

**UNIVERSITY OF ESSEX**

**ESSEX LAW SCHOOL**

**LLM in International Commercial & Business Law**

**Academic Year 2024-25**

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**DISSERTATION**

Expanding the Definition of 'Product': Legal Implications of Including Software and AI  
under the New EU Product Liability Directive

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**Registration Number:** 2411517

**Number of Words:** 11640 (excluding table of contents, list of abbreviations,  
footnotes and bibliography) (including abstract)

**Date Submitted:** 10.09.2025

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### **List of Abbreviations**

AI Liability Directive	AILD
Artificial Intelligence	AI
Bureau Européen des Unions de Consommateurs	BEUC
Court of Justice of the European Union	CJEU
Directive (EU) 2024/2853	New PLD
European Centre for International Political Economy	ECIPE
European Economic Community	EEC
European Law Institute	ELI
Internet of Things	IoT
Open-Source Software	OSS
Product Liability Directive 85/374/EEC	Original PLD
Software-as-a-Service	SaaS

## **Abstract**

After nearly four decades of reliance on the 1985 Product Liability Directive, the European Union undertook a major reform through the adoption of the New Product Liability Directive. The reform responds to the digital transformation and the circular economy by significantly expanding the scope of liability. Its most notable innovations include the broader definition of ‘product’ to encompass software, AI systems, and digital manufacturing files, the easing of claimants’ evidentiary burdens, and the introduction of new procedural mechanisms such as disclosure of evidence and presumptions of defectiveness and causation. From the claimant’s perspective, the New Directive strengthens access to justice by mitigating information asymmetries and lowering barriers to initiating proceedings. It also removes outdated thresholds that previously restricted compensation. From the other standpoint, however, these developments materially increase litigation exposure, extend liability to new categories of actors, and create significant legal uncertainties in assessing defectiveness and causation within complex digital systems. This paper critically examines the New Directive’s legal architecture, arguing that while it advances consumer protection, it simultaneously risks deterring innovation and paves the path for mass litigation. The analysis highlights how unresolved ambiguities may generate fragmented jurisprudence and long-tail liabilities, underscoring the need for greater doctrinal clarity to balance fairness with innovation.

## **Introduction**

The Product Liability Directive 85/374/EEC<sup>1</sup> (the “**Original PLD**”) was a foundational legislative instrument introduced by the then European Economic Community (the “**EEC**”) to harmonise the laws of Member States concerning liability for defective products. Adopted on 25 July 1985 after nearly a decade of negotiation, the Original PLD established a strict liability regime for producers whose defective products caused damage to consumers.<sup>2</sup> This marked a deliberate shift away from traditional fault-based liability frameworks under tort or contract law, reflecting broader trends in global legal landscapes, particularly those emanating from the United States, where the consumer expectations test and strict liability had gained considerable traction following landmark court rulings<sup>3</sup> and the Second Restatement on Torts.<sup>4</sup>

The rationale behind the Original PLD was both legal and political. From a consumer protection standpoint, it aimed to simplify the burden of proving fault by introducing a uniform standard for liability that focused on product defectiveness rather than the producer’s conduct. At the same time, it sought to address the fragmentation and inadequacy of national legal regimes, which had resulted in inconsistent standards of compensation and judicial outcomes across Member States.<sup>5</sup> The EEC’s intervention into tort law through the Original PLD was, thus, seen as a strategic legal innovation

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<sup>1</sup> 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 L210/29 (PLD 1985).

<sup>2</sup> *ibid* art 1.

<sup>3</sup> *Escola v Coca Cola Bottling Co* 24 Cal 2d 453, 150 P 2d 436 (Cal 1944); *Greenman v Yuba Power Products Inc* 59 Cal 2d 57, 377 P 2d 897 (Cal 1963); *Henningsen v Bloomfield Motors Inc* 32 NJ 358, 161 A 2d 69 (1960).

<sup>4</sup> Robert F Harchut, ‘Products Liability - Restatement (Second) of Torts - Section 402A – Uncertain Standards of Responsibility in Design Defect Cases - After Azzarello, Will Manufacturers be Absolutely Liable in Pennsylvania’ (1979) 24 Villanova Law Review 1035.

<sup>5</sup> Jean-Sébastien Borghetti, ‘Taking EU Product Liability Law Seriously: How Can the Product Liability Directive Effectively Contribute to Consumer Protection?’ (2023) 1 French Journal of Legal Policy 1, 2.

which simultaneously responded to consumer tragedies like the Thalidomide scandal<sup>6</sup> and positioned the Community at the forefront of harmonised legal development.

Over time, while the PLD gained doctrinal recognition and served as a legislative model even outside the EU<sup>7</sup>, its practical relevance remained limited for decades.<sup>8</sup> Transposition delays, a low volume of judicial decisions in national courts throughout the 1990s and early 2000s, and a general absence of robust litigation indicated the Original PLD's underutilisation.<sup>9</sup> However, it gradually gained familiarity among European lawyers and became an established feature of private law across the Union. By the 2010s, after almost four decades of its adoption, although few questioned its legal existence or the principle of strict liability it embodied, critical reflections began to emerge regarding its continued adequacy in the face of technological change.<sup>10</sup>

The most significant challenge to the Original PLD emerged from the digital transformation of the global economy. With the increasing ubiquity of software, artificial intelligence, fundamental assumptions underpinning the Original PLD began to appear outdated. In 2018, the European Commission launched an evaluation of the Original PLD to assess its fitness for purpose in the digital era.<sup>11</sup> While the Commission

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<sup>6</sup> S Whittaker, *Liability for Products: English Law, French Law, and European Harmonization* (Oxford University Press, 2005) 433.

<sup>7</sup> M Lunney, 'Product Liability in the Rest of the World' in H Koziol and others (eds), *Product Liability: Fundamental Questions in a Comparative Perspective* (De Gruyter 2017) 413, 414; Y Shiomi, 'Product Liability in Japan' in H Koziol and others (eds), *Product Liability: Fundamental Questions in a Comparative Perspective* (De Gruyter 2017) 62, 66.

<sup>8</sup> S Whittaker, *The Development of Product Liability* (CUP 2010).

<sup>9</sup> European Commission, *Second Report on the Application of Directive 85/374 on Liability for Defective Products* COM (2000) 893 final.

<sup>10</sup> K Nemeth and J Carvalho, 'Time for a Change: Product Liability in the Digital Era' (2019) 9 *Journal of European Consumer and Market Law* 160; T Cabral, 'Liability and Artificial Intelligence in the EU: Assessing the Adequacy of the Current Product Liability Directive' (2020) 27(5) *Maastricht Journal of European and Comparative Law* 615; C Cauffman, 'Robo-liability: The European Union in Search of the Best Way to Deal with Liability for Damage Caused by Artificial Intelligence' (2018) 25(5) *Maastricht Journal of European and Comparative Law* 527; DM Charlotte, 'The Product Liability Directive at the Age of the Digital Industrial Revolution: Fit for Innovation?' (2019) 8(4) *Journal of European Consumer and Market Law* 149.

<sup>11</sup> European Commission, *Evaluation of 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* SWD (2018) 157 final.

concluded that the Original PLD remained generally adequate and effective, it acknowledged that certain core concepts including, *inter alia*, the concept of ‘product’, were ill-suited to modern production models, including those shaped by digital technologies and the circular economy.<sup>12</sup> Furthermore, it was observed that legal fragmentation across Member States exacerbated uncertainty for manufacturers and consumers alike, particularly where intangible digital elements, such as software updates or AI-generated outputs, played a direct role in causing harm. This not only hindered legal clarity and consumer protection but also undermined the very harmonisation the Original PLD had originally sought to achieve.<sup>13</sup>

In response, the European Commission initiated a dual-track legislative reform in 2022. On 28 September 2022, it presented two proposals; namely the proposal for the AI Liability Directive<sup>14</sup> (the “**AILD**”), which focuses on easing the burden of proof for fault-based liability in AI-related harm, and the proposal for the Revised Product Liability Directive<sup>15</sup>, which aims to modernise the Original PLD’s strict liability framework by incorporating digital and intangible products into its scope. The latter, officially adopted in 2024 as Directive (EU) 2024/2853<sup>16</sup> (the “**New PLD**”), represents a doctrinal shift in EU product liability law. It expands the definition of ‘product’ to explicitly include software, addresses issues regarding software modification and integration into other systems, and reduces evidentiary burdens for claimants through various mechanisms<sup>17</sup> as shall be discussed in this paper.

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<sup>12</sup> *ibid* 52.

<sup>13</sup> *Evaluation* (n 10) 26.

<sup>14</sup> European Commission, Proposal for a Directive of the European Parliament and of the Council on Adapting Non-Contractual Civil Liability Rules to Artificial Intelligence (AI Liability Directive) COM (2022) 496 final.

<sup>15</sup> European Commission, Proposal for a Directive of the European Parliament and of the Council on Liability for Defective Products COM (2022) 495 final.

<sup>16</sup> Directive (EU) 2024/2853 of the European Parliament and of the Council of 13 June 2024 on liability for defective products [2024] OJ L2024/2853 (PLD 2024).

<sup>17</sup> Shu Li and Béatrice Schütte, ‘The proposal for a revised Product Liability Directive: The emperor’s new clothes? (2023) 0(0) Maastricht Journal of European and Comparative Law 1, 3.



This legal evolution is significant not only for its substantive reforms, but also for what it reveals about the limits of static legal frameworks in rapidly evolving technological environments. However, while the New PLD is commendable in its ambition, early academic commentary<sup>18</sup> has questioned whether the reforms go far enough in clarifying liability boundaries, avoiding over-complexity, and maintaining internal coherence. These concerns form the backdrop of this thesis, which aims to critically examine whether the New PLD provides an adequate liability regime in the digital age, and to evaluate its legal and practical implications for stakeholders across the EU.

This dissertation addresses the central research question of whether the New EU Product Liability Directive adequately balances consumer protection with the need to safeguard innovation in digital markets. The problem is situated within international commercial and business law, as it concerns the regulation of cross-border commerce in digital technologies and services. The rationale lies in the New PLD's unprecedented expansion of 'product' and addition of procedural mechanisms to ease burden of proof, which raises complex questions of liability for economic operators. Academically, the topic matters because it exposes unresolved doctrinal tensions between strict liability and technological innovation, while practically it is significant for shaping litigation risk, investment behaviour, and consumer trust across the internal market. The objectives of this study are to critically evaluate the New PLD's legal architecture,

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<sup>18</sup> Shu Li and Béatrice Schütte, 'The proposal for a revised Product Liability Directive: The emperor's new clothes?' (2023) 0(0) *Maastricht Journal of European and Comparative Law* 1; G Wagner, 'Liability Rules for the Digital Age: Aiming for the Brussels Effect' (2023) 13(3) *Journal of European Tort Law* <<http://dx.doi.org/10.2139/ssrn.4320285>> accessed 4 August 2025; J de Bruyne, O Dheu and C 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 and Security Review* <<http://dx.doi.org/10.2139/ssrn.4239792>> accessed 4 August 2025; P Hacker, 'The European AI Liability Directives – Critique of a Half-Hearted Approach and Lessons for the Future' (2023) 51 *Computer Law and Security Review* <<https://doi.org/10.1016/j.clsr.2023.105871>> accessed 4 August 2025.

assess its implications for stakeholders, and identify whether it strikes an appropriate equilibrium between innovation and accountability. The scope is confined to the EU framework and comparative insights where relevant, while limitations arise from the Directive's recent adoption, meaning that analysis necessarily *anticipates* rather than evaluates long-term judicial application.

Keeping in view the abovementioned objectives, this dissertation is structured into five main chapters, following this introduction, to provide a focused legal analysis of the New PLD and its legal implications. Chapter One shall evaluate the Original PLD's limitations, in order to have a better understanding of the rationale behind the emergence of the New PLD. This foundational chapter shall set the tone for the rest of the paper and is crucial to later understand and examine the implications of the New PLD. Chapter Two shall critically examine the expanded definition of 'product', with a particular focus on the inclusion of software, and it shall critically examine whether this redefinition is *prima facie* adequate in covering all aspects of digitalisation. Chapter Three shall discuss the legal implications of the expansion of 'product' under the New PLD. Chapter Four shall investigate the procedural adaptations in the New PLD, especially those relating to burden of proof, causation, and access to evidence in complex digital contexts and their legal implications. Chapter Five shall evaluate the legal and practical uncertainties that persist post-revision. A final conclusion will reflect on the effectiveness of the New PLD in addressing the liability challenges posed by emerging technologies, as well as the legal implications that arise from its application, and propose pathways for future reforms.

This study is grounded in a doctrinal legal methodology, also known as the black-letter approach. The research method will involve a structured interpretation of relevant legislative provisions, comparative assessment with the Original PLD, and

critical engagement with scholarly commentary. Furthermore, the dissertation necessarily engages with a range of foreign legal materials, including statute law and jurisprudence from other jurisdictions. The research will utilise both primary legal sources and secondary sources, including journal articles, legal databases, reports, etc. These tools will support a comprehensive evaluation of all the dimensions of this research paper.

### **Chapter One: Deficiencies in the Original PLD**

What are the limitations of the Original PLD, a legal instrument born in an era when VCRs and floppy disks were considered cutting-edge, in a world of self-learning algorithms, constant software updates and cloud-based services? This chapter seeks to answer this question by critically examining the shortcomings of the EU's original product liability regime in light of contemporary technological and market realities. Adopted at a time when the regulatory focus was limited to tangible consumer goods and industrial manufacturing risks, the Original PLD introduced a strict liability regime aimed at harmonising product liability laws and protecting consumers harmed by defective products. However, nearly four decades later, the Original PLD was widely acknowledged to have become insufficient for addressing the legal challenges posed by digitalisation.<sup>19</sup>

This chapter is structured to provide a comprehensive doctrinal critique of the Original PLD. It shall firstly outline the broad foundational flaws inherent in the Directive's regime and examine how these shortcomings persisted in practice, broadly

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<sup>19</sup> K Nemeth and J Carvalho, 'Time for a Change: Product Liability in the Digital Era' (2019) 9 Journal of European Consumer and Market Law 160; T Cabral, 'Liability and Artificial Intelligence in the EU: Assessing the Adequacy of the Current Product Liability Directive' (2020) 27(5) Maastricht Journal of European and Comparative Law 615; C Cauffman, 'Robo-liability: The European Union in Search of the Best Way to Deal with Liability for Damage Caused by Artificial Intelligence' (2018) 25(5) Maastricht Journal of European and Comparative Law 527.

as well as in the face of technological advancement. In the second section, the discussion shall move to examine the limitations of the Original PLD particularly in relation to the advent of digital and circular economy. In this way, this chapter shall build a foundational understanding for assessing the necessity for the New PLD.

### **Foundational Flaws of the Original PLD**

The current section of this chapter shall outline the broad foundational flaws of the Original PLD that impacted its overall effectiveness, as have also been identified by the European Commission in its evaluation report in 2018.<sup>20</sup> At its core, the Original PLD introduced a harmonised regime of *strict liability* at the EU level, designed to facilitate consumer redress in instances where defective products result in compensable harm. Under this framework, injured parties were not required to establish the producer's fault<sup>21</sup>, but were obligated to instead prove the existence of a defect, the occurrence of damage, and the causal nexus between the two.<sup>22</sup> The following discussion shall examine how the seemingly consumer-favoured approach carried with it fundamental flaws at its core in relation to its application.

Firstly, it is to be noted that the Original PLD's legal force was seen to be qualified by its character as a *maximum harmonisation* instrument as recognised by the Court of Justice of the European Union (the “CJEU”) in various judgments.<sup>23</sup> This classification precluded Member States from enacting or maintaining higher levels of consumer protection in areas harmonised by the Original PLD, even if domestic legal

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<sup>20</sup> European Commission, *Evaluation of 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* SWD (2018) 157 final.

<sup>21</sup> D Fairgrieve and others, ‘Product Liability Directive’ in P Machnikowski (ed), *European Product Liability: An Analysis of the State of the Art in the Era of New Technologies* (Intersentia 2017) 17.

<sup>22</sup> Tiago Sérgio Cabral, ‘Liability and Artificial Intelligence in the EU: Assessing the Adequacy of the Current Product Liability Directive’ (2020) 27(5) Maastricht Journal of European and Comparative Law 615, 616.

<sup>23</sup> Marija Karanikić Mirić, ‘Product Liability Reform in the EU’ in D Duić and T Petrašević (eds), *Digitalization and Green Transformation of the EU* (2023) 7 EU and Comparative Law Issues and Challenges Series 383, 385.

traditions had historically provided for broader remedial entitlements.<sup>24</sup> Thus, at a foundational level, the Original PLD had an overriding effect to the national legal systems with an aim to maximise harmonisation throughout the EU member states.

The objective underpinning *maximum harmonisation* was to ensure legal certainty and parity of liability exposure for producers operating within the internal market. However, this objective attracted sustained criticism for subordinating national standards of consumer protection to a pan-European minimum, thereby potentially eroding safeguards which were previously afforded under domestic law.<sup>25</sup> The CJEU affirmed the preclusive effect of the PLD in several key decisions. Notably, in Case C-52/00 *Commission v France* [2002]<sup>26</sup>, Case C-154/00 *Commission v Greece* [2002]<sup>27</sup>, and Case C-183/00 *González Sánchez v Medicina Asturiana SA* [2002]<sup>28</sup>, the CJEU held that where the PLD is applicable, its provisions prevail over conflicting national rules, thereby constraining the scope of domestic legislative or judicial discretion in areas of overlap. Thus, in practice, the Original PLD's classification as a *maximum harmonisation* tool restricted the legislative autonomy of Member States as well as entrenched an inflexible liability standard that struggled to accommodate evolving national consumer protection paradigms or respond dynamically to market developments.

Secondly, in terms of compensable harm, the Original PLD's definition of 'damage' as enshrined in Article 9<sup>29</sup> was both restrictive and fragmented. It entirely excluded non-material harm, such as emotional distress or reputational injury. Even

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<sup>24</sup> Shu Li and Béatrice Schütte, 'The proposal for a revised Product Liability Directive: The emperor's new clothes?' (2023) 0(0) Maastricht Journal of European and Comparative Law 1, 2.

<sup>25</sup> C Schmid, 'The Instrumentalist Conception of the Acquis Communautaire in Consumer Law' in S Grundmann and M Schauer (eds), *The Architecture of European Codes and Contract Law* (Kluwer Law International 2006) 265–267.

<sup>26</sup> Case C-52/00 *Commission v France* [2002] ECR I-3827.

<sup>27</sup> Case C-154/00 *Commission v Greece* [2002] ECR I-3879.

<sup>28</sup> Case C-183/00 *González Sánchez v Medicina Asturiana SA* [2002] ECR I-3901.

<sup>29</sup> PLD 1985, art 9.

more significantly, the Original PLD denied compensation for damage to the defective product itself, limiting recovery only to consequential loss.<sup>30</sup> This forced consumers to pursue parallel claims under contract law for recovery of the value of the defective good, thereby fragmenting liability and procedural pathways. Such artificial separation of tortious and contractual remedies undermined the Directive's overarching goal of facilitating consumer redress and legal clarity as pointed out in the Commission's Evaluation Report.<sup>31</sup>

A further foundational shortcoming of the Original PLD lied in its dual limitation regime, which imposed both a three-year subjective limitation period and a ten-year longstop period on claims for compensation. Under Article 10 of the Directive<sup>32</sup>, an injured party's right to bring an action was extinguished three years from the date on which they became, or ought reasonably to have become, aware of the damage, the defect, and the identity of the producer. This provision placed a considerable burden on consumers. More critically, under Article 11<sup>33</sup>, the Original PLD imposed a strict ten-year longstop period from the date the product was put into circulation, after which all claims were permanently extinguished, regardless of when the harm became apparent.<sup>34</sup> This rigid temporal cut-off disproportionately favoured producers and failed to account for the delayed emergence of certain harms. Therefore, in this way this extinguishment of rights was arguably incompatible with the nature of

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<sup>30</sup> Marija Karanikić Mirić, 'Product Liability Reform in the EU' in D Duić and T Petrašević (eds), *Digitalization and Green Transformation of the EU* (2023) 7 EU and Comparative Law Issues and Challenges Series 383, 386.

<sup>31</sup> European Commission, Evaluation of 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 SWD (2018) 157 final.

<sup>32</sup> PLD 1985, art 10.

<sup>33</sup> PLD 1985, art 11.

<sup>34</sup> Tiago Sérgio Cabral, 'Liability and Artificial Intelligence in the EU: Assessing the Adequacy of the Current Product Liability Directive' (2020) 27(5) *Maastricht Journal of European and Comparative Law* 615, 618.

certain products that may not reveal their harmful effects within the prescribed timeframe.

Additionally, the Directive imposed a EUR Five Hundred threshold below which damage was not compensable.<sup>35</sup> While likely intended to exclude trivial claims, this threshold disproportionately affected consumers facing moderate but significant harm and was opposed by multiple consumer organisations and NGOs.<sup>36</sup> Furthermore, legal fragmentation arose from cross-border e-commerce and direct consumer imports, where non-EU producers would supply goods to EU consumers without any intermediary, which was entirely unlike the traditional ‘pipeline’ supply chains that existed at the time of legislation of Original PLD.<sup>37</sup> In such cases, the absence of an EU-based economic operator rendered the Original PLD toothless, leaving harmed individuals without a liable entity against whom to claim compensation. This not only undermined the consumer protection objectives of the Original PLD but also distorted market competition by placing EU producers at a disadvantage vis-à-vis foreign counterparts who would operate beyond the reach of EU law. Thus, with the foundational flaws of the Original PLD’s regime outlined as aforementioned, the discussion shall move to examine the technological blindspots of the Directive in the subsequent section.

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<sup>35</sup> European Commission, *Report on the Application of the Product Liability Directive* COM (2018) 246 final, 7 May 2018 (Brussels) 6.

<sup>36</sup> BEUC (The European Consumer Organisation), *Product Liability 2.0 - How to make EU rules fit for consumers in the digital age* (7 May 2020) 15–16

<[https://www.beuc.eu/sites/default/files/publications/beuc-x-2020-024\\_product\\_liability\\_position\\_paper.pdf](https://www.beuc.eu/sites/default/files/publications/beuc-x-2020-024_product_liability_position_paper.pdf)> accessed 8 August 2025; Future of Life Institute, *Comments on the Commission’s Inception Impact Assessment on “Civil liability - adapting liability rules to the digital age and artificial intelligence”* (28 July 2021) 4; The Future Society, *Liability rules for Trust in Excellence & Excellence in Trust - Inception Impact Assessment - Adapting liability rules to the digital age and circular economy* (Belgium, 28 July 2021) 6–7.

<sup>37</sup> Christiane Busch, ‘When Product Liability Meets the Platform Economy: A European Perspective on *Oberdorf v Amazon*’ (2019) 8(5) *Journal of European Consumer and Market Law* 173.

## The Original PLD's Technological Blind Spots

This section of the current chapter shall discuss the aspects of Original PLD which directly impaired the ability of the Original PLD to regulate liability in the digital and circular economy. It is clear that the Original PLD was enacted in a technological landscape where products were largely physical, standalone, and localised, far removed from today's interconnected digital ecosystems. As a result, the scope of the Original PLD was clearly insufficient to cover intangible, evolving, and hybrid products that characterise the current market.<sup>38</sup> In particular, the definition of 'product' under the Original PLD, was centred around physical movables<sup>39</sup>, with no explicit reference to software, digital content, or artificial intelligence.<sup>40</sup> This possessed the potential to generate considerable ambiguity, particularly where digital elements are embedded in, or operate independently of, physical hardware.<sup>41</sup> Whether intangible digital products, such as standalone software or cloud-based services, or online products listed on marketplaces outside of EU<sup>42</sup>, fell within the purview of the Original PLD remained a contested issue, giving rise to legal uncertainty for both producers and consumers. However, the role of the courts in interpreting the Original PLD had been extremely

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<sup>38</sup> Vibe Ulfbeck and Paul Verbruggen, 'Online Marketplaces and Product Liability: Back to Where We Started?' (2022) 30(6) *European Review of Private Law* 975, 998; Catherine M Sharkey and others, 'Product Liability and Online Marketplaces: Comparison and Reform' (2024) 73 *ICLQ* 477 <<https://doi.org/10.1017/S0020589324000046>> accessed 8 August 2025.

<sup>39</sup> PLD 1985, art 2.

<sup>40</sup> Christoph Busch, 'Rethinking Product Liability Rules for Online Marketplaces: A Comparative Perspective' (2021) paper presented at the Consumer Law Scholars Conference, Boston <<http://dx.doi.org/10.2139/ssrn.3784466>> accessed 8 August 2025.

<sup>41</sup> European Commission, *Impact Assessment Report—Accompanying the Proposal for a Directive of the European Parliament and of the Council on liability for defective products* SWD (2022) 316 final, 11 <<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52022SC0316>> accessed 8 August 2025.

<sup>42</sup> BEUC, *Is it Safe to Shop on Online Marketplaces?* (February 2021) <[https://www.beuc.eu/sites/default/files/publications/beuc-x-2021-004\\_is\\_it\\_safe\\_to\\_shop\\_on\\_online\\_marketplaces.pdf](https://www.beuc.eu/sites/default/files/publications/beuc-x-2021-004_is_it_safe_to_shop_on_online_marketplaces.pdf)> accessed 8 August 2025; A Berzon, S Shiffett and J Scheck, 'Amazon Has Ceded Control of its Site. The Result: Thousands of Banned, Unsafe or Mislabeled Products' *The Wall Street Journal* (23 August 2019) <<https://www.wsj.com/articles/amazon-has-ceded-control-of-its-site-the-result-thousands-of-banned-unsafe-or-mislabeled-products-11566564990>> accessed 8 August 2025.



successful in cases such as *Case Boston Scientific*<sup>43</sup> and *Case Sanofi Pasteur*<sup>44</sup>, which drew considerable scholarly praise and attention.<sup>45</sup> Regardless, despite this success in interpreting the Original PLD to keep it line with technological advancements, the growing issues, such as the increasingly blurred distinction between products and services and the outdated definition of product, became more and more tenuous with the increasing development of technology.<sup>46</sup>

Secondly, a central shortcoming of the Original PLD lied in its outdated interpretation of ‘defectiveness’ and ‘damage’. Under Article 6<sup>47</sup>, a product was considered defective only if it failed to provide the safety that a person was entitled to expect, taking into account all relevant circumstances, including presentation, use, and the time it was put into circulation.<sup>48</sup> While this formulation may have sufficed in the context of traditional goods, it struggled to accommodate the safety expectations of products that evolve after sale, particularly in a digital and connected environment where products would receive remote updates or rely on dynamic data inputs. Moreover, the Directive’s refusal to treat later improvements in a product’s design as evidence of defectiveness, unlike other regimes at the time such as that of US<sup>49</sup>, created

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<sup>43</sup> Case C-503/13 *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt – Die Gesundheitskasse* [2015] ECLI:EU:C:2015:148; Case C-504/13 *Boston Scientific Medizintechnik GmbH v Betriebskrankenkasse RWE* [2015] ECLI:EU:C:2015:148.

<sup>44</sup> Case C-621/15 *NW v Sanofi Pasteur* [2017] ECLI:EU:C:2017:484.

<sup>45</sup> B Van Leeuwen & P Verbruggen, ‘Resuscitating EU Product Liability Law? Contemplating the effects of Boston scientific medizintechnik’ (2015) 23(5) *European Review of Private Law* 899.

<sup>46</sup> Dr Nikos Th. Nikolinakos, ‘Aligning liability rules with the digital age and circular economy: the revised EU Product Liability Directive’ (2025) 31(4) *CTLR* 126, 128.

<sup>47</sup> PLD 1985, art 6.

<sup>48</sup> Marija Karanikić Mirić, ‘Product Liability Reform in the EU’ in D Duić and T Petrašević (eds), *Digitalization and Green Transformation of the EU* (2023) 7 EU and Comparative Law Issues and Challenges Series 383, 386.

<sup>49</sup> M Reimann, ‘Product Liability’ in M Bussani and AJ Sebok (eds), *Comparative Tort Law* (Edward Elgar Publishing 2021); D Wuyts, ‘The Product Liability Directive – More than Two Decades of Defective Products in Europe’ (2014) 5(1) *Journal of European Tort Law* 10.

further limitations in consumer protection by shielding producers from comparative liability where evolving technological benchmarks suggested otherwise.<sup>50</sup>

Apart from this, Article 7(1)(e)<sup>51</sup> of the Original PLD had introduced the controversial ‘development risks defence’, which was described by Cabral and other commentators as the ‘State of the Art Defence’<sup>52</sup>, that absolved producers of liability if the state of scientific and technical knowledge at the time of circulation did not permit discovery of the defect.<sup>53</sup> Although it was justified in its drafting for leaving space for innovation, this defence nonetheless shifted the burden of innovation-related risk to the consumer, contradicting the very ethos of strict liability and undermining the Original PLD’s effectiveness in cases involving emerging technologies or undiscovered vulnerabilities. As a result, the Original PLD failed to incentivise proactive safety assessments and raised serious questions about equitable risk distribution between producers and consumers in the digital age.

In addition, the Original PLD’s inability to accommodate the lifecycle of digital products exposed further inadequacies.<sup>54</sup> Apart from the ‘development risks defence’ as discussed above, the so-called ‘later-defect defence’, which exempted producers from liability for defects arising after the product had been put into circulation, reflected

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<sup>50</sup> Marija Karanikić Mirić, ‘Product Liability Reform in the EU’ in D Duić and T Petrašević (eds), *Digitalization and Green Transformation of the EU* (2023) 7 EU and Comparative Law Issues and Challenges Series 383, 386.

<sup>51</sup> PLD 1985, art 7(1)(e).

<sup>52</sup> Tiago Sérgio Cabral, ‘Liability and Artificial Intelligence in the EU: Assessing the Adequacy of the Current Product Liability Directive’ (2020) 27(5) *Maastricht Journal of European and Comparative Law* 615, 618.

<sup>53</sup> M Mildred, ‘The Development Risk Defence’ in D Fairgrieve (ed), *Product Liability in Comparative Perspective* (CUP 2005) 167; BA Koch, ‘The Development Risk Defence of the EC Product Liability Directive’ (2018) 20(1–4) *Pharmaceuticals Policy and Law* 163; M Karanikić, ‘Development Risks’ (2006) 54(3) *Anali Pravnog fakulteta u Beogradu* 117; Guillem Izquierdo Grau, ‘The Development Risks Defence in the Digital Age’ (2025) 16 *European Journal of Risk Regulation* 197 <<https://doi.org/10.1017/err.2024.43>> accessed 8 August 2025.

<sup>54</sup> European Commission, *Impact Assessment Report—Accompanying the Proposal for a Directive of the European Parliament and of the Council on liability for defective products* SWD (2022) 316 final, 17–18 <<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52022SC0316>> accessed 8 August 2025.

an outdated assumption that a producer relinquishes control upon distribution.<sup>55</sup> This assumption was untrue because in today's digital environment, producers often maintain prolonged control over products through software patches, firmware updates, or remote access mechanisms. Such interventions may themselves introduce defects or cybersecurity vulnerabilities, thereby undermining the safety of the product post-market. Yet, under the Original PLD regime, victims were precluded from redress, even where harm resulted directly from a defective update issued by the original producer. These systemic oversights were compounded by the Original PLD's silence on damages involving digital property. For instance, data loss or damage to non-tangible assets, which are increasingly common in digital harm scenarios, were not covered in the scope of the Original PLD.<sup>56</sup>

The shortcomings of the Original PLD were similarly apparent in the context of refurbished or remanufactured products. In a circular economy where the reuse, upgrading, and repair of digital goods are centrally essential to their usage, the Original PLD failed to establish clear liability rules for economic actors modifying and reintroducing products into circulation, thus, limiting liability only to producers of the defective products. This limitation impaired remedies for consumers harmed by altered products.<sup>57</sup>

## **Chapter Conclusion**

Therefore, together, these broad foundational flaws and the limitations particularly in context of digital and circular economy highlight the obsolescence of the

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<sup>55</sup> European Commission, *Impact Assessment Report—Accompanying the Proposal for a Directive of the European Parliament and of the Council on liability for defective products SWD (2022) 316 final*, 11 <<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52022SC0316>> accessed 8 August 2025.

<sup>56</sup> European Commission, *Inception Impact Assessment: Adapting Liability Rules to the Digital Age and Circular Economy*, Ref Ares (2021) 4266516 (30 June 2021) 4.

<sup>57</sup> Dr Nikos Th. Nikolinakos, 'Aligning liability rules with the digital age and circular economy: the revised EU Product Liability Directive' (2025) 31(4) CTLR 126, 129.

Original PLD in regulating an environment shaped by digitalisation. While the Original PLD's original framework aimed to strike a balance between producer liability and consumer redress, its failure to evolve in tandem with the digital and circular economies compromised both objectives. Therefore, the Original PLD's inability to address all aspects of digitalisation underscored the urgency of reforms, a gap that the New PLD arguably seems to address, as shall be discussed in the next chapter.

## **Chapter Two: Redefining 'Product' in the Digital Era**

Building on the critique in Chapter One, this chapter turns to one of the most significant reforms introduced by the New PLD, which is the expanded definition of 'product', that is one of the focal points of this paper.

This chapter is structured in three sections. The first section shall provide a brief overview of the broader framework of the New PLD to analyse how the legislation has seemed to tackle the issues observed in its predecessor. The second section shall provide an analytical overview of the expanded definition of 'product' under the New PLD. The final section shall seek to critically assess whether this revised scope of 'product' sufficiently addresses the challenges of the digital age, with particular attention to digital data, software, and hybrid goods-services models. This discussion will evaluate whether this redefinition meaningfully resolves the deficiencies prevalent in its predecessor and secondly whether it leaves further critical gaps in the regulation of emerging technologies.

### **Framework of the New PLD**

In direct response to the deficiencies of the Original PLD as identified in the previous chapter, the New PLD substantially broadens the operational reach of product liability. While now expressly retaining its legal force as a maximum harmonisation

instrument<sup>58</sup>, as well as its foundational principle of strict liability for damage caused to a natural person by a defective product<sup>59</sup>, it recalibrates the framework to address the realities of a digital, interconnected, and circular economy.<sup>60</sup> This section shall provide an overview of the framework of the New PLD in light of its predecessor's deficiencies.

Firstly, in the New PLD, the assessment of defectiveness is modernised, by reference to the lack of safety that a person is entitled to expect or that is required under EU or national law<sup>61</sup> as relevant to determining whether a product meets the safety expectations of the public at large under Article 7(1)<sup>62</sup>, in order to protect the “the health and property of consumers”<sup>63</sup>. Although the test for defectiveness is largely the same as it was in Original PLD, the non-exhaustive circumstances under which a product is to be deemed defective have been expanded, by reflecting the case law of the CJEU, where factors such as interconnectedness & self learning capabilities of products are now to be taken into account by the courts when determining a product's defectiveness.<sup>64</sup> This marks an upgrade from the Original PLD, which was silent on such digital-era considerations and thus ill-equipped to address safety risks arising from interconnected and software-dependent products.

Accordingly, the scope of compensable harm is also broadened in the New PLD to further include psychological injury and the destruction, deletion or corruption of non-professional data.<sup>65</sup> This constitutes as a deliberate legislative shift towards a liability framework capable of capturing the multifaceted risks of modern products,

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<sup>58</sup> PLD 2024, art 3.

<sup>59</sup> PLD 2024, art 1.

<sup>60</sup> European Commission, *Commission Staff Working Document, 'Subsidiarity Grid—Accompanying the document Proposal for a Directive of the European Parliament and of the Council on liability for defective products'* SWD (2022) 315 final, 28 September 2022 (Brussels).

<sup>61</sup> PLD 2024, art 7.

<sup>62</sup> PLD 2024, art 7(1).

<sup>63</sup> PLD 2024, Recital 30.

<sup>64</sup> Dr Nikos Th. Nikolinakos, 'Aligning liability rules with the digital age and circular economy: the revised EU Product Liability Directive' (2025) 31(4) CTLR 126, 134.

<sup>65</sup> PLD 2024, art 6.

both physical and digital, unlike its predecessor which restricted the scope of damage to physical aspect only.<sup>66</sup>

Procedurally, the New PLD removes the EUR Five Hundred minimum claim threshold and obliges manufacturers to disclose relevant evidence.<sup>67</sup> The burden of proof is also eased in technically complex matters<sup>68</sup>, such as those involving AI, to address the evidentiary imbalance that historically disadvantaged consumers. Furthermore, liability is no longer confined to traditional manufacturers. Software developers, relevant digital service providers and other economic operators who substantially modify products post-market can now be held liable where such modifications result in a defective product.<sup>69</sup> In cross-border supply chains, EU-based importers, authorised representatives, and, in certain circumstances, online platforms<sup>70</sup> can also be pursued for defective products originating outside the Union, closing the enforcement gap that previously left harmed individuals without an accountable entity.

One of the most significant reforms, which forms the main focus of this paper, is the explicit inclusion of software, operating systems, firmware, applications, AI systems, digital manufacturing files such as CAD models used in 3D printing, and electricity, alongside traditional movables.<sup>71</sup> Not only this but the scope of the New PLD is further expanded to encompass ‘related services’, namely digital services that are integrated into or interconnected with a product and whose absence would impair its core functionality.<sup>72</sup> This approach remedies the outdated physical-goods focus of

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<sup>66</sup> Dr Nikos Th. Nikolinakos, ‘Aligning liability rules with the digital age and circular economy: the revised EU Product Liability Directive’ (2025) 31(4) CTLR 126, 133.

<sup>67</sup> PLD 2024, art 9.

<sup>68</sup> PLD 2024, art 10.

<sup>69</sup> PLD 2024, art 8.

<sup>70</sup> PLD 2024, art 8(4).

<sup>71</sup> PLD 2024, art 4.

<sup>72</sup> *ibid.*

the Original PLD and recognises the hybrid nature of modern goods–services configurations, as shall be discussed in detail in the subsequent section of this chapter.

Furthermore, the New PLD addresses the full lifecycle of products by imposing liability for changes made after market placement, including software updates or modifications, whether issued by the manufacturer directly or by third parties with the manufacturer’s authorisation, as has been clarified in its Recital 19.<sup>73</sup> This embeds a continuing monitoring obligation that directly counters the Original PLD’s static market-placement assumption. The following section will continue from the last aspect discussed hereinabove, regarding the expanded definition of ‘product’ in the New PLD.

### **Overview of the Recalibrated Scope of ‘Product’**

As discussed briefly in the last section, the New PLD expressly extends its scope to encompass software, AI and digital manufacturing files. This redefinition closes the regulatory gap that left many intangible and hybrid products beyond the reach of strict liability. This section of the current chapter shall provide a detailed overview of the expanded definition of ‘product’ in the New PLD.

Article 4 of the New PLD defines a product as *‘all movables, even if integrated into, or interconnected with, another movable or an immovable; it includes electricity, digital manufacturing files, raw materials and software.’*<sup>74</sup> The foremost important aspect of this expansion is the addition of ‘software’ and ‘digital manufacturing files’. Firstly, as to the extent of the New PLD regarding software (including AI systems), it can be clarified when read in conjunction with its Recital 13.<sup>75</sup> This recital makes it clear that software, whether standalone or integrated, is a product for liability purposes regardless of the delivery method, be it stored, accessed through a network or cloud, or

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<sup>73</sup> PLD 2024, recital 19.

<sup>74</sup> PLD 2024, art 4(1).

<sup>75</sup> PLD 2024, recital 13.

supplied through Software-as-a-Service (the “SaaS”) model.<sup>76</sup> For instance, if there is a defect in cloud-based navigation software (often used in autonomous vehicles), and that defect leads to an accident, then such damage could trigger liability under the New PLD, even though the program is never *physically* installed on the car. This illustrates how a software irrespective of its delivery method is treated as a ‘product’ for liability purposes under the New PLD.

Furthermore, in context of software, the New PLD deliberately excludes free and open-source software that is developed or distributed outside the course of commercial activity as has been suggested in Recital 14, thereby safeguarding the culture of innovation and research that such projects depend upon.<sup>77</sup> At the same time, liability is not entirely displaced; where a manufacturer chooses to integrate open-source software into its product, responsibility for defects arising from that integration rests with the manufacturer rather than the software developer, thereby creating room for innovation for the developers. By contrast, software falls squarely within the scope of the New PLD where it is supplied in exchange for payment, or where personal data is exchanged for purposes that extend beyond improving security, compatibility, or interoperability; all of which are markers that signal a commercial context.<sup>78</sup> In this way, the New PLD preserves space for non-commercial innovation while ensuring that commercial uses of software remain subject to strict liability.

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<sup>76</sup> Lisa M Baird & others, ‘The New EU Product Liability Directive: Implications for Software, Digital Products, and Cybersecurity’ (Reed Smith LLP, 2 July 2025) <<https://www.reedsmith.com/en/perspectives/2025/07/eu-product-liability-directive-software-digital-products-cybersecurity>> accessed 15 August 2025; Luke Coleborn and Nick Sheerin, ‘The New EU Product Liability Directive’ (Shoosmiths LLP, 8 January 2025) <<https://www.shoosmiths.com/insights/articles/the-new-eu-product-liability-directive>> accessed 15 August 2025.

<sup>77</sup> PLD 2024, recital 14.

<sup>78</sup> *ibid.*



Secondly, under the redefinition of product, digital manufacturing files are now included.<sup>79</sup> To understand the extent of this expanded scope, it can be best exemplified through a previously non-covered product such as a defective CAD file.<sup>80</sup> Under the UK law, as analysed in detail by Chris Willett<sup>81</sup>, such files fell entirely outside the scope of product liability, on account of their inherently intangible and non-physical nature. Such was the case for EU despite being interpreted expansively by the courts. This created a significant regulatory lacuna, that if a defective CAD file led to the production of a faulty 3D-printed object, any resulting harm to a third party would leave the victim without recourse under the regime. In this respect, the New PLD marks a decisive shift. By expressly recognising digital manufacturing files as ‘products’ under Article 4<sup>82</sup>, it ensures that a defective CAD file used in additive manufacturing can trigger liability where it results in physical harm during production. This development brings digital design tools, once excluded from the EU’s tort law framework, within the ambit of strict liability, thereby aligning the regime with the realities of modern production.

Another important aspect of the redefinition of ‘product’ lies in its treatment of digital services, a domain that had long existed in a legal grey area under the old regime. Whereas the Original PLD drew a rigid line between products and services, the New PLD recognises that in the digital age this boundary has become increasingly blurred. Therefore, under the New PLD, it is clarified under its Recital 17<sup>83</sup> that while digital services in isolation remain outside the definition of ‘product’, strict liability is now extended to related services that are integrated into, or interconnected with, a product

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<sup>79</sup> PLD 2024, art 4(2).

<sup>80</sup> Geraint Howells, Christian Twigg-Flesner and Chris Willett, Protecting the Values of Consumer Law in the Digital Economy: The case of 3D-printing in A. De Franceschi and R. Schulze (eds.), *Digital Revolution - Challenges for Law* (Beck, 2019)

<sup>81</sup> *ibid.*

<sup>82</sup> PLD 2024, art 4(2).

<sup>83</sup> PLD 2024, recital 17.

and are indispensable to its safe and effective operation.<sup>84</sup> For instance, as exemplified under the New PLD in the abovementioned recital, the continuous supply of traffic data to a navigation system, or the provision of a health-monitoring service linked to a wearable device, etc., are now expressly included within the liability framework. Likewise, a failure to deliver essential software updates, such as critical security patches for known vulnerabilities, can now ground liability where such omissions compromise product safety.<sup>85</sup> In this way, the New PLD seems to reconcile the modern interplay between products and services.<sup>86</sup>

However, the expansion of the redefinition of ‘product’ remains subject to several exclusions and safeguards; reasoned to promote consistency and harmony with the other regimes applicable. It is noted that the New PLD does not affect the operation of EU personal data protection law<sup>87</sup>, nor does it displace contractual or non-contractual liability regimes under national law<sup>88</sup>, including those implementing other EU legislation such as the proposed AILD. Likewise, existing special liability systems in force prior to 30 July 1985 remain unaffected.<sup>89</sup> While the rationale of maintaining consistency with parallel regimes may appear justified, it creates uncertainty for victims navigating overlapping frameworks. For instance, leaving liability for data-related harm or algorithmic discrimination to other regimes such as the proposed AILD dilutes the protective function of strict liability and exposes claimants to higher burdens of proof under fault-based standards. This is seen as a failure to provide a clear approach to liability in cases such as injuries caused by Blackbox Medical AI where the damage is

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<sup>84</sup> PLD 2024, art 4(3).

<sup>85</sup> PLD 2024, recital 19.

<sup>86</sup> Dr Nikos Th. Nikolinakos, ‘Aligning liability rules with the digital age and circular economy: the revised EU Product Liability Directive’ (2025) 31(4) CTLR 126, 132.

<sup>87</sup> PLD 2024, Art 2(4)(a).

<sup>88</sup> PLD 2024, Art 2(4)(b).

<sup>89</sup> PLD 2024, Art 2(4)(c).

caused by the opaque self-reasoning of the AI.<sup>90</sup> Similarly, excluding entire domains such as pre-1985 national liability systems may create ‘liability vacuums’, where the injured party faces procedural hurdles and inconsistent remedies across jurisdictions. In effect, the cumulative effect of these exclusions is to weaken harmonisation and risk leaving claimants without a predictable route to redress in precisely those high-risk domains where consumer protection ought to be most robust.

Nonetheless, by expressly encompassing software, digital manufacturing files, and related services, the New PLD signals a deliberate expansion and recalibration of product liability to reflect contemporary production and consumption patterns. This expanded definition represents a conceptual as well as a functional evolution of the regime, legislated with the intent of covering all the realities of a market in which the sources of risk are no longer confined to physical goods. The next section shall critically assess whether this redefinition addresses all the challenges in relation to digitalisation, and if so, then to what extent does it seem to fulfill its purpose.

### **Critical Appraisal of the New PLD’s Scope of ‘Product’**

The redefinition of ‘product’ in the New PLD represents a significant advancement, yet a number of interpretative uncertainties and doctrinal challenges remain. This section of the current chapter critically examines three central areas of contention, namely; the treatment of digital data, the status of software as an autonomous product, and the incorporation of related digital services.

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<sup>90</sup> MN Duffourc and S Gerke, ‘The proposed EU Directives for AI liability leave worrying gaps likely to impact medical AI’ *npj Digit. Med.* 77(6) *npj Digital Medicine* (2023) 5 <<https://doi.org/10.1038/s41746-023-00823-w>> accessed 20 August 2025.

## 1. Digital Data: Between Exclusion and Functional Relevance

Firstly, one of the most contested issues which has been identified by academic scholars is whether digital data should be conceived as a product in its own right.<sup>91</sup> The Original PLD excluded information altogether from its scope, treating it as an intangible good falling outside the boundaries of strict liability.<sup>92</sup> This position was affirmed by the CJEU recently in the *Krone Case*<sup>93</sup> where information contained in a print newspaper was deemed out of the scope of product. This formal exclusion produced gaps in consumer protection, particularly in situations where defective or misleading information rendered a product unsafe. For instance, incorrect instructions on the use of food products could transform consumables into hazardous goods.<sup>94</sup> Furthermore, there was a risk of reading and interpreting this exclusion as an implicit exclusion of standalone software as identified by Wagner.<sup>95</sup> Thus, the exclusion of digital data including information posed risky implications regarding the applicability of the liability regime, paving path for lacunae to exist in the regime.

What appears surprising is that the New PLD largely maintains this position, declining to categorise digital data as a ‘product’ *per se*. Article 4 draws a distinction between digital manufacturing files, which are explicitly included, and other types of digital data, such as training datasets for artificial intelligence systems, which remain excluded.<sup>96</sup> In principle, this means that information in the form of digital data does not fall within the definition of a product<sup>97</sup>, even where its role may be decisive for product

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<sup>91</sup> D Wuyts, ‘The Product Liability Directive—More Than Two Decades of Defective Products in Europe’ (2014) 5(1) Journal of European Tort Law 1, 5.

<sup>92</sup> PLD 1985, art 2.

<sup>93</sup> CJEU, Case C-65/10 *Krone*, para 42.

<sup>94</sup> Machnikowski P, ‘Product Liability Directive’ in P Machnikowski (ed.), *European Product Liability* (Intersentia 2016) 48.

<sup>95</sup> Gerhard Wagner, ‘Software as a product’ in Sebastian Lohsse, Reiner Schulze and Dirk Staudenmayer (eds), *Smart Products* (Nomos 2022), 157, 171; Gerhard Wagner, ‘Liability Rules for the Digital Age - Aiming for the Brussels Effect’ (2023) European Journal of Tort Law, 13-14.

<sup>96</sup> PLD 2024, art 4(1), 4(2); PLD 2024, recital 14.

<sup>97</sup> PLD 2024, recital 13.

safety, such as instructions necessary for the safe and careful usage of a particular product.

Thus, this position is not without criticism. Academic commentators have long argued that treating digital data as a product, at least in certain circumstances if not all, would better achieve the PLD's ultimate objective of consumer protection.<sup>98</sup> In this respect, the Commission's Impact Assessment clearly shows that while forty-five percent of stakeholders supported liability where defective data influenced the functioning of a physical product.<sup>99</sup> Nevertheless, the New PLD adopts a narrow approach, confirming that only digital manufacturing files, such as CAD files used in 3D printing, are brought within the definition.<sup>100</sup> This approach leaves unresolved the concerns regarding other functional digital data, such as incorrect digital data in the form of instructions or defective training sets for AI, which should be regarded as a product, considering their capacity to cause serious safety risks.

## **2. Software: Recognition as a Product in Its Own Right**

Secondly, the treatment of software under the New PLD represents one of the most pressing and complex questions in the modernisation of EU product liability law. Unlike traditional goods, software assumes multiple forms and functions that resist easy categorisation. It may be fully integrated into a product, such as the software enabling the autonomous functions of vehicles; or it may operate independently as an application running on a device without relying on continuous connectivity.<sup>101</sup> The New PLD covers both, regardless of the mode of delivery, as already discussed previously.

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<sup>98</sup> 4 B Koch, 'Product Liability 2.0—Mere Update or New Version?' in S Lohsse, R Schulze and D Staudenmayer (eds), *Liability for Artificial Intelligence and the Internet of Things* (Nomos 2019) 104, 105.

<sup>99</sup> Commission, *Impact Assessment Report Accompanying the Proposal for a Directive on Liability for Defective Products* SWD (2022) 316 final, 66.

<sup>100</sup> *ibid* 67.

<sup>101</sup> Shu Li and Béatrice Schütte, 'The proposal for a revised Product Liability Directive: The emperor's new clothes?' (2023) 0(0) *Maastricht Journal of European and Comparative Law* 1, 7,8.

However, this broad recognition of software as a product does not eliminate all uncertainty. The blurred boundary between products and services continues to present challenges. It is to be noted that this distinction is legally significant, as it determines whether strict liability applies, and decides the level of consumer protection available.<sup>102</sup> In this respect, the difficulty lies particularly in hybrid or evolving digital business models that do not fall neatly into either category. For this purpose, cloud-based medical diagnostic software may be considered. Hospitals and clinics increasingly rely on platforms where diagnostic algorithms are hosted remotely, with patient data processed in real-time to generate recommendations. While the algorithm itself performs a function akin to a product, its continuous operation depends on a cloud service model that resembles an ongoing digital service. A defect in the algorithm may lead to misdiagnosis and harm, yet it is unclear whether such a platform should be treated as a ‘product’ under the New PLD or merely as a service. This ambiguity demonstrates how some complex business models still fall into grey zones between product and service classifications.

### **3. Related Services: Redrawing the Product–Service Boundary**

A further area of uncertainty arises from the treatment of ‘related services’. Article 4(3) introduces the concept of a related service as a digital service that is integrated into or interconnected with a product, and whose absence would prevent the product from performing one or more of its functions.<sup>103</sup> By doing so, the New PLD partially redraws the line between products and services, extending liability to certain digital services without fully collapsing the dichotomy.

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<sup>102</sup> J Hojnik, ‘Technology Neutral EU Law: Digital Goods Within the Traditional Goods/Services Distinction’ (2017) 25(1) *International Journal of Law and Information Technology*, 79–80.

<sup>103</sup> PLD 2024, art 4(3)

This inclusion is both innovative and problematic. On one hand, it recognises that product safety is increasingly dependent on interconnected services. For example, the continuous provision of traffic data to a navigation system or the supply of health monitoring data via a wearable device are indispensable to the safe operation of those products.<sup>104</sup> On the other hand, the requirement of ‘functionality’ as the criterion for inclusion is open to competing interpretations. A literal interpretation would treat any influence on performance as functional, while a more restrictive reading, supported by Recital 17, links functionality specifically to safety.<sup>105</sup> The consequences of this interpretative choice are significant as have been identified by Shu Li and Beatrice.<sup>106</sup> If functionality is tied strictly to safety, many services with indirect but important impacts, such as discriminatory datasets used in financial services or predictive policing tools, may fall outside the scope of liability.<sup>107</sup>

## **Chapter Conclusion**

The New PLD undoubtedly marks a substantial improvement over the 1985 regime, addressing previously unregulated areas such as software, CAD files, and interconnected services. Yet its drafting leaves open several contentious issues. The outright exclusion of digital data fails to account for its growing role in shaping product safety, while the uncertain status of a few hybrid models highlights the persistent difficulty in distinguishing between products and services. Likewise, the functionality criterion for related services risks narrowing consumer protection if interpreted restrictively.

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<sup>104</sup> PLD 2024, recital 17.

<sup>105</sup> *ibid.*

<sup>106</sup> Shu Li and Béatrice Schütte, ‘The proposal for a revised Product Liability Directive: The emperor’s new clothes?’ (2023) 0(0) *Maastricht Journal of European and Comparative Law* 1, 7,8.

<sup>107</sup> P Hacker, ‘Teaching Fairness to Artificial Intelligence: Existing and Novel Strategies Against Algorithmic Discrimination Under EU Law’ (2018) 55(4) *Common Market Law Review* 1143, 1160.

Thus, while the expanded scope of ‘product’ represents an ambitious attempt to modernise EU product liability law, its ambiguities are likely to generate significant interpretative disputes before the courts. By virtue of the discussion made in this section, the New PLD may therefore be understood as a necessary but incomplete recalibration, closing old gaps while leaving new ones for future judicial and legislative clarification.

### **Chapter Three: Legal Implications of the Expansion of ‘Product’**

Building on the discussion from the previous chapter, which highlighted the inherent strengths of the New PLD and unresolved ambiguities regarding ‘product’, this chapter turns towards the legal implications of the expansion of ‘product’. It shall be established that this expansion is not merely a technical adjustment for digitalisation but carries far-reaching consequences for the liability landscape across the EU. By enlarging the scope of what may give rise to strict liability, the New PLD effectively opens the door to a significant increase in product liability claims, particularly against digital companies. The ripple effect of this development is likely to be felt most prominently in the field of collective redress, as consumer associations, litigation funders, and law firms seize upon the new opportunities for coordinated mass claims. Accordingly, this chapter shall focus on this broader legal implications, examining the rise of litigation actions across the EU as a direct corollary of the redefined scope of ‘product’, and critically appraising the multifaceted implications that this evolution presents.



## The Case Study of Netherlands

Every reform of liability law brings with it a chain of legal and economic consequences, and the New PLD is no exception.<sup>108</sup> Not only the expanded definition of ‘product’, but the elimination of the minimum thresholds for claims as discussed above alongside other revisions for making the New PLD consumer-friendly, as well as the new procedural mechanisms<sup>109</sup> designed to make redress more accessible which shall be discussed subsequently, make the New PLD bear certain legal consequences. Thus, as shall be discussed hereinbelow, the New PLD inevitably reshapes the litigation landscape across the European Union. These changes will most directly affect all the economic operators that now fall within the ambit of strict liability.

For this purpose, the case study of Netherlands<sup>110</sup> provides a particularly compelling case through which to examine these legal implications. As it is the first Member State to initiate the transposition of the New PLD<sup>111</sup>, it offers an early laboratory for observing how the New PLD’s provisions may operate in practice. The proposed Dutch implementation involves amendments to Books 6 and 7 of the Dutch Civil Code<sup>112</sup>, alongside transitional adjustments in the New Civil Code<sup>113</sup>, and has already been subject to a public consultation process.<sup>114</sup>

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<sup>108</sup> O Guinea, D Pandya and V Sharma, *Collective Action in the Netherlands: Why it Matters for the Transposition of the Product Liability Directive* (ECIPE Policy Brief No 11/2025, European Centre for International Political Economy 2025) 5.

<sup>109</sup> PLD 2024, art 9,10.

<sup>110</sup> O Guinea, D Pandya and V Sharma, *Collective Action in the Netherlands: Why it Matters for the Transposition of the Product Liability Directive* (ECIPE Policy Brief No 11/2025, European Centre for International Political Economy 2025).

<sup>111</sup> CMS, *Transposition Time – Netherlands, Finland, and Sweden: Update on the EU Member States’ Adoption of the New Product Liability Directive* (CMS Law-Now, 22 May 2025) <<https://cms-lawnow.com/en/ealerts/2025/05/transposition-time-netherlands-finland-and-sweden-update-on-the-eu-member-states-adoption-of-the-new-product-liability-directive>> accessed 21 August 2025.

<sup>112</sup> Burgerlijk Wetboek Boek 6 [Dutch Civil Code, Book 6: General Law of Obligations]; Burgerlijk Wetboek Boek 7 [Dutch Civil Code, Book 7: Particular Agreements].

<sup>113</sup> Burgerlijk Wetboek (New Dutch Civil Code).

<sup>114</sup> O Guinea, D Pandya and V Sharma, *Collective Action in the Netherlands: Why it Matters for the Transposition of the Product Liability Directive* (ECIPE Policy Brief No 11/2025, European Centre for International Political Economy 2025).

It is important to be noted that the Dutch legal system possesses certain features that make it unusually receptive to mass litigation in comparison to other jurisdictions within the EU, making it favourable for this paper's discussion.<sup>115</sup> It is noted that although the Netherlands formally applies the 'loser pays' principle<sup>116</sup>, in practice cost-shifting is modest, as prevailing defendants typically recover only a fraction of their actual legal expenditure. This creates a litigation environment with comparatively limited downside risks for claimants. Moreover, Dutch law permits the rapid establishment of ad hoc qualified entities capable of bringing collective claims, often supported by third-party litigation funders.<sup>117</sup> Importantly, collective actions are authorised across all areas of civil law, giving the system a breadth of procedural openness rare within the Union.

A further factor accentuating the significance of the Netherlands in this context is its procedural model of opt-out collective actions.<sup>118</sup> This system automatically includes similarly situated claimants within proceedings unless they actively withdraw, resulting in a naturally expansive claimant pool and enhancing the potential scale of liability for defendants. Combined with the relatively low barriers to initiating such actions, this framework positions the Netherlands as one of the EU's most attractive jurisdictions for collective redress.

Finally, the country's economic profile deepens its relevance to this inquiry. Netherlands ranks among the Union's most digitised economies, with Dutch firms

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<sup>115</sup> F Erixon & others, *The Impact of Increased Mass Litigation in Europe* (ECIPE Occasional Paper 3/2025, Brussels 2025).

<sup>116</sup> Wetboek van Burgerlijke Rechtsvordering (Code of Civil Procedure), art 237(1).

<sup>117</sup> BIICL, Collective Redress: The Netherlands (2020) <[https://www.collectiveredress.org/documents/31\\_the\\_netherlands\\_report.pdf](https://www.collectiveredress.org/documents/31_the_netherlands_report.pdf)> accessed 21 August 2025; A Knigge and I Wijnberg, 'Class/collective actions in The Netherlands: overview' (Houthoff, 1 September 2020) <[https://www.houthoff.com/-/media/houthoff/publications/aknigge/thomson-reuters\\_class\\_collective-actions-in-the-netherlands\\_overview.pdf](https://www.houthoff.com/-/media/houthoff/publications/aknigge/thomson-reuters_class_collective-actions-in-the-netherlands_overview.pdf)> accessed 21 August 2025.

<sup>118</sup> O Guinea, D Pandya and V Sharma, *Collective Action in the Netherlands: Why it Matters for the Transposition of the Product Liability Directive* (ECIPE Policy Brief No 11/2025, European Centre for International Political Economy 2025) 4.

demonstrating some of the highest rates of intensive digital technology adoption, as evidenced by Eurostat’s Digital Intensity Index.<sup>119</sup> This performance reflects sustained governmental initiatives to accelerate digitalisation and support the growth of data-driven business models. The combination of advanced digitalisation and a litigation-friendly environment renders the Netherlands especially prone to a surge of claims arising from the expanded definition of ‘product’ under the New PLD. Thus, due to the aforementioned reasons, the case study of Netherlands shall be crucial for this paper in evaluating the legal implications as a direct consequence of transposition of the New PLD in Netherlands.

### **Interpretive Ambiguities**

Against this background, it is observed that the expansion of the “product” definition clearly broadens potential liability and blurs traditional distinctions between goods and services as earlier discussed. However, in the case of software, courts will increasingly face the challenge of pinpointing the locus of defect: whether it lies in the original code, in subsequent updates, or in failures of manufacturers to monitor and respond to anomalous behaviour. This is evidenced by the report of the European Centre for International Political Economy (the “**ECIPE**”), which has identified this as the number one factor in impacting the rise in liability claims, particularly collective actions.<sup>120</sup> More critically, this raises the question of whether strict liability now imposes continuing obligations akin to regulatory monitoring, particularly in relation to IoT (the “**Internet of Things**”) devices where malfunctions may emerge dynamically over time and there exists uncertainty regarding the devices being subject

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<sup>119</sup> Eurostat, ‘Digital Intensity by NACE Rev. 2 activity’ <[https://ec.europa.eu/eurostat/databrowser/view/ISO-C\\_E\\_DIIN2\\_custom\\_5140920/default/table?lang=en](https://ec.europa.eu/eurostat/databrowser/view/ISO-C_E_DIIN2_custom_5140920/default/table?lang=en)> accessed 21 August 2025.

<sup>120</sup> O Guinea, D Pandya and V Sharma, Collective Action in the Netherlands: Why it Matters for the Transposition of the Product Liability Directive (ECIPE Policy Brief No 11/2025, European Centre for International Political Economy 2025) 5,6.

to hacking.<sup>121</sup> If so, then such interpretive ambiguity creates fertile ground for disputes, and under the Dutch model of collective actions, this uncertainty could translate into a surge of aggregated claims targeting entire sectors as has been made clear in the discussion above.

### **Problems with OSS**

Furthermore, the regulatory treatment of open-source software (the “OSS”) underscores the difficulties ahead. While the New PLD reasonably excludes OSS distributed outside commercial contexts<sup>122</sup> as discussed above in this paper, once monetised or integrated into commercial products, liability attaches to the manufacturer rather than the original OSS developer.<sup>123</sup> Given the decentralised and anonymous nature of OSS development where anyone can set up their own individual servers<sup>124</sup>, manufacturers may be unable to trace vulnerabilities or allocate responsibility. This has the potential to give rise to speculative litigation. Claimants, who will be faced with uncertainty over the proper defendant, may simply target the manufacturer as the most visible actor in the supply chain. In a litigation-friendly jurisdiction such as the Netherlands, where funders and consumer groups actively support collective actions, this is likely to encourage expansive claims against digital operators.<sup>125</sup>

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<sup>121</sup> Nilan Johnson Lewis PA, ‘Recent IoT Class Actions Highlight Need for Manufacturers & Vendors of Connected Products to Be Aware of Liability Risks’ (Nilan Johnson Lewis PA, 28 January 2020) <<https://nilanjohnson.com/recent-iot-class-actions-highlight-need-for-manufacturers-vendors-of-connected-products-to-be-aware-of-liability-risks/>> accessed 21 August 2025.

<sup>122</sup> PLD 2024, recital 14.

<sup>123</sup> *ibid.*

<sup>124</sup> S Ravindh Raman & others, ‘Challenges in the Decentralised Web: The Mastodon Case’ in Proceedings of the Internet Measurement Conference (IMC ’19) (ACM 2019) 217 <<https://doi.org/10.1145/3355369.3355572>> accessed 21 August 2025.

<sup>125</sup> O Guinea, D Pandya and V Sharma, Collective Action in the Netherlands: Why it Matters for the Transposition of the Product Liability Directive (ECIPE Policy Brief No 11/2025, European Centre for International Political Economy 2025) 6.

## Comparative Insight

Comparative experience strengthens this prediction. In the United States, class actions have already been filed against manufacturers of consumer security systems, alleging that design vulnerabilities facilitated unlawful surveillance.<sup>126</sup> Similarly, social media platforms have been targeted for allegedly defective in-app reporting mechanisms that failed to prevent harmful content from proliferating, with plaintiffs arguing that liability lies not only in the harmful content itself but in the platforms' defective design choices.<sup>127</sup> By noting that Dutch practice is receptive to extending liability into adjacent areas such as product defects in digital platforms, the transposition of the New PLD shall provide a doctrinal basis for these claims to proliferate further, and thus, lead the way to further mass litigation.

## Chilling Effect as a Result of Rise in Claims

As a consequence of mass litigation claims, the implications for economic operators shall be profound. Collective litigation introduces a high degree of unpredictability, both in terms of subject (whether firms have complied with their obligations) and object (the likelihood of being sued, which often correlates with size and visibility rather than with the gravity of harm).<sup>128</sup> This unpredictability shall influence corporate strategy, particularly in innovation. Firms that have the potential to be exposed to litigation risk will be incentivised to direct R&D efforts towards

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<sup>126</sup> Nilan Johnson Lewis PA, 'Recent IoT Class Actions Highlight Need for Manufacturers & Vendors of Connected Products to Be Aware of Liability Risks' (Nilan Johnson Lewis PA, 28 January 2020) <<https://nilanjohnson.com/recent-iot-class-actions-highlight-need-for-manufacturers-vendors-of-connected-products-to-be-aware-of-liability-risks/>> accessed 21 August 2025.

<sup>127</sup> Dechert, 'Federal Court Dismisses Products Liability Challenge to Social Media Platforms' Content Moderation Tools' (Dechert, March 2025) <<https://www.dechert.com/knowledge/re-torts/2025/3/federal-court-dismisses-products-liability-challenge-to-social-m.html>> accessed 21 August 2025.

<sup>128</sup> O Guinea, D Pandya and V Sharma, Collective Action in the Netherlands: Why it Matters for the Transposition of the Product Liability Directive (ECIPE Policy Brief No 11/2025, European Centre for International Political Economy 2025) 22.

established, low-risk technologies rather than disruptive innovations.<sup>129</sup> The chilling effect shall be particularly concerning in the Netherlands, which is consistently ranked among the EU's most innovative economies and is the third-largest private investor in R&D after Germany and France.<sup>130</sup> However, there is a high chance that these investments are vulnerable to diversion if litigation risk escalates. And if this happens, then the consequences falling from the transposition of the New PLD shall go directly against one of its main objectives, which is to balance liability with innovation.

Empirical evidence supports this concern. Kempf and Spalt<sup>131</sup> found that in the United States, mass litigation led to a decline in the market value of highly innovative firms within three days of being targeted.<sup>132</sup> The ECIPE has applied such findings to the Dutch context, where innovative companies play a disproportionate role in the economy, and suggested that mass litigation could erode billions of euros in market capitalisation. Now, although this is framed as an economic consequence of the transposition of the New PLD, its significance in our context lies in its translation into a legal implication, which is that the New PLD's expanded liability regime increases the exposure of firms to speculative and high-value claims, thereby reshaping the calculus of risk management and compliance. In legal terms, the New PLD's provisions as discussed earlier impose ongoing monitoring obligations and broaden the spectrum of actors who may be held strictly liable. This reallocation of legal risk is not merely ancillary to economic harm but operates as a structural constraint on innovation, since

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<sup>129</sup> W Kip Viscusi and Michael J Moore, 'Product Liability, Research and Development, and Innovation' (1993) 101 *Journal of Political Economy* 161.

<sup>130</sup> European Commission, *Research and development expenditure by business sector – indicator (rd\_e\_berdindr2)*, Eurostat <[https://ec.europa.eu/eurostat/databrowser/view/rd\\_e\\_berdindr2/default/table](https://ec.europa.eu/eurostat/databrowser/view/rd_e_berdindr2/default/table)> accessed 21 August 2025.

<sup>131</sup> Elisabeth Kempf and Oliver G Spalt, *Attracting the Sharks: Corporate Innovation and Securities Class Action Lawsuits* (European Corporate Governance Institute – Finance Working Paper No 614/2019, 26 September 2020) <<http://dx.doi.org/10.2139/ssrn.3143690>> accessed 21 August 2025.

<sup>132</sup> *ibid* 1805-1834.

firms must design their legal strategies, contractual arrangements, and internal governance frameworks around the heightened probability of collective litigation. In this sense, the economic effects of reduced investment in innovation are themselves the downstream consequence of the New PLD's legal architecture, which, by lowering evidentiary thresholds (as will be discussed in the next chapter) and expanding the concept of 'product', creates a litigation environment that structurally disadvantages firms operating at the technological frontier.

### **Chapter Conclusion**

In sum, the Dutch case illustrates the paradox at the heart of the New PLD. On one hand, in theory, the New PLD strengthens consumer protection by broadening liability and facilitating redress in a digitalised economy. On the other, in practice, it risks creating systemic over-exposure for digital firms and manufacturers, distorting innovation incentives, and undermining economic competitiveness. Policymakers transposing the New PLD must therefore calibrate carefully between these competing imperatives, ensuring that the PLD's laudable objectives do not inadvertently destabilise Europe's most dynamic and digitalised economies, thereby going against the principal objective of balancing liability and innovation.

### **Chapter Four: Procedural Adaptations in the New PLD**

In the previous section, it was demonstrated that the rise in litigation claims is likely to constitute the downstream legal consequence of the New PLD's architecture. By extending the definition of 'product', the New PLD constructs a litigation environment that disproportionately burdens firms operating at the technological frontier. This chapter now turns to provide doctrinal substantiation of the thesis developed earlier: namely, that the New PLD rebalances the liability regime in favour

of claimants, thereby materially heightening litigation exposure for producers and, in turn, disincentivising innovation. To this end, the discussion will focus on the procedural mechanisms introduced by the New PLD, particularly those that lower evidentiary thresholds for claimants. If the analysis confirms that these provisions systematically ease claimants' path to recovery, then it follows that the likelihood of increased claims and the consequent chilling effect on digital firms as highlighted in the previous chapter becomes an inevitable outcome.

### **Procedural Mechanisms in the New PLD**

The Original PLD contained no harmonised rules on procedure, leaving Member States to apply their own civil-process traditions.<sup>133</sup> In practice, this meant that claimants often faced insurmountable evidentiary barriers in establishing defect and causation, particularly in technologically complex cases. The New PLD directly intervenes in this landscape, not only refining the substantive scope of strict liability, but also alleviating the claimant's burden of proof through disclosure obligations and rebuttable presumptions.<sup>134</sup> The decision to legislate in this space is therefore not ancillary, rather it reveals a normative commitment to lowering barriers to recovery, even at the cost of predictability for producers.<sup>135</sup>

During the drafting process, two options were debated. The first maintained the burden of proof with the claimant, but equipped them with ancillary procedural tools, most notably access to relevant information in the hands of producers, and presumptions of defect or causation under defined conditions. The second was far more

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<sup>133</sup> M Buiten, A de Streel and M Peitz, 'EU Liability Rules for the Age of Artificial Intelligence' (2021) <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3817520](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3817520)> accessed 24 August 2025.

<sup>134</sup> European Commission, *Explanatory Memorandum to the Proposal for a Directive of the European Parliament and of the Council on Liability for Defective Products*, COM (2022) 495 final, 28 September 2022, p 2.

<sup>135</sup> Shu Li and Béatrice Schütte, 'The proposal for a revised Product Liability Directive: The emperor's new clothes?' (2023) 0(0) *Maastricht Journal of European and Comparative Law* 1, 18-19.



radical, where there was suggested a wholesale reversal of the burden of proof, coupled with the removal of the development risk defence, which would have rendered producers liable even for defects undetectable at the time of placing the product on the market.<sup>136</sup> Ultimately, the legislature rejected the second option, but the fact that it was seriously entertained underscores how far the pendulum seems to have swung towards claimants. What emerged in the final text, therefore, was a compromise. It kept the position that the burden of proof formally remains with the claimant, but the New PLD creates statutory shortcuts that in practice make the claimant's position significantly stronger than under the 1985 regime.<sup>137</sup>

### **1. Presumption of Defectiveness**

One of the most striking innovations is found in Article 9 of the New PLD<sup>138</sup>, which establishes a harmonised framework for disclosure of evidence. In highly technical markets, producers invariably hold an informational monopoly over the design, safety testing, and compliance data of their products. The increasing sophistication of products, especially those incorporating AI systems and digital components, has only deepened this asymmetry.<sup>139</sup> The New PLD's solution is to empower courts to order disclosure where the claimant has established sufficient plausibility of their claim.<sup>140</sup> However, this is not *a carte blanche* for discovery. Three safeguards are built into the framework for this purpose. First, the plausibility requirement prevents frivolous claims; second, the principle of proportionality limits

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<sup>136</sup> European Commission, *Explanatory Memorandum to the Proposal for a Directive of the European Parliament and of the Council on Liability for Defective Products*, COM (2022) 495 final, 28 September 2022, p 9-10.

<sup>137</sup> Shu Li and Béatrice Schütte, 'The proposal for a revised Product Liability Directive: The emperor's new clothes?' (2023) 0(0) Maastricht Journal of European and Comparative Law 1, 19.

<sup>138</sup> PLD 2024, art 9.

<sup>139</sup> Shu Li and Béatrice Schütte, 'The proposal for a revised Product Liability Directive: The emperor's new clothes?' (2023) 0(0) Maastricht Journal of European and Comparative Law 1, 19.

<sup>140</sup> PLD 2024, art 9(1).

the scope of disclosure to what is strictly necessary; and third, courts must balance disclosure against the protection of trade secrets and confidential information.<sup>141</sup> This framework is designed to maintain equilibrium as it allows claimants access to the evidence essential to establish defect and causation, while tempering this with safeguards for producers' legitimate economic interests.

The crucial point, however, is the sanction for non-compliance. If the defendant fails to disclose as ordered under Article 9(1), the court is bound to presume defectiveness.<sup>142</sup> This transforms disclosure from a mere procedural facilitation into a substantive lever of liability. In effect, the evidentiary rules force defendants into a dilemma, either reveal internal data (with potential implications for confidentiality and IP) or face presumptive liability. In a litigation environment already broadened by the New PLD's expanded definition of 'product' as discussed in the previous chapter, this presumption directly encourages individuals to bring litigation claims against economic operators, and substantially increases settlement pressure as it reshapes bargaining dynamics hugely to the claimant's advantage. Therefore, in this way, the presumption of defectiveness under Article 10(2)(a) of the New PLD further paves the path for mass litigation across the EU Member States.

## **2. Presumptions for Non-Compliance & 'Obvious Malfunction'**

Beyond the presumption of defectiveness in case of non-disclosure by the defendant, the New PLD codifies a suite of rebuttable presumptions under Article 10, designed to further alleviate the claimant's evidentiary burden. It provides that defectiveness shall further be presumed in two more situations. Firstly, where the

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<sup>141</sup> PLD 2024, art 9.

<sup>142</sup> PLD 2024, art 10(2)(a).

product does not comply with mandatory safety requirements; and secondly, where the damage is caused by an obvious malfunction.<sup>143</sup>

Each of these categories raises its own doctrinal issues. Non-compliance with safety requirements, while seemingly straightforward, can in fact require highly technical proof, particularly where the product integrates machine learning or other opaque technologies.<sup>144</sup> Similarly, the concept of ‘obvious malfunction’ remains undertheorised. The New PLD’s example of a warning mechanism like a smoke alarm, for instance, is ill-suited to all aspects of the digital context, where malfunction is rarely obvious to a lay observer.<sup>145</sup> This is reasoned on the basis that warning mechanism such as a smoke alarm exemplifies a malfunction that is immediately perceptible to the user because its failure is both tangible and temporally proximate, i.e., when smoke is present but the alarm does not sound, the defect is obvious, observable, and directly linked to the risk. By contrast, in digital products, malfunction may manifest through imperceptible errors in code, data processing, or algorithmic output which may not reveal themselves until much later, if at all. Thus, while the smoke alarm analogy is apt for traditional consumer goods, it is doctrinally inadequate for the digital environment where malfunction is rarely self-evident to a lay consumer. In this manner, Recital 33 leaves it up to the courts to define the concept case by case, which risks divergent national jurisprudence and legal uncertainty.

### **3. Presumption of Causation**

Furthermore, Article 10(3) establishes that, where defectiveness has been proved or presumed, a causal link shall also be presumed if the damage is ‘typically

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<sup>143</sup> PLD 2024, art 10(1).

<sup>144</sup> P Hacker, ‘The European AI Liability Directives – Critique of a Half-Hearted Approach and Lessons for the Future’ (2023) 51 Computer Law and Security Review, 22 <<https://doi.org/10.1016/j.clsr.2023.105871>> accessed 25 August 2025.

<sup>145</sup> PLD 2024, recital 33

*consistent*’ with the defect in question.<sup>146</sup> Here again, the New PLD uses an indeterminate standard. While typicity may be readily identifiable in classical product cases, in complex digital systems the boundaries of what is ‘typically consistent’ may themselves require expert testimony, thereby shifting the burden to the defendant for rebuttal as under Article 10(5).<sup>147</sup> In this manner, this further favours the claimants by alleviating their burden of proof and going against the economic operators, thereby proving this thesis.

#### **4. The Last-Resort Presumption**

Most controversially, Article 10(4) introduces a ‘last-resort’ presumption, designed for cases where excessive technical or scientific complexity makes proof impossible, even with disclosure.<sup>148</sup> Under this provision, defectiveness and causation may be presumed in cases of technical and scientific complexity where defectiveness or causation is demonstrated ‘*likely*’<sup>149</sup>. This formulation, though intended to prevent claimants from being excluded where opacity is insurmountable, introduces profound uncertainty. Now, it has to be noted that this is still an amended version from the previous language of the Article where presumption was made in cases where a product merely ‘*contributed*’ to the damage, whereby critics such as Wagner had rightfully argued that if ‘contribution’ alone suffices, then the presumption ceases to function as an evidentiary aid and becomes instead a form of enterprise liability.<sup>150</sup> However, notwithstanding the removal of the ‘contribution’ presumption from the final text of the New PLD, it may still be contended that the present framework still unduly privileges claimants. The residual presumption, available where excessive technical or scientific

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<sup>146</sup> PLD 2024, art 10(3).

<sup>147</sup> PLD 2024, art 10(5)

<sup>148</sup> PLD 2024, art 10(4).

<sup>149</sup> PLD 2024, art 10(4)(b).

<sup>150</sup> G Wagner, ‘Liability Rules for the Digital Age: Aiming for the Brussels Effect’ (2023) 13(3) Journal of European Tort Law, 217-218 <<http://dx.doi.org/10.2139/ssrn.4320285>> accessed 25 August 2025.

complexity renders proof unattainable, effectively enables liability to be imposed even in circumstances where the claimant has failed to substantiate defectiveness or causation. The author is of the view that doctrinally, this comes close to endorsing the proposition that an absence of demonstrable proof is excusable merely because the subject-matter is complex, thereby shifting the risk of scientific uncertainty onto defendants rather than remaining with claimants. In this context, the European Law Institute (the “ELI”) has also warned that the vagueness of the standard risks inconsistent application across Member States.<sup>151</sup>

Therefore, in this manner, the risk is that Article 10(4) becomes the default route in cases involving AI or algorithmic opacity, thereby eroding the conceptual boundaries of strict liability and tilting the regime towards *de facto* insurance. In this way, it also leads to further smoothing the path for bringing mass litigation claims across EU, as has been argued by the author in this paper.

### **Critical Appraisal**

Taken together, Articles 9 and 10 represent a profound recalibration of procedural equilibrium in EU product liability. What began in 1985 as a regime premised on strict liability subject to well-defined conditions has evolved into a framework where claimant-facilitating presumptions increasingly displace the traditional burden of proof. The effect, when combined with the expanded scope of ‘product’, is to expose digital firms, software developers, manufacturers and other economic operators to mass litigation risks at precisely the points where technological innovation is most pronounced.

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<sup>151</sup> ELI, *Feedback on the European Commission’s Proposal for a Revised Product Liability Directive* (2022) 19 [https://www.europeanlawinstitute.eu/fileadmin/user\\_upload/p\\_eli/Publications/ELI\\_Feedback\\_on\\_the\\_EC\\_Proposal\\_for\\_a\\_Revised\\_Product\\_Liability\\_Directive.pdf](https://www.europeanlawinstitute.eu/fileadmin/user_upload/p_eli/Publications/ELI_Feedback_on_the_EC_Proposal_for_a_Revised_Product_Liability_Directive.pdf)> accessed 25 August 2025.

This is not to deny that the reforms respond to genuine concerns of access to justice. In cases involving AI-enabled or digitally complex products, traditional proof requirements would often exclude claimants altogether. The New PLD's innovations can thus be defended as necessary adaptations to technological reality. But the broader thesis remains, that by easing evidentiary burdens and creating statutory presumptions, the New PLD structurally reallocates risk towards economic operators, with predictable consequences for innovation, investment, and litigation dynamics.

## **Chapter Conclusion**

The evidentiary reforms of the New PLD are best understood as the procedural expression of its substantive expansion of liability. By granting claimants access to evidence, presuming defect in defined situations, and offering last-resort presumptions in cases of complexity, the New PLD lowers barriers to litigation in ways that directly support its compensatory function. Yet this very architecture embeds a systemic tilt against defendants, particularly digital companies. As such, this chapter confirms the claim advanced in Chapter Three, that there is a high potential for mass litigation claims to flow directly from the New PLD's legal design, which prioritises claimants' access to justice over all other factors.

## **Chapter Five: Post-Reform Uncertainties and Ambiguities**

The preceding chapters have sought to demonstrate how the New PLD reshapes the contours of liability in the digital and circular economy. By enlarging the statutory meaning of 'product', the New PLD alters the liability landscape in ways that may structurally disadvantage firms operating at the technological frontier. This chapter conclusively tests that thesis by identifying, systematising and critically assessing the principal areas of uncertainty that the New PLD leaves unresolved. The analysis

proceeds from the fundamentals (what counts as a ‘product’) to the procedural mechanisms that govern proof and causation, and to the borderline tensions with parallel legal regimes, because it is at these fault lines that future legal and practical consequences will arise.

## 1. The Boundary Problem

A first, and foundational, ambiguity concerns the status of digital data vis-à-vis the product concept. The New PLD explicitly recognises digital manufacturing files (e.g. CAD files) and software as products<sup>152</sup>, but it does not treat all digital data as a product in itself; data that merely informs a product remains excluded even where it materially influences operation or safety.<sup>153</sup> This selective inclusion is doctrinally coherent in principle<sup>154</sup>, since it distinguishes executable templates from raw information<sup>155</sup>, but it creates an uncomfortable gap. Due to this, functional datasets used to train AI models or to feed runtime decision-making can cause exactly the kind of safety failures that liability paradigms are meant to capture, yet they fall outside the product label.

This particular gap matters in practice. A defective CAD file used to drive an additive-manufacturing process now sits squarely within the New PLD, so a physical injury during printing can attract product liability where previously no route existed.<sup>156</sup> By contrast, a training dataset that skews an AI controller into hazardous behaviour remains formally data, not a product, and the victim’s route to redress becomes more tortuous and fragmented. The legal outcome is an odd dichotomy in which the ‘form’

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<sup>152</sup> PLD 2024, art 4(2).

<sup>153</sup> PLD 2024, recital 13.

<sup>154</sup> P Machnikowski, ‘Product Liability Directive’ in P Machnikowski (ed.), *European Product Liability* (Intersentia 2016), 48.

<sup>155</sup> Shu Li and Béatrice Schütte, ‘The proposal for a revised Product Liability Directive: The emperor’s new clothes?’ (2023) 0(0) *Maastricht Journal of European and Comparative Law* 1, 4-5.

<sup>156</sup> B Berman, ‘3-D printing: The New Industrial Revolution’ (2012) 55 *Business Horizons*, 155.

of the digital data determines liability, without putting in consideration the ‘risk’ it may possess.

## **2. Hybrid Business Models**

The New PLD’s explicit recognition of software as a product is a paradigmatic advance since software providers are brought into the product chain, and both embedded and standalone software are covered.<sup>157</sup> Yet the instrument stops short of a precise statutory definition of ‘software’. This leaves unsettled whether particular business models that blur product/service boundaries (notably those that are not the classic SaaS model but other variants) should be classified as a product or as a service, a question that will determine whether extra-contractual strict liability can be invoked.<sup>158</sup>

The practical consequence is a doctrinal friction between contractual regimes that provide one set of remedies and expectations and product liability which provides another.<sup>159</sup> Without clearer statutory signposts, courts are likely to be forced into fine-grained, fact-sensitive delineations, a space that will pave the path for forum shopping and lead to inconsistent rulings across Member States.

## **3. Related services and the Functionality Test**

The New PLD allows related services to be treated as components where they are integrated with, 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.<sup>160</sup> This is a welcome attempt to capture interdependence between code, cloud services and

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<sup>157</sup> PLD 2024, recital 13.

<sup>158</sup> J Hojnik, ‘Technology Neutral EU Law: Digital Goods Within the Traditional Goods/Services Distinction’ (2017) 25(1) *International Journal of Law and Information Technology*, 79–80.

<sup>159</sup> Shu Li and Béatrice Schütte, ‘The proposal for a revised Product Liability Directive: The emperor’s new clothes?’ (2023) 0(0) *Maastricht Journal of European and Comparative Law* 1, 6.

<sup>160</sup> PLD 2024, art 4(3).



hardware<sup>161</sup>, as the New PLD's primary criterion as functionality is now sufficiently specified as opposed to the one observed in the tentative text.<sup>162</sup> However, two interpretative tracks are possible as have been highlighted earlier in Chapter Two; firstly, a broad reading (any effect on performance is functional) and secondly, a narrower safety-linked reading (only performance that affects safety qualifies as identified in Recital 17<sup>163</sup>). If Member States or courts adopt the narrower approach, many services that materially shape outcomes could fall outside product liability despite producing serious harms.

#### **4. OSS Traceability Problem**

The New PLD tries to strike a balance by keeping free software or OSS developed outside commercial activity excluded, whereas OSS integrated into commercial products included for liability for manufacturers.<sup>164</sup> In practice, however, OSS often originates from decentralised contributors whose identities are unknown; tracing a root cause through layered dependencies and tens of thousands of commits can be practically impossible.<sup>165</sup> This traceability deficit means manufacturers may be forced to assume legal exposure for defects they cannot realistically investigate or anticipate, and claimants may press speculative claims against firms that are merely downstream integrators. This will have the likely impact of decreasing the risk-taking capabilities of digital firms and ultimately decrease innovation as opposed to the New PLD's objectives.

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<sup>161</sup> Dr Nikos Th. Nikolinakos, 'Aligning liability rules with the digital age and circular economy: the revised EU Product Liability Directive' (2025) 31(4) CTLR 126, 132.

<sup>162</sup> Shu Li and Béatrice Schütte, 'The proposal for a revised Product Liability Directive: The emperor's new clothes?' (2023) 0(0) Maastricht Journal of European and Comparative Law 1, 4.

<sup>163</sup> PLD 2024, recital 17.

<sup>164</sup> PLD 2024, recital 14.

<sup>165</sup> S Ravindh Raman & others, 'Challenges in the Decentralised Web: The Mastodon Case' in Proceedings of the Internet Measurement Conference (IMC '19) (ACM 2019) 217 <<https://doi.org/10.1145/3355369.3355572>> accessed 21 August 2025.

## 5. Procedural Uncertainty

The New PLD provides important procedural aids as discussed in Chapter Four, notably court-ordered disclosure and rebuttable presumptions. These tools are intended to correct information asymmetries between sophisticated economic operators and injured consumers. Yet several indeterminacies remain.

Firstly, the notion of an ‘obvious malfunction’<sup>166</sup> (used as a trigger for presumption) is pitched at a lay example in the New PLD as was discussed in detail earlier, but in digital systems the visibility threshold is much higher, since failures are often latent, opaque and detectable only by forensic reverse-engineering. Applying the ordinary ‘obvious malfunction’ yardstick to AI-driven IoT devices will therefore produce inconsistent results and require intense expert litigation, resulting in a flip of the burden of proof.

Secondly, the New PLD’s test that causation may be presumed where the damage is ‘typically consistent’<sup>167</sup> with the defect inserts a fact-sensitive and elastic standard that, in complex algorithmic cases, will itself call for technical proof and expert evidence. Once a court accepts such typicality, the burden shifts to the defendant to rebut, a movement that, in practice, favours claimants and heightens defendants’ exposure.

Finally, the last resort relief in Article 10(4)<sup>168</sup> is a well-intentioned access-to-justice measure but risks being deployed as a low-threshold gateway for liability where sophisticated defendants hold most of the knowledge. The effect is to lower the claimant’s evidentiary bar in high-complexity cases, yet again, to the commercial

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<sup>166</sup> PLD 2024, recital 33.

<sup>167</sup> PLD 2024, art 10(3).

<sup>168</sup> PLD 2024, art 10(4).

operator's disadvantage, with legal implications that point towards risking mass litigation claims and deterring innovation.

## **6. Interplay with Other Legal Regimes**

The New PLD expressly avoids supplanting data-protection remedies and other sectoral regimes, yet the boundary lines are porous. Where harms arise through algorithmic discrimination, privacy breaches, or purely non-safety injures, victims must pursue different legal tracks. Moreover, because the New PLD is a maximum-harmonisation instrument<sup>169</sup>, Member States cannot expand coverage for categories, even if domestic courts believe it necessary for consumer protection. That centralised ceiling will almost inevitably produce pressure points where national policymakers or judges consider supplementary remedies to fill perceived gaps.

## **Concluding Observations**

Taken together, these ambiguities create fertile ground for mass litigation and for doctrinal divergence between Member States. The New PLD is a necessary modernising intervention, yet its drafting choices, with selective inclusion of digital artefacts, an under-specified functionality test for related services, an OSS-traceability problem, and flexible but indeterminate evidentiary presumptions, all point to future judicial contestation. Empirically, these doctrinal uncertainties will translate into increased claims, a heavier evidentiary burden on defendants, reputational risk, and crucially for the dissertation's thesis, a predictable chilling effect on innovation unless Member States and the CJEU supply clarifying boundaries and robust guidance.

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<sup>169</sup> PLD 2024, art 3.

## **Conclusion**

This dissertation has examined the transformation of the product liability framework in the European Union, focusing on the New PLD and, in particular, its expanded definition of ‘product’. The core thesis has been that while the New PLD is a necessary response to the challenges of digitalisation, its legal architecture creates a litigation environment that structurally disadvantages firms operating at the technological frontier. This conclusion will now bring together the doctrinal analysis, legal implications, and procedural reforms discussed throughout, and conclude whether the New PLD achieves its intended balance between consumer protection and innovation.

At one level, the New PLD represents an indispensable step in closing the regulatory gaps left by the Original PLD. The expansion of liability to cover software, AI systems, and digital manufacturing files corrects the longstanding inadequacy of a framework that was designed for a pre-digital economy. This modernisation ensures that consumers are not left remediless when harm arises from defects in emerging technologies, thereby aligning liability law with the realities of twenty-first century markets. Similarly, the introduction of disclosure duties, rebuttable presumptions of defectiveness, and other procedural innovations strengthen access to justice by addressing the inherent informational asymmetries between consumers and businesses. From the perspective of consumer protection, therefore, the New PLD is both timely and normatively justified.

Yet the very features that make the New PLD more protective of consumers simultaneously expose stakeholders to novel and, in some cases, indeterminate risks. The analysis in this paper has demonstrated that these uncertainties are not merely theoretical. Empirical evidence suggests that the prospect of heightened mass claims

has tangible deterrent effects on firms' willingness to invest in frontier innovation. Where litigation risk becomes an institutionalised cost of operation, firms may rationally shift away from disruptive innovation towards incremental improvements, eroding Europe's competitiveness in key digital sectors. Thus, what begins as a reform designed to enhance accountability may, in practice, operate as a structural disincentive for precisely those firms best positioned to advance technological progress. The New PLD, in this sense, risks undermining its own stated aim of supporting the twin objectives of consumer protection and innovation.

To answer the central research question of this thesis, it can be stated that the New PLD tilts the liability regime decisively in favour of claimants, both by expanding the circle of potentially liable actors and by alleviating their burden of proof. While this is defensible from the perspective of consumer justice, it carries a corollary risk of over-deterrence for economic operators. The resulting environment is one in which liability becomes unpredictable, mass litigation more likely, and innovation more costly. If unaddressed, these dynamics may weaken the very digital economy that the Directive purports to regulate more effectively.

Nevertheless, the findings of this dissertation should not be read as a wholesale rejection of the New PLD. Rather, they suggest the need for a recalibration of its doctrinal design. Clarifying the boundary between products and services, codifying standards instead of broad examples for what constitutes an 'obvious malfunction' in digital contexts, and introducing safe-harbour provisions for firms that comply with recognised testing and monitoring protocols would all mitigate the risks identified. In addition, an EU-level interpretative framework to guide national courts could help prevent fragmentation and provide greater certainty to economic operators. Such

measures would not only preserve the Directive's consumer protection objectives but also restore balance by reducing the chilling effects on innovation.

Ultimately, the New PLD marks a critical step forward, but its ambiguities and doctrinal uncertainties risk entrenching a cycle of litigation that disadvantages digital firms. By recognising and addressing these shortcomings, the EU has the opportunity to create a liability regime that genuinely protects consumers while fostering, rather than constraining, technological progress.

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