

The proposed new Product Liability Directive

Reviving the consumer friendly
approach of the existing directive,
for the 21st century





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Introduction

For the average consumer (or the ‘public at large’, to borrow a phrase) the mere use of modern technology, particularly at the cutting edge, can be bewildering. Imagine, then, trying to pursue a claim that such technology was defective. The complexities of demonstrating that a particular vehicle’s AI algorithm is defective when one autonomous vehicle collides with another autonomous vehicle; or that a safety-critical phone update was defective and caused a loss of data; are easy to grasp but hard to master.

Simplifying these complexities is at the heart of the European Commission’s proposed new Product Liability Directive, intended to overhaul a 37 year old regime, with a perspective firmly rooted in the shoes of the average consumer. Product liability law – welcome to the 21st century.



Will this lead to more claims?

Although the intention in numerous parts of the proposed new Directive is to facilitate and streamline the claims process, there are many new areas that will be likely battlegrounds in the future. Not only because new concepts are introduced, but because the scope of the product liability regime will widen.

Combine that with enhanced rights for claimants to bring collective actions across the EU, as of 25 June 2023, including in class actions spanning multiple Member States, and it is sensible to predict an increase in litigation. Indeed, the European Commission's accompanying impact assessment report predicts a rise in product liability insurance premiums for businesses selling products in the EU, in recognition of increased exposure to businesses.

Some of the facilitative schemes in the proposed Directive (compulsion of disclosure from defendants, easing of the burden of proof in some scenarios) are likely to embolden litigation funders to support class actions in injury, property damage and loss of data claims.



How does this affect the UK?

There has been a 'wait and see' approach in the UK, to understand the European Commission's intended direction of travel before declaring a position. Many UK producers sell to the EU and would inevitably prefer not to deal with two wildly different product regimes. Indeed it would be wise for them to note that product regulatory compliance will be more important to the determination of defect under the proposed Directive, and non-compliance can move the burden of proof from claimant to defendant.

However, against the consumer friendly approach of the proposed Directive is a string of UK case law that is pro defendant; where the 'no-fault' regime is eroded, and it is made clear that consumers are not entitled to expect some products to be 100% safe. Might a political pressure to demonstrate that the UK is 'open for business' lead to a more defendant friendly regime in the UK? We must wait and see.

To help you understand the key changes in the proposed Directive, we have set out the basics that apply to both the current and proposed new regime; and then engaged a range of colleagues from various offices to talk about the intended new features.



The basics

The core approach of the proposed new Directive, and the existing Directive, is identical in many respects. The key commonalities are:

1. If a person suffers damage, and it is caused by a defective product, they are usually entitled to compensation. That person does not have to be the contractual purchaser.
2. The regime is principally concerned with private individuals who suffer damage; consumer claims, not business to business claims.

Defect is considered from the perspective of the objective person, or in the proposed Directive, the “public at large”. It is relevant to consider the product’s instructions and warnings, packaging, and its range of reasonably expected use; in addition to the safety of its design and its manufacture.
3. The regime is ‘no-fault’ because it focuses not on the acts or omissions of the defendant but on the safety of the product. Subject to certain defences, if a product is defective and caused the damage, the defendant is liable regardless of its (lack of) knowledge of defect.
4. Damage includes injury, death, and damage to property. Damage to the product itself is outside the scope of the regime.
5. Manufacturers, own-branders, and importers (into the EU) are potentially liable. More than one can be pursued and all can be liable in full to the claimant (though a claimant cannot double recover). In addition, ‘mere’ suppliers can fall within the regime if they fail to identify within a reasonable time one of the above economic operators.
6. Defences are available even if defect is established, including where the state of scientific and technical knowledge at the time of placing the product on the market was not such that the defect could be discovered (the ‘state of the art’ defence).

The major changes in the proposed Directive, intended to operate with the principles above, are outlined below.

“Product” is expanded from tangible items to intangible items, and includes digital manufacturing files (e.g. 3D printer designs) and software (whether or not incorporated into a tangible item).



Hinal Patel
London

The Directive will likely lead to an increase in the exposure for software companies. They will need to more carefully consider the product descriptions and warranties included in their terms and conditions and service agreements involving consumer end users, to help guard against potential defect claims directly from consumers.

For companies integrating third party software into their consumer products, the landscape is unlikely to change - they remain exposed to consumers for defective products, even when they are caused by third party software. However, those third party software companies that have their software integrated into a third party consumer product are now vulnerable to consumers directly if their software is defective. Again, these software companies will need to consider how to minimise this exposure (through product descriptions and warranties) which is in addition to the exposure they already face vis a vis the product OEM company.



Russell Cowie
London

A defendant can be liable not just for an ‘item’ (tangible or intangible), but for a related service ‘integrated into, or inter-connected with’ a product. There is a related service if ‘its absence would prevent the product from performing one or more of its functions’.

This new aspect of the Directive brings about an interesting development in product liability law, and recognises the ever-increasing presence of software in a digital world.

One can, for example, imagine its application to a home security device with a subscription service. If the device fails to detect and prevent a burglary and damage to the home it is meant to protect, due to a failure to perform the ongoing monitoring service, we consider this would likely be a related service in respect of which the Directive would apply.



Udo Pickartz
Düsseldorf

The ‘damage’ that a claimant can sue for is expanded beyond injury and damage to property, to ‘loss or corruption of data’, as long as it is ‘not used exclusively for professional purposes’.

The General Data Protection Regulation and equivalent regimes have already shown the change in the use and importance of data and data integrity. There is hardly an area of life where no data is produced, stored and used. This now of course includes even household goods and other products that are often connected via the internet, have passwords and account data, holding information about the user. If a product running on software and data is damaged, the result will be the same as with a previously covered manual fault.

However, for producers and distributors, this new level of liability and wider applicability opens new areas of litigation, in particular for industries relying on data. This will probably also stretch to the wider infrastructure, i.e. the way data is transported and can be lost will no longer be limited to a specific location. It will be interesting to see what one needs to show as a consequence of the loss or corruption of data. If a product was unusable after the incident, this should be easy but there may also be indirect damages or a quasi ‘moral’ element that can be claimed.

Damage now expressly includes ‘medically recognised harm to psychological health’.



Jacques-Antoine Robert
Paris

It could be considered that “medically recognised harm to psychological health” defined in Article 4 of the Proposal includes the notion of anxiety damage, already admitted in some European countries. Recital 17 of the preamble of the Proposal’s “in the interest of legal certainty” appears to make compensation conditional on the recognition of a medical harm to psychological health without defining it. In other words, anxiety damage and, more broadly, psychological damage will probably have to be recognised by a doctor or a person with medical expertise in order to be eligible for compensation (speciality of the healthcare professional is not mentioned).

In addition to medical care, the effectiveness of a treatment could substantiate the reality of the damage (those conditions being already requested by some French jurisdiction such as the Court of Appeal of Bordeaux, 7 October 2021). The Proposal seems to confirm the principle of evidencing damages, and should limit a trend in some case law that led to the extension of the recognition of psychological damage without serious control. The consequences of this text are uncertain. It could be construed as a new category of damage being created. With this respect, the question of double compensation in the face of the principle of full reparation will have to be addressed.

Where the manufacturer and importer of a product are outside the EU, a fulfilment service provider (“FSP”) can be held liable. A FSP is a natural or legal person commercially offering at least two of the following: warehousing, packaging, addressing, and dispatching of a product. The FSP does not need to own the product itself.



Emma Spence
London

This represents a substantial broadening of the list of potential Defendants, encompassing entities beyond those found in a traditional supply chain and increasing the probability that a Claimant will be able to identify a viable target within the EU. This approach is in keeping with the Regulation (EU) 2019/1020 which requires FSPs to co-operate with market surveillance authorities. FSPs include the fulfilment branches of online marketplaces, and commonly facilitate sales between non-EU manufacturers and EU consumers.

A FSP typically carries out many of the same functions as a traditional “importer” but has not, historically, carried the same potential liabilities. Given that FSPs are only a potential target in the absence of other, more closely connected, EU-based entities, it will be interesting to see whether FSPs become more reluctant to facilitate (perhaps reflected in increased costs) the supply of products in these circumstances.

Where there is no identified manufacturer, importer or distributor within the EU, an online platform can be held liable to the consumer.



Rebecca King
Bristol

Over recent years we have seen substantial growth in the number of online platforms which enable the sale of new, second-hand and home-made products by third-parties, ranging from the ‘work from home’ individual to large global vendors, with limited (if any) restrictions. The online platform has a relatively narrow ‘reasonable care’ duty in respect of checking that products sold through its platform are safe.

The decision to extend responsibility for defective products to online platforms clearly capture these marketplaces and increases litigation risk for such entities which range from significant global players to new start-ups. In some instances the same entity is both an online platform and a fulfilment service provider, such that there would be two potential routes to pursue that entity.



Mauro Teresi
Milan

The factors relevant to defect are expanded to include both reasonably foreseeable use and misuse of the product, product safety requirements (including cybersecurity requirements), and intervention by a regulatory authority.

Manufacturers can be held liable for damages resulting from a misuse of their product if such misuse was “reasonably foreseeable”. Therefore, in order to mitigate the product liability risk, in addition to ensuring compliance with applicable safety requirements as well as with any interventions by competent regulatory authorities, manufacturers will also have to explore the potential uses. That would include those different from the originally intended ones, to which their products may be put; and consider providing warnings or instructions with respect to the identified reasonably foreseeable potential misuses.

Likewise, manufacturers may have a duty to warn consumers of the dangers of altering the product, as the modification of the product would also be considered a misuse, whenever the alteration of the product is reasonably foreseeable.

Defect can take into account ‘the specific expectations of end-users for whom the product is intended’.



Annabelle Bruyndonckx
Brussels

This is a new criterion, and although it may be interpreted as introducing a subjective aspect into an otherwise objective assessment, recital 22 of the proposal provides that “The assessment of defectiveness should involve an objective analysis and not refer to the safety that any particular person is entitled to expect”. Moreover, it appears to be targeting “Some products [which] entail an especially high risk of damage to people and therefore give rise to particularly high safety expectations”.

With this language, the Commission echoes the European Court of Justice’s position, where it adopted a risk-based approach in finding that pacemakers and implantable cardioverter defibrillators were subject to “specific requirements” of the group of users for whom the products were intended, and that “the safety requirements for those devices which such [users] are entitled to expect are particularly high”. By doing so, the Commission seems not to be altering the objective nature of a defectiveness assessment but, rather, to be taking into account a specific class of consumers.

Software updates and upgrades, and related services, are relevant to defect. A product that was not defective when placed on the market can be held defective if a subsequent service or software update made it defective. The 10 year longstop (which extinguishes a claim 10 years after placing on the market) is extended if the product was ‘substantially modified’ at a later date. This could feasibly include a software update.



Olivia Darlington
Dubai

Consumers would be able to claim compensation if the updates, upgrades or related services make the product defective and cause damage. This could include compensation where manufacturers have failed to address cybersecurity vulnerabilities. This raises some interesting liability issues. For example, under the Directive, even when AI has acted completely independently and rendered a product defective, an AI manufacturer, or an entity which incorporates the AI system into its product, would still have strict liability under the Directive. This is a clear steer away from the idea that AI could have a separate legal personality, as was previously mooted by the European Parliament in its report to the European Commission, on robotics, in 2017. It emphasises that economic operators rather than consumers should bear such risk.

In general, companies that are subject to the proposed directive are likely to come under greater scrutiny from their insurers. Insurers will want to have a better understanding of a company’s software and AI hygiene and their cybersecurity policies and procedures, as well as that of their third party providers. Furthermore, companies may see their insurance premiums increase as a result of the potential for the 10 year longstop date to be extended if a product is “substantially modified” by a software update or upgrade or related services, since they may have to keep claims, or anticipated claims, on their books for longer.



Minesh Tanna
London

Defect can take into account ‘the effect on the product of any ability to continue to learn after deployment’.

The inclusion of this provision underlines the Commission’s desire to adapt the existing product liability regime to the digital age and, moreover, to future-proof it against further advancements in AI. Currently, only very few AI systems continue to learn after deployment, but this will change in the future. By allowing self-learning to be considered in the assessment of a “defect” in any AI system, the Commission is (sensibly) placing greater responsibility on manufacturers of self-learning AI systems to ensure that the system can be controlled by humans post-deployment.



Olivier Mignolet
Brussels

A claimant with a plausible claim can seek an order for a defendant to disclose relevant evidence. Failure by the defendant to provide such disclosure will result in a presumption of defect.

According to recital 30, the purpose is to rebalance the position of both parties where claimants are at a disadvantage compared to manufacturers in terms of access to, and understanding of, information on how a product was produced and how it operates. The condition for the claimant to order such a disclosure is that he/she has presented facts and evidence sufficient to support the plausibility of the claim for compensation. No threshold is provided for assessing what is “plausible”. The Proposal does also not indicate how the court will assess what is relevant evidence nor how it will assess what is a ‘failure’ to provide such relevant evidence.

Reversing the burden of proof in case of a lack of collaboration to evidence is not unprecedented and can be found in recent national laws (see for instance art. 8.4 of the New Belgian Civil Code). One can also make a link between art. 8.1 of the Proposal and article 10.14 of Regulation (EU) 2017/745 of 5 April 2017 on medical devices, which provides that if a competent authority considers or has reason to believe that a medical device has caused damage, it shall, upon request, facilitate the provision of the information and documentation to the claimant, except where disclosure of said information and documentation is ordinarily dealt with in the context of legal proceedings.



Raquel Ballesteros
Madrid

A presumption of defect also occurs if the claimant establishes that the product does not comply with mandatory safety requirements ‘intended to protect against the risk of the damage that has occurred’; or where the damage was caused by an ‘obvious malfunction of the product during normal use or under ordinary circumstances’.

The proposed Directive elevates the importance of regulatory compliance. A defendant can argue that a product is not defective if it complies with product safety requirements, although this will not be determinative. However, a claimant benefits from a presumption of defect if there was a breach of mandatory safety requirements designed to protect against the risk of damage that has occurred. In addition a causal link between defect and damage can be presumed. This will put the burden on the defendant to prove an alternate explanation for an illness; which may be difficult unless the defendant can obtain and analyse a claimant’s medical records.

It is likely to be a point of argument as to what is an ‘obvious malfunction’. There is a risk that just because a product causes harm, it will be presumed to have ‘obviously malfunctioned’. This has the potential consequence of bringing the consumer expectation closer to an entitlement that 100% of products should be safe at all times.



Alexandre Regniault
Paris

If the court ‘judges that the claimant faces excessive difficulties, due to technical or scientific complexity’, to prove defect or causation (or both), those facts can be assumed. This is so if ‘sufficiently relevant evidence’ demonstrates 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’.

How do we define technical or scientific complexity? The explanatory memorandum refers to “those involving pharmaceuticals, smart products or AI-enabled products”. However, it will probably be applied in more scenarios, and determined on a case by case basis by national courts taking into account the complex nature of the product, or the technology, or the information or data to be analysed by the claimant. A presumption of causality or defectiveness was not recognised by the CJEU in its decision of 21 June 2017, although it validated the evidentiary approach. The impact of this new presumption will depend on the way the European countries will embed the rules into each national system.

Allowing defect to be established on the basis of a “likely” defect or cause of the damage seems dangerous if not corroborated by objective items such as the assessment of the products’ benefit/risk, or other relevant information available. The manufacturers will have one chance to escape those presumptions, by establishing the absence of “excessive difficulties” to prove an alleged defect or the likelihood of defect or causal link. It may be a hard balancing act to show that a claim is not complex, while at the same time seeking to mount a robust defence.



Closing comments



David Kidman
London

It is clear from all of these remarks that there are going to be different perspectives on the proposed new regime, and a range of battlegrounds in various jurisdictions. Furthermore, the above topics are only the main proposed changes; there are many more talking points.

For example, how will differences in national regimes, when applying the proposed new Directive, affect the conduct and outcome of class actions across multiple Member States under the Collective Redress Directive? Is the European Commission’s impact assessment report for the proposed new Directive correct in estimating a relatively modest increase in product liability insurance premiums, or will the cost to businesses in fact be significantly higher?

Our contact details are on the following page. Do not hesitate to contact any of us to discuss the topics further; whatever your sector and whatever your interest.

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