The new Product Liability Directive

An update on the EU's modernised, consumer-friendly product liability regime

On 18 November 2024, the the new Product Liability Directive (**PLD**) was published and will come into force on 9 December 2024. It will update the EU-wide regime governing claims by consumers for compensation where a product causes them harm. The EU's current product liability regime dates back to 1985.

The overhaul is a response to digital advancements, the circular economy and global supply chains, and is designed to ease the way for claimants to pursue legal action, in particular in complex cases. Member States must implement these changes into their national laws by December 2026.

The revised PLD retains many similarities to the current regime and the principle of strict liability (i.e. irrespective of fault). It is still the case, at least formally, that for liability to arise, the consumer must prove that a defect in a product caused them to suffer loss or damage of a type that falls within the scope of the PLD. However, within that overall framework, the PLD introduces very significant claimant-friendly changes, including:

- expanding the scope of the definitions of "product" (to include e.g. software) and "damage" (to include medically recognised psychological harm);
- broadening the list of potential defendants to include additional stakeholders in the supply chain;
- creating rebuttable presumptions as to defect and causation to help claimants prove their case; and
- requiring Member States to introduce important procedural changes, including the introduction of disclosure requirements and extending the limitation "longstop" in cases of latent harm.

We anticipate profound implications for all businesses involved in the supply chain for products that are placed on the EU market across all product categories. We expect certain businesses producing or reliant on digital products, as well as the life sciences sector, to feel this most acutely. This briefing highlights the key changes to help businesses prepare to mitigate the increased litigation risk presented by the PLD.

1. Liability extended to digital products and AI

The regime has always had a broad remit in terms of types of products covered, but a significant change is the explicit inclusion of software within the definition of "products" in scope. All software – whether embedded in hardware or distributed independently – will fall within the regime. This includes software updates, upgrades and AI.

This extension also applies to interconnected devices, such as those forming part of the Internet of Things (IoT). Connected services refer to digital services that are integrated into or connected with a product, such that the product cannot perform its functions without them. Examples include cloud services for smart devices or real-time data services for navigation systems.

The significance of all this is that producers of software, including AI applications and IoT devices, can for the first time be held liable under the EU's no-fault liability regime if the software they produce causes harm to consumers (including data loss or damage to mental health – see below).

2. Additional defendants: extension to ARs, FSPs and online platforms

The PLD uses the term "economic operator" to describe those who can be liable, echoing other EU legislation, and there is an expanded list of potential defendants in or adjacent to the supply chain. The intention is to ensure there is always an EU-based entity which may be held responsible for damage caused by the product. There may be more than one potential defendant.

The regime retains a hierarchy of potential defendants with primary liability focussed on the manufacturer of products or components (including e.g. the software developer) or – where the manufacturer is based outside the EU – on the importer into the EU or the manufacturer's authorised representative (AR). Where there is no such importer or AR, a fulfilment service provider (FSP) may be liable.

Where one of those entities cannot be identified, then others may be held liable in certain circumstances: distributors (where they fail to identify an economic operator or their own distributor within one month of a request) and online platforms (where the average consumer would believe that the product is provided either by the platform itself or by a user under its control, and where it fails to identify a relevant EU economic operator).

3. New types of recognised compensable harm: loss of personal data and damage to psychological health

The PLD will extend the scope of protected legal interests. The destruction or corruption of personal data may constitute a harm that can give rise to a claim for compensation. The Recitals clarify that this is distinct from data leaks or breaches of data protection rules and it does not cover situations where data is stolen.

Although damages for pain and suffering have often been recognised as recoverable damage under the existing rules, the PLD specifies that medically recognised damage to psychological health is recoverable (including where not accompanied by any physical injury). Concerns have been expressed that this will open the door to "worried well" litigation (i.e. by those who are currently in good health but are anxious about becoming ill).

4. New test for defectiveness

The basic test for defectiveness is very similar to that under the current regime (i.e. the product "does not provide the safety that a person is entitled to expect") with a direction that the Court take into account "all circumstances". Now however, the words "or that is required under Union or National law" have been added to the test, meaning that products which breach mandatory safety legislation are likely to be defective. In addition, the list of specific factors that the court must take into account when assessing defectiveness (alongside all other circumstances) has been redefined to align with modern technologies and regulatory frameworks.

- **Regulatory compliance**: The Court shall take into account "relevant product safety requirements, including safety-relevant cybersecurity requirements". As noted, safety requirements of EU or national law have now been included into the main definition of defectiveness. This will include new regulations such as the General Product Safety Regulation or the AI Act.
- **Product recall**: The Court must take into account any recall or similar intervention by a competent authority. There are concerns here around a potential chilling effect on the willingness of manufacturers to undertake precautionary field safety corrective action.
- **Technological factors**: The effect of a product's ability to learn after being placed on the market or to acquire new features; the reasonably foreseeable effect of other products that can be expected to be used together with the product including by means of inter-connection; and any relevant safety-relevant cybersecurity requirements. These factors recognise the dynamic nature of modern products and the risks associated with interconnected and evolving technologies.
- **Ongoing control**: Product liability extends beyond the point of sale if the manufacturer retains control over the product, such as through the ability to provide software updates or upgrades. This marks a shift from the traditional "factory gate principle" to a model where manufacturers have ongoing responsibilities for product safety.

5. Defect and causation to be presumed in appropriate cases

The new legislation introduces "rebuttable presumptions" to make it easier for claimants to prove defect and/or causation in certain circumstances. The presumptions can be summarised as follows:

- defectiveness must be presumed where: the claimant demonstrates that the product does not comply with mandatory product safety requirements intended to protect against the risk of the damage suffered; or where the damage was caused by an "obvious malfunction" of the product during reasonably foreseeable use or under "ordinary circumstances"; or where the

defendant fails to comply with its disclosure obligations (see below);

- causation between defect and damage must be presumed where it has been established that the product is defective and the damage caused is of a kind "typically consistent" with the defect in question; and
- defectiveness or causal link, or both, must be presumed where the claimant faces "excessive difficulties, in particular, due to technical or scientific complexity" to be able to prove either defectiveness or causation or both, and where the claimant demonstrates that it is "likely" that the product is defective or that there is a causal link (or both).

Although the EU Commission maintains that the burden of proof remains on the claimant and that it has not been reversed, it is not difficult to conceive of situations which could result in a de facto reversal. In such cases, the burden would shift to the defendant to prove that the product was not defective and/or that the defect did not cause the damage. This could be particularly challenging in complex cases involving e.g. multiple competing causes.

6. No minimum or maximum thresholds for claims

The PLD does not provide any minimum or maximum financial limitations on liability:

- This exposes companies to unlimited financial liability, which is particularly significant in cases of mass harm or widespread product defects.
- At the other end of the scale, the minimum financial threshold for claims will be removed. This may be significant in the mass claims context, where it may now be worthwhile to bring smaller value claims on a collective basis (facilitated by the Representative Actions Directive (**RAD**) - for further analysis on the RAD see here and here).

7. New disclosure obligations

The PLD introduces a significant procedural change in the form of disclosure obligations that may present a real challenge for defendants, in particular in those jurisdictions in which disclosure of evidence is not yet a standard feature in civil litigation.

At the request of a claimant, courts may order defendants to disclose "necessary and proportionate" evidence (e.g. documents) when claimants have presented a "plausible" case. This provision is aimed at addressing (perceived) information asymmetries between consumers and manufacturers.

Courts will be required to consider the protection of confidential information (including legal professional privilege) and trade secrets and must consider the legitimate interests of all parties including third parties. These protections could become highly relevant when considering that source code, algorithms or the data sets used to train and validate AI could become the subject matter of product liability claims.

These new requirements are likely to pose one of the most challenging practical developments for defendants, in particular in those Member States without a meaningful existing disclosure practice or procedure. In civil litigation in Germany e.g. courts may order disclosure of specific documents at an advanced stage of the litigation, but have been quite hesitant to make use of the new disclosure provisions introduced by the German legislator over recent years when implementing EU legislation.

A failure to comply with a requirement to give disclosure will, as noted above, give rise to a rebuttable presumption as to defect. There is currently uncertainty around precisely when a failure to disclose will give rise to such a presumption (e.g. this is not expressly linked to any materiality limitation). The link between non-compliance with a disclosure order and presumptions of fact is alien to some Continental European jurisdictions, so it is expected that this feature will be the subject of much debate in product liability litigation, as will be the fairly ambiguous tests for whether disclosure is "necessary and proportionate" and whether the party seeking disclosure has presented a "plausible case".

On a more positive note, at a fairly late stage of the EU negotiations, the disclosure obligation was made reciprocal, so defendants may also require the disclosure of "relevant evidence" at the claimant's disposal in certain circumstances.

In any event, businesses should carefully assess whether their document retention policies comply with regulatory standards and will sufficiently enable them to defend future product liability claims, which can be brought for up to 25 years after the exposure to a product in cases of latent harm (see below).

8. Extended limitation period for latent harm cases

At first sight, the PLD stipulates the same limitation periods as the current regime: a the three-year "standard" limitation period and a ten-year "longstop" or "expiry" limitation period.

However, the expiry period will be extended to 25 years in cases of latent personal injury (where the symptoms of a personal injury are "according to medical evidence, slow to emerge"). This was a somewhat arbitrary figure emerging from the EU political negotiations. There will be obvious challenges

in defending cases after such a period and it also creates implications for the insurability of product liability risks.

9. Exemptions

Similar defences apply in the PLD as with the old regime e.g. if it is probable that the defectiveness that caused the damage did not exist at the time the product was placed on the market; or that the objective state of scientific and technical knowledge at the time the product was placed on the market was not such that the defectiveness could have been discovered (the development risks defence or state of the art defence).

However, software and AI face specific restrictions on exemptions that may be available to other products. If liability would otherwise be excluded because the defect did not yet exist at the time the product was placed on the market, an economic operator will nevertheless be liable if the defect is due to a related service, software (including updates or upgrades), a lack of updates necessary to maintain safety or a substantial modification of the product.

There could therefore be liability e.g. for defects caused by an update installed after the product has been placed on the market or due to the lack of such an update. The reference to a *lack* of software updates may be seen to effectively introduce a (product liability) obligation by the back door for software developers to provide updates in order to maintain product safety in circumstances where they may have no such obligation through existing provisions under the EU's tech regulation framework.

10. Transfer of claims and collective actions

The PLD explicitly allows claims to be transferred and assigned to third parties and entities such as consumer associations and non-governmental organisations can bring claims on behalf of injured parties. This formal recognition of collective actions, combined with the concurrent EU developments related to the RAD, in our view may lead to an increase in group litigation and class actions based on product liability.

11. Conclusion

The adoption of the PLD marks a pivotal moment in the evolution of product liability law in the EU. Reflecting the technological advancements and complexities of modern economies, the PLD ushers in significant changes that businesses will need to navigate carefully. The inclusion of digital products such as software, AI, and connected services under the scope of product liability, as well as the inclusion of privately used data in the definition of damage, signal a broader, more sophisticated approach to consumer protection in the digital age. The inclusion of medically recognised psychological harm as a standalone basis for claims under the regime may lead creative claimants (and their funders and lawyers) to bring innovative types of claims against providers of digital services.

Another fundamental shift is the extension of liability beyond traditional manufacturers to include a wide range of economic operators, from importers to online platforms. This extension underscores the EU's commitment to ensuring that there is always an entity responsible within an EU jurisdiction, regardless of how complex or globalised a product's supply chain may be. For businesses, this requires heightened diligence across the entire supply chain, as the risk of liability no longer stops at the factory gate but extends throughout the product's lifecycle, including to updates that are being provided years after a product has been launched.

Particularly notable is the PLD's potential impact on the digital sector. The imposition of no-fault liability for software, AI systems, and connected devices, coupled with an implicit obligation to update products to maintain safety, places a substantial burden on companies to ensure their products are continuously safe throughout their lifecycle.

The PLD's introduction of procedural advantages for claimants in the form of presumptions of facts and disclosure obligations will make it easier for injured parties to pursue and succeed in claims. This shift is likely to create an environment where claimants have a much stronger position in litigation. This could lead to increased numbers of claims, in particular when the PLD's claimant-friendly features are coupled with the Member States' enhanced collective action regimes and with wider changes to the European litigation market, such as the increased availability of legal funding and the increasing sophistication of, and coordination between, claimant firms.

For prior analysis on the PLD please see here:

The EU Product Liability Directive: Key Implications for Software and AI, Moritz Becker, Lutz Riede, Kristina Weiler, Anita Bell, Christina Moellnitz

A new regime for a new era: How the EU Product Liability Directive will reshape product liability in Germany, Moritz Becker, Patrick Schroeder, Martin Mekat, Kristina Weiler, Anita Bell, Hannah Meyer

Text of the new EU Product Liability Directive is agreed – what happens next?, Harriet Hanks, Andrew Austin

Reform of the EU Product Liability Directive: Where are we now?, Andrew Austin, Harriet Hanks, Emma Franck-Gwinnell, Victor Garcia Lopez

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