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Creating a proportionate Product Liability Directive

Executive summary

The revised Product Liability Directive (PLD) will play a key role in ensuring that Europeans continue to be protected in the digital age.¹ Consumers must be fairly compensated when defective products cause harm, and legal certainty for businesses is vital to encourage investment and innovation. Together, these assurances foster trust, confidence in new technologies and growth.

To achieve this balance, the following adjustments should be taken into account for an effective modernisation of the liability regime:

- ▶▶ Any expansion of scope to the definition of a product must be clear and proportionate;
- ▶▶ The criteria used to assess the defectiveness of products should be made more objective, removing elements outside of the manufacturer's control;
- ▶▶ The definition of damage should not include immaterial losses such as the loss or corruption of data or damage to psychological health;
- ▶▶ More robust safeguards, such as confidentiality presumptions and fines, are needed to protect trade secrets in the disclosure of evidence;
- ▶▶ What a claimant must do and prove before alleviating the burden of proof should be clarified; and
- ▶▶ The compensation thresholds should be maintained and updated rather than eliminated to prevent frivolous claims and provide legal certainty for businesses and their insurers.

¹ COM(2022) 495 final.



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Scope

Inclusion of software

The proposal significantly broadens the definition of product, capturing not only tangible products but also all types of software (including all standalone software not linked to a tangible product) and all components, regardless of the intended purpose. This means that a whole host of large and small software providers, the majority with low-risk and benign uses, will need to cope with a framework they are today largely unfamiliar with. Recent estimates put the number of companies developing software in Europe at more than 370,000, employing almost 1.5 million people.²

Any expansion of scope beyond finished tangible products must be clear and proportionate. The greater legal exposure for software developers, in combination with the expanded definition of damage and the unclear concept of defectiveness, may not achieve the desired legal certainty and will likely result in higher prices for software.

In addition, measures should be taken to prevent unintended consequences, including potentially holding software developers liable for damage caused by taking action to prevent exploits. For instance, an operating system removes a malicious app from users' devices, resulting in lost user data for which the operating system could be liable.

Exclusion of open-source software

We welcome the recognition that open source software (OSS) should be treated differently and excluded from the scope of the PLD. OSS is openly shared and freely accessible, usable, modifiable and redistributable. Contributors cannot know all possible intended uses, and liability exemption is crucial so they can freely contribute to OSS development and innovation.

However, the proposed exemptions for OSS are very narrow and only set out in recitals. It should be clarified within the articles that OSS and its use, regardless of the purpose, is excluded. The current proposal could result in developers or manufacturers facing full liability for defects due to the use of OSS components, which could create problems for the development of OSS in Europe.

Inclusion of AI systems

The proposal expands the scope of products covered to all artificial intelligence (AI) systems. AI encompasses a broad range of technologies that can take innumerable forms and be integrated into products and services in even more ways. There is currently no evidence showing that the current liability regimes

² IBISWorld, *Software Development in the EU – Market Research Report*, March 2022.

do not properly address AI systems overall. Higher-risk AI use cases will be regulated by the future AI Act.³

To reduce overlap with the proposed AI Liability Directive (AILD),⁴ which establishes a fault-based liability framework for AI based on the AI Act, we recommend introducing an ‘AI Act exception’ to Art. 6(1)(f) to specify that non-compliance with the AI Act cannot be used to show defectiveness under the PLD. With this clarification, harm caused by AI technology that fails to comply with the upcoming AI Act’s requirements can be compensated under the AILD, whilst the PLD would still apply when a defect is not linked to non-compliance with the AI Act.



Definitions

It is vital that key PLD definitions are consistent with those set out in existing legislation, particularly those in the New Legislative Framework (NLF). This will ensure that parties can rely on guidance documents, namely the Blue Guide,⁵ to understand and interpret critical language in the PLD.

Defectiveness of a product

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.’⁶ The definition is vague and risks undermining legal certainty. The criterion must ensure that the defectiveness standard is objective and does not extend to regulatory compliance considerations.

The proposal refers to ‘reasonably foreseeable use and misuse’ in relation to defining the defectiveness of a product.⁷ The misuse of a product does not indicate defectiveness, and manufacturers should not be held liable for misuse under strict liability. The notion of ‘foreseeable’ already implies some degree of fault. National liability regimes already cover these kinds of scenarios as fault-based, e.g. breach of vigilance/monitoring duties. Similarly, the reference to the effect ‘of other products that can reasonably be expected to be used together with the product’ should be deleted.⁸ Such scenarios should – and are – covered under national fault-based liability regimes. At the very least, this must be modified to account for the information manufacturers provide consumers to guide their use of a product. The law must remove liability for manufacturers

³ COM(2021) 206 final.

⁴ COM(2022) 496 final.

⁵ 2022/C 247/01.

⁶ Art. 6(1) of the proposal.

⁷ Art. 6(1)(b), *ibid.*

⁸ Art. 6(1)(d), *ibid.*

for all misuse that is reasonably foreseeable, but for which the manufacturer has included relevant warnings.

The proposal expands the notion of defectiveness to the ‘effect on the product of any ability to continue to learn after deployment,’ directly targeting AI systems.⁹ In practice, such learning will likely happen outside the provider’s control because the user deploying the AI system may have retrained the system according to their needs or be feeding their own input data to the system. The proposed AI Act recognises the complexity of allocating responsibilities across different actors, notably that users may exercise control over the input data.¹⁰ For this reason, this consideration of defectiveness should be deleted from Art. 6.

The proposal also requires that defectiveness considers any intervention by a regulatory authority or an economic operator related to product safety.¹¹ However, interventions by an economic operator are often aimed at establishing the product’s conformity with regulatory obligations. In most cases, non-conformity with regulatory obligations does not cause any damage or result in the product being defective within the meaning of product liability law. This is particularly the case for safety-relevant cybersecurity requirements.¹²

Finally, the proposal establishes that the ‘specific expectations of the end-users for whom the product is intended’ play a role for evaluating a product’s defect.¹³ This is a subjective test and should therefore be removed.

Manufacturer’s control

The definition of ‘manufacturer’s control’ in the context of the related service should be properly reflected in the recitals to avoid an overly broad interpretation.¹⁴ The definition clearly states that the manufacturer must ‘authorise,’ for instance, the integration of a component. However, Recital 15 goes further by including behaviour such as ‘otherwise influenc[ing components] supply by a third party,’ which lacks precision and legal certainty.



Economic operators liable for defective products

Fulfilment services providers and online marketplaces

⁹ Art. 6(1)(c), *ibid.*

¹⁰ Art. 29(3) of the AI Act proposal,.

¹¹ Art. 6 (1)(g) of the proposal.

¹² Art. 6(1)(f), *ibid.*

¹³ Art. 6(1)(h), *ibid.*

¹⁴ Art. 4(5), *ibid.*

We welcome the recognition that businesses with no power over the manufacturing process, such as online marketplaces and retailers, should not be considered liable for damage caused by defective products.¹⁵ It would be unfair and inadequate to expand the scope of the PLD to make online marketplaces liable for damages caused by defective products sold via them, although they do not act as a retailer or importer, and hence never take possession of the physical product. In this regard, Art. 20 of the General Product Safety Regulation¹⁶ or the DSA will enable consumers to identify traders (manufacturer or importer) from whom to seek redress.

We also support the reference to the DSA liability exemption to ensure coherence and consistency with product safety regulations.¹⁷ 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 Art. 7(3) and instead refer to Art. 7(5) for fulfilment service providers, as the marketplace provision in Art. 7(6) does.

Authorised representative

The proposal includes the authorised representative as another potentially liable operator for defective products where there is no EU-based manufacturer or importer. This is a proportionate allocation of liability. However, the concept of authorised representative should continue to be strengthened, in line with existing regulations, to make it meaningful for consumers and verifiable to prevent fraud.

Refurbished and remanufactured goods

The proposal extends liability to repairers, refurbishers, remanufacturers and businesses that ‘substantially modify’ products. We welcome this allocation of responsibility, which is essential to help promote the circular economy.

However, we are concerned that some ‘emerging’ circular economy business practices, i.e. refurbishment and remanufacturing, would not be captured by this provision. In some situations, these practices may allegedly return a product to the specification to which it was placed on the market by the original equipment manufacturer (OEM) and thus would not constitute a ‘substantial modification.’ This would result in the liability remaining with the OEM. OEMs should not be held liable for self-repair or repair or remanufacturing done through non-certified parties. We would also welcome greater clarity on the thresholds that constitute a ‘substantial modification.’

¹⁵ Recital 28, *ibid*.

¹⁶ COM(2021) 346 final.

¹⁷ Recital 28 of the proposal.



Disclosure of evidence

Whilst victims should have fair access to evidence to support their claims, information disclosure requirements must not result in the release of sensitive data or trade secrets. The PLD must contain sufficient safeguards to prevent fishing expeditions, whilst also encouraging a harmonised approach across Member States to prevent forum shopping.

The text rightly contains protections for confidential information and trade secrets.¹⁸ However, these provisions are vague and limit disclosure to what is 'necessary and proportionate,' which must consider 'the legitimate interests of all parties.' Art. 8(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. There is a risk that the practical application of the Art. 8 provisions is subject to the particularities of national courts and laws. Consequently, this 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 generally fragmented across Member States.

The Directive should clarify that, when determining whether to order the defendant to disclose information, national courts must consider inter alia that disclosing such information is 'relevant and necessary' for the claimant to demonstrate that the product is defective. This phrasing would ensure more detailed consideration for disclosure. To further safeguard the confidentiality of sensitive information, a presumption of confidentiality should be introduced for any and all material disclosed, not only information 'used or referred to in the course of the legal proceedings' as the text currently suggests. Additional measures to consider could be a mandatory, court-led, private review of all material that could be considered a trade secret and the introduction of confidentiality rings. The PLD should also determine that each Member State must have a system of administrative fines in place, provided for by national law, in the event of a breach of confidentiality. Administrative fines should adequately respond to the nature, gravity and consequences of the breach.

It is also notable that the proposal does not create reciprocal rights for defendants, such as the right to request medical records, proof of purchase or financial loss. Under the proposed framework, the claimant would only disclose information about what they want to prove. The scope may differ for any arguments the defendant may want to prove as a counterargument. Thus to create balance, the proposal should be amended to give the defendant the right to request additional relevant information as part of discovery. If the claimant refuses to disclose the relevant evidence, the defendant should not be obliged to disclose the information either. Introducing this balance is particularly

¹⁸ Art. 8(2)–(4), *ibid.*

important, considering that when a defendant denies a request for disclosure of evidence, the presumption of defectiveness is automatically invoked.



Alleviation of the burden of proof

We support the desire to ensure victims can still claim compensation even in complex situations. However, there is little practical evidence to support the claim that certain parties currently struggle to prove causality between defect and harm. Clarifying what the claimant must do and prove before alleviating the burden of proof is essential to prevent excessive litigation and potential non-legitimate claims.

Art. 9(4) allows for the burden of proof to be eased for scientifically or technically complex cases. However, this approach has the contradictory effect that the more difficult it is to prove a defect, the easier it is to prove a defect, as the defect becomes assumed. If the burden of proof is to be reversed for reasons of technical or scientific complexity, then we suggest that this should be within tightly controlled limits set out for national courts to apply. Art. 9(4) could provide greater legal certainty by further clarifying what constitutes 'excessive difficulties' in proving the causal link between a product's defectiveness and the damage. Additionally, more information regarding what will be considered 'sufficiently relevant evidence' would reduce the paragraph's ambiguity.

The PLD should be technology agnostic. The reference in Recital 34 to medical devices, read in conjunction with Art. 9(4), creates a quasi-presumption that all innovative medical devices are complex or high-risk. The portfolio of products in the medical technology industry is extremely diverse, ranging from high-tech products such as surgical robots to everyday products such as glasses or plasters. A blanket presumption of innovative medical technology as a 'complex product' does not reflect the sector's reality and will result in the reversal of the burden of proof for an entire industry sector, which is unwarranted in light of the strong shift in EU product safety legislation in this sector.¹⁹

The proposal also gives a presumption of defectiveness where the damage was caused by an 'obvious malfunction' of the product during 'normal use or under ordinary circumstances.'²⁰ This is problematic because there is no definition or guidance on how to interpret the terms 'obvious malfunction,' 'normal use' or 'ordinary circumstances.' A lower legal test for an 'obvious malfunction' than for 'defect' effectively renders the concept of 'defect' irrelevant.



Compensation thresholds

¹⁹ Regulations (EU) 2017/745 and 2017/746.

²⁰ Art. 9(2)(c) of the proposal.

We support the rights of victims to seek compensation for damage caused by defective products, as well as the need to ensure a harmonised approach across Member States so that victims with similar claims can receive comparable compensation wherever they are in Europe.

Considering the proposal's broadened scope and the new rules for alleviating the burden of proof for victims, the minimum threshold of €500 for property damage should be maintained to avoid excessive litigation and burdensome administration for businesses. A minimum threshold prevents frivolous claims and maintains the back-stop nature of the regime, whilst an upper maximum allows for insurable risks. Instead of eliminating it, updating and increasing the financial ceiling is a more appropriate solution to balance the claimant's interests and provide legal certainty. These figures should be subject to maximum harmonisation to address issues the Commission has identified with the current divergence across Member States in implementing the thresholds.



Compensation for data loss and psychological harm

Victims should be fairly compensated when defective products cause death, physical injury or damage to property. However, we caution against including compensation for immaterial losses, such as the loss or corruption of data or damage to psychological health.

The procedural burdens for all parties involved in the case of non-material damages would be disproportionate, in part due to the fact that such damages are notoriously difficult to quantify.²¹ The inclusion of non-material damages under the PLD would hold manufacturers and developers liable for consequences that are unforeseeable and potentially unlimited. This would materially increase the price of products for end-users. Existing EU legislation, such as the GDPR, already provides redress mechanisms for consumers for many types of non-material damages.²² Providing a separate, potentially overlapping basis for compensation here and elsewhere can create confusion, and lead to forum shopping and double claims for a single harm.

Further, it is uncertain in the current text whether indirect damages could be compensated, or to what extent liability applies to data losses that could have been mitigated with appropriate backups. The text includes a provision that an economic operator's liability may be reduced when damage is caused by both the product and the fault of the injured person.²³ As a general principle, certain national frameworks considers it a requirement for entrepreneurs to regularly back up relevant data. It should be clarified that failure to regularly back up

²¹ For example, if a student failed to submit a paper due to a software crash that caused data loss or corruption, resulting in a failed class, they could sue the developer for compensation of all the consequential damages, e.g. an additional year of studies and lost income.

²² Regulation (EU) 2016/679.

²³ Art. 12(2) of the proposal.

relevant data by consumers should also be considered negligent and therefore reduce the damage to be compensated.

The proposal stipulates that the definition of damage includes material loss resulting from psychological harm. However, greater clarification is needed to identify the scope of what aspects of such loss are to be compensated and, in particular, what claimants must prove to claim such damage, i.e. diagnosis by a medical professional and/or defined conditions.²⁴ The current proposal does not outline whether this would, for example, cover the cost of treatment or loss of income. If the material loss to be compensated is decided under national tort law, then this should also be clarified.



Limitation periods

The ten year limitation period for victims to claim under the PLD for software (Art. 14) does not take into account the average lifespan for software or consumer expectations. For example, a survey by German consumer organisation VZBV, demonstrated that consumers expect to receive smartphone updates for a period of five years.²⁵

It should also be clarified that releasing a software update does not constitute a fresh placing on the market for the purposes of the limitation period. Otherwise, this limitation period has the potential to extend indefinitely for software, when taken in conjunction with the implicit obligation of producers to provide ongoing software updates for products.

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²⁴ Art. 4(6) of the proposal.

²⁵ 'Consumers want smartphone updates for five years,' available at <https://www.vzbv.de/pressemitteilungen/verbraucher-wuenschen-sich-fuenf-jahre-lang-smartphone-updates>.

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