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Contributing Editors:
Adela Williams & Tom Fox
Arnold & Porter

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An Update on Proposed Changes to the Product Liability Directive


Dr Adela Williams


Tom Fox

Arnold & Porter

Introduction

On 28 September 2022, the Commission published a proposal for a new Product Liability Directive (PLD)[1] to replace the existing PLD, Directive 85/374/ECC.[2] The proposal addresses liability for products such as software and digital services, and clarifies the rules applicable to companies that substantially modify products for resale. It also suggests that the claimant's burden of proof should be relaxed in certain circumstances and aims to ensure that consumers are compensated for defective products manufactured outside the EU.

Background

Since its adoption in 1985, the PLD has allowed consumers who suffer physical injury or damage to property caused by a defective product to claim compensation without having to prove fault by the producer. Subject to certain statutory defences, it suffices to show that the product does not provide the safety a person is entitled to expect, taking all circumstances into account. Proof is required of causation and damage.

The Commission's formal evaluation[3] published in 2018 found that the PLD largely achieves its aim of maintaining a "fair apportionment of risk" between consumers and producers, but suggested that "further reflection" was needed on its application to new technologies. Over the course of this and other evaluations, it was repeatedly suggested that the PLD regime makes it too difficult for claimants to succeed in their claims, and that this is particularly the case when products are new and/or technologically complex. Calls to make necessary updates to the PLD to adapt it to technological progress have long been conflated with the desire of some stakeholders to make liability easier to establish, and the new proposal represents a continuation of that dual approach.

What Changes are Proposed?

The proposal's stated aim is to provide legal certainty by updating the product liability regime to reflect the modern digital and circular economy. The Commission considers that this requires making it easier for consumers to obtain compensation. The Impact Assessment Report[4] discussed a range of options, however, those incorporated into the proposed new PLD include:

- amending the definition of "product" to include software and digital manufacturing files, so that AI systems and AI-enabled goods are within scope;
- expanding the range of potential defendants to capture authorised representatives of non-EU based manufacturers, third parties who make substantial alterations to a product after it has been placed on the market and "fulfilment service providers";
- introducing a disclosure obligation to rebalance the liability regime in favour of claimants;
- removing the lower threshold and upper ceiling on the value of claims;
- adding data loss and psychological harm to the types of actionable damage;
- extending the limitation period from 10 years to 15 years where personal injury is latent; and
- alleviating the burden of proof by introducing certain rebuttable presumptions. For example, causation is presumed where defect has been established and the damage is of a kind typically consistent with the defect.

Status of Software and Data

It has long been acknowledged that updates to clarify the status of software and data, and address the fact that modern technological products may develop and be updated over time, were necessary. It is anomalous at present, for example, that medical devices legislation regards software as a product, but its status under the PLD is unclear. The proposed PLD seeks to achieve clarification in this area by explicitly including software and software updates, digital manufacturing files and digital services. However, there seems no reason why these updates could not have been addressed by quite simple amendments to some of the definitions in the existing PLD without the need for wholesale revision. It remains to be seen whether the proposed clarifications in the final version of the new proposed PLD will achieve this successfully.

Producer *Versus* Economic Operator

The new proposed PLD moves away from imposing liability on the "producer" of a product and instead lists various types of "economic operator" who can be held liable for a defective product, depending on their qualifications and involvement. The list of economic operators includes the manufacturer of the product or a component, the provider of a related service, the authorised representative, the importer and the fulfilment service provider (i.e., an entity which does not own the product but offers at least two of the following services: warehousing; packaging; addressing; and dispatching of a product), or the distributor. This more sophisticated approach to liability brings the legislation into line with modern EU product legislation, although arguably to some extent it is already inferred under the existing regime; there is, for example, already a party based within the EU with potential liability for products manufactured in third countries, because the importer is liable as a producer and suppliers can be liable as a producer unless they can, within a reasonable time, identify the producer, importer, or the person who supplied it to them.

Definition of "Defect"

Missing from the existing PLD proposal is a clear definition of "defect". However, as before, the proposal explains how defectiveness is to be assessed in a product. The entitled expectation of safety is now that of "the public at large" rather than "a person" but it is unclear whether that by itself makes, or is intended to make, any difference, and there seems to be a continued insistence that this is an objective test. The level of safety that the public at large is entitled to expect is still to be assessed by reference to "all the circumstances", but now, in addition to the existing specific circumstances that already have to be taken into account (i.e. presentation, reasonably expected use etc.), there is a shopping list of new factors that must be considered.

Some of these additional circumstances are in line with general updating to account for technological change, such as the "moment in time when the product was placed on the market or put into service or, where the manufacturer retains control over the product after that moment, the moment in time when the product left the control of the manufacturer". Others such as product safety requirements and regulatory interventions seem unnecessary additions, as, to the extent relevant, these would presumably be included in "all the circumstances" under the current regime. One addition to the mandatory list of circumstances could be taken as indicating a desire to take a different approach to the assessment of safety. That is "the specific expectations of the end-users for whom the product is intended". End users' actual expectations have arguably always been a potentially relevant circumstance, albeit unlikely by themselves to be decisive when assessing the objective entitlement to a level of safety that a court must determine. However, the inclusion of this as a mandatory circumstance for consideration maybe signposts an intention to lay greater weight, when assessing safety, on what is actually expected rather than on what people are entitled to expect. Seen in that light, the shift from "a person" to "the public at large" could also be understood as a similar signpost. Both sit slightly uneasily with the continued insistence that the test for safety is an objective one.

An important change from the existing PLD is that the proposal envisages that, in certain circumstances, liability would continue to apply where a defect came into being after a product has already been placed on the market or put into service. This would cover defects arising, for example, as a result of software updates under the manufacturer's control, due to a manufacturer's failure to address cybersecurity vulnerabilities, and in relation to machine learning. This differs from the exclusion of liability under Article 7(b) of the existing PLD, which exempts the manufacturer from liability when the defect did not exist in the product at the time when it was put into circulation by him.

Disclosure Obligation

Article 8 of the proposed PLD introduces a disclosure regime, which is similar to the right to information from the manufacturer under the German Medicines Act regime. For jurisdictions that already have a US- or English-style disclosure regime this will not necessarily make a lot of difference, but elsewhere it may impact defendants to a greater extent.

Alleviation of Burden of Proof

The headline change affecting the balance of liability is arguably the new Article 9 of the proposed PLD. This starts by reiterating the current position that a claimant must prove defect, damage and causation of damage by the defect. However it then provides that the defectiveness of the product shall be presumed where:

- the defendant fails to give the required disclosure under Article 8;
- the claimant can show that the product does not comply with mandatory safety requirements that are intended to protect against the risk of the damage that has occurred; or
- the claimant establishes that the damage was caused by an obvious malfunction of the product during normal use or under ordinary circumstances.

While these proposals arguably do not involve a major shift from the assessment of defect under the existing PLD, Article 9 also introduces a presumption of causation 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".

A further presumption of causation is introduced where a claimant faces "excessive difficulties, due to technical or scientific complexity" in proving causation. This applies where a claimant "has demonstrated, on the basis of sufficiently relevant evidence, that: (a) the product contributed to the damage; and (b) it is likely that the product was defective or that its defectiveness is a likely cause of the damage, or both". The defendant can challenge the existence of "excessive difficulties" and can rebut the presumptions.

These alleviations come close to a reversal of the burden of proof in the circumstances described and, if implemented, seem likely to trigger significant satellite litigation as the meaning of these provisions is worked out in the context of Member State legal systems. Under the existing PLD, matters such as the standard of proof and how that would be met in practice were left to the legal systems of the individual countries, however the proposal as currently drafted is a much more sternly harmonising measure than its predecessor.

Divergent National Law Provisions

The harmonisation trend is made explicit by Article 3 which prohibits Member States from having divergent national law provisions. This appears to be qualified only by Article 2 which allows special liability systems that existed before the 1985 PLD to continue. This was previously in Article 13 of the PLD and was understood to be aimed at the continuation of the German liability regime applicable to medicinal products.

By way of slight counterbalance to the generally pro-consumer thrust of the proposed changes, the development risks defence is now no longer optional for Member States, but is required to be included in national product liability regimes. This defence exonerates economic operators where the state of scientific and technical knowledge at the relevant time was not such that the defectiveness could be discovered. The word "objective" has been introduced prior to "state of scientific knowledge", seemingly to underline that it is not the economic operator's subjective knowledge that is relevant.

How Does This Relate to the EU's Recent AI Proposals?

In April 2021, the Commission became the first major regulator to propose a law on artificial intelligence, the Regulation on artificial intelligence (AI Act).[5] The AI Act sets out the key safety requirements for AI systems and the new PLD would make such rules part of the assessment of whether a product is defective.

The Commission also published a proposal for an AI Liability Directive,[6] which will cover non-contractual civil liability generally. The intention, according to the PLD FAQs,[7] is to capture infringements to fundamental rights caused by defective AI, which is a type of harm that falls outside the product liability regime. In particular, the Commission states that no overlap is intended between claims brought under the proposed no fault-based PLD and the fault-based AI Liability Directive. The proposal is also intended to be complementary to existing EU liability and EU safety legislation.

Consultation

There have been a series of responses to consultation submitted, flagging potential issues with the proposal. Some responders have argued that embedded software/AI should be treated differently to standalone software/AI. Others have argued that embedded software/AI should be within scope but standalone software/AI should not, on the basis that the latter is designed in a 'use-agnostic' way, and that it is therefore not appropriate to make the manufacturer subject to strict liability. These objections likely reflect a growing realisation that software developers and coders at multiple levels may be exposed to strict liability as opposed to contractual or negligence liability, with potentially significant consequences for the viability and insurability of their activities, particularly if they are individuals or small and medium-sized enterprises. This may have a chilling effect on key technological growth areas, where Europe is already perceived as being at something of a disadvantage compared to other jurisdictions.

What Next?

The formal legislative process is underway, with the proposal currently being evaluated by European Parliamentary committees (see: Legislative Observatory).[8] It is difficult to say how long the proposal will take to become final legislation. Based on the consultation responses, and the points in the analysis above, it is possible that there may yet be changes to the proposal as drafted. However, if it is favourably received by the European Parliament and Council, the new PLD could be in force by 2024/2025.

Endnotes

1. https://single-market-economy.ec.europa.eu/document/3193da9a-cecb-44ad-9a9c-7b6b23220bcd_en.
2. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31985L0374.
3. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2018:157:FIN.
4. https://single-market-economy.ec.europa.eu/document/348b3e35-7d1a-43df-8e9d-296fc09e2c3c_en.
5. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0206.
6. https://ec.europa.eu/info/files/proposal-directive-adapting-non-contractual-civil-liability-rules-artificial-intelligence_en.
7. https://ec.europa.eu/commission/presscorner/detail/en/qanda_22_5791.
8. https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2022/0302(COD)&l=en.

Dr Adela Williams is a partner in the London office of Arnold & Porter, specialising in product liability litigation (unitary actions and group litigation), principally involving life sciences clients and including claims involving unlicensed medical products in the research context as well as marketed products. Such litigation has often involved co-ordinating proceedings within Europe and advising on forum and other jurisdictional issues. Past cases include the fetal anticonvulsant litigation and the successful defence of group litigation involving more than 100 claims relating to the "third generation" oral contraceptive pill on behalf of two of the defendant manufacturers.
Adela also advises clients in relation to the regulation of medicinal products, medical devices, foods and cosmetics in the EU and acts on their behalf in litigation arising from the decisions of regulatory bodies. She is also an Assistant Coroner.

Arnold & Porter
Tower 42, 25 Old Broad Street
London EC2N 1HQ
United Kingdom

Tel: +44 20 7786 6115
Email: adela.williams@arnoldporter.com
URL: www.arnoldporter.com

Tom Fox is a counsel in the London office of Arnold & Porter, whose practice focuses on litigation and general product safety regulatory work. His main litigation practice concerns the defence of product liability claims on behalf of medical device and pharmaceutical companies. He also has considerable experience of commercial litigation and personal injury. He has further experience in bringing judicial review actions based on public and administrative law on behalf of pharmaceutical companies, both at the Court of Justice of the European Union and in national courts. Tom advises on general product safety and regulatory issues such as conformity marking, labelling, and compliance with standards in relation to chemicals and a range of consumer products including electrical and electronic goods, clothing, cosmetics, and toys.

Arnold & Porter
Tower 42, 25 Old Broad Street
London EC2N 1HQ
United Kingdom

Tel: +44 20 7786 6187
Email: tom.fox@arnoldporter.com
URL: www.arnoldporter.com

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Please contact Dr Adela Williams or Tom Fox in the London Office for UK or EU product liability enquiries, and Anand Agneshwar in the New York Office for US enquiries.

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