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IN THIS ISSUE

The European Commission has recently published its long-awaited proposal to update the European's strict "no fault" product liability regime under the Product Liability Directive ('PLD'). It seeks to broaden the strict liability regime in Europe significantly to cover damage and physical harm caused by defective software in general and AI systems in particular. The authors address the key changes and impacts for producers.

Changes to the EU's Strict Product Liability Regime

ABOUT THE AUTHORS



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It is well known that since 2018 the EU Commission has been in the process of reviewing the Product Liability Directive 85/374/EEC (the **PLD**) [LINK¹] which has been considered for some time now to be unfit for the digital age. Since the adoption of the PLD over 35 years ago, there have been significant changes in the way products are produced and distributed, and product safety and market surveillance rules have been modernised. The PLD, however, has not kept pace.

The European Commission has now published its much-anticipated proposal for a new PLD updating the strict liability regime for consumers to recover compensation for defective products on a "no-fault" basis (the **Proposal**). These new reforms seek to radically reform the strict liability regime and are of significance to manufacturers and importers supplying products in the EU as well as online marketplaces and fulfilment providers in some cases.

Why is this Important?

Since 1985 the PLD has underpinned the European legal regime for product liability as it launched the measure of strict liability onto the product liability field; allowing claimants compensation if they can show a defective product caused them damage. Businesses have therefore relied on the PLD (and local laws implementing it) as a benchmark for decades when making development and policy decisions and now

the guidelines are to change dramatically – and almost exclusively in favor of a potential claimant.

The Proposal expands the scope of the PLD to cover new intangible products including digital content, software, and data. Technology and digital health companies which currently consider themselves out of scope (smart products, internet of things (IoT), automated vehicles, drones etc.) will now need to reconsider and adapt to their product liability risk profile and insurance coverage in respect of any goods marketed in the EU.

The Proposal also broadens the pool of potential defendants to include software developers as manufacturers and in certain circumstances online marketplaces and fulfilment service providers and imposes disclosure obligations on defendants to produce evidence in support of claims which many European defendants would not have been subject to before. This appears to be a real shift in exposure for manufacturers supplying products in the EU and will require them to reassess their risk profile in those markets.

It remains to be seen if the UK will follow suit in imposing similar changes to the Consumer Protection Act 1987 (**CPA**) which is the legislation implementing the PLD into UK law. Post-Brexit, it is not under any obligation to do so but we know that similar proposals are being considered as part of the

¹ [EUR-Lex - 31985L0374 - EN - EUR-Lex \(europa.eu\)](#)

Office for Product Safety and Standards (OPSS) recent call for evidence in its consultation to reform product safety laws in the UK as some proposals considered as reflected in the Proposal. This is consistent with both the UK and EU's focus on ensuring a high level of protection for consumers when it comes to using products in the digital age and as part of the circular economy.

The Proposal

The Proposal was published on 28 September 2022 [LINK²] to fix various shortcomings identified in the recent evaluation of the PLD including:

1. additional clarity as to how to apply the PLD's relatively old definitions and concepts to modern technology and software-incorporated devices so that liability rules catch these and reflect the nature and risks of products in the digital age and circular economy;
2. making the burden of proof hurdle easier for claimants involved in complex cases (such as pharmaceutical or AI-enabled products) but at the same time ensuring a fair balance between the legitimate interests of manufacturers, injured persons, and consumers in general; and

3. removing limitations on low value compensation claims.

What is Being Proposed?

Whilst the Proposal makes considerable changes across the board, we set out those below which we consider will have the greatest impact on European businesses:

1. Widening the Scope of "Product" to Include Software

The definition of "product" will be amended to include digital manufacturing files and software.

Software is included regardless of whether it is integrated into a tangible product or not. The source code of software, however, is not to be considered as a product for the purposes of this Directive as this is pure information and open-source software will also be carved out. The developer or producer of software should be treated as a manufacturer and specific reference is made to "AI system providers" falling within the manufacturer definition.

By explicitly widening the scope of the PLD to include software, injured persons have a better chance of being compensated where products such as smart systems are made unsafe through software updates or cybersecurity incidents. This clearly brings smart products, IoTs, 3D printing,

² https://single-market-economy.ec.europa.eu/document/3193da9a-cecb-44ad-9a9c-7b6b23220bcd_en

automated vehicles, drones etc into the scope of the strict liability regime.

2. List of Potential Defendants
Increased

The Proposal makes it clear that where the manufacturer of a defective product is based outside the EU, the importer of the defective product and any Authorized Representative of the manufacturer can be held liable for damage caused by that product. By doing so it includes the possibility of Authorized Representatives of non-EU businesses and even "fulfilment service providers" (i.e. warehouse, packing and postage providers) being liable for defective products.

If a manufacturer/AR cannot be found, the Proposal provides, in certain circumstances, that retailers, distributors and online market platforms could also be sued. For some time now it has been unclear as to the extent to which an online market platform in particular could be caught under the strict liability regime given its role as an intermediary facilitating the sale of third-party goods to customers. However, the Proposal makes it clear that a platform cannot simply hide behind its intermediary role and must now consider whether it has adequate contractual protections and policies in place to deal with this additional product liability risk.

3. Modifications - No Escape

In addition, the Proposal aims to reinforce sustainable product initiatives by ensuring consumers have rights to compensation for harm caused by defective modified products. Products are now rightly designed to be more durable, reusable, repairable and upgradable so provided it can be shown the defective modification was under the control of the manufacturer who placed that product on the market, the manufacturer will remain liable for any defect caused as a result of the modification.

When a product is modified substantially outside the control of the original manufacturer, it is considered to be a new product and following the proposed amends, the limitation period will restart, and it should be possible to hold the third-party modifier liable.

4. Definition of Damage Extended

Although damage to psychological health has been recognised in case law, the definition of damage will now include "*medically recognised harm to psychological health*" in addition to death, physical injury, or property damage.

The definition will also include specific reference to any loss or corruption of data that is not used exclusively for professional purposes. This is a significant change and means that product liability risks will cross-over with cyber security risks.

5. Mixed-use Property Included in the Definition of Property

Individuals who suffer damage to any property will be compensated provided property is not used exclusively for professional purposes. Professional property is excluded from scope, but any mixed-use property will fall within the proposed new PLD.

The current limitation on claims with a threshold lower than 500.00 EUR has also been removed in turn widening the opportunity for groups of claimants to bring class actions under the PLD.

6. More Detail Added to Definition of "Defectiveness"

If a claimant wishes to rely on the strict liability regime of the PLD and recover compensation, they must show the product in question was defective. The PLD sets out a few circumstances to be considered in deciding whether a product is defective (presentation, use of the product and when it was put into circulation) but the Proposal goes much further as circumstances proposed include:

- a. whether the product is able to continue to learn after it had been put on the market – being a clear nod to AI;
- b. the effect on the product by other products which might be expected to be used with it;

- c. whether the product met relevant product safety requirements (including any cyber security requirements);
- d. whether a product safety issue has previously arisen where a regulator or economic operators has intervened; and
- e. the expectations of the end-user of the product for whom it is intended.

Whilst we will have to see how the courts interpret the above guidance, our first impression is the changes appear focused on making it easier for claimants. The inclusion of a subjective "expectation" factor moves the definition of defect away from an objective analysis to one more focused on how the claimant perceived the product and the reliance on previous regulator intervention will make it harder for a producer/manufacturer to defend a product if it has been involved in a product recall or any adverse regulatory decision.

7. Burden of Proof in Complex Cases

The Proposal suggests rebuttable presumptions of fact be introduced to alleviate a claimant's evidential difficulties in complex cases where certain conditions are met. The claimant will still need to show the relevant product was defective and they suffered damage as a result, but:

- a. where the court considers a defendant has failed to comply with its disclosure obligations or

the claimant can show the product did not meet mandatory safety requirements or damage was caused by an obvious malfunction when in normal use – a defect will be presumed;

- b. if a defect is established but the cause of the damage is very hard to demonstrate, if the damage is "*of a kind typically consistent with the defect in question*", causation will be presumed; and
- c. where a court judges that the claimant faces excessive difficulties, due to technical or scientific complexity, to prove the defectiveness of the product, or the link between its defectiveness and the damage, defectiveness shall be presumed where the claimant has demonstrated that: the product contributed to the damage; and it is likely that the product was defective or that its defectiveness is a likely cause of the damage, or both.

Defendants can contest the existence of excessive difficulties, but the Proposal seems to shift the burden of proof to businesses to show there was not a defect, giving the claimant an apparent easier shot at compensation. The logic being that manufacturers have expert knowledge and are better informed than the injured person so it should be for them to rebut the presumption but ultimately this should be decided on a case-by-case basis.

It is however worth noting that the "state of the art" defence (applicable in cases where manufacturers could not have discovered a defect based on the state of scientific and technical knowledge at the time that the product was placed on the market) remains available; however hard it may be to rely on in practice.

8. Greater Defendant Disclosure

Explicit reference is provided for in the Proposal for courts to order any defendant to disclose relevant evidence at their disposal. Disclosure obligations should be limited to what is necessary and proportionate (with protection given to trade secrets where appropriate) but where a claimant can show they have sufficient evidence to support a plausible claim, the courts are encouraged to order disclosure in such circumstances.

This is a significant change to the rules of civil procedure in most European jurisdictions. It will require European businesses to review whether it is adequately prepared for a disclosure order as most will not previously have been geared up for disclosure in litigation. We recommend such businesses review document retention policies and implement new policies and training so those required understand how to handle disclosure obligations out the outset of claims.

The new provision is focussed solely on the disclosure rights of an injured person but presumably courts will need to consider

similar requests from defendants for claimants to disclose relevant evidence (medical records, evidence of damage etc) and we can update you further once decisions are made.

9. Limitation Extension

The PLD currently provides that no claim can be brought 10 years from the date on which the defective product is put into circulation.

The Proposal seeks to amend this by including a carve out in situations where an injured person has not been able to initiate proceedings within 10 years due to the latency of a personal injury. In such cases, the limitation long stop will be extended to 15 years.

Not only does this place less pressure on a claimant to bring any action timeously, it will have the knock on effect of adding significant obligations on businesses who will need to extend their document retention and monitoring processes for a greater period.

10. Introducing an Additional Directive on Artificial Intelligence

The Proposal confirms that Artificial Intelligence (AI) systems and AI-enabled goods are products which fall within the scope of the PLD. As such should a defective AI product cause damage, the strict liability regime of the PLD will apply (as it would with any non-AI product). Developers will therefore continue to be responsible for any

damage caused by AI systems that learn independently and for the deployment updates or lack thereof.

The Proposal also notes that not only hardware manufacturers but also software providers and providers of digital services that affect how the product works (such as a navigation service in an autonomous vehicle) can be held liable.

What to Look Out For

A feedback period has been offered to everyone until 30 November 2022 and all feedback will be published online and be summarised by the Commission. The Proposal and the summary of feedback will then be presented to the European Parliament and Council who will consider the proposals and decide whether they should be adopted. There will then be a transition period to allow businesses to prepare accordingly for the new regime.

In the meantime, technology companies in particular and online marketplaces should review the Proposal in detail and consider how it impacts their business and risk profile for product liability exposure. It will also be necessary to monitor further reforms in consumer law (particularly the implementation of the Collective Redress Directive which will apply from June 2023 to Members States) which will pave the way for EU representative actions led by consumer groups and potentially cross-border. Early reflections suggest there is a considerable

change coming for European businesses and the way claims are handled in Europe as the changes not only make individual claims easier but open the door for quasi class actions for groups of consumers – albeit still with seemingly greater restrictions than available to claimants in US jurisdictions.

Whether these proposed revisions will be carried into English law through amendments to the CPA remains to be seen but we continue to monitor progress of the concurrent review of the CPA by the OPSS and will provide a further update as soon as we can.

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