

## **Inclusion of the Product Liability Directive (PLD) in the Digital Package's Fitness Check**

### **Why the PLD needs be included in the Digital Package**

The new PLD extends liability to **software, AI, and digital services** but has developed independently from other EU digital laws. As a result, EU legislation provides for overlapping responsibilities and inconsistencies in definitions and in evidence rules. This leads to higher compliance costs, as well as fragmented consumer remedies across the Single Market.

The PLD already functions as a digital directive. The Commission should, therefore, use the Digital Package to **align the PLD with the EU's broader digital legislation**. This initiative presents an opportunity for precise **recital clarifications**, **soft-law guidance**, and **cross-act coherence** on definitions - on *inter alia* evidence disclosure, evidentiary standards, and proportionality. This would strengthen coherence across the EU's digital framework, while preserving consumer protection and providing clarity for businesses.

### **Key issues needing alignment**

#### **- PLD evidence disclosure obligations (Art. 9)**

The PLD requires a defendant to disclose evidence under certain circumstances in cases where compensation is claimed in proceedings before a national court for damage caused by a defective product. Similar requirements already exist under other EU digital laws (AI Act 2024/1689, CRA 2024/2847, MDR 2017/745). As a result, companies may face requests for identical evidence but under laws that apply different standards. The Digital Package could rationalise these obligations by linking PLD disclosure to the European Commission's "provide once, use many times" compliance repositories.

#### **- Rebuttable presumptions of defect and causation (Art. 10)**

Even though they are designed to ease the evidentiary burden for claimants in complex cases, the application of the presumptions effectively reverses the burden of proof. As a result a company could comply fully with the AI Act or MDR standards yet still be treated as if its product were presumed to be defective, simply because the claimant alleges that causation is difficult to prove. This uncertainty discourages innovation. The Digital Package could bring additional clarity if compliance with the applicable digital safety regimes was held to rebut the presumption of defect in Article 10 of the PLD.

#### **- Harmonisation of legal definitions: "product" vs "service"**

The PLD now covers software updates, digital files and connected services, but definitions diverge from those in the AI Act, Cyber Resilience Act and Data Act. Therefore, it is unclear for companies whether a technology is treated as a product, a service, or both, depending on which law applies. Such misalignment creates compliance burdens and litigation risks. This initiative offers a chance to harmonise definitions across legislation, ensuring similar technologies are treated consistently across the EU.

#### **- Guidance on the 25-year "expiry period" (Art. 17)**

Extending the limitation period to twenty-five years recognises the risk of latent harms, but it has unintended cost consequences, especially in MedTech and pharmaceutical sectors. Insurers project upward pressure on liability insurance costs, raising barriers to the development of AI-enabled health solutions and digital therapeutics – key priorities in the Competitiveness Compass and the AI Continent Action Plan. Guidance delivered through the Digital Package should clarify how the expiry period applies in digital contexts, ensuring proportionality while preserving consumer protection.

#### **- Prevent fragmentation across Member States**

The PLD provides Member States discretion on issues such as the state-of-the-art defence. If exercised unevenly, this would encourage forum shopping and distort competition within the Single Market. Divergent national interpretations would undermine the EU's goal of coherence in digital regulation. By issuing harmonised interpretative guidance or clarifying recitals through this initiative, the Commission could safeguard consistency from the outset.

## **Conclusion**

To avoid duplication and uncertainty, we encourage the Commission to align the PLD with adjacent frameworks through targeted recitals and guidance that addresses the following: disclosure (Art. 9), burden of proof (Arts. 7(2) and 10), general terminology coherence, application of the Article 17 expiry period in digital contexts, as well as coordinated national implementation.

The upcoming Digital Fitness Check, which will stress-test the coherence and cumulative impact of the EU digital acquis, offers an opportunity to evaluate digital product safety and liability frameworks - including the PLD - with a focus on coherence, evidentiary interfaces, and administrative burden.

## ANNEX: Proposed amendments and guidance

### 1) Disclosure obligations (Art. 9)

- **New recital - place after recital (43):**

*“(XX) Without prejudice to Article 9(4)-(7), and where appropriate, national courts may allow disclosure obligations under this Directive to be satisfied by reference to information already submitted to Union databases established under sectoral legislation, in line with the ‘once-only’ principle. This should help avoid duplication while safeguarding confidentiality, trade secrets and proportionality.”*

**Justification:** Procedural streamlining to prevent parallel, duplicative requests without altering burdens or creating new presumptions.

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### 2) Evidentiary weight of compliance (Arts. 7(2) and 10)

- **New recital - place after recital (48):**

*“(XX) In assessing defectiveness under Article 7(2) and when applying Article 10, national courts shall take account of a product’s compliance with applicable Union legislation and standards. Such compliance shall carry sufficient evidentiary weight to rebut the presumption of defectiveness having regard to all the circumstances of the case.”*

**Justification:** Clarifies interfaces with horizontal digital-safety regimes without changing burdens or introducing new presumptions.

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### 3) Coherence of legal definitions (‘product’ vs ‘service’; software, updates, related services)

- **New recital - place after recital (12):**

*“(XX) For consistency across Union digital legislation, the concepts used in this Directive - such as product, related service, software and updates - should be interpreted in a manner that promotes coherence with analogous concepts in the Union acquis (including the AI Act 2024/1689, Cyber Resilience Act 2024/2847, Data Act 2023/2854, and Digital Services Act 2022/2065), without prejudice to each act’s scope and legal effects.”*

**Justification:** Reduces uncertainty from divergent terminology while avoiding cross-importation that could expand or narrow scope unintentionally. Can be supported by Commission staff working guidance providing a non-binding “definitions mapping” table and illustrative case studies.

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### 4) Expiry period (Art. 17 PLD)

- **New recital - place after recital (58):**

*“(XX) For products with digital elements, guidance should clarify how the “expiry period” in Article 17 interacts with software updates and upgrades that do not constitute a ‘substantial modification’, and with situations where a product is substantially modified, in which case a new period may apply in accordance with Article 17(1)(b).”*

**Justification:** Interpretative clarification of existing rules; avoids suggesting flexible or variable expiry durations. Commission guidance with practical examples (e.g., routine security patches vs. functionality-altering upgrades) should provide clarity.

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### 5) Preventing fragmentation across Member States (national options and derogations)

- **Commission Notice (guidance) and transparency measure:**

The Commission should issue a Notice on the application of the PLD that sets out model criteria for the exercise of national options and derogations (including the development risk defence), provides practical indicators for assessing the state of scientific and technical knowledge, clarifies interfaces with software updates and related services, and addresses proportionality and confidentiality in evidence handling. The Notice should also explain how PLD concepts interface with adjacent regimes (*incl. AI Act 2024/1689, CRA 2024/2847, MDR 2017/745, DSA 2022/2065*), without prejudice to each Act’s scope and legal effects, and include illustrative case studies to support consistent administrative and judicial practice. In addition, the Commission should establish and maintain a public tracker listing Member State choices on optional provisions and derogations, the notifications received, and the Commission’s opinions with dates, to create visibility and drive soft convergence.

**Justification:** Promotes consistent application, deters forum shopping, and supports Single Market coherence, without altering PLD liability provisions or constraining Member State prerogatives by new recital language.