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Contributing Editors:
Dr Adela Williams & Tom Fox
Arnold & Porter

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The New EU Product Liability Directive


Dr Adela Williams


Tom Fox

Arnold & Porter

Introduction

In previous analysis chapters for *ICLG – Product Liability*, we have discussed the development of the new EU Product Liability Directive. Now that it is has finally arrived, we round off our analysis series with the following commentary on the final text.

The new Product Liability Directive (EU) 2024/2853 ("New PLD") was published in the Official Journal of the European Union on 18 November 2024. It entered into force on 9 December 2024. Member States must transpose the New PLD into their national laws and implement the changes by 9 December 2026. Directive 85/374/EEC ("Old PLD") will be repealed from 9 December 2026, but will continue to apply with regard to products placed on the market or put into service before that date.

This chapter focuses on the key changes introduced by the New PLD and reassesses what issues these changes may resolve or cause.

Products in Scope: Software and AI

One of the main justifications for revisiting the Old PLD was a concern that the product liability regime had not kept pace with technology. It was not "fit for the digital age" and it was, at the least, unclear whether and, if so, how the provisions of the Old PLD would cover products such as software, artificial intelligence ("AI"), and related services.

The New PLD states explicitly that "product" means "all movables, even if integrated into, or inter-connected with, another movable or an immovable; it includes electricity, digital manufacturing files, raw materials and software". By this and other definitions, the New PLD clarifies that it covers all types of software, including applications, operating systems and AI systems. The exception is, as stated in Article 2(2), that the New PLD does not apply to free and open-source software developed or supplied outside the course of a commercial activity.

Article 12 states that, where manufacturers of defective software are "microenterprises", or "small enterprises" as defined elsewhere in EU legislation (Commission Recommendation 2003/361/EC), they may be protected from a claim for contribution or indemnity by a manufacturer who has integrated the defective software into another product. This is curious, because Article 12 also specifies that the protection only applies if contractually agreed with the integrating manufacturer. It is unclear what this adds to the existing ability to include contractual indemnity provisions in relation to product liability in contracts between economic operators up and down the supply chain, whether supplying software or not. Further, Article 12 does not, in any event, provide protection to the microenterprise or small enterprise from a claim brought directly against it by a consumer.

Manufacturers may be held liable for any defect that existed at the moment their software or AI system was released. This includes defects that became apparent after their release, as a result of updates, upgrades or a machine-learning feature. The definition of a component includes "any item, whether tangible or intangible, raw material or related service, that is integrated into, or inter-connected with, a product". "Related service" is in turn defined as "a digital service that is integrated into, or inter-connected with, a product in such a way that its absence would prevent the product from performing one or more of its functions". This wording, when read alongside the recitals to the New PLD, confirms that a manufacturer or supplier of software or products incorporating software is likely to have dynamic and ongoing responsibilities in relation to such products; for example, providing updates to correct vulnerabilities such as cybersecurity. Such continuing responsibilities imposed on the manufacturer or supplier depend upon the control that a manufacturer has over the product. The degree of control, the ability of a product to learn and acquire new features, reasonably foreseeable effects of inter-connectivity, and safety-relevant cybersecurity requirements are all included among the relevant circumstances to be taken into account for the purposes of determining whether a product is defective under Article 7 of the New PLD.

Definition of Manufacturer and Liability of Economic Operators

As anticipated, the "producer" concept used in the Old PLD has been replaced and updated in the New PLD by the "economic operators" concept – consistent with other recent EU product legislation. The entity principally responsible for a defective product under the new legislation is still, however, the "manufacturer". This is a defined term meaning "any natural or legal person who (a) develops, manufactures or produces a product; (b) has a product designed or manufactured, or who, by putting their name, trademark or other distinguishing features on that product, presents themselves as its manufacturer; or (c) develops, manufactures or produces a product for their own use". Consequently, "manufacturer" is not limited to an entity that physically makes a product, but can include other economic operators, such as brand owners.

The New PLD separately calls out, as a potentially liable party, the "manufacturer of a defective component", where a component was integrated into, or inter-connected with, a product within the manufacturer's control and caused that product to be defective.

Consistent with the position under the Old PLD, where the manufacturer is based outside the EU, the importer of a

defective product or component may also be liable. "Importer" is a defined term meaning any natural or legal person who places a product from a third country on the EU market. However, in a new departure, under the New PLD, if the manufacturer has appointed an authorised representative based in the EU (defined as "any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on that manufacturer's behalf in relation to specified tasks"), then the authorised representative is also a potentially liable party. This is likely to be a significant change for manufacturers and authorised representatives, particularly since, under Article 16 of the new EU General Product Safety Regulation 2023/988 ("EU GPSR"), manufacturers of all products (and not just more heavily regulated products like medicines, medical devices, cosmetics, foods, and CE-marked products) must have a "responsible person" for product compliance based in the EU, and this is likely to be the authorised representative in many cases.

If there is no importer established within the EU and no authorised representative, then the "fulfilment service provider" may be liable. Fulfilment service providers are businesses that offer at least two of commercial warehousing, packaging, addressing, and dispatching of products, without having ownership of the product. (The definition does not include postal or freight/delivery services.)

For many entities based in, or operating through, an affiliate based in the EU, the position is likely to remain unchanged for most products. However, some additional analysis may be required for certain products, particularly those where there is a new requirement for an EU-based "responsible person" under the EU GPSR, or for products that involve cross-border digital services that are potentially captured by the revised definition and increased scope of the term "product".

Liability of defendants is to be "joint and several", but without prejudice to national laws on indemnity and contribution. Claimants may opt to pursue multiple defendants if responsibility for a potential defect is unclear, and businesses need to consider which parts of their supply chain may attract liability and ensure that appropriate contractual and insurance protections are in place.

Definition of Defect

The essence of the New PLD, as with the previous legislation, is a "no fault" liability regime where it is sufficient for liability purposes to establish that a product is defective without any need to establish negligence or other culpability by the defendant. The definition of defectiveness arrived at by Article 7 of the New PLD therefore appears broadly familiar and largely unchanged: "A product shall be considered defective where it does not provide the safety that a person is entitled to expect or that is required under Union or national law." With the possible exception of the final phrase "...or that is required under Union or national law", this appears to be a restatement of the position as it was in the Old PLD, with the main difference being a much longer list of circumstances that must specifically be considered. As before, "all circumstances" must be taken into account when assessing defectiveness, so the list is not necessarily exhaustive. A good many of the additions, such as relevant product safety requirements or product recalls, are matters that would have been relevant circumstances to be taken into account under the Old PLD.

Certain of the circumstances specifically listed at Article 7(2) of the New PLD seem particularly prone to conflicting interpretation, including: the effect on the product of any ability to continue to learn or acquire new features after it is placed on the market or put into service; and the reasonably foreseeable effect on the product of other products that can be expected to be used together with the product, including by means of inter-connection. Both of these elements involve the application of new principles to new types of products with novel supply structures and likely differential levels of ongoing control over products, including, in particular, software and AI.

Finally, some commentators have drawn attention to the final phrase of Article 7(1) ("...or that is required under Union or national law") as being a significant addition to the New PLD, suggesting that this may mean that defectiveness can be established simply by showing that there has been a breach of a safety requirement under EU or national law, without the need to carry out the assessment of "all the circumstances". However, such an interpretation appears inconsistent with Article 2(2), which provides that all circumstances must be taken into account and then specifically includes relevant product safety requirements at Article 2(2)(e) as one of such circumstances. Even in the case of a failure to comply with safety requirements, it would of course still be necessary to show that this defectiveness caused the damage. In these circumstances, the position for claimants and defendants would seem likely to be essentially the same as under the Old PLD: a generalised allegation of defectiveness is insufficient to establish liability.

Actionable Damage

The basic rule (subject to alleviations) remains that the claimant must prove the defect, damage, and causation of the damage by the defect. Innovations in terms of damage that are now actionable under the New PLD include the addition of data loss and psychological harm ("medically recognised damage to psychological health") to the types of actionable damage.

In a parallel development, recital 19 to the EU GPSR notes that "[t]he World Health Organisation defines 'health' as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity", and recital 23 to the EU GPSR references the risk to mental health posed by digitally connected products, particularly in vulnerable consumers such as children. While the actual obligations imposed by EU GPSR are not so explicit in this regard, it has been suggested that this has significance for the risk assessment of products. Now that psychological harm is expressly actionable under the New PLD, this argument perhaps has greater force.

The previous minimum and maximum damage thresholds have been removed. There remain limited exclusions, namely: (1) damage to the defective product itself or to a product integrated or inter-connected with the product by the manufacturer or within the manufacturer's control; and (2) damage to property (including data) that is exclusively for professional (i.e. non-consumer) use.

It is foreseeable that satellite litigation may take place, arguing about the recoverability of psychological harm and data loss, in particular if these involve significant changes from the pre-existing civil law damages regime in a Member State. It is also foreseeable that there will be arguments about the scope of the limited exclusions described above.

Disclosure

The New PLD introduces a new standard requirement that claimants and/or defendants may obtain disclosure of relevant information with a view to addressing any asymmetry of information between the parties. This is likely to be an important new tool for claimants given that many EU jurisdictions have limited or no disclosure mechanisms.

Claimants need only provide "facts and evidence to support the plausibility of the claim for compensation" to obtain disclosure, so it is not likely to be difficult for them to obtain disclosure. A claimant may be required to disclose evidence if the defendant has demonstrated the necessity of such evidence for countering a claim, in particular new rebuttable presumptions (see below regarding the burden of proof).

The disclosure obligation is supposed to be limited to what is "necessary and proportionate" and within the other party's disposal. Courts are supposed to be empowered to manage the disclosure process in a way that preserves confidentiality, e.g. not disclosing trade secrets.

It is also a requirement that Member States' courts be empowered to "require such evidence [i.e. the disclosure] to be 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". While apparently balanced by the requirements of necessity and proportionality, this requirement is capable of wide interpretation and seems likely to result in disputes concerning the level of curation and education required to comply when dealing with less well-informed litigation opponents.

A major factor in relation to disclosure is that the failure to disclose relevant evidence exposes defendants to a presumption that their product is defective (Article 10(2)(a) of the New PLD). This may seem likely to trigger disputes in relation to the meaning of "relevant" and create difficulties for defendants in cases where documents are held by other companies within the same group. On the face of it, particularly given the claimant's ability to complain that the disclosure provided is inadequate in terms of how accessible and easy it is to understand, the introduction of such a presumption potentially hands quite a significant weapon to claimants. It is likely to require tight management of the process by the courts in order to avoid unfairness, and there will very likely be divergent decisions across Member States.

For defendants, particularly in jurisdictions where there is limited experience of disclosure, it will be important to consider resources to ensure appropriate record-keeping and information management, so that the relevant business unit(s) know what information they have and are able to produce it efficiently (and accessibly) in response to disclosure requests.

For jurisdictions where it is possible to argue for exemptions from disclosure on the grounds of privilege, it may be worth reviewing whether this applies to the work product and/or relevant communications of in-house counsel. If not, the use of external counsel to preserve privilege in appropriate cases should be considered.

Burden of Proof

In principle, the claimant continues to bear the burden of proving the defect, damage, and the causality between defectiveness and the damage. However, the New PLD introduces certain rebuttable presumptions to make proving defect and causation easier for claimants. A rebuttable presumption of defectiveness will apply if:

- the defendant fails to disclose "necessary and proportionate" evidence to meet its duty of disclosure;
- the claimant demonstrates non-compliance with the relevant product safety regulations of the EU; or
- the claimant demonstrates that 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. Further, it 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.

Finally, a court must presume defectiveness if the claimant has demonstrated that defectiveness and/or causation is "likely" but is faced with "excessive difficulties", due to the technical or scientific complexity of a product, in proving their case.

Depending upon the civil standard of proof in the particular jurisdiction, this last provision may be unnecessary, because being able to show that something is likely implies that it can be shown to be more likely than not, i.e. the balance of probabilities test is met and there is no need for a presumption to assist in proving the case. That the presumption was thought to be a necessary alleviation for claimants probably reflects the fact that a different standard of proof exists in some EU jurisdictions and this is harder to satisfy than the "balance of probabilities".

The rebuttable presumptions throw up more questions than they answer. What level of difficulty is "excessive" for a claimant to face? What level of scientific or technical complexity is such that a claimant should not be expected to engage with it? Recital 34 to the New PLD explicitly refers to medical devices as technically and scientifically complex products, but do most consumers really have any greater understanding of how long-established technologies, such as televisions and washing machines, function? It is not clear whether the intention is to limit the provision to instances where the technology is so novel (the only real expertise lies with the manufacturer) or whether it is intended to be broader than that. There is plainly a risk that any claimant can say that how the product works is beyond their technical capabilities to assess, and therefore it is sufficient that defectiveness is possible and must be presumed unless rebutted. The effect of this in practice is a reversal of burden of proof.

Manufacturers will need to positively provide evidence to prove the safety of their products. This means being able to produce records demonstrating testing, risk assessment, post-marketing surveillance, and compliance with regulatory standards. Therefore, records of these should be kept up to date in such a way that they can be effectively deployed. In other words, companies will need to make even greater efforts to make sure they know their products and can evidence their safety.

Development Risks Defence (Article 11(1)(e))

The development risks defence in Article 11 applies to exempt defendants from liability when "the objective state of scientific and technical knowledge at the time the product was placed on the market or put into service or during the period in which the product was within the manufacturer's control was not such that the defectiveness could be discovered". It is intended to protect innovators. There is scope under Article 18 of the New PLD to derogate from including such a defence in whole or in part, where Member States choose to do so.

It is not clear how important this defence is in practice, because the concept of defect (necessary for liability) already requires consideration of "all circumstances". Those circumstances include product characteristics, standards and safety requirements, reasonably foreseeable use, etc., at a particular moment in time when the product was placed on the market or left the control of the manufacturer. If the issue was not discoverable with the knowledge/technology of the time, then it is not clear that defectiveness can be established, because there will not have been an applicable legal requirement nor could any person be entitled to expect to be safe from an unknown hazard. If that analysis is correct, then there is no need for the development risks defence. However, it remains an important totem

of recognition by EU legislators that innovators require protection, and it is possible that it may, on occasion, prove a valuable backstop for defendants where, thanks to new presumptions as to defect and causation, a claimant might otherwise succeed.

Limitation and Extinguishment of Right to Bring a Claim

The limitation cut-off under Article 17 of the New PLD is three years from the date on which the injured person became aware, or should reasonably have become aware, of all three of the following: (a) the damage; (b) the defect; and (c) the identity of the relevant economic operator that can be held liable for that damage. As with the Old PLD, the laws of Member States regulating suspension or interruption of the limitation period are not affected.

Again, as with the Old PLD, there is an overall 10-year long-stop extinguishment of rights to bring a claim running from the date that the defective product was placed on the market, put into service, or made available following substantial modification. However, the time for extinguishment of rights is extended to 25 years in cases of latent injury in respect of which it was not possible (due to the latency) to commence proceedings within the 10-year period. This is potentially significant in terms of the likely increased cost of insurance cover for businesses, and the need to retain records for longer periods in order to satisfy disclosure requirements and enable an effective product liability defence.

Future Developments

The New PLD specifies that the Commission shall, by 9 December 2030, and every five years thereafter, evaluate the application of this Directive and submit a report to the European Parliament, to the Council and to the European Economic and Social Committee. These reports shall include information about the cost and benefits of the transposition of this Directive, a comparison with OECD countries, and the availability of product liability insurance. This perhaps indicates a degree of acknowledgment that the proposed legislation may have unintended effects and require amendment or clarification at some stage.

The process of developing the New PLD started out with the repeated insistence that the Old PLD was not fit for purpose and needed to be updated in line with technological developments. Over the course of the process, it became clear that, for some stakeholders and contributors at least, the main intention was to revisit the "fair apportionment of risk" mentioned in the recitals to the Old PLD dating from 1985 as the basis of its regime, and rebalance this in favour of claimants. With the introduction of disclosure and rebuttable presumptions, it has arguably achieved this. It remains to be seen how these changes will affect the ability of claimants to obtain redress in practice. It will also be interesting to see whether the UK, whose national product liability legislation remains based on the Old PLD, will approach updating the legislation in a similar way.

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
LinkedIn: www.linkedin.com/in/adela-williams-b0412b50

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 in 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
LinkedIn: www.linkedin.com/in/tom-fox-86582a12

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