Linklaters

The new EU Product Liability Directive

25 January 2024



Almost four decades after its adoption, the EU Product Liability Directive (PLD) is being completely revised. The reform was prompted by the challenges that technological progress posed to the Directive's decades-old definitions and concepts, but it ultimately led to a fundamental reform of EU product liability law as a whole. In this alert, we highlight the most important changes and the consequences for national product liability law in selected EU Member States.

Scope of application

Defect and damage

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Highlights

To bring the PLD up to speed with the digital age, circular economy business models and global value chains, the compromise text includes

> a significant extension of the scope of covered economic actors, products and damages,
> new presumptions for the defect and/or causality,
> disclosure rights,
> changes to the liability exemptions, and
> longer expiry periods in case of latent damages.

From the point of view of defendants, the amendments have the potential to change the current liability landscape significantly. They should adapt their processes to the new rules, monitor the transposition in the Member States in which they are active, and implement appropriate risk prevention mechanisms. Where relevant, they should also watch out for the progress of the work on an AI Liability Directive aiming at a targeted reform of the respective national liability regimes (read more) and new collective redress mechanisms (read more).

Scope of application

The new PLD sets a wider definition of 'product' and broadens the circle of liable parties significantly.

Broadening the range of products covered

The new PLD will apply not only to tangible products but also to intangible goods. In particular, in line with the reform's aim to adapt product liability law to the digital age, the new PLD will explicitly apply to software and digital manufacturing files:

- Software is covered regardless of whether it is placed on the market as a stand-alone product or is subsequently incorporated as a component into other products, and regardless of how it is supplied or used. It includes "operating systems, firmware, computer programs, applications or AI systems". On the other hand, the source code of software is not considered as a product. Moreover, to avoid impeding innovation or research, the new PLD does not apply to open-source software that is developed or supplied outside the course of a commercial activity.
- Digital manufacturing files, which contain the functional information necessary to produce a tangible item by enabling the automated control of machinery or tools, such as drills, lathes, mills and 3D printers, are also considered as products (e.g., CAD files used to create 3D-printed goods).

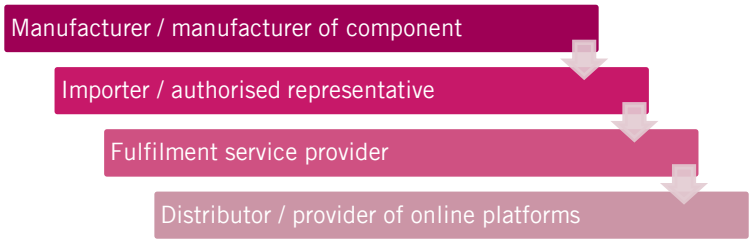
Temporal scope of application

The new PLD will apply to products placed on the market or put into service 24 months after its entry into force.

Liable economic operators

The manufacturer and the manufacturer of a component that has caused the product's defect are primarily liable. Any person that substantially modifies a product already placed on the market or put into service may also be considered a manufacturer. Software developers (including AI system providers) are treated as manufacturers, but the manufacturer's right to recourse against the software developer can be limited (e.g., in case of SMEs).

If the manufacturer is located outside the EU, the importer or – new compared to the old regime – the authorised representative of the manufacturer may be held liable. If those are also located outside the EU, liability could shift to the fulfilment service provider, which includes "any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching of a product, without having ownership of the product", with exceptions concerning postal services and freight transport services. Where such economic operators cannot be identified in the EU, distributors and providers of online platforms shall also be liable subject to certain conditions.



By extending the scope of application, the PLD will be modernised and brought in line with other legislation (e.g., by introducing a layered personal scope). In practice, this will lead to a considerable expansion of the EU product liability regime, which companies will have to adapt to.

Defect and damage

As under the old regime, an injured person will be entitled to claim damages caused by a defective product.

Definition of defect

The assessment of defectiveness should involve an objective analysis of the safety that a person is entitled to expect, referring to the expectations of the public at large rather than those of any particular person, or the safety that is required under Union or national law. The revised PLD inter alia mentions the following aspects to take into account when assessing the defectiveness:

- Courts will consider, amongst others, the characteristics, the intended purpose, and the properties of the product in question as well as the specific needs of the group of users for whom the product is intended.
- Product safety requirements, including safety-related cybersecurity requirements, will also be relevant.
- Moreover, to consider the increasing prevalence of inter-connected products, the assessment should factor in the effects products can have on one another.
- Also, to target AI systems, the product's ability to learn after its deployment will have to be taken into account. Since machine learning enables products to adapt to safety hazards, this ability might alter safety expectations, too.

However, as was the case under the previous regime, a product will not be considered defective merely because a better product (incl. updates or upgrades) is placed on the market.

Relevant time for the existence of a defect

As under the old regime, the moment in time when the product is placed on the market or put into service will be relevant for determining whether the product is defective. However, if the manufacturer retains control of the product after that time, the relevant moment will be when the product leaves the manufacturer's control. In particular, this may be relevant in case of software updates under the manufacturer's control, a failure to address cybersecurity vulnerability, or machine learning. Hence, developers could be held liable for emerging technologies that learn independently and for deployment of updates or lack thereof.

Damage

Damages covered continue to include death, personal injury and property damage. In addition, the PLD now explicitly mentions medically recognised harm to psychological health. Moreover, destruction or corruption of data that is not used for professional purposes will also be covered.

In practice, the question of how to quantify the monetary value of these new categories of damage will often arise.





Burden of proof

In principle, the claimant continues to bear the burden of proving the defect, the damage and the causality between defectiveness and the damage. However, the new PLD alleviates the claimant's burden of proof by introducing new (rebuttable) presumptions for the defect and/or causality in light of the practical difficulties of proving causation for complex products:

- The defectiveness may be presumed if
  - the defendant does not meet its duty of disclosure (see below),
  - the claimant demonstrates that the product does not comply with applicable mandatory safety requirements, or
  - the damage was caused by an obvious malfunction of the product during normal use under ordinary circumstances.
- A causal link is presumed if the damage caused is typically consistent with the defect in question. Moreover, it should will be possible for a court to find a product defective without establishing its actual defectiveness, where it belongs to the same production series as a product already proven to be defective.
- The defect, the causal link or both shall also be presumed if the claimant
  - faces excessive difficulties, in particular due to technical or scientific complexity, in meeting his burden of proof, and
  - demonstrates that is likely that the product was defective and/or likely contributed to the damage.

  Determination of the technical or scientific complexity should be made on a case-by-case basis, considering, for instance, the complex nature of the product (e.g., an innovative medical device), the complex nature of the technology used (e.g., machine learning), the complex nature of the data and information to be analysed by the claimant, and the complex nature of the causal link (e.g., the link between a pharmaceutical or food product and the onset of a health condition, or the inner workings of an AI system). It remains to be seen whether this will lead to an actual simplification in practice or whether it will create new uncertainty, for instance with regard to the requirements of likelihood.

All of these presumptions will, in principle, be rebuttable, but in practice they are likely to lead to a *de facto* reversal of the burden of proof and thus to significant liability risks for potential defendants. Overall, the multitude of presumptions in favour of claimants is a real game changer in some jurisdictions.

> In many cases, it will be difficult for the defendants to rebut the new presumptions. If doubts remain, they may be held liable. The risk of a *non liquet* situation is thereby shifted from the claimant to the defendant and the wording of the respective provisions will give courts the option for a liberal interpretation of the requirements.



Disclosure

To further address the information asymmetry and the obstacles for claimants to prove their claims, the PLD also establishes a new disclosure obligation for defendants to provide the necessary evidence upon a duly reasoned request by the claimant. On this basis, claimants might, for instance, gain access to construction or product planning data.

However, courts will have to ensure that the information is limited to what is necessary and appropriate to substantiate the claim. Therefore, courts will have to consider the legitimate interests of all parties to achieve a fair balance of these interests (e.g., trade secrets or confidential information). To that end, they have to take specific measures necessary to preserve confidentiality of, for example, business secrets.

Due to the full harmonisation effect of the new PLD, it is unlikely that national legislators will restrict disclosure obligations as part of the implementation of the PLD. Depending on how much disclosure is already possible under the current law in a specific jurisdiction, the effect of the new rules will differ.

In addition, the impact on defendants will also depend on how the courts will deal with the new provisions. If the national courts and the CJEU do not exercise a sense of proportion when interpreting the new rules, the floodgates will be opened to disclosure requests that could have a blackmailing potential similar to that of Anglo-American class actions.

Moreover, judges are entitled to order that the evidence is presented in an easily accessible and easily understandable manner, if such presentation is deemed proportionate by the national court in terms of costs and effort for the required party. It cannot be discarded that a judge may on this basis order defendants to produce *ad hoc* documents providing the information sought by claimants, which can be very controversial.

In many European jurisdictions, companies are not familiar with disclosure and now have to adapt their documentation, document retention and document classification policies. It is crucial to prevent the publication of business secrets and successful fishing expeditions aiming for detrimental information on, for example, the development process, product testing, the assessment of competitors' products, alternative design options and the like. Information packages that will likely be requested in contentious scenarios should be readily available and reasonable in scope.

Finally, it is also worth noting that defendants will have similar disclosure rights vis-à-vis claimants should they need evidence for the purposes of countering a claim for compensation, in particular for rebutting the new presumptions. Companies should make use of those rights to create a level playing field. Information and documents provided by claimants will often hint to alternative causes or allow a challenge of damage positions.



The introduction of disclosure requirements deeply interferes with the national civil procedural law of some Member States. The same applies to the new rules to alleviate the claimant's burden of proof. Together, these measures will lead to a significant procedural disadvantage for defendants who are already strictly liable regardless of fault.

Exemptions from liability

The new PLD modifies the exemptions to the liability of economic operators:

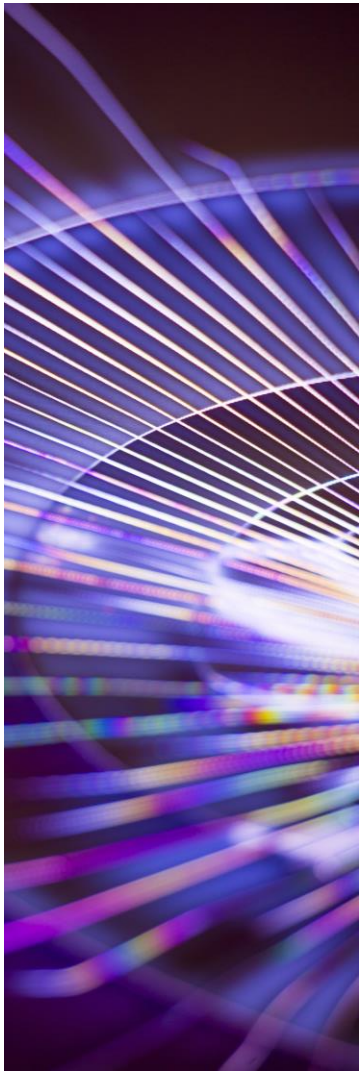
- As before, liability will be excluded if the defectiveness did probably not exist when the product was put into circulation. What is new compared to the old PLD is that this exemption shall not apply where the defectiveness is due to
  - a related service,
  - software, including software updates or upgrades,
  - the lack of providing software updates or upgrades necessary to maintain safety, or
  - a substantial modification.

  This is because digital technologies enable manufacturers to retain control over the product beyond the time of its launch, whether in the form of upgrades, updates or machine learning algorithms. However, the counter-exception will only apply if the related service, the software etc. is within the manufacturer's control. They should be considered within the manufacturer's control where they are supplied by that manufacturer or where that manufacturer authorises them or influences their supply by a third party.
- As mentioned, economic operators that carry out repairs or other operations that involve substantial modifications may also be held liable. In this case, liability will be excluded if the damage is related to a part of the product not affected by the modification.

Further exemptions will continue to apply, albeit sometimes with a slightly different wording and/or clarifications (e.g., if the economic operator did not put the product into circulation, or if the defect is due to compliance with legal requirements). Importantly, the exemption for scientifically and technically undiscoverable defects (the so-called "state of the art defence") will in principle continue to apply, but, at the Council's request, the Member States will still have the option of derogating from this exemption.

On the other hand, the previous exemption from liability for products placed on the market outside of professional activity has been deleted. Moreover, the current lower threshold for property damages and the maximum liability limits for personal injury, which were left to the discretion of the Member States under the current regime, are to be discontinued.

Overall, exemptions remain limited in line with the general approach to support consumer claims. In practice, due to the high thresholds applied, for instance for the state of the art defence, they did not play an important role in the past and are unlikely to become relevant in the future.



Limitation and expiry periods

Like under the current PLD, a limitation period of 3 years will apply starting from the day the claimant became aware, or should reasonably have become aware, of the damage, the defectiveness and the identity of the defendant.

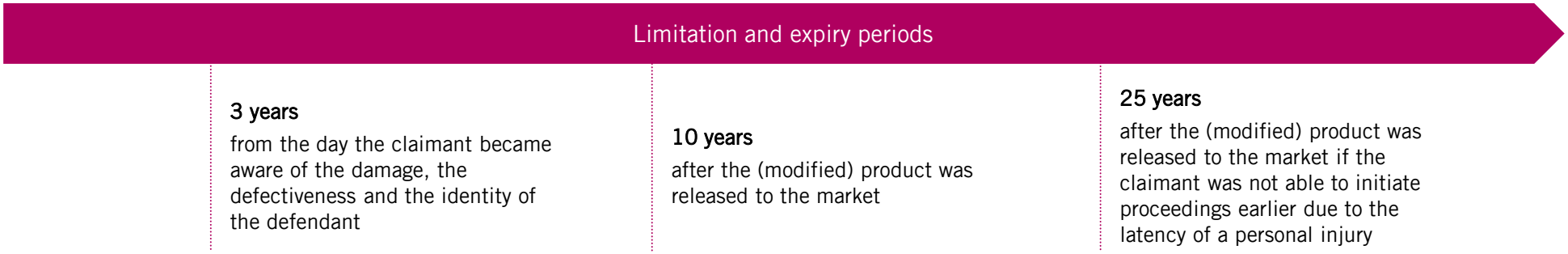
In any case, the claim will – as is currently the case – expire within 10 years or – in deviation from the current regime – after 25 years if the claimant was not able to initiate proceedings earlier due to the latency of a personal injury. While the previous PLD referred to the date on which the producer put the product which caused the damage into circulation, the new PLD refers to

> the date on which the defective product which caused the damage was placed on the market or put into service or,

> in the case of substantially modified products, the date the product was made available on the market or put into service subsequent to the substantial modification

While the general limitation period stays the same, the shift of the starting point for the expiry period as well as the extension of the expiry period in cases of latent damages lead to increased uncertainty regarding liability risks for products that have been on the market without the emergence of any issue. While there was so far a reasonable assumption that damage claims were unlikely after a certain amount of the product's lifetime had passed, the new provisions lead to risks well beyond this point in time.

> For defendants, the new, very long expiry period of 25 years for latent damages could entail incalculable liability risks depending on how it will be applied in practice.

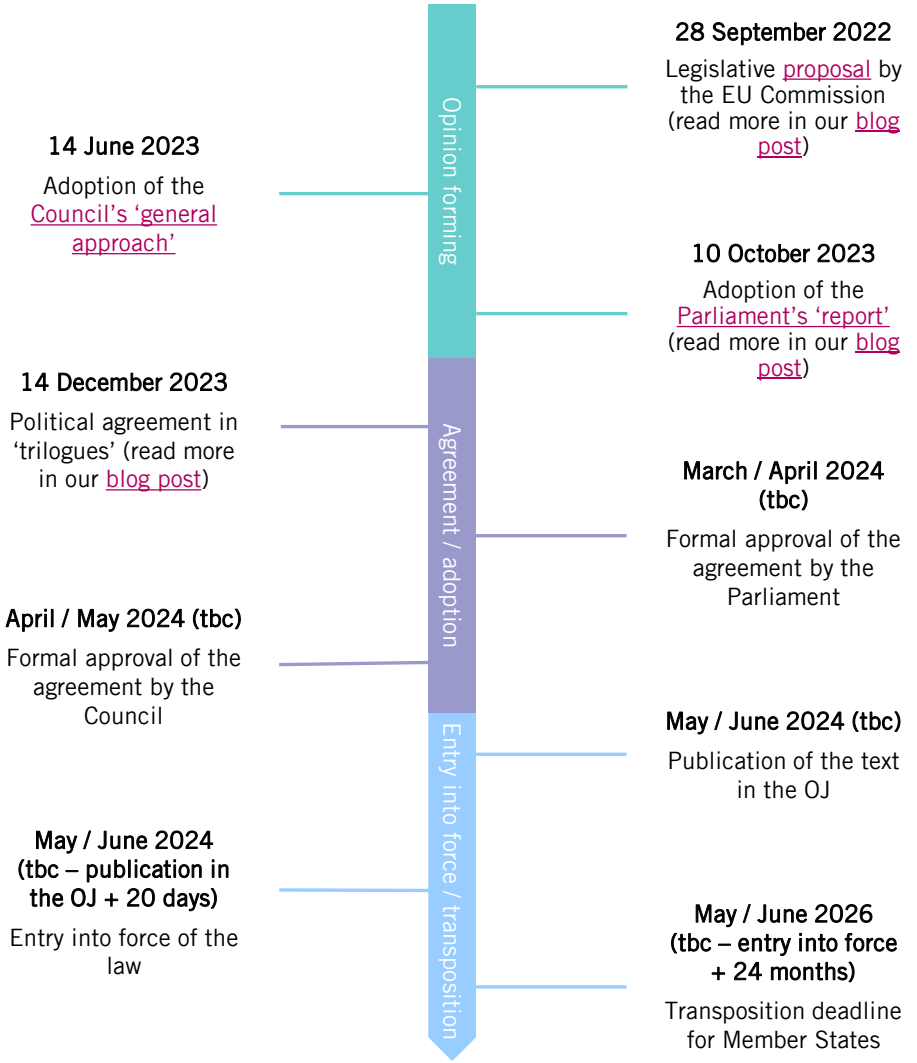


Transposition into national laws - timeline

Following formal adoption by the EU Parliament and the Council, the PLD will be published in the Official Journal of the EU (OJ) and enter into force on the 20th day following its publication. Afterwards, it has to be transposed into national law within 24 months. Hence, we expect the new rules to enter into force in mid-2026.

Yet, it is already evident that the new PLD will necessitate far-reaching changes to national product liability law (see overview of the most important aspects on the next page). In part, this also affects the fundamentals of national civil procedural law. Nevertheless, the Directive gives the Member States little room for manoeuvre. Rather, they are generally not allowed to maintain or introduce, in their national law, provisions diverging from those laid down in the PLD, including more or less stringent provisions to achieve a different level of consumer protection (principle of full harmonisation).

The period until the rules apply should be used by companies to familiarise their employees with the new rules and implement appropriate risk prevention mechanisms. Where applicable, they should also closely monitor the progress of the planned AI Liability Directive, which aims at facilitating claims relating to malfunctioning AI systems under national fault-based liability regimes (read more in our blog post on the proposal for this Directive). On our blog Product-LiabilityLinks, we will keep you posted about further developments as regards the PLD's implementation in the Member States as well as the AI Liability Directive.



Transposition into national laws – highlights in selected EU Member States



Belgium

- It remains to be seen how the new provisions alleviating the burden of proof for claimants will interact with the existing claimant-friendly rules on evidence in Belgium.
- The new regime on disclosure of evidence will broaden the currently limited possibilities to compel document production under Belgian law.
- The introduction of an expiry period of 25 years will create one of the longest time limits in Belgian civil liability law.



France

- The current state of the art exemption is not applicable if "*the damage was caused by an element of the human body or by products derived from it*". This provision is inconsistent with the new PLD and needs to be revised.
- Although the new PLD explicitly excludes from its scope damages caused to the "*property used for professional purposes*", it does not prohibit Member States to extend their national laws to such damages and France may keep its current legislation to that end.



Germany

- The new disclosure obligations go well beyond what is currently possible under German law and will require new approaches to document retention policies.
- The new assumptions regarding all three requirements for a product liability claim – existence of a defect, a damage and a causal nexus between the two – renders the defence much more difficult and has the potential to lead to early settlements to the detriment of manufacturers without proper investigations of a claim by the courts.



Spain

- In light of current claimant-friendly case law, it is expected that judges will not be strict with regard to requiring claimants to prove the conditions for the alleviations of the burden of proof.
- The reference to product safety requirements as an element to assess defectiveness will assist defendants in relation to highly regulated products.

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