
New directive on liability for defective products

The Official Journal of the European Union of November 18, 2024, publishes the new [EU Directive 2024/2853, of October 23, 2024, on liability for defective products](#), which will derogate and replace [Council Directive 85/374/EEC of July 25, 1985](#).

Legal flash

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Key aspects

- The new directive is aimed at harmonizing the laws of the Member States on the liability of manufacturers for damage caused by defective products, ensuring consumer protection in the internal market.
- It addresses the challenges and opportunities arising from **technological developments**, particularly in relation to **digital products** and **artificial intelligence**, and it imposes **stricter obligations and responsibilities** on the economic operators involved in the production, distribution and supply of related products and services, as well as on online platform suppliers.
- It introduces various developments and significant changes in relation to the concept of product, defect, liable party and compensable damage (for example, psychological damage is now included).
- Member States have until December 9, 2026, to transpose the new directive.



EU Directive 2024/2853, of October 23, 2024, on liability for defective products (“the Directive”) is aimed at harmonizing the Member States’ regulations, improving consumer protection and adapting to the new challenges and opportunities arising from the new technologies, particularly in relation to digital products and artificial intelligence.

It also implies increased obligations and liability for economic operators involved in the production, distribution and supply of products and related services, as well as for online platforms providers, who will have to adopt the measures required to ensure the safety of the products and services they offer and make available the relevant evidence in the event of damage claims.

The Member States have until December 9, 2026, to transpose the new Directive, at which time they must regulate certain aspects such as the calculation of compensation or the applicable procedural rules.

The main innovations and changes introduced by the new Directive, as well as their practical implications for companies, are highlighted below.

Scope of application

The new Directive extends the material scope of liability for defective products by expressly including the following as products:

- **Software**, understood as any operative system, IT program, application or artificial intelligence system. However, it is excluded open source software developed or supplied outside of a commercial activity, as well as information that is not a product, such as the content of digital files or the mere source code of the software.
- **Digital manufacturing files**, understood as digital versions or models of a movable good, which contain the functional information necessary to produce a tangible item through the automated control of machinery or tools, such as drills, lathes, mills or 3D printers.
- **Related digital services**, understood as digital services that are integrated into, or interconnected with a product in such a way that their absence would prevent the product from performing one or more of its functions. These services are considered components of the product in which they are integrated or with which they are interconnected when they are under the control of the manufacturer of that product. Examples of related services include the provision of traffic data in navigation systems or certain health monitoring services.
- **Intangible products**, including raw materials, such as gas, water and electricity.



The new Directive maintains the temporary scope of application of liability for defective products, establishing that it applies to products placed on the market or, where applicable, put into service, after December 9, 2026. It also provides transitory provisions to ensure the continuity of liability under the regime of the former 1985 Directive for damage caused by products placed on the market or put into service before that date.

Concept of defectiveness

The new Directive maintains the concept of defectiveness from the 1985 Directive, defining it as the lack of safety that a person is entitled to expect or that is required under EU or national law. However, it introduces additional or clarifying criteria to assess the defectiveness of a product, considering certain circumstances:

- > The effect on the safety of the product of any ability to continue to **learn or acquire new features** after being placed on the market or put into service, as may be the case with software or artificial intelligence systems.
- > The effect on the safety of the product of other products that can be expected to **be used in conjunction with the product**, including by means of interconnection, as may be the case with intelligent products;
- > When the product **has left the manufacturer's control**, considering that, in the digital era, many products remain under the manufacturer's control after being placed on the market or put into service, such as the provision of updates or improvements to software or related services.
- > The cybersecurity **vulnerability of the product**, understood as the lack of compliance with the security requirements relevant to cybersecurity or exposure to cyberattack risks that could affect the security of the product.
- > **Relevant interventions relating to product safety** by **competent authorities or economic operator**, such as a product recall or the provision of updates or improvements to software or to related services.
- > The **lack of means to log information about the operation of the product** as required under EU or national law.

Economic operators liable for defective products

As a new development, in addition to the classic economic operators liable for defective products (manufacturers, importers, authorized representatives and distributors), the new Directive extends the subjective scope liability for damaged caused by defective



products, by expressly including the following as economic operators liable for defective products:

- > The **manufacturer of a defective component** that caused that product to be defective.
- > **The provider of a related service**, understood as the provider of a digital service that is integrated into, or interconnected with a product in such a way that its absence would prevent the product from performing one or more of its functions.
- > The **provider of an online platform**, understood as providers of online intermediary services that allow consumers to conclude distance contracts with traders, as can happen in the case of ecommerce platforms.
- > Operators who **substantially modify a product**, understood as the entities that modify the product after it has been placed on the market or put into service, in a way that changes the product's original performance, purpose or type, without that change having been foreseen in the manufacturer's initial risk assessment, and who changes the nature of the hazard, creates a new hazard or increases the level of risk.
- > In the case of **manufacturers of a product or a component established outside the Union**, and under certain circumstances, the following entities may be considered economic operators liable for defective products: (i) the importer; (ii) its authorized representative; (iii) the fulfillment service provider; and (iv) the distributor.

Liability regime

Although the new Directive maintains the no-fault liability regime for producers for damages cause by defective products— establishing that producers must be liable without the need for the injured person having to prove their fault or negligence—amendments are introduced in relation to the following aspects:

- > **Concept of damage.** The concept of damage is extended to include the destruction or corruption of data that is not not used for professional purposes, such as digital files deleted from a hard drive, as well as the costs of recovering or restoring that data. It also clarifies that the concept of personal injury includes medically recognized and certified damage to psychological health that affects the victim's general state of health and could require therapy or medical treatment.
- > **Grounds for exemption.** The same grounds for exemption as in the 1985 Directive apply, with a few clarifications and exceptions. Manufacturers, importers and distributors can be exonerated from liability if they prove that: (i) they did not



introduce the product on the market, put it into service, or make it available on the market; (ii) it is probable that the defectiveness did not exist when they placed the product on the market, put it into service or made it available on the market; or that the defectiveness came into being after that moment; (iii) the defectiveness is due to compliance of the product with legal requirements; (iv) the state of scientific and technical knowledge was not such that the defectiveness could be discovered; and (v) defectiveness is attributable to the design of the product or to the instructions given by the manufacturer of the product into which a component was integrated.

- > **Rebuttable presumptions.** Several presumptions are introduced to alleviate the injured person's evidential difficulties, without inverting the burden of proof. The defectiveness of a product is presumed when: (i) the defendant fails to comply with the obligation to disclose relevant evidence that is at the defendant's disposal; (ii) the claimant demonstrates that the product does not comply with mandatory product safety requirements laid down in EU or national law; or (iii) the claimant demonstrates that the damage was caused by an obvious malfunction of the product during reasonably foreseeable use or under ordinary circumstances. Also, the causal link between the defectiveness of the product and the damage is presumed where the damage caused is of a kind typically consistent with the defect in question. The defectiveness of the product or the causal link between its defectiveness and the damage, or both, is also presumed where, despite the disclosure of evidence, the claimant (i) faces excessive difficulties, particularly due to technical or scientific complexity, in proving the defectiveness of the product or the causal link between its defectiveness and the damage; and (ii) demonstrates that it is likely that the product is defective or that there is a causal link between the defectiveness of the product and the damage.
- > **Limitation period.** The three-year limitation period for bringing proceedings to claim compensation for damage caused by defective products is maintained, , which will be calculated from the day on which the injured person became aware, or should reasonably have become aware of the damage, the defective nature and the identity of the relevant economic operator. National law regulating the suspension or interruption of the limitation period will not be affected.
- > **Expiry.** The ten-year expiry period for the injured person to claim compensation for damage caused by defective products is maintained; which is calculated from the date on which the defective product that caused the damage was placed on the market or put into service, unless that injured person has started proceedings against an economic operator before that expiry period. However, the Directive establishes the exception to this time period, stipulating that where an injured person has not been able to start proceedings within the 10 years due to the latency of a personal injury, the injured person will no longer be entitled to compensation under this Directive on the expiry of a period of 25 years from when the defective product causing the damage was put on the market or put into service, unless that injured person has started proceedings against an economic operator before that period.



- > **Possibility of derogation from development risk defense.** Member States continue to have power to maintain in their legal systems existing measures, or introduce new measures, under which economic operators are liable even if they prove that the objective state of scientific and technical knowledge did not permit the defectiveness to be discovered, provided certain requirements of proportionality, justification and notification are met. However, certain requirements are added for introducing or amending those measures, such as: (i) they must be justified by public interest objectives, (ii) they must be limited to specific categories of products, (iii) they must meet the requirements of proportionality and suitability, and (iv) they must be subject to approval by the Commission.
- > **Right of recourse.** In the event that several economic operators are held liable for the same damage, an economic operator that has compensated the injured person will be entitled to pursue remedies against other economic operators liable, in accordance with national law.

Practical implications for economic operators

Of the practical implications for companies under the new Directive, we highlight the following:

- > They must review and adapt their contracts, general conditions, privacy policies, labels, and the instructions and warnings relating to the products and services they offer, to ensure that they meet the safety and information requirements under the new Directive.
- > They must implement preventive, detection and corrective measures for defects in their products and services, as well as update and improve measures, particularly in the case of digital and artificial intelligence products and services that can evolve or learn after being introduced on the market or put into service.
- > They must have systems for registering, preserving and managing the information and data relating to the functioning, safety and traceability of the products and services they offer, as well as the means to present that information and data in an accessible and comprehensible way when they are requested or ordered by a national court in relation to a claim over damage caused by defective products.
- > They must have adequate insurance coverage to meet possible claims over damage caused by defective products, considering that the new Directive does not establish a financial limit on the manufacturer's liability, unless the Member States opt to establish one, and it extends the type and amount of the compensable



damages, as well as the rebuttable presumptions facilitating the injured person's evidence.

For additional information, please contact our [*Knowledge and Innovation Group*](#) lawyers or your regular contact person at Cuatrecasas.

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