden on manufacturers.

Minimum threshold

European Commission's proposal

The Commission has removed the minimum financial threshold of €500. This would allow claimants to bring actions of any value under the PLD.

Insurance Europe's assessment

- Together with the collective actions scheme introduced by the Directive on representative actions for the protection of the collective interests of consumers, the removal of the threshold is likely to result in a significant number of speculative claims.
- This may also lead to an increase in cases of fraud, as the cost of proving the manufacturer's innocence in court will typically exceed the costs of paying the claim.
- The overall costs may also increase because the manufacturer's costs for handling claims and/or the insurer's costs of covering the risks will increase. This will affect the marginal profit of the manufacturer, which will ultimately lead to increased costs being factored into the price charged to the end consumer.

Key messages

- To avoid litigation in an excessive number of cases, the PLD should encourage alternative dispute resolution mechanisms, especially for low-value claims.

Other aspects

- In its recitals, the PLD should include, as an example of material losses resulting from death or personal injury, the misdiagnosis made by an AI system (eg, defective Bluetooth technology or electromagnetic field cases).
- The PLD should include a clear mention that surgeons will not be seen as manufacturers when they combine prosthetic components in the same implant (as has been the case in some markets). The PLD should also clarify at what point in time a personal injury is considered as occurring and what costs are covered when defective medical implants are involved.
- To ensure legal certainty, the PLD should also refer to the apportionment of liability when one of the economic operators in the value chain becomes bankrupt.
- The Directive should also clarify that the maximum harmonisation clause only refers to the liability framework and will not affect the compensation levels set at national level.