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# Client Alert

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### **New EU Product Liability Directive Comes Into Force**

# The Directive expands the scope of liability to digital products (including AI systems), fulfilment service providers, and online platforms, while reducing the burden of proof for claimants.

On 9 December 2024, the new Directive on Liability for Defective Products, <u>Directive (EU) 2024/2853</u> (Product Liability Directive), came into effect. Companies are strongly encouraged to prepare for the stricter liability standards that will be enforced by 9 December 2026, at the latest.

The directive significantly expands the scope of company liability to include digital products, such as software and artificial intelligence (AI) systems. When assessing a product's potential defects, authorities and courts must now consider cybersecurity requirements. Fulfilment service providers and operators of online platforms will also be held accountable for defective products. Additionally, the directive introduces procedural requirements, including streamlined evidence facilitation, disclosure obligations, and a revised allocation of the burden of proof.

This Client Alert highlights the most significant changes and their potential impact on companies. It outlines steps companies can take now to prepare for the new standards and mitigate risks, offering an explanation of the legal requirements to support strategic decision-making.

#### **Goal and Time Frame**

One of the goals of the Product Liability Directive, which came into effect on 9 December 2024, is to adapt previous product liability rules to the digital era.<sup>1</sup> Unlike its predecessor, Directive 85/374/EC,<sup>2</sup> the Product Liability Directive includes procedural requirements, such as the burden of proof.

EU Member States are required to implement the Product Liability Directive within two years.<sup>3</sup> While products placed on the market or put into operation before 9 December 2026 remain in scope of the old regulations even after the implementation deadline,<sup>4</sup> companies should already start preparing for stricter liability standards.

#### **Expanded Product Definition**

The Product Liability Directive broadens liability to include digital products, such as **software**,<sup>5</sup> including **AI systems**.<sup>6</sup> Adhering to its neutral stance regarding technology, the directive covers all types of

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software and AI systems. Both standalone AI systems<sup>7</sup> and AI components integrated within other products therefore fall under the directive's scope.<sup>8</sup> Digital data not classified as software is not considered a product, unless it involves digital manufacturing files. For example, a faulty computer-aided design file used in 3D printing could cause damage during production.<sup>9</sup>

The directive also covers components that are integrated into a product. This includes digital services, known as *related services*, <sup>10</sup> such as navigation systems, voice assistants, or health monitoring programmes.<sup>11</sup> This inclusion is significant because, typically, the Product Liability Directive generally does not apply to services.

#### **Defectiveness of the Product**

Similar to the previous directive, a product is deemed defective if it does not meet the expected or legally required level of safety. When assessing defectiveness, factors such as the product's presentation, characteristics, labeling, foreseeable use, and the impact of other products used in conjunction with it are taken into account (see Article 7 of the Product Liability Directive).<sup>12</sup> A new consideration is that products, especially AI systems, which continue to **learn or gain new functions after being launched in the market**, can also be deemed defective. According to the Product Liability Directive, manufacturers may be held liable if such products develop unexpectedly "harmful" behaviour<sup>13</sup> To address this aspect of "learning" products, the Product Liability Directive considers the point in time at which the product exits the manufacturer's control.<sup>14</sup>

An important consideration is whether the product meets the relevant **safety requirements**. These requirements may arise from regulations like the EU AI Act and other EU legislation, such as the **EU Cyber Resilience Act** that came into effect on 10 December 2024.<sup>15</sup> Manufacturers can protect themselves by proactively complying with these and other product safety standards. They might opt to follow codes of conduct<sup>16</sup> or guidelines even before such laws apply to their products.

Another new aspect is the inclusion of **cybersecurity** requirements in evaluating defectiveness.<sup>17</sup> Manufacturers are now liable for damages resulting from cybersecurity vulnerabilities, such as cyberattacks. This change increases the liability risk associated with insufficient cybersecurity, in addition to potential claims under Article 82 of the GDPR.<sup>18</sup>

#### **Liable Economic Operators**

The new Product Liability Directive expands the range of liable parties to ensure that individuals based in the EU who suffer harm have a valid claim for damages against an entity based within the EU.<sup>19</sup> The directive extends beyond the traditional roles found in conventional supply chains, flexibly including other economic operators in its scope liability.<sup>20</sup>

In addition to manufacturers and importers, the following entities are now also held liable: authorised representatives, fulfilment service providers, and, in certain cases, online platforms providers.<sup>21</sup> Fulfilment service providers are defined as individual or legal entities that commercially offer at least two of the following services: warehousing, packaging, addressing, and dispatching of products that they do not own.

#### **Definition of Manufacturer**

Under the Product Liability Directive, the term "manufacturer" includes both individuals and legal entities who develop, manufacture, or produce products, even if they create products solely for their own use.<sup>22</sup> Additionally, anyone who designs a product or has it manufactured and then attaches their name or

trademark to it ("quasi-manufacturer"), is also considered a manufacturer. This definition aligns with the term "product manufacturer" as used in the EU AI Act<sup>23</sup> and partially with the definition of a provider in the EU AI Act. Consequently, providers of AI systems are also considered manufacturers.<sup>24</sup>

#### **Exemption From Liability**

Under the new legal framework, an exemption from liability is only applicable if **probability** suggests that the defect causing the damage did not exist at the time the product was placed on the market.<sup>25</sup>

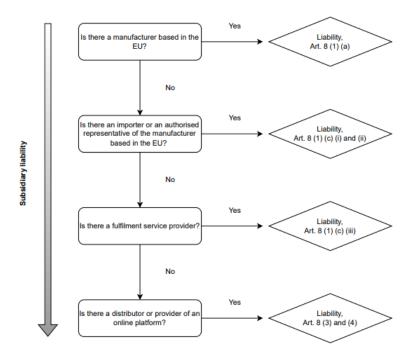
This exemption does not extend to **digital products** if the error is within the **manufacturer's control**, such as software bugs, even if the product undergoes substantial modifications, like updates.<sup>26</sup> The ongoing development of an AI system through continuous learning can also be considered a substantial modification.<sup>27</sup> Providers of AI systems are liable for errors that occur after the product is placed on the market if they supply, authorise, or otherwise consent to the use of the machine-learning software.<sup>28</sup>

#### Transfer of liability

If the manufacturer lacks control over substantial modification to its product or if the product is provided by another party, liability may transfer to the importer, authorised representative, or fulfilment service provider. In such cases, the manufacturer not liable for the damage.<sup>29</sup> The importer, the manufacturer's authorised representative, or the fulfilment service provider may be liable in their place (the latter only if neither the importer nor the authorised representative is based in the EU).<sup>30</sup>

Subsidiary liability extends to distributors<sup>31</sup> and **online platforms** if they present a product in a way that leads consumers to believe it is provided by them or is under their control.<sup>32</sup> However, online platforms acting solely as intermediaries are not held liable, similar to the provisions in the Digital Services Act.<sup>33</sup>

# Overview of Economic Operators Liable for Defective Products, Article 8 of the Product Liability Directive



Source: Latham & Watkins

#### **Extension of Damages**

Similar to its predecessor, the Product Liability Directive provides compensation only for specific types of damages. A notable addition is the inclusion of compensation for **destroyed or corrupted private data**, along with **any resulting financial losses**.<sup>34</sup> Damages resulting from inadequate cybersecurity measures, such as hacker attacks, can also lead to claims.<sup>35</sup>

Costs incurred for the rescue or recovery of data are reimbursable, provided they have actually been incurred.<sup>36</sup> However, free restoration methods, such as backups, do not qualify for claims.<sup>37</sup> This underscores the directive's aim to balance consumer interests with the responsibilities of liable parties in the digital economy.

Compensation for **non-material damage** under the Product Liability Directive is **significantly restricted**. Such compensation is only available if the damage falls within the scope of the directive and is eligible for compensation under national law.<sup>38</sup> The directive excludes pure violations of privacy or discrimination,<sup>39</sup> thereby limiting liability compared to Article 82 of the GDPR. Notably, the EU legislator explicitly rejected the idea of including compensation for immaterial damage caused by data leaks.<sup>40</sup> Nonetheless, liability under other legal frameworks, particularly the GDPR, remains unaffected.<sup>41</sup> The directive authorises national legislators to determine the precise scope of non-material damages during implementation.<sup>42</sup>

Additionally, the Commission is developing a separate "**Al Liability Directive**",<sup>43</sup> which will complement the Product Liability Directive.<sup>44</sup> This new directive is designed to streamline the process of providing evidence for damages commonly associated with AI, such as discrimination or violations of personal or intellectual property rights. Unlike the Product Liability Directive, the AI Liability Directive will be applicable in the **B2B sector**,<sup>45</sup> thus significantly expanding the potential liability risks for companies.

# Facilitation of Evidence Through Disclosure Obligations and Distribution of the Burden of Proof

Under the Product Liability Directive, injured parties benefit from several facilitations concerning evidence. They must prove the product's defectiveness, the damage suffered, and the causal link between that defectiveness and that damage.<sup>46</sup> However, in court proceedings, they only need to present facts and evidence to support the **plausibility** of their claim or damages. The manufacturer is then required to disclose any evidence they have.<sup>47</sup> The directive leaves the specifics of implementation to the national legislator.

The directive mandates adherence to regulations concerning confidentiality and trade secrets.<sup>48</sup> In turn, Member States can require claimants to disclose evidence they possess that would benefit the defendant.<sup>49</sup> Whether this reciprocal obligation for claimants will have practical significance remains to be seen. The legislative process prompted concerns that trade secrets, such as source or AI codes, might not be sufficiently protected due to low disclosure thresholds.

Another new aspect is that courts can now require evidence to be presented in an accessible and understandable manner.<sup>50</sup> This requirement can be particularly challenging in cases involving complex digital issues, potentially necessitating the reprocessing of existing information to meet these standards. While the directive recommends preparing **documentation in a clear and comprehensible** manner, in practice, this requirement may create significant challenges — for example, how can source code be

made accessible and understandable? Will the understanding of a technical layperson suffice, or is higher expertise necessary?

If the defendant fails to meet their disclosure obligations, the directive allows for a **reduction in the burden of proof**, which could lead **to a legal presumption**.<sup>51</sup> For example, the court may assume a product defect if the manufacturer fails to disclose relevant evidence,<sup>52</sup> if the product violates safety requirements, or if an obvious malfunction exists.<sup>53</sup> In the case of AI systems, non-compliance with the EU AI Act can lead to the presumption of an error.

Courts may find a product defective even if the claimant cannot prove defectiveness or causality **due to technical complexity**, as long as the defectiveness or causality is **plausible and probable**.<sup>54</sup> This regulation is relevant only if, despite the disclosure of evidence and considering all relevant circumstances, evidentiary difficulties persist.

With these rules, the Product Liability Directive aims to address the complexity, autonomy, and opacity of AI systems (the so-called "**black box effect**"), which, according to the European legislator, complicate the attribution of unlawful acts.<sup>55</sup> This could require the manufacturer to prove that their AI system is free of defects or at least did not cause the claimed damage. Providing such negative evidence is often very challenging.

#### **Unlimited Scope of Liability**

The new Product Liability Directive eliminates the previous limits on liability and deductibles, meaning companies could now face substantial liability amounts.<sup>56</sup> This change, combined with the streamlined processes for mass enforcement by consumers with legal protection insurance, greatly increases the liability risk for businesses. Notably, specialised plaintiff law firms can efficiently consolidate claims from injured individuals — even for relatively small amounts — and pursue them with ease. Furthermore, claims could be filed through representative actions, including such under the Directive (EU) 2020/1828.<sup>57</sup>

#### **Conclusion and Outlook**

The directive introduces significant changes: It broadens the definition of products to encompass software and AI systems and extends liability to include digital services. The scope of liable parties is expanded, introducing new disclosure obligations and easing the evidentiary requirements for claimants. Moreover, previous liability caps and deductibles have been removed, which is particularly important given the increasing number of lawsuits. **Starting 9 December 2026**, companies should prepare for stricter liability standards. Legislators in the Member States have two years to implement the directive, although the scope for adjustments is limited due to the directive's fully harmonising nature.<sup>58</sup>

Uncertainty remains as to how the disclosure obligations for the defendant will be implemented in alignment with substantive and procedural law in each Member State, and to what extent national legislators will establish additional regulations to protect trade and business secrets. Companies should begin their preparations early, ensuring their documentation is as transparent and comprehensible as possible. Additionally, they need to consider the numerous connections with other EU legislation, such as the EU AI Act, to minimise future liability risks.

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#### Endnotes

<sup>&</sup>lt;sup>1</sup> Recital 3 of the Product Liability Directive.

<sup>&</sup>lt;sup>2</sup> Full text available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31985L0374.

<sup>&</sup>lt;sup>3</sup> Article 22 (1) of the Product Liability Directive.

<sup>&</sup>lt;sup>4</sup> Article 21 (1) of the Product Liability Directive.

<sup>&</sup>lt;sup>5</sup> Article 4 (1) of the Product Liability Directive.

<sup>&</sup>lt;sup>6</sup> Recital 13 of the Product Liability Directive.

<sup>&</sup>lt;sup>7</sup> Cf. Article 6 (2) in conjunction with Annex III and Article 7 of the Regulation (EU) 2024/1689 ("EU AI Act").

<sup>&</sup>lt;sup>8</sup> Article 6 (1) of the EU AI Act.

- <sup>9</sup> Article 4 (2), Recital 16 of the Product Liability Directive.
- <sup>10</sup> Article 4 (3) of the Product Liability Directive.
- <sup>11</sup> Recital 17 (4) of the Product Liability Directive.
- <sup>12</sup> Article 7 (2), Recital 32 of the Product Liability Directive.
- <sup>13</sup> Recital 32 of the Product Liability Directive.
- <sup>14</sup> Article 7 (2) (e), Recital 32 of the Product Liability Directive.
- <sup>15</sup> Regulation (EU) 2024/2847 ("Cyber Resilience Act"); full text available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R2847.</u>
- <sup>16</sup> Cf. Article 95 of the Al Act.
- <sup>17</sup> Article 7 (1) (f) of the Product Liability Directive.
- <sup>18</sup> Article 82 (1) of the GDPR. The right to compensation under both the Product Liability Directive and the GDPR is intended to coexist, as noted in Recital 20 Product Liability Directive. However, the scope of liability under the Product Liability Directive is quite limited, as discussed in section VI.
- <sup>19</sup> Recital 37 (1) of the Product Liability Directive.
- <sup>20</sup> Recital 37 (2) of the Product Liability Directive.
- <sup>21</sup> Article 8 (3)-(4), Recital 38 of the Product Liability Directive.
- <sup>22</sup> Article 4 (10) (a) and (c) of the Product Liability Directive.
- <sup>23</sup> See Article 2 (1) (e), Article 3 (3) of the AI Act; however, for manufacturers as defined by the AI Act, the emphasis is on the act of placing the product on the market or putting it into service.
- <sup>24</sup> Recital 13 of the Product Liability Directive.
- <sup>25</sup> Article 11 (1) (c) of the Product Liability Directive. This is particularly relevant for AI systems that evolve through machine learning. However, the exceptions in Article 11 (2) Product Liability Directive must be taken into account.
- <sup>26</sup> Article 11 (1) (b) (c) of the Product Liability Directive. For the definition of "substantial modification", see Article 4 (18) Product Liability Directive.
- <sup>27</sup> Recital 40 of the Product Liability Directive.
- <sup>28</sup> Recital 50 of the Product Liability Directive.
- <sup>29</sup> Article 8 (2) of the Product Liability Directive.
- <sup>30</sup> Article 8 (1) (c) of the Product Liability Directive.
- <sup>31</sup> Article 8 (3) of the Product Liability Directive.
- <sup>32</sup> Article 8 (4) of the Product Liability Directive.
- <sup>33</sup> Article 6 (3) of the Regulation (EU) 2022/2065 ("Digital Services Act"); available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R2065</u>.
- <sup>34</sup> Article 6 (1), (2) of the Product Liability Directive.
- <sup>35</sup> Recital 55 of the Product Liability Directive.
- <sup>36</sup> Recital 20 of the Product Liability Directive.
- <sup>37</sup> Recital 20 of the Product Liability Directive.
- <sup>38</sup> Article 6 (2) of the Product Liability Directive.
- <sup>39</sup> Cf. Recital 24 of the Product Liability Directive.
- <sup>40</sup> Cf. Recital 20 (4) of the Product Liability Directive.
- <sup>41</sup> Cf. Recital 20 (3) of the Product Liability Directive.
- <sup>42</sup> Cf. Article 6 (2) of the Product Liability Directive: "The right to compensation shall also cover non-material losses resulting from the damage referred to in paragraph 1 of this Article, in so far as they can be compensated for under national law."
- <sup>43</sup> European Commission, Proposal for a AI Liability Directive COM (2022) 496 final, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022PC0496</u>.
- <sup>44</sup> Article 1 (3) (b) of the AI Liability Directive.
- <sup>45</sup> Article 2 (7) of the AI Liability Directive.
- <sup>46</sup> Article 10 (1) of the Product Liability Directive.
- <sup>47</sup> Article 9 (1) and (2) of the Product Liability Directive. A similar concept is also included in Article 3 AI Liability Directive.
- <sup>48</sup> Cf. Article 9 (4) of the Product Liability Directive.
- <sup>49</sup> Article 9 (2) of the Product Liability Directive.
- <sup>50</sup> Article 9 (6) of the Product Liability Directive.

- <sup>51</sup> Article 10 (2) (a), (4) of the Product Liability Directive.
- <sup>52</sup> Article 10 (2) (a), Article 9 (1) of the Product Liability Directive.
- <sup>53</sup> Article 10 (2) (b), (c) of the Product Liability Directive.
- <sup>54</sup> Article 10 (4) of the Product Liability Directive.
- <sup>55</sup> Cf. Recital 48 of the Product Liability Directive.
- <sup>56</sup> The predecessor directive capped the maximum liability amount at €85 million and also included a deductible for the injured party of up to €500.
- <sup>57</sup> Full text available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020L1828</u>.
- <sup>58</sup> Article 3 of the Product Liability Directive.