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Research Article

THE NEW EU PRODUCT LIABILITY DIRECTIVE: DOCTRINAL ANALYSIS

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ABSTRACT

Background: The question of who bears liability when an AI system causes harm has long been debated in the field of AI and law. When the EU proposed the Product Liability Directive and the AI Liability Directive in 2022, many expected the two instruments to jointly determine how such cases would be handled. This picture changed once the AI Liability Directive was withdrawn in February 2025 and the revised Product Liability Directive was adopted in October 2024. The result is that the EU now provides harmonised liability rules only for situations in which AI products injure consumers or other natural persons. With this shift, current discussions on AI liability can either examine the consequences of withdrawing the AI Liability Directive or look closely at how the updated Product Liability Directive (EU) 2024/2853 ("Directive") allocates responsibility. This article takes the latter approach. For the consumer and naturalperson contexts to which the Directive applies, it argues that the debate should turn to analysing the specific liability structure the Directive sets out.

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Methods: The revised Directive is not an easy instrument to interpret, given its distinctive terminology, high level of detail, and extensive lex specialis provisions when compared to the general rule of fault-based liability. Although it replaces the 1985 Directive—and thus builds on an existing body of scholarship—the 2024 revision introduces changes that necessitate renewed analysis. The most suitable method for understanding this revised liability regime, clarifying its ambiguities, novelties, and problematic aspects, is the doctrinal legal approach. Accordingly, this article employs doctrinal analysis to examine and systematise the revised Directive.

Results and conclusions: The article organises the Directive's provisions into four categories: first, the scope of application, defining when product liability applies; second, the elements of liability, specifying what the claimant must prove; third, the defences, indicating the exemptions from liability on which the defendant may rely; and finally, the procedural rules, governing disclosure of evidence, relevant to both parties, and the conditions under which the burden of proof, resting on the claimant, may shift to address evidentiary challenges.

On the basis of this fourth feature—procedural rules that ease the claimant's evidentiary burden—the article argues that the Directive alters how EU product liability should be conceptually defined. Under the 1985 Directive, the framework rested on two conceptual axes defining strict product liability: first, replacing fault with product defectiveness; and second, limiting defences, both of which made product liability "strict". Since the new procedural rules further strengthen the claimant's position, the article concludes that the revised Directive adds a third axis to the concept of strict product liability, thereby making the regime even stricter through burden-alleviation rules.

1 INTRODUCTION

If an AI system causes damage, who is legally responsible for compensating the victim? This has been one of the central questions in contemporary debates in the field commonly referred to as "AI and law". Since October 2024, however, the answer has become clearer—at least with respect to consumers and other natural persons. That date marks the adoption of the revised Product Liability Directive (EU) 2024/2853 ("Directive"). This Directive now covers situations where damage is caused by AI, meaning the debate

The author has explored this issue in a blog post, see: Deimante Rimkute, 'AI Liability After the AILD Withdrawal: Why EU Law Still Matters?' (Oxford Business Law Blog, 1 April 2025) https://blogs.law.ox.ac.uk/oblb/blog-post/2025/04/ai-liability-after-aild-withdrawal-why-eu-law-still-matters accessed 30 May 2025.

² Full title: Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 On Liability for Defective Products and Repealing Council Directive 85/374/EEC [2024] OJ L 2853/1.

³ See information, for example, in 'Liability for Defective Products' (European Commission: Internal Market, Industry, Entrepreneurship and SMEs, 8 December 2024) https://single-market-economy.ec.europa.eu/single-market/goods/free-movement-sectors/liability-defective-products_en-accessed 30 May 2025.



should shift from identifying who bears responsibility to investigating how that responsibility is structured and applied in practice.

This question, however, is not straightforward. The Directive is a complex instrument, characterised by distinctive terminology, a high level of regulatory detail, and extensive *lex specialis* provisions. Although it replaces the 1985 Directive–and thus its commentary rests on an existing body of scholarship—the 2024 revision introduces changes that necessitate additional doctrinal work. This is where the present article makes its contribution: it offers a doctrinal analysis⁴ of the revised Directive, aiming to provide a coherent and systematic understanding of its structure, key features, and novelties.

This article pursues this aim by grouping the Directive's provisions into four categories. The first concerns the starting point in the Directive's applicability—the scope of application, which defines whether disputes fall under the product liability regime (Section 2). The second category addresses matters forming the evidentiary burden of the claimant—namely, the elements of liability that must be proven to obtain compensation (Section 3). The third examines the defendant's escape routes from liability. That is, the exemptions from liability, invoked by the defendant to avoid responsibility (Section 4). Finally, the fourth category concerns the procedural rules, proposing remedies to evidentiary difficulties (Section 5).

By organising the Directive's provisions in this manner, the article also advances a broader conclusion about how product liability should be defined as a legal concept (Section 1). It argues that the 2024 Directive requires a reconsideration of this concept: product liability should no longer be understood solely as faultless liability—defined by product defectiveness and by narrowly circumscribed defences—but also as a regime that includes a third, procedural element, namely the alleviation of the claimant's burden of proof. The discussion begins with this revised definition of the concept of product liability.

2 DEFINING PRODUCT LIABILITY

Product liability is commonly defined as "no-fault" liability for a particular factual situation—damage caused by defective products. This standard definition, however, is not particularly helpful, as it merely explains what this type of liability is not (i.e., not fault-based) or limits itself to describing the circumstances in which it applies. The aim of this section, therefore, is to propose a more precise conception of product liability in 2024.

The starting point of this inquiry is the observation that, in the EU—unlike in the common law tradition—product liability is a regime established by legislation. Any conception of it must therefore begin with what the law itself provides, rather than how courts have defined

⁴ More about the methodology here: Jan M Smits, 'What is Legal Doctrine?: On the Aims and Methods of Legal-Dogmatic Research' in Rob van Gestel, Hans-W Micklitz and Edward L Rubin (eds), Rethinking Legal Scholarship: A Transatlantic Dialogue (CUP 2017) 210. doi:10.2139/ssrn.2644088.

it over time. In the EU, the law itself shows that the development of product liability has unfolded in two distinct phases. The first phase refers to EU product liability between 1985 and 2024.⁵ This phase began in 1985, when the Product Liability Directive was adopted in response to a series of major industrial disasters that exposed the inadequacy of fault-based liability in addressing such cases.⁶ The second phase begins in 2024, when the 1985 Directive was replaced by the 2024 Directive in response to different concerns—namely, growing criticism that the 1985 Directive was no longer adequate to address the challenges posed by new types of goods, particularly those involving digital technologies.⁷ This brief overview matters for our task of defining the concept of product liability for one simple reason. If such a definition of the concept must be grounded in the law, and the law has developed in two distinct phases, then we must also consider whether there are two corresponding conceptions of product liability. In other words, while the classic understanding of product liability derived from the 1985 Directive, we should not assume that this definition still fully applies today. To assess whether the concept has changed, the understanding of product liability implied in the 1985 Directive must be clarified.

Under the 1985 Directive, the features that defined product liability as a *lex specialis*, strict, or, in other words, a victim-friendly liability regime were twofold. The first was that, under this regime, fault was replaced by another, so-called "strict" element—product defectiveness. This framed the regime as an *obligation de résultat*: the manufacturer had to ensure that the product was safe and did not cause harm, rather than merely exercising due care to make it safe (*obligation de moyens*). This made product liability stricter because it was easier to prove the strict element of product defectiveness than to establish fault. That assessment was outcome-based—the product had to be made in a way that avoided defectiveness. The second axis was that the product liability regime limited and predetermined the defences available to the defendant, so that liability could be avoided only in clearly defined and exceptional circumstances, for example, by showing that the

We do not consider period before 1985 because then product liability claims were largely governed by fault-based rules applied to a specific factual matrix – damage caused by a product. Read about it here: Duncan Fairgrieve and others, 'Product Liability Directive' in Piotr Machnikowski (ed), European Product Liability: An Analysis of the State of the Art in the Era of New Technologies (Intersentia 2016) 17.

⁶ ibid 20.

Read about the debate here: Sebastian Lohsse and others, 'Liability for Artificial Intelligence' in Sebastian Lohsse, Reiner Schulze and Dirk Staudenmayer (eds), Liability for Artificial Intelligence and the Internet of Things (Nomos 2019) 9. doi:10.5771/9783845294797-9; K Alheit, 'The Applicability of the EU Product Liability Directive to Software' (2001) 34 Comparative and International Law Journal of Southern Africa 188; Daily Wuyts, 'The Product Liability Directive – More than Two Decades of Defective Products in Europe' (2014) 5(1) Journal of European Tort Law 1. doi:10.1515/jetl-2014-0001; Gerhard Wagner, 'Software as a Product' in Sebastian Lohsse, Reiner Schulze and Dirk Staudenmayer (eds), Smart Products (Nomos 2022) 164. doi:10.5771/9783748929772-157.

⁸ Thomas Verheyen, 'Modern Theories of Product Warnings and European Product Liability Law' (2019) 15(3) Utrecht Law Review 44. doi:10.36633/ulr.541.

⁹ Cees van Dam, European Tort Law (3rd edn, OUP 2013) para 1003-3, 301.



defect could not have been detected given the state of scientific and technical knowledge at the time. This approach contrasted with fault-based liability, where the range of possible defences was much broader and less favourable to victims.

Turning now to the concept of product liability under the 2024 Directive, it becomes apparent that the regime maintains the two original axes. Product liability can still be defined as a form of no-fault, or strict, liability in which (1) fault is replaced by another element (product defectiveness) and (2) the available defences are narrowly limited. However, the initial doubt as to whether the concept remains truly the same reveals that the Directive introduces an additional structural feature. This third axis is the use of presumptions—mechanisms capable of shifting the burden of proof in establishing defectiveness and causation from the claimant to the defendant (discussed in Section 5).

The article argues that this new feature should be recognised as a third axis that further defines product liability alongside the two already described. This third feature renders product liability under the 2024 Directive even more "strict" and more favourable to claimants. The idea that presumptions make a liability regime stricter is not entirely new. Similar arguments have been made in discussions of fault-based liability, where regimes in which fault is presumed were described as *de jure* fault-based but *de facto* strict (or semistrict), since their practical outcomes closely resemble those of strict liability. Accordingly, to understand what constitutes "strict product liability," we must consider all the structural elements that contribute to its strictness.

3 SCOPE OF APPLICATION

The scope of application is always the starting point, because when damage occurs, the first question is which liability regime applies—product liability or another. At first glance, the question of the scope of application may seem relatively innocuous and academic attention often focuses on matters such as the elements of liability or defences. In practice, however, the scope of application is anything but innocuous. Because the Directive establishes a regime that is generally more favourable to claimants, defendants have strong incentives to argue that a given case falls outside its scope, while claimants will argue the opposite.

These disputes usually focus on three key concepts. The first is what qualifies as a product, since the Directive only applies if the damage was caused by something that meets the Directive's definition of a "product." The second concerns who can be held liable, as a claim cannot be brought against just anyone involved with the product. The third concerns who is entitled to claim damages, because the Directive does not confer standing to all persons

See the overview of the debate on the use of presumptions to establish fault in this article: Francesco Parisi and Giampaolo Frezza, 'Burdens of Proof in Establishing Negligence: A Comparative Law and Economics Analysis' (2023) 9 Italian Law Journal 77.

without distinction. The following paragraphs examine each of these concepts in more detail, beginning with the definition of a "product."

Product. The provision, which defines which goods fall under the Directive, is Article 4(1). It defines products as "all movables, even if integrated into, or interconnected with, another movable or an immovable; it [also] includes electricity, digital manufacturing files, raw materials, and software." This definition entails several notable changes. The first notable change is that the Directive is no longer limited to tangible goods. It now explicitly includes certain non-tangible items—digital manufacturing files and software (including AI). This expansion, however, is not without limits. While software is generally covered, free and open-source software "is not (Article 2(2), Recital 14). The same applies to digital files: when such files are manufacturing files—for example, those used in advanced production processes such as CAD, CAM, or IoT-based systems, they are included, whereas generic digital files such as text documents, images, or videos are not. ¹³

Another notable change in the Directive definition of a product is that it now also covers raw materials. ¹⁴ More revolutionary, it extends its scope to certain product-related services, ¹⁵ but only where two conditions are met: (1) the service is embedded in, or essential to, the product's functionality (Article 4(3)); and (2) it has a direct impact on the product's safety. ¹⁶ This means that services such as traffic data for vehicle navigation, health-monitoring functionalities, smart-home safety systems, and software updates, upgrades, or machine-

Directive (EU) 2024/2853 (n 2) recital 13. Although the core text does not define software, the Recitals of the Directive offer a non-exhaustive list, including operating systems, firmware, computer programs, applications, and AI systems. They also clarify that software is covered regardless of mode of supply, whether it is a standalone product, integrated component, stored on a device, accessed via cloud or network, or provided as software-as-a-service (SaaS)..

¹² Free and open source software is typically governed by licenses that permit anyone to run, copy, distribute, study, and improve it; and must not be provided during commercial activity, for example, "in exchange for a price, or for personal data used other than exclusively for improving the security, compatibility, or interoperability of the software." See, Directive (EU) 2024/2853 (n 2) recital 14.

¹³ ibid, recital 16.

Importantly, the revised definition now encompasses materials that are not manufactured but are extracted or harvested, including raw materials and primary agricultural products, such as gas, water, farm goods, fishery products, and game, which were previously excluded under the 1985 Directive. See, Council Directive 85/374/EEC of 25 July 1985 On the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products [1985] OJ L 210/29, art 2. For the context see, for example, Duncan Fairgrieve and Richard Goldberg, Product Liability (3rd edn, OUP 2020) 221. doi:10.1093/oso/9780199679232.001.0001.

See, for example, Directorate-General for Communication, 'EU Adapts Product Liability Rules to Digital Age and Circular Economy' (European Commission, 9 December 2024) https://commission.europa.eu/news/eu-adapts-product-liability-rules-digital-age-and-circular-economy-2024-12-09_en accessed 7 November 2025.

See, Directive (EU) 2024/2853 (n 2) recital 17. Also, Gerhard Wagner, 'Next Generation EU Product Liability – For Digital and Other Products' (2024) 15(2) Journal of European Tort Law 185-6. doi:10.1515/jetl-2024-0011.



learning processes may now fall within the Directive's scope.¹⁷ The Directive, therefore, applies "well beyond the realm of both pure manufacturing and products *sensu stricto*".¹⁸

Caution is nevertheless required when applying the Directive to services. The inclusion of related services should not lead to the misunderstanding that the Directive applies to services in general. Pure information content—such as media files, e-books, source code, or other forms of data that merely constitute "information"— remains outside the Directive's scope. In this regard, the clarification given by the CJEU in *Krone-Verlag* (Case C-65/20) outlives the Directive's revision: harm caused solely by incorrect information contained in a medium such as a newspaper does not make that medium a defective product under the PLD. In 20

Persons entitled to claim damage. A second gatekeeper from the application of the Directive concerns who is permitted to bring a product liability claim. The Directive does not grant standing to any person in general. It grants standing only to natural persons who have suffered harm as a result of a defective product (Article 5(1)).²¹ This, however, raises a question: does the Directive apply in the same way to all natural persons? That would seem counterintuitive, as product liability has traditionally been understood as a consumeroriented regime. To answer this, Article 5 must be read together with Article 6, which defines "damage." Article 6 makes it clear that certain categories of compensable harm remain limited to non-professional or not exclusively professional use. Accordingly, while the Directive extends protection to all natural persons, particularly in relation to damage to health, it provides a narrower protection for those acting in a professional capacity, where the damage concerns property or data. In that sense, the Directive formally protects all natural persons but, in practice, offers stronger protection to consumers.

Liable parties. The last gatekeeper from the application of the directive concerns liable parties. A claimant seeking compensation under the Directive cannot sue just anyone involved with the product. Only certain parties—those explicitly listed in the Directive—can be held liable. Importantly, this may not always be the company that actually manufactured the defective product. Liability can extend further down the supply chain to others who played a role in bringing the product to the market. To capture this broader scope, the Directive uses the term "economic operators." This includes not only the manufacturer (of the product or one of its components) but also the provider of a related service, the authorised representative, the importer, the fulfilment service provider, and, in some cases, the distributor (Article 4(15)).

¹⁷ Directive (EU) 2024/2853 (n 2) recitals 17, 19, 35.

Jan De Bruyne, Orian Dheu and Charlotte Ducuing, 'The European Commission's Approach to Extra-Contractual Liability and AI: An Evaluation of the AI Liability Directive and the Revised Product Liability Directive' (2023) 51 Computer Law & Security Review 105894. doi:10.1016/j.clsr.2023.105894.

¹⁹ See, Directive (EU) 2024/2853 (n 2) recital 13.

²⁰ Case C-65/20 VI v KRONE-Verlag Gesellschaft mbH & Co KG [2021] ECLI:EU:C:2021:471, para 42.

²¹ It shall be noted that the revised Directive also includes persons who have inherited this right or to whom it has been subrogated, as well as persons acting on behalf of one or more injured persons. See, Directive (EU) 2024/2853 (n 2) art 5(2).

In assigning the responsible party, the Directive follows a "chain of liability" principle: there is a set order in which potential defendants are approached. If the first entity in the chain (e.g., the manufacturer) cannot be held liable, the claim moves to the next party (e.g., importer). In total, there are four tiers in this chain of liability. The first tier consists of manufacturers, a term that the Directive defines broadly. It includes two groups. First are the "real manufacturers"—those who actually produce the product, including when they make it for their own use²² (Article 4(10)(a), (c)). Second are "manufacturers by labelling"—parties that have a product made by someone else but place it on the market under their own name, trademark, or another identifying sign (Article 4(10)(b)). Although these two categories involve different levels of control over design and production, the Directive does not require the claimant to track down the "real manufacturer" before suing a "manufacturer by labelling." This approach was confirmed by the CJEU in *Fennia* (Case C-264/21) and remains relevant even after the Directive's revision.²³

When the manufacturer is not established or cannot be identified within the EU (Article 8(3)), the Directive allows the claimant to pursue other economic operators in the supply chain. Before listing which operators may be held liable, it is necessary to explain why this expansion exists and what purpose it serves. The underlying rationale reflects the Directive's victim-protection logic: its objective is to ensure that those harmed by defective products have a realistic chance of obtaining compensation when the manufacturer (the primary responsible party) cannot be reached.

The criteria that bound these other liability parties—namely, importers, authorised representatives, fulfilment service providers, and distributors—is that they are not random third parties. In factual terms, each operator can contribute to the process by which unsafe products reach consumers through import, handling, storage, or sale. At the same time, these economic operators profit from the activity that results in the unsafe product being placed on the market.²⁴ If they take part in an activity that generates risk and derive economic benefit from it,²⁵ it is reasonable that they also bear part of that risk and be held liable when the manufacturer is unavailable, and the product causes harm.

²² It appears that with this addition to include into manufacturers notion also the manufactures that manufacture for their own use codifies the CJEU's judgment in Veedfald (Case C-203/99). In that case, the Court held that a service provider may be liable under the Directive where it uses a self-manufactured product in the course of providing a service and the defect lies in that product, rather than in the service itself. See, Case C-203/99 Veedfald v Århus Amtskommune [2001] ECR I-3569, ECLI:EU:C:2001:258, para 12.

²³ Case C-264/21 Keskinäinen Vakuutusyhtiö Fennia v Koninklijke Philips NV [2022] ECLI:EU:C:2022:536, para 35.

²⁴ Marco Cappelletti, Justifying Strict Liability: A Comparative Analysis in Legal Reasoning (OUP 2022) 73-4. doi:10.1093/oso/9780192859860.001.0001.

²⁵ Read about risk creation as justification for strict liability in Guido Calabresi, The Costs of Accidents: A Legal and Economic Analysis (Yale UP 1970) 50-4.



However, not all operators contribute equally to this process. The Directive recognises this, giving some operators higher priority than others. This further hierarchy appears to rest on two main factors: the operator's role in placing the product on the market or making it available to users, and their degree of proximity to the manufacturer. Based on these criteria, the second possible defendants, if the manufacturer is not established in the EU, are the importers and authorised representatives (Article 8(1)(c)). These actors have the closest connection to both the manufacturer and the product's entry into the EU market, which explains why they are second. The importer places the product on the EU market and bears compliance responsibility (Article 4(12)), while the authorised representative acts as the manufacturer's proxy, carrying out specific duties related to product compliance and communication with authorities under a defined mandate.²⁶

The third-tier operators are fulfilment service providers²⁷—those who handle key logistics tasks such as warehousing, packaging, shipping products (Article 8(1)(c)). The claimant may turn to them only if no importer or authorised representative is established within the Union. Their inclusion recognises their practical role in enabling products, particularly from outside the EU, to reach consumers, bypassing standard product placement procedures designed to ensure safety.²⁸ This is especially relevant in the context of cross-border e-commerce, where fulfilment service providers often act as *de facto* importers.²⁹ At the bottom of the hierarchy are the fourth-tier operators—distributors and online platforms (Article 8(3)-(4)).³⁰ They serve as "last-resort" defendants, liable only

See, for example, Netherlands Enterprise Agency and Netherlands Food and Consumer Product Safety Authority, 'Product Safety and the Role of the Authorised Representative' (Business.gov.nl, 2024) https://business.gov.nl/regulation/product-safety-and-role-of-authorised-representative/ accessed 7 June 2025. Importantly, authorised representatives can be assigned additional administrative tasks (e.g., drafting the EU declaration of conformity or affixing CE marking) may be delegated by the manufacturer when permitted by law and the mandate.

²⁷ Directive (EU) 2024/2853 (n 2) art 4(13). The Directive defines fulfilment service provider as "any natural or legal person offering, in the course of a commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching of a product, without having ownership of that product". This definition excludes postal services (art. 2(1) of Directive 97/67/EC), parcel delivery services (art. 2(2) of Regulation (EU) 2018/644), and other postal or freight transport services.

²⁸ Read about it, for example, here: 'What Does It Mean "Placing a Product on the Union Market"?' (European Commission: Energy Efficient Products, 2024) https://energy-efficient-products.ec.europa.eu/faqs-0/what-does-it-mean-placing-product-union-market_en accessed 7 June 2025.

²⁹ See, Directive (EU) 2024/2853 (n 2) recital 37.

³⁰ It is important to note, however, that the inclusion of online platforms in this tier is conditional: they can be held liable only if the criteria in Article 6(3) of the Digital Services Act are met – that is, where the platform actively presents the product or otherwise enables the specific transaction (Article 8(4)). See, Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market for Digital Services and amending Directive 2000/31/EC (Digital Services Act) [2022] OJ L 277/1. On the other hand, if online platforms function as a manufacturer, importer, authorized representative, fulfilment service provider, or distributor, then they take on the same liabilities as those operators, i.e. Article 8(4) is not applied. See, Directive (EU) 2024/2853 (n 2) recital 38.

when the claimant cannot identify a higher-tier operator. Their inclusion can be justified by the "soft power" they have, i.e. they decide which products to distribute or host on their platforms and can therefore influence whether unsafe products reach consumers while benefiting from this activity. However, since they do not control a product's initial entry into the market, they are placed at the bottom.

4 ELEMENTS OF LIABILITY

To obtain compensation, the claimant must prove that the damage was caused by a defective product. In other words, defectiveness and damage must be shown to stem from the same event, with the damage occurring as a result of the defect. This assessment is structured around three elements: product defectiveness, damage, and causation. Under the general rule, it is the claimant's responsibility to establish all three. This section, however, will address only two elements: product defectiveness and damage. Causation is regulated by the Directive only to the extent that it is presumed and will therefore be examined separately in Section 5.

Damage. The starting point of any delict claim is actual damage—without it, there is no basis for compensation. The claimant must therefore show that a product defect caused real harm, both factually and in monetary terms. Damages are generally classified as economic (quantifiable financial losses such as medical or funeral expenses, property damage, and lost income)³¹ and non-economic (intangible harm such as pain and suffering, emotional distress, loss of enjoyment of life, or loss of companionship).³² However, many legal systems restrict recovery for certain types of harm—typically pure economic loss or emotional distress.

The Product Liability Directive adopts a similar approach by limiting compensable damage to three categories: (1) damage to health, including medically recognised psychological harm; (2) damage to property; and (3) damage to data. This means that infringements of personality rights, privacy breaches, acts of discrimination, and pure economic loss (e.g. loss of salary) fall outside its scope.³³ The Directive then narrows these categories further through specific exclusions. It does not cover damage to the defective product itself; damage to another product caused by a defective component where both are made or controlled by the same manufacturer; property used exclusively for professional purposes; or destruction or corruption of data used for professional purposes (Article 6(1)(b)-(c)).

On the other hand, while Directive does not cover every type of damage, that does not stop Member States from allowing those excluded types of damage to be compensated under

³¹ David A Fischer and others, Products Liability: Cases and Materials (West Academic Publishing 2022) 673.

³² ibio

³³ See, Directive (EU) 2024/2853 (n 2) recital 24.



their own national law.³⁴ They can do this in two ways: through another national liability regime, such as fault-based liability, or by extending the product liability regime to additional types of damage. If they choose the latter option, they may replicate the same rules set out in the Directive. But in that case, the legal basis is national law, not EU law. The Member State is essentially creating a parallel national regime inspired by the Directive rather than implementing the Directive itself. CJEU case law confirms this approach. In *Moteurs Leroy Somer v Dalkia France* (Case C-285/08), the CJEU held that damage to exclusively professional property falls outside the scope of the PLD, but Member States are free to adopt equivalent national regimes.³⁵

Product defectiveness. The concept of "defect" is considered to be the core concept, upon which product liability turns,³⁶ and is widely regarded as the most complex element of the product liability.³⁷ The Directive addresses it through two main tests: the classic "consumer expectations test", and a second – newly introduced – test that can be called "safety required by law test" (Article 7(1)). To assist in the process, the Directive also introduces a list of circumstances that must or must not be (solely) considered when assessing whether a product is defective, outlined in Article 7(2) and (3). The main uncertainty, however, concerns the new test – introduced late in the trilogue negotiations – whose meaning sparks the debate.³⁸ This article, therefore, begins with that second test.

At first glance, the "safety required by law" test might suggest that any failure to meet legal safety standards automatically makes a product defective. However, when the Directive is read in full, this conclusion proves too broad. References to what is "required", whether by law or by other relevant requirements, appear in different provisions and lead to different legal consequences. For instance, Article 10(2)(b) establishes a presumption of defectiveness where a product breaches mandatory Union or national safety rules specifically aimed at preventing the kind of harm that occurred. By contrast, Article 7(2)(f) treats "relevant product safety requirements, including safety-relevant cybersecurity requirements" as merely one factor among several in the overall assessment of defectiveness. The question, then, is how these provisions relate to one another. This article takes the view that not every regulatory breach renders a product unsafe, and therefore not every breach renders it defective. As Table 1 shows, the legal consequences depend on the nature of the breach and its impact on the product's safety. If the breached rule directly renders the product unsafe, Article 7(1) applies, and the product is defective. If the breach raises a legitimate safety concern but does not in itself demonstrate unsafety,

³⁴ ibid, recitals 23, 24.

³⁵ Case C-285/08 Moteurs Leroy Somer v Dalkia France and Ace Europe [2009] ECR I-4733, ECLI:EU:C:2009:351, paras 28, 31.

³⁶ Fischer and others (n 31) 115.

³⁷ Fairgrieve and Goldberg (n 14) 324.

³⁸ For example, considering remarks by, Piotr Machnikowski, 'Defectiveness' (The New Product Liability Directive: Doctrinal, Comparative and Interdisciplinary Approaches: Conference, Maastricht University, 17-18 October 2024).

Article 10(2)(b) creates a rebuttable presumption of defectiveness. If the relevant requirement is not established in law, or is not breached but still relevant in context, it serves only as a factor in the assessment under Article 7(2)(f).

Table 1.

Article / Concept	Purpose	Meaning
Art. 7(1)	Establishing an actual defect	A breach of a legal rule establishes defectiveness only if (1) the rule is established in law (EU / national), and (2) the breach actually makes the product unsafe.
Art. 10(2)(b)	Presumption of defect (evidentiary facilitation)	A presumption of defectiveness arises if (1) mandatory product safety requirements laid down in law (EU / national) are breached, and (2) those requirements are intended to protect against the relevant risk of damage. This presumption does not require proof that the breach made the product unsafe, but if it did, then Art. 7(1) applies.
Art. 7(2)(f)	Assessment factor	Product safety requirements shall be assessed when investigating defectiveness. They do not need to be established in law (national / EU) or breached. However, if they are established in law (national / EU) and breached, then Art. 7(1) or Art. 10(2)(b) may become applicable.

Source: Author

Next, the classic consumer expectations test is broader and more open-ended than the "safety required by law" test. While the factors listed in Article 7(2) are technically relevant to both, in practice, they offer greater guidance when applying the consumer expectations test. A useful starting point in discussing consumer expectations is to identify the type of defect that caused the damage. Doctrine distinguishes three categories: manufacturing defects (the design is sound, but production errors make the product unsafe),³⁹ design defects (the design itself fails to provide adequate safety),⁴⁰ and information defects (insufficient instructions or warnings).⁴¹ These categories shape what a reasonable consumer may expect. For manufacturing defects, consumers can *prima facie* expect almost full conformity with the intended safe design; any safety-relevant

³⁹ Fischer and others (n 31) 115.

⁴⁰ ibio

⁴¹ Sanne B Pape, Warnings and Product Liability: Lessons Learned from Cognitive Psychology and Ergonomics (Eleven International Publishing 2012) 277, also Fairgrieve and Goldberg (n 14) 355.



deviation will generally fail the consumer expectations test.⁴² A reasonable consumer expects a product to be correctly manufactured, not that the manufacturer might make preventable errors in production. By contrast, for design and information defects, establishing defectiveness is not as straightforward.⁴³ Expectations depend more heavily on the surrounding context, in which the circumstances listed in Article 7(2) become relevant. A practical approach is therefore: first ask whether the issue is a manufacturing defect; if not, proceed to the broader Article 7(2) assessment.

Article 7(2) sets out a broad – and importantly, non-exhaustive – list of circumstances that may be considered when assessing defectiveness. Several points emerge from analysing these factors. First, some of them can be read as effectively implying (primary) duties for the producing process, and their breach may strongly support a finding of defectiveness. This is evident, for example, in the obligation to consider the specific needs of the intended users (Article 7(2)(h))⁴⁴ or the effects the product may have when used together with other products (Article 7(2)(d)). A failure to consider these factors may constitute a strong argument for defectiveness. Second, if these circumstances are understood to imply duties of production, it becomes apparent that the Directive formulates these duties at different levels of strictness. In some cases, the wording almost suggests that failing to satisfy a given circumstance effectively implies defectiveness, for instance, where a product fails to fulfil its safety function in situations where the very purpose of it is to prevent harm (Article 7(2)(i)). In others, the Directive simply calls for consideration of reasonably foreseeable use (Article 7(2)(b)), leaving room for a more context-sensitive assessment.

Third, some circumstances do not necessarily impose duties on operators but instead serve a contextual function, guiding the time or object of the assessment. For example, Article 7(2)(a) concerns the object of the assessment, namely how the product is presented, its labelling, design, technical features, composition, packaging, and instructions for assembly, installation, use, or maintenance. Article 7(2)(e), meanwhile, directs the assessment of defectiveness by "locking" it to the moment when the product was placed on the market or left the manufacturer's control, on the logic that the manufacturer can only impact safety while it still has control over the product. At the same time, it communicates when this moment should be "unlocked", i.e., when the product is no longer under the manufacturer's ongoing control, as is often the case with

⁴² Van Dam (n 9) 427-8.

⁴³ ibio

For this circumstance the relevant Directive (EU) 2024/2853 (n 2) recital 30. It highlights that fair apportionment of risks, especially when a product poses "high risks of causing damage," gives rise to "particularly high safety expectations." This principle has also been affirmed by the CJEU, which, in a case concerning a heart stimulator, recognized that patients have particularly high expectations of the safety of medical devices. For the reference, see joined Cases C-503/13, C-504/13 Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt – Die Gesundheitskasse and Betriebskrankenkasse RWE [2015] ECLI:EU:C:2015:148, para 39.

digital products. This implies that the moment from which assessment of such products is not necessarily fixed to their placement on the market.

On the other hand, as already noted, the Directive not only sets out the circumstances to be considered when assessing defectiveness, it also identifies circumstances that cannot be relied upon (at least not on their own). Article 7(3) is a key provision here. It states that a product cannot be considered defective solely because a better or updated version has been, or is later, placed on the market. When viewed in the broader tradition of product liability, this provision might at first appear to restrict the approach taken in the US, in particular, the alternative design test, which is closely associated with the so-called risk-utility test. Under this test, claimants can argue that a practical and cost-effective safer design of the demonstrated by existing products, could have prevented the harm. If the safety benefits of that alternative design outweigh the costs of implementation, the product is considered defective.

The fact that the EU rejects an unrestricted version of this test reflects a clear normative choice—prioritising consumer safety over economic efficiency. As Taschner, one of the Directive's original drafters, argued, the risk-utility test ultimately favours producers, whereas the European approach is that if a manufacturer cannot place a sufficiently safe product on the market, it should not place it on the market at all.⁵⁰ However, this does not mean that alternative designs or risk-utility reasoning must be entirely disregarded. A textual reading of Article 7(3) confirms that the alternative design test is not excluded from the defectiveness analysis; it is simply not decisive on its own. A safer or more advanced alternative design may still inform the overall assessment of defectiveness when considered alongside other relevant factors. In this sense, "alternative design" reasoning can operate as supporting evidence within the Article 7(2) framework.⁵¹

⁴⁵ Fairgrieve and Goldberg (n 14) 336-9.

Examples include a commercial coffee urn that exploded due to the absence of a simple pressurereducing valve; a lawn chair with a metal mechanism under the armrest that severed a user's finger, where a protective housing could have averted the injury; or an industrial machine with a sharp edge that caused harm, where the edge served no purpose and could have easily been smoothed for safety. See more, David G Owen, *Products Liability in a Nutshell* (10th edn, West Academic Press 2023) 225.

⁴⁷ ibio

David G Owen, *Products Liability Law* (3rd edn, West Group 2015) 300.

⁴⁹ ibid 303.

⁵⁰ Hans Claudius Taschner, 'Product Liability: Basic Problems in a Comparative Law Perspective' in Duncan Fairgrieve (ed), Product Liability in Comparative Perspective (CUP 2005) 160. doi:10.1017/ CBO9780511493850.011.

⁵¹ The indirect implication of the argument presented here is that, while alternative design cannot serve as the sole argument, other individual factors expressly listed in Article 7(2) of Directive (EU) 2024/2853 may, in principle, be sufficient on their own.



5 EXEMPTIONS FROM LIABILITY

As is typical in delict cases, even where all elements of liability are established, the defendant may still avoid liability by invoking an exemption, a circumstance which, if proven, releases the operator from liability. In the Directive, such exemptions are set out in Article 11 and, arguably, also in Article 13. Conceptually, these exemptions appear to be united by a common criterion: the operator is not liable where the risk that led to the damage lay outside their objectively reasonable sphere of control. In this sense, the exemptions implement a principle of fairness – liability under the PLD is strict but not absolute; the operator should not be held liable where it was not within their power to prevent the product from being defective.

To start with, exemptions of the Directive can be categorised into four broader categories. The first category covers situations where liability is exempted because the relevant operator did not place the product on the market (in the case of a manufacturer or importer, Article 11(1)(a)) or did not make it available on the market (in the case of a distributor, point (b)).⁵² Accordingly, if the operator was not involved in introducing the product to the consumer and therefore did not contribute to the defective product reaching them, they should not be held responsible for the resulting damage.⁵³

The second category concerns the absence of a defect at the time it was placed, put into service, or made available on the market, as provided in Article 11(1)(c). Accordingly, if the product had no defect when it entered circulation, the operator cannot be held liable. This exemption ensures that the operator is responsible only for risks within its sphere of control and cannot be held accountable for changes occurring after the product has left that sphere. However, precisely for this reason, an important limitation applies to digital products. Where the operator retains control, i.e. over software, related services, safety updates, or subsequent modifications, and the defect stems from those controlled elements, the operator cannot rely on this exemption (Article 11(2)).

The third category consists of compliance-based (Article 11(1)(d)) and development-risk (point (e)) defences. Under these, the defendant is not held liable where the product was made in accordance with the legal or state-of-the-art standards available at the relevant time. This reflects the idea that it would be unfair to penalise an operator for following the law⁵⁴ or to expect them to prevent what was objectively impossible to detect and fix. While the compliance-based defence is relatively clear, whether the product complied with

⁵² By analogy, this should be applied to online platform. See, of Directive (EU) 2024/2853 (n 2) recital 37, "provisions of this Directive relating to distributors should apply analogously to such online platforms."

⁵³ This exemption is not applied to authorised representative because it only represents manufacturer, it does not directly place it on the market, so too fulfilment service provider, whose role is logistical, to ensure that the product reaches the consumer.

⁵⁴ Geraint Howells (ed), Law of Product Liability (2nd edn, LexisNexis Butterworths 2007) 403.

requirements or not, the development risk defence is more open-ended in nature. In *Commission v United Kingdom* (Case C-300/95), the CJEU clarified that this defence requires invoking three elements: (1) the defect could not have been discovered given the highest level of scientific and technical knowledge available at the time; (2) that knowledge must have been objective; and (3) it must have been reasonably accessible,⁵⁵ as AG Tesauro pointed out—assessed in light of the actual opportunities for such information to circulate.⁵⁶

The fourth category consists of situations where the damage is attributable to another person, not the defendant. The Directive expressly allows this defence in two cases. First, where the defendant is a component manufacturer, the defect in the final product is attributable to the design of that product or to the instructions given by its manufacturer, rather than to the component itself (Article 11(1)(f), referring to Article 8(1)(b)). Second, where the defendant is a modifier, the defect concerns a part of the product that was not affected by the modification (Article 11(1)(g), referring to Article 8(2)).

Conceptually, this fourth category can also be complemented by a third situation, mentioned in Article 13(2). This provision establishes contributory negligence, which ensures that the operator is not held fully or partly responsible where the damage was caused, or partially caused, by the injured party's fault. The Directive does not specify whether "fault" refers to ordinary or gross negligence. However, Recital 55 provides guidance through an example: a user failing to install essential safety updates, conduct which may not, at *prima facie*, amount to gross negligence unless the user was under a clear obligation to do so. Nevertheless, beyond the specific cases covered by Article 11 and Article 13(1), the Directive generally does not allow reliance on the acts or omissions of a third party to reduce or exclude liability (Article 13(1)), for example, where a hacker exploits a cybersecurity vulnerability and contributes to the damage.⁵⁷ In such cases, the operator remains fully liable to the injured person.

6 PROCEDURAL MATTERS

A key novelty of the Directive is that it goes beyond substantive rules to introduce procedural provisions. The rationale for this development lies in the problem of evidentiary deficiency—situations in which claimants are unable to substantiate their claim due to a lack of necessary evidence. Even under a strict liability regime, this problem persists, particularly in cases involving technically complex products such as pharmaceuticals or AI systems, where it can be difficult for the claimant to prove that the product was defective or that it caused the damage. To address this, the Directive introduces procedural mechanisms

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⁵⁵ Case C-300/95 Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland [1997] ECR I-2649, ECLI:EU:C:1997:255, para 29.

⁵⁶ ibid, Opinion of Advocate General Tesauro, para 24 AG.

⁵⁷ See, Directive (EU) 2024/2853 (n 2) recital 55.



designed to assist claimants, specifically concerning the disclosure of evidence and the allocation of the burden of proof, which will now be examined in more detail.

Evidence disclosure. The evidentiary starting point in any dispute is access to the evidence. In AI-related product defect cases, for example, this may include logs, training data, or internal performance records, the kind of information that could reveal whether the product was defective. Yet the claimant, who bears the burden of proving defectiveness, typically has no access to such material. Vandenbussche describes this as a problem of evidentiary asymmetry: one party carries the burden of proof, while the other controls the information needed to meet it. In evidence law, such imbalances are addressed through disclosure rules, which compel the party in control of the evidence to provide it. While national civil procedures already allow for this in principle, the Directive goes a step further by introducing product-liability-specific disclosure rules in Article 9. These rules aim to balance the interests of both sides: they require courts to protect trade secrets (Article 9(5)), but at the same time, they must also ensure that evidence is provided "in an easily accessible and easily understandable manner" (Article 9(6)), which is particularly important for the claimant.

Presumptions. Evidentiary difficulties, however, do not end with disclosure. Even where the court orders the defendant to provide evidence, the defendant may still refuse to comply. In such a situation, the claimant is left unable to prove defectiveness because she simply cannot access the necessary information. Vandenbussche refers to this as a problem of "evidentiary impossibility". In such a case, Directive proposes a consistent with evidence law response – presumption of defectiveness (Article 10(2)(a)). This shifts the burden of proof to the defendant. In practice, this means that if the judge remains in doubt about the relevant facts at the end of the proceedings, the decision will be resolved against the party bearing the burden of proof—in this case, the defendant.

Disclosing evidence, on the other hand, is not a panacea in itself. Even with balanced disclosure rules, they may offer little help when the issue lies not in the unavailability of evidence, but in the limits of what can be known or demonstrated at all. Some facts are simply unprovable with a reasonable degree of certainty—for instance, when no existing scientific or technical knowledge can confirm or refute them. The law, however, does not remain indifferent to this problem of "evidentiary uncertainty".60 A common response is to lower the standard of proof: instead of requiring the claimant to establish a fact with the usual level of certainty (i.e., a reasonable degree of certainty), courts may accept a less demanding threshold, such as proof based on probability.61 This approach is also reflected

⁵⁸ Wannes Vandenbussche, 'Dealing with Evidentiary Deficiency in Tort Law' (SSRN, 15 February 2019) doi:10.2139/ssrn.3335377 https://ssrn.com/abstract=3335377 accessed 7 June 2025.

⁵⁹ ibid 12

⁶⁰ Israel Gilead, Bernhard A Koch and Michael D Green (eds), Proportional Liability: Analytical and Comparative Perspectives (De Gruyter 2013) 328, para 11.

⁶¹ ibid

in the revised Directive. Under Article 10(4)(a-b), if the claimant faces excessive difficulties due to technical or scientific complexity, the standard of proof is reduced to what is "likely" when establishing defectiveness and/or causation. Accordingly, for instance, if an AI system makes a decision that results in physical harm and its reasoning cannot be fully reconstructed, the claimant may meet the burden of proof by showing that it is likely that a defect in the system contributed to the harmful outcome, even without identifying the precise algorithmic flaw.

Another group of presumptions in the Directive concerns neither evidentiary impossibility nor evidentiary uncertainty, but instead permits a presumption based on prima facie evidence—that is, evidence allowing the court to treat a fact as proven "at first sight," drawing on general experience that "if X occurs, then Y (the legally relevant fact) usually follows or shall be implied."62 But before turning to the discussion of this group of presumptions, it is useful to recall the broader context in which they operate. While terminology for this legal phenomenon carries across jurisdiction, reasoning based on prima facie or circumstantial evidence is commonly associated with the doctrine of res ipsa *loquitur* ("the thing speaks for itself"). 63 It is described this way because, in certain cases, the very nature of the event provides its own explanation on how that event should be evaluated. As the classics put it, "in the ordinary course of things, bags of flour do not fall from warehouse windows, stones are not found in buns, cars do not mount the pavement, and slippery substances are not left on shop floors."64 Likewise, in the ordinary course of things, a bottle or boiler does not suddenly explode.⁶⁵ These situations are usually presented to reveal that sometimes the very occurrence of the event serves as strong *prima facie* evidence that something would not ordinarily happen without a defect.⁶⁶ In those cases, courts may, on that basis, presume defectiveness—and in some circumstances, also causation.

This reasoning is explicitly codified in the Directive. In particular, Article 10(2)(b) allows courts to presume defectiveness where a product fails to comply with mandatory product-safety requirements specifically intended to protect against the relevant risk, treating that non-compliance as *prima facie* sufficient. Likewise, Article 10(2)(c) applies when damage results from an "obvious malfunction" during "reasonably foreseeable" use, which the Directive considers sufficient to establish defectiveness. Accordingly, under this provision, if an autonomous cleaning robot suddenly accelerates and injures a user during normal operation, this obvious malfunction may allow the court to presume defectiveness without identifying the precise point of failure in the Al's control logic. The Directive extends this presumption-based logic to causation. Under Article 10(3), once defectiveness is

⁶² Vandenbussche (n 58) 20

⁶³ Fairgrieve and Goldberg (n 14) 684.

⁶⁴ Adrian Keane and Paul McKeown, The Modern Law of Evidence (9th edn, OUP 2012) 81.

⁶⁵ W Page Keeton and others, *Prosser and Keeton on the Law of Torts* (5th edn, West Publishing Co 1984) 244-55.

⁶⁶ ibid



established, causation may also be presumed where the type of damage is "typically consistent" with the defect in question, since certain harms are so characteristically linked to such defects that no further proof is required.⁶⁷ To illustrate, if an AI-operated drone has a known defect affecting navigational stability and subsequently crashes, the resulting property damage may be regarded as typically consistent with that defect, meaning the claimant need not provide additional evidence linking the defect to the crash.

7 CONCLUSIONS

The purpose of this article is doctrinal: to clarify the structure of the revised Directive by identifying its key features and novelties, and by analysing how its provisions work together as a coherent framework for resolving disputes involving product-caused damage, particularly harm resulting from AI products. To that end, the article organised the Directive's provisions into four categories. It began with the scope of application, defining when product liability applies. The second part examined the elements of liability, focusing on damage and defectiveness, and proposed a way to conceptualise the new "safety required by law" test alongside the traditional "consumer expectation" test in light of recent revisions. The third part addressed exemptions from liability, relevant to the defendant, explaining why such exemptions appear both in the dedicated article and elsewhere in the Directive. Finally, the article analysed the new structural addition to the product liability regime—the inclusion of procedural rules. Because of this fourth feature—procedural rules that ease the claimant's evidentiary burden-the Directive alters how EU product liability should be conceptually defined. Whereas the 1985 Directive rested on two conceptual axes that rendered the regime "strict"-replacing fault with product defectiveness and limiting defences—the revised Directive adds a third axis: burden-alleviation rules, which make liability even stricter in practice. Accordingly, if a proper definition of strict liability must consider all structural elements that contribute to its strictness, including this third axis.

REFERENCES

- 1. Alheit K, 'The Applicability of the EU Product Liability Directive to Software' (2001) 34 Comparative and International Law Journal of Southern Africa 188
- Bruyne JD, Dheu O and Ducuing C, 'The European Commission's Approach to Extra-Contractual Liability and AI: An Evaluation of the AI Liability Directive and the Revised Product Liability Directive' (2023) 51 Computer Law & Security Review 105894. doi:10.1016/j.clsr.2023.105894
- 3. Calabresi G, The Costs of Accidents: A Legal and Economic Analysis (Yale UP 1970)

- 4. Cappelletti M, Justifying Strict Liability: A Comparative Analysis in Legal Reasoning (OUP 2022). doi:10.1093/oso/9780192859860.001.0001
- Fairgrieve D and Goldberg R, Product Liability (3rd edn, OUP 2020). doi:10.1093/ oso/9780199679232.001.0001
- 6. Fairgrieve D and others, 'Product Liability Directive' in Machnikowski P (ed), European Product Liability: An Analysis of the State of the Art in the Era of New Technologies (Intersentia 2016) 17
- 7. Fischer DA and others, *Products Liability: Cases and Materials* (West Academic Publishing 2022)
- 8. Gilead I, Koch BA and Green MD (eds), *Proportional Liability: Analytical and Comparative Perspectives* (De Gruyter 2013)
- 9. Howells G (ed), Law of Product Liability (2nd edn, LexisNexis Butterworths 2007)
- 10. Keane A and McKeown P, The Modern Law of Evidence (9th edn, OUP 2012)
- 11. Keeton WP and others, *Prosser and Keeton on the Law of Torts* (5th edn, West Publishing Co 1984)
- 12. Lohsse S and others, 'Liability for Artificial Intelligence' in Lohsse S, Schulze R and Staudenmayer D (eds), *Liability for Artificial Intelligence and the Internet of Things* (Nomos 2019) 9. doi:10.5771/9783845294797-9
- 13. Machnikowski P, 'Defectiveness' (The New Product Liability Directive: Doctrinal, Comparative and Interdisciplinary Approaches: Conference, Maastricht University, 17-18 October 2024)
- 14. Owen DG, Products Liability in a Nutshell (10th edn, West Academic Press 2023)
- 15. Owen DG, *Products Liability Law* (3rd edn, West Group 2015)
- 16. Pape SB, Warnings and Product Liability: Lessons Learned from Cognitive Psychology and Ergonomics (Eleven International Publishing 2012)
- 17. Parisi F and Frezza G, 'Burdens of Proof in Establishing Negligence: A Comparative Law and Economics Analysis' (2023) 9 Italian Law Journal 77
- 18. Rimkute D, 'AI Liability After the AILD Withdrawal: Why EU Law Still Matters?' (Oxford Business Law Blog, 1 April 2025) https://blogs.law.ox.ac.uk/oblb/blog-post/2025/04/ai-liability-after-aild-withdrawal-why-eu-law-still-matters accessed 7 June 2025
- 19. Smits JM, 'What is Legal Doctrine?: On the Aims and Methods of Legal-Dogmatic Research' in Gestel R, Micklitz HW and Rubin EL (eds), *Rethinking Legal Scholarship:* A Transatlantic Dialogue (CUP 2017) 207. doi:10.2139/ssrn.2644088
- 20. Taschner HC, 'Product Liability: Basic Problems in a Comparative Law Perspective' in Fairgrieve D (ed), *Product Liability in Comparative Perspective* (CUP 2005) 155. doi:10.1017/CBO9780511493850.011



- 21. Van Dam C, European Tort Law (3rd edn, OUP 2013)
- 22. Vandenbussche W, 'Dealing with Evidentiary Deficiency in Tort Law' (SSRN, 15 February 2019) doi:10.2139/ssrn.3335377
- 23. Verheyen T, 'Modern Theories of Product Warnings and European Product Liability Law' (2019) 15(3) Utrecht Law Review 44. doi:10.36633/ulr.541
- 24. Wagner G, 'Next Generation EU Product Liability For Digital and Other Products' (2024) 15(2) Journal of European Tort Law 172. doi:10.1515/jetl-2024-0011
- 25. Wagner G, 'Software as a Product' in Lohsse S, Schulze R and Staudenmayer D (eds), Smart Products (Nomos 2022) 157. doi:10.5771/9783748929772-157
- 26. Wuyts D, 'The Product Liability Directive More than Two Decades of Defective Products in Europe' (2014) 5(1) Journal of European Tort Law 1. doi:10.1515/jetl-2014-0001

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АНОТАЦІЯ УКРАЇНСЬКОЮ МОВОЮ

Дослідницька стаття

НОВА ДИРЕКТИВА ЄС ПРО ВІДПОВІДАЛЬНІСТЬ ЗА ЯКІСТЬ ПРОДУКЦІЇ: ДОКТРИНАЛЬНИЙ АНАЛІЗ

Дейманте Рімкуте

КІЦАТОНА

Вступ. Питання про те, хто несе відповідальність, коли система ШІ завдає шкоди, вже давно обговорюється в галузі ШІ та права. Коли ЄС запропонував Директиву про відповідальність за якість продукції та Директиву про відповідальність ШІ у 2022 році, багато хто очікував, що ці два документи спільно визначатимуть, як будуть розглядатися такі випадки. Ця ситуація змінилася після того, як Директива про відповідальність ШІ була відкликана в лютому 2025 року, а переглянута Директива про відповідальність за якість продукції була схвалена в жовтні 2024 року. У результаті ЄС тепер забезпечує гармонізовані правила відповідальності лише у випадках, коли продукти ШІ завдають шкоди споживачам або іншим фізичним особам. З огляду на цю зміну, актуальні дискусії щодо відповідальності ШІ можуть або розглянути наслідки відкликання Директиви про відповідальність ШІ, або уважно розглянути, як оновлена Директива (ЄС) 2024/2853 («Директива») розподіляє відповідальність. У цій статті використовується другий підхід. Що стосується споживачів та фізичних осіб, до яких застосовується Директива, стверджується, що дискусія має зосередитися на аналізі конкретної структури відповідальності, встановленої Директивою.

Методи. Розглянута Директива не є простим інструментом для тлумачення, зважаючи на її специфічну термінологію, високий рівень деталізації та розширені положення lex specialis порівняно із загальним принципом відповідальності за вчинене діяння. Хоча вона замінює Директиву 1985 року – і таким чином грунтується на наявному корпусі наукових досліджень – перегляд 2024 року вносить зміни, які вимагають повторного аналізу. Найкращим методом для розуміння розглянутого режиму відповідальності, уточнення його неоднозначностей, нововведень та проблемних аспектів є доктринальний правовий підхід. Відповідно, у цій статті використовується доктринальний аналіз для вивчення та систематизації зазначеної Директиви.

Результати та висновки. У статті положення Директиви поділено на чотири категорії: перша— сфера застосування, яка визначає, коли притягуються до відповідальності за якість продукції; друга— елементи відповідальності, які визначають, що позивач повинен довести; третя— захист, що вказує на винятки у сфері відповідальності, на які може посилатися відповідач; і, нарешті, процесуальні правила, які регулюють розкриття доказів, що стосуються обох сторін, та умови, за яких тягар доказування, що лежить на позивачі, може бути перекладений для вирішення доказових проблем.

На основі цієї четвертої ознаки – процесуальних правил, що полегшують доказовий тягар позивача — у статті стверджується, що Директива ЄС змінює концептуальне визначення відповідальності за якість продукції. Згідно з Директивою 1985 року, ця структура грунтувалася на двох концептуальних засадах, що визначають сувору відповідальність за якість продукції: по-перше, заміна продукції з дефектом; та по-друге, обмеження захисту, обидва з яких зробили відповідальність за якість продукції «суворою». Оскільки нові процесуальні правила ще більше зміцнюють позицію позивача, у статті зроблено висновок, що у проаналізованій Директиві було додано третій пункт до концепції суворої відповідальності за якість продукції, що робить режим ще суворішим завдяки правилам полегшення тягаря доказування.

Ключові слова. Директива про відповідальність за якість продукції, відповідальність штучного інтелекту, європейське деліктне право, відповідальність за якість продукції, штучний інтелект та право, відповідальність за програмне забезпечення.