

# Commission Guidance for Implementation of the EU Product Liability Directive

In 2024, the European Union made significant changes to the EU product liability regime by amending the Product Liability Directive (“PLD”), to update it in light of technological and other developments. The EU and EFTA Member States, together with Northern Ireland, are required to transpose the revised PLD by the end of 2026. The law will then enter into application in product liability cases before judges throughout the EU, EFTA and Northern Ireland.

While an objective of the PLD is harmonization, this will be difficult to achieve because core concepts of the Directive are set forth in open-ended language that lacks clarity. EU Member States are already implementing the PLD without resolving the many uncertainties in the text. In some cases, key terms in EU Member States’ implementing legislation are even more uncertain than the Directive itself. The resulting legal uncertainty and divergence will worsen once national judges start applying the law, each according to their own diverse legal traditions.

Uneven and inconsistent implementation of the PLD will prejudice the EU business environment, undermining internal market goals and deterring European investment, innovation and competitiveness.

It is imperative that the Commission issue guidance to clarify how key provisions of the PLD should be interpreted and applied by EU Member States. Pending the issuance of such guidance, the Commission should propose an extension of the timeline for PLD implementation.

This paper explains why Commission guidance is urgently needed to support the coherent, harmonized application of the PLD across the European Union. After a brief outline of the major changes introduced by the PLD, the paper focuses on the new legal presumptions of defectiveness, harm, and causation. The paper explains how divergent legal standards are already emerging in relation to the presumptions and the assessment of product defectiveness.

## The Revised Product Liability Directive and its Impact

The PLD’s objective is to modernize the EU’s product liability regime on a harmonized basis in light of technological developments, digitization and evolving supply chains. To that end, the revised PLD introduces significant changes to the product liability regime. First, the PLD will now apply to a broader range of

products, including digital and software products. Second, for all subject products, the PLD introduces mandatory presumptions in relation to the defectiveness of a product, causation, and harm, which apply when certain trigger conditions are met.

These are far-reaching changes to long-standing evidentiary standards and procedural rules in Member State law, especially for innovative products. It is vital that changes of such profound importance to the rights and interests of consumers and companies be clear. The effective functioning of the internal market also depends on the adoption of clear, common rules that are capable of consistent and predictable application.

The revised PLD does not meet these standards, because several of the law's most consequential provisions turn on wording that lacks clarity. Remarkably, it is not clear what impact the revised PLD has on the claimant's burden of proof nor what evidentiary thresholds apply to the parties when the PLD's presumptions are engaged. Even the legal conditions that trigger the application of the presumptions are unclear.

In transposing the PLD, Member States are not attempting to resolve these uncertainties and, instead, they are simply copying the PLD's unclear wording. As a result, the problem of ensuring consistent and predictable application across the internal market will fall on national judges. Yet, with thousands of judges from more than 30 countries that have diverse legal traditions, evidentiary standards and procedural rules, it is inevitable that the PLD will be interpreted and applied in divergent ways.

There is a straightforward, practical solution: the Commission should issue urgent guidance on how key provisions of the law should be interpreted and applied. The Commission has a longstanding practice of issuing guidance to facilitate the harmonized application of EU law, whether aimed at initial transposition or subsequent application. In this case, even though Commission guidance would not be formally binding, it would significantly lower the risks of fragmentation resulting from divergent application in national courts. This would make a strongly positive contribution to the achievement of the PLD's objectives, with no obvious downsides.

## **Uncertainty in the PLD: Presumptions of Defectiveness, Harm and Causation**

The PLD's provisions on the presumptions of defectiveness, harm and causation give rise to uncertainty in two principal areas: first, the legal consequences of the presumptions themselves; and, second, the scope of the PLD's conditions for triggering the application of the presumptions. Commission guidance is needed to clarify each of these two areas of uncertainty.

### **The legal consequences of the presumptions are unclear.**

Remarkably, the PLD fails to make clear the legal consequences of the mandatory presumptions it creates. Article 10(1) of the PLD states that the claimant must prove the defectiveness of a product, damage and the causal link between them. This suggests that the claimant is expected to bear the burden of proof. However, the remainder of Articles 10(2)–(4) immediately casts considerable doubt on this position. These paragraphs provide that defectiveness and/or causation “shall be presumed” when certain conditions are met. On its face, this means that, when the presumptions apply, the defectiveness of a product, harm and causation is treated as

established, unless the defendant proves the reverse with evidence. This effectively reverses the usual burden of proof, which, according to Article 10(1), supposedly applies to the claimant.

There is, therefore, an inherent and unresolved tension in the language used in Article 10. These textual uncertainties are confirmed by the divergent explanations of Article 10 given by the Commission and the Member States. In Recital 42 to the Directive, the Commission notes that to achieve a fair apportionment of risk, “a person that claims compensation ... should bear the burden of proving the damage, the defectiveness of a product and the causal link between the two, in accordance with the standard of proof applicable under national law”. In Recital 46, the Commission has said the presumptions in Articles 10(2)-(4) merely “alleviate” the claimant’s burden. While some Member States seem to agree with the Commission’s “alleviation” theory, other Member States have said explicitly that the presumptions reverse the burden of proof.<sup>1</sup>

It is wholly unsatisfactory for the revised PLD to lack clarity about the legal consequences of a foundational provision of the law. The PLD is supposed to harmonize EU law. Yet, the unclear language in Article 10 prompts divergent explanations about its meaning. These divergences will almost certainly grow when the law is applied by national courts.

Besides this lack of clarity on the burden of proof, Article 10 also fails to address the evidentiary thresholds that apply in relation to the presumptions, even in conceptual terms. If the Article 10 presumptions indeed merely “alleviate” the claimant’s burden rather than reversing it, the Directive fails to elaborate on the extent to which the burden of proof must be “alleviated” on a harmonized basis. Although unusual for EU law to address such procedural matters, it is the very essence of the PLD. The PLD does not indicate, for example, whether, under this alleviated burden, the claimant must satisfy the ordinary civil standard of proof or, if not, whether the applicable harmonized alleviation standard must be rather close to the regular standard or markedly lower. So far, the draft transposition laws also fail to tackle this important question. In the interests of legal certainty and predictability across the internal market, clarification of the extent of alleviation is needed.

Further, from the perspective of the defendant, neither the PLD nor the draft transposition laws made public so far clarify what evidentiary threshold it must meet to displace a presumption once engaged. The same range of options for the evidentiary standard apply to the defendant’s rebuttal: from a standard akin to the ordinary civil standard of proof to one that is markedly lower. The PLD and the transposition laws are silent.

Without Commission guidance, the uncertainties in the PLD will inevitably lead to national judges holding claimants and defendants to divergent evidentiary standards across countries. In the context of the PLD, these divergent approaches will lead to forum shopping by claimants, which is unfair to defendants, and inimical both to the harmonization objectives of the PLD and the overall goals of the internal market.

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<sup>1</sup>Report of the Product Liability Inquiry (Sweden), SOU 2025:103, p. 199.; Proposal on Product Liability Act (Denmark), Doc. 3812830, pp. 20, 95 - 100; Product Liability Working Group Report (Finland), Doc. 2026:8, pp. 38 - 39.

## The PLD's trigger conditions for the presumptions are unclear.

The PLD's presumptions are triggered when certain legal conditions are met. These conditions are set out in Articles 10(2)-(4) of the PLD and are central to the operation of the presumptions. In essence, they serve as the legal gateway to the presumptions. It is, of course, very important for the trigger conditions to be clear. A judge and the parties must know when the gate should be opened to allow the claimant an easier pathway to success in its case; and this gateway should be applied consistently and predictably across the internal market.

In several instances, the PLD fails to make clear when and how the gateway operates, because the PLD's trigger conditions rely on wording that is open-ended and indeterminate, meaning that the words can easily be interpreted and applied differently. Consider these examples:

- Article 10(2)(a) provides that defectiveness shall be presumed when the defendant fails to disclose “relevant evidence”. The term “relevant” is not defined, nor does the Directive distinguish between deliberate non-disclosure and situations where evidence is unavailable, outside the defendant's possession, or subject to legitimate confidentiality constraints. Applied mechanistically, the provision risks triggering a presumption in circumstances that do not reflect either obstruction or bad faith by a defendant. In order to preserve proportionality, the presumption should apply only where non-disclosure reflects an unjustified failure to cooperate, rather than where legitimate or practical reasons explain the absence of production.
- Article 10(2)(c) provides that defectiveness shall be presumed when damage is caused by an “obvious malfunction” during “reasonably foreseeable use” or under “ordinary circumstances”. Each of these terms could be applied in quite different ways. What is “obvious” may vary depending on perspective; what is “reasonably foreseeable” depends on how the intended use of the product is defined; and “ordinary circumstances” admits a wide range of interpretations. Without guidance, the provision risks being applied differently, including in situations where alternative explanations for a malfunction are plausible. For the sake of clarity, the presumption should be confined to cases in which the malfunction is so clear and abnormal that defectiveness is the only reasonable explanation for the facts, assessed objectively by reference to the intended use and product instructions.
- Article 10(3) provides for a presumption of a causal link between the defectiveness of a product and damage, where it has been established that the product is defective and the damage is “typically consistent with the defect in question”. The concept of “typically consistent” is not defined, and the Directive does not indicate what benchmark and evidentiary basis is required to establish that harm is “typical”. Absent objective evidence of a pattern of typical harm, the term risks being applied on the basis of assertion rather than demonstrated experience. The fulfilment of the condition should, though, be grounded in evidence that a particular type of damage is, indeed, ordinarily associated with the defect in question, rather than on predictive or speculative reasoning.

- Article 10(4)(a) establishes a presumption of defectiveness and/or causation partly on the basis that the claimant faces “excessive difficulties” in particular due to “technical or scientific complexity”. None of these words is defined any further.

Without clarification, this provision risks becoming a default pathway for triggering a presumption in cases involving innovative products. Indeed, in preparing for the transposition of the law, Sweden, Germany and Denmark have even said that this provision targets innovative products.<sup>2</sup> Guidance on the meaning of the words “excessive” and “complexity” should prevent the provision becoming a tool to discriminate against innovative products that are an essential part of a flourishing and competitive European economy.

The use of the word “excessive” in the condition indicates that a high bar must be reached to trigger the presumption. Claimants routinely face considerable difficulties in product liability cases, especially if the case is weak. Given the word “excessive”, these difficulties should not trigger a presumption. Instead, the word “excessive” should refer to “difficulties” that significantly exceed those a claimant ordinarily faces.

The assessment should also take account of all the circumstances, including the type of product at issue. Similarly, the word “complexity” should be understood as involving a higher level of complication than is usual for a product of the type at issue. Thus, the mere fact that an innovative product is complex should not trigger a presumption. Courts should also consider other available procedural tools to alleviate the claimant’s difficulties before concluding that they are “excessive”.

Troublingly, in some draft transposition laws (e.g., Finland and Sweden), the word “excessive” has been dropped, making it easier to establish a presumption. This approach highlights the need for the Commission guidance to explain the word’s important role in striking an appropriate balance of interests between claimants and defendants.

- Finally, Article 10(4)(b) requires that the claimant demonstrate that it is “likely” that the product is defective or that there is a causal link. The Directive does not clarify how the word “likely” should interact with Member States’ usual civil standard of proof nor how the word “likely” should be applied on a harmonized basis. If interpreted as permitting a presumption on the basis of mere plausibility or conjecture, the threshold would be materially lower than prevailing standards in many Member States. The term should be interpreted as requiring substantive evidentiary support to prove that defectiveness and causation are more likely than not. The mere existence of a conceivable possibility should not suffice.

The Directive is also silent on procedural issues surrounding the application of the presumptions. It does not set out what steps a national court should follow in determining whether the conditions for a presumption are met. It does not indicate whether courts should make a finding on the applicability of the presumption before proceeding to the merits, or how parties are to be informed of the evidentiary standard governing their case. Although the Member States have a degree of discretion in organizing procedural matters, the Commission should ensure that all Member States guarantee procedural rights, including following an appropriate

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<sup>2</sup>Report of the Product Liability Inquiry (Sweden), SOU 2025:103, p. 107.; Draft law of the Federal Government (Federal Council, 775/25), p. 49; Proposal on Product Liability Act (Denmark), Doc. 3812830, p. 97.

process to establish whether the claimant has proved the trigger conditions and giving the parties adequate notice of the evidentiary standards that apply to their case.

All of these matters should be clarified through urgent Commission guidance that aims to guarantee the integrity of the internal market, by ensuring that national judges across 30 countries apply the law consistently and predictably.

## **Uncertainty in the PLD: Criteria for Assessing Defectiveness**

The Directive also includes a general legal standard for establishing the defectiveness of a product. This provision, which is found in Article 7, would appear to be most relevant when the mandatory presumptions do not apply; it could also be relevant in assessing whether a presumption of defectiveness applies.

Article 7(1) provides that a product is defective where it “does not provide the safety that a person is entitled to expect or that is required under Union or national law”. The Directive, therefore, identifies the applicable health and safety standards as a core plank of the benchmark for assessing product defectiveness. This is important, because many PLD products are already subject to stringent health and safety regulation, together with the related conformity assessment procedures to ensure that a product complies with the health and safety regulation. It is appropriate for Article 7 to place weight on compliance with health and safety standards. Regulators are free to set the standards high and producers devote considerable resources to ensuring ongoing conformity with them. Regulatory compliance should, therefore, have a central place in assessing defectiveness.

In the draft transposition laws published to date, some Member States have not given regulatory compliance the weight it is accorded in the Directive. In Sweden, the implementing measure defines defectiveness by reference to whether the product provides the level of safety “that can legitimately be expected”, without reproducing the Directive’s formulation that compliance with mandatory safety requirements must be taken into account. In France, the transposition shortens the list of relevant circumstances that follow the introductory definition and does not retain the Directive’s express reference to objective legal standards in that context.

These drafting choices alter the content of the defect assessment. While regulatory compliance may still be raised as one factual consideration, it is no longer embedded as an express element within the definition itself. This shifts the weight of the legal analysis away from the objective benchmark of regulatory compliance, giving more weight to expectations that depend on perspectives.

Commission guidance would, again, be beneficial to explain that regulatory compliance is a central plank in the assessment of product defectiveness. Guidance could also assist national judges as they apply the law to ensure that they prescribe the appropriate weight to compliance with health and safety laws in deciding whether a product is defective.

## Conclusion

Guidance from the Commission is essential to clarify key terms in the PLD, notably those presented in this paper. To allow time to address ambiguity in the PLD text and issue guidance, the Commission should rapidly propose an extension of the implementation deadline. Without guidance, PLD implementation will result in a patchwork of national legal standards, uneven litigation exposure, forum shopping, and fragmentation of the internal market. Through guidance, the Commission can support Member States in framing national implementing legislation in a way that is consistent with the directive's goals, and assist with national courts' post-implementation interpretation.