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Committee on the Internal Market and Consumer Protection
Committee on Legal Affairs

31.1.2024

PROVISIONAL AGREEMENT RESULTING FROM INTERINSTITUTIONAL NEGOTIATIONS

Subject: **Proposal for a directive of the European Parliament and of the Council on Liability for defective products**
(COM(2022)0495 – C9-0322/2022 – 2022/0302(COD))

The interinstitutional negotiations on the aforementioned proposal for a directive have led to a compromise. In accordance with Rule 74(4) of the Rules of Procedure, the provisional agreement, reproduced below, is submitted as a whole to the Committee on the Internal Market and Consumer Protection
Committee on Legal Affairs for decision by way of a single vote.

2022/0302 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on liability for defective products

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure,

[1] OJ C […], […], p. […].

Whereas:

(1) ***In order to improve the proper functioning of the internal market, it is necessary to ensure that competition is not distorted and the movement of goods is not obstructed.*** Council Directive 85/374/EEC[2] lays down common rules on liability for defective products with the aim of removing divergences between the legal systems of Member States that may distort competition and affect the movement of goods within the internal market ▌***. Greater harmonisation of the common rules on liability for defective products laid down in that Directive should further contribute to the achievement of these objectives, while entailing an increased*** degree of protection of ▌***consumers' and other natural persons'*** health or property***.*** ▌

(2) Liability without fault on the part of the relevant economic operator remains the sole means of adequately solving the problem of a fair apportionment of the risks inherent in modern technological production.

(3) Directive 85/374/EEC ***has been an effective and important instrument, but*** needs to be revised in light of developments related to new technologies, including artificial intelligence (AI), new circular economy business models and new global supply chains, which have led to ▌***inconsistencies*** and legal uncertainty, in particular as regards the meaning of the term 'product'. Experience gained from applying Directive 85/374/EEC has also shown that injured persons face difficulties obtaining compensation due to restrictions on making compensation claims and due to challenges in gathering evidence to prove liability, especially in light of increasing technical and scientific complexity. This includes claims for damages related to new technologies ▌. The revision will therefore encourage the roll-out and uptake of such new technologies, including AI, while ensuring that claimants can enjoy the same level of protection irrespective of the technology involved***, and that all businesses benefit from more legal certainty and a level playing field***.

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[2] ***[1]*** 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 (OJ L 210, 7.8.1985, p. 29).

(4) A revision of Directive 85/374/EEC is also needed in order to ensure coherence and consistency with product safety and market surveillance legislation at Union and national level. In addition, there is a need to clarify basic notions and concepts to ensure coherence and legal certainty***, a level playing field in the internal market*** and to reflect recent case law of the Court of Justice of the European Union.

(5) Considering the extensive nature of the amendments that would be required and in order to ensure clarity and legal certainty, Directive 85/374/EEC should be repealed and replaced with a new Directive.

(6) In order to ensure ***that*** the Union's product liability regime is comprehensive, no-fault liability for defective products should apply to all movables***, including software***, including when they are integrated into other movables or installed in immovables.

(7) Liability for defective products should not apply to damage arising from nuclear accidents, in so far as liability for such damage is covered by international conventions ratified by Member States.

(8) In order to create a genuine internal market with a high and uniform level of ▌ protection ***of consumers and other natural persons***, and to reflect the case law of the Court of Justice, Member States should not ▌ , in respect of matters within the scope of this Directive, maintain or introduce more, or less, stringent provisions than those laid down in this Directive.

(9) Under the legal systems of Member States an injured person may have a claim for damages on the basis of contractual liability or on grounds of non-contractual liability that do not concern the ***manufacturer's liability for*** defectiveness of a product ▌ ***as established in this Directive. This concerns for example*** liability ▌ ***based on warranty or on fault, or strict liability of operators for damages caused by the properties of an organism, resulting from genetic engineering***. Such provisions, which also serve to attain***,*** inter alia***,*** the objective of effective protection of consumers ***and other natural persons***, should remain unaffected by this Directive.

(10) In certain Member States, injured persons may be entitled to make claims for damages caused by pharmaceutical products under a special national liability system, with the result that effective protection of ▌ ***natural persons*** in the pharmaceutical sector is already attained. The right to make such claims should remain unaffected by this Directive. ***Furthermore, amendments to such special liability systems should not be precluded as long as they do not undermine the effectiveness of the system of liability provided for in this Directive or its objectives.***

(10a) Compensation schemes outside the context of liability regimes, such as national health systems, social security schemes or insurance schemes, fall outside the scope of this Directive and should therefore not be precluded. For example, some Member States have in place schemes to provide compensation in respect of pharmaceutical products that cause harm but are, however, not defective.

(11) Decision No 768/2008/EC[3] of the European Parliament and of the Council lays down common principles and reference provisions intended to apply across sectoral product legislation. In order to ensure consistency with such legislation, it is appropriate to align certain provisions of this Directive, in particular the definitions, to that Decision.

(12) Products in the digital age can be tangible or intangible. Software, such as operating systems, firmware, computer programs, applications or AI systems, is increasingly common on the market and plays an increasingly important role for product safety. Software is capable of being placed on the market as a standalone product and may subsequently be integrated into other products as a component, and is capable of causing damage through its execution. In the interest of legal certainty it should therefore be clarified that software is a product for the purposes of applying no-fault liability, irrespective of the mode of its supply or usage, and therefore irrespective of whether the software is stored on a device ▌***,*** accessed through ***a communication network or*** cloud technologies ▌***, or supplied through a software-as-a-service model.*** However, ***information*** is not to be considered ▌a product***, and therefore product liability rules should not apply to the content of digital files, such as media files or ebooks or the mere source code of software*** ▌. The developer or producer of software, including AI system providers within the meaning of [Regulation (EU) …/… (AI Act)], should be treated as a manufacturer.

[3] Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products.

(13) ***Free and open-source software, where the source code is openly shared and users can freely access, use, modify and redistribute the software or modified versions thereof, can contribute to research and innovation on the market. Such software is subject to licences that allow anyone the freedom to run, copy, distribute, study, change and improve the software.*** In order not to hamper innovation or research, this Directive should not apply to free and open-source software developed or supplied outside the course of a commercial activity***, since products so developed or supplied are by definition not placed on the market. Developing or contributing to such software should not be understood as making it available on the market. Providing such*** ▌ software ***on open repositories should not be considered as making it available on the market, unless this occurs in the course of a commercial activity. In principle, the supply of free and open-source software by non-profit organisations should not be considered as taking place in a business-related context, unless the supply occurs in the course of a commercial activity*** ▌ . However**,** where software is supplied in exchange for a price or personal data is used other than exclusively for improving the security, compatibility or interoperability of the software, and is therefore supplied in the course of a commercial activity, the Directive should apply.

(13a) If free and open-source software supplied outside the course of a commercial activity is subsequently integrated by a manufacturer as a component into a product in the course of a commercial activity and that is therefore placed on the market, it would be possible to hold that manufacturer liable for damage caused by the defectiveness of such software, while not the manufacturer of the software itself because they would have not fulfilled the conditions of placing a product or component on the market.

(14) ***Whereas digital files as such are not products under this Directive,*** digital manufacturing files, which contain the functional information necessary to produce a tangible item by enabling the automated control of machinery or tools, such as drills, lathes, mills and 3D printers, should be considered as products, in order to ensure ▌***the*** protection ***of natural persons*** in cases where such files are defective. For ***example, a defective computer-assisted-design (CAD) file used to create a 3D-printed good that causes harm would give rise to liability under this Directive, when they are supplied or developed in the course of a commercial activity. For*** the avoidance of doubt, it should also be clarified that ▌***raw materials, such as gas and water, and electricity are products***.

(15) It is becoming increasingly common for digital services to be integrated in or inter-connected with a product in such a way that the absence of the service would prevent the product from performing one of its functions ▌. While this Directive should not apply to services as such, it is necessary to extend no-fault liability to such digital services as they determine the safety of the product just as much as physical or digital components. Such related services should be considered as components of the product to which they are inter-connected, when they are within the control of the manufacturer of that product ▌***. Examples of such related services include the continuous supply of traffic data in a navigation system, a health monitoring service that relies on sensors of a physical product to track the user's physical activity or health metrics, a temperature control service that monitors and regulates the temperature of a smart fridge, or a voice assistant service, which allows control of one or more products by using voice commands. Internet access services should not be treated as related services, since they cannot be considered as part of the product within*** the manufacturer***'s control and it would be unreasonable to make manufacturers liable for harm caused by shortcomings in such services. Nevertheless, a product that relies on such services and that fails to maintain safety in the event of a loss of connectivity could be found to be defective under this Directive***.▌

(15a) Related services and other components, including software updates and upgrades, should be considered to be within the manufacturer's control where they are integrated, inter-connected or supplied by the manufacturer itself or where the manufacturer authorises or consents to their supply by a third party, for example where the manufacturer of a smart home appliance consents to the provision by a third party of software updates for its appliance or where a manufacturer presents a related service or component as part of the product even though it is supplied by a third party. A manufacturer should not be considered to have consented to integration or inter-connection merely by providing for the technical possibility to integrate or inter-connect or by recommending certain brands or by not prohibiting potential related services or components.

(15b) In addition, once a product has been placed on the market, it should be considered to be within the manufacturer's control in so far as the manufacturer retains the technical ability to supply software updates or upgrades itself or via a third party.

(16) In recognition of the growing relevance and value of intangible assets, the ▌ ***destruction*** or corruption of data, such as ▌ ***digital files*** deleted from a hard drive, should also be compensated, including the cost of recovering or restoring the data. As a result, the protection of ▌ ***natural persons*** requires compensation for material losses resulting not only from death or personal injury, such as funeral or medical expenses or lost income, and from damage to property, but also for ▌ ***destruction*** or corruption of data. Nevertheless, ***destruction or corruption of data is distinct from data leaks or breaches of data protection rules, and*** compensation for infringements of Regulation (EU) 2016/679 of the European Parliament and of the Council[4], Directive 2002/58/EC of the European Parliament and of the Council[5], Directive (EU) 2016/680 of the European Parliament and of the Council[6] and Regulation (EU) 2018/1725 of the European Parliament and of the Council[7] is not affected by this Directive. ***Destruction or corruption of data does not automatically result in a material loss, if the victim is able to retrieve the data at no cost, such as when a back-up of the data exists or the data can be downloaded again, or an economic operator restores or recreates temporarily unavailable data, for example in a virtual environment.***

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4 ***[1]*** Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (OJ L 119, 4.5.2016, p. 1).

5 ***[2]*** Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (OJ L 201, 31.7.2002, p. 37).

6 ***[3]*** Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA, OJ L 119, 4.5.2016, p. 89.

7 ***[4]*** Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39.

(17) In the interests of legal certainty, it should be clarified that personal injury includes medically recognised ***and medically certified*** damage to psychological health ***that affects the victim's general state of health, and could require therapy or medical treatment, taking into account, inter alia, the International Classification of Diseases of the World Health Organisation***.

(17a) In order to reflect this Directive's objective of providing compensation only for natural persons, damage to property used exclusively for professional purposes should not be compensated under this Directive. In respect of data, in order to address a potential risk of litigation in an excessive number of cases, the destruction or corruption of data that is used for professional purposes, even if not exclusively so, should not be compensated under this Directive.

(18) While Member States should provide full and proper compensation for all material losses resulting from death, or personal injury, or damage to or destruction of property and ▌***destruction*** or corruption ***of data***, rules on calculating compensation should be laid down by Member States. Furthermore, ***compensation of non-material losses resulting from the damages covered by*** this Directive***, such as pain and suffering,*** should ▌***be provided in so far as they are compensable under national law***.

(18a) Types of damage other than those provided for in this Directive, such as pure economic loss, privacy infringements or discrimination, should not by themselves trigger liability under this Directive. However, this Directive should not affect the right to compensation for any damages, including non-material, under other liability regimes.

(19) In order to protect ▌***natural persons***, damage to any property owned by a natural person should be compensated. Since property is increasingly used for both private and professional purposes, it is appropriate to provide for the compensation of damage to such mixed-use property. In light of this Directive's aim to protect ▌***natural persons***, property used exclusively for professional purposes should be excluded from its scope.

(20) This Directive should apply to products placed on the market or, where relevant, put into service in the course of a commercial activity, whether in return for payment or free of charge, for example products supplied in the context of a sponsoring campaign or products manufactured for the provision of a service financed by public funds, since this mode of supply still has an economic or business character. ***The concept of putting into service is relevant for products that are not placed on the market prior to their first use, as can be the case in the field of lifts, machinery or medical devices.***

(20a) In so far as national law provides, the right to compensation for injured persons should apply both to direct victims, who suffer damage directly caused by a defective product, and to indirect victims, who suffer damage as a result of the direct victim's damage.

(20b) Taking into account the increased complexity of products, of business models and of supply chains, and considering that the aim of this Directive is to ensure that consumers can easily exercise their right to get compensation in case of damage caused by defective products, Member States should ensure that competent consumer protection authorities or bodies provide all relevant information to affected consumers to enable them to effectively exercise their right to compensation in accordance with this Directive. In doing so, Member States should have regard to existing obligations for cooperation between national authorities responsible for enforcing consumer protection laws, in particular those under Regulation (EU) 2017/2394 of the European Parliament and of the Council [full ref. to be added in fn]. National consumer protection authorities or bodies should regularly exchange relevant information they become aware of and closely cooperate with market surveillance authorities. Member States can also encourage the competent consumer protection authorities or bodies to provide information to consumers to better enable them to effectively exercise their right to compensation in accordance with the directive.

(21) This Directive should not affect the various means of seeking redress at national level, whether through court proceedings, non-court solutions, alternative dispute resolution or representative actions under Directive (EU) 2020/1828[8] of the European Parliament and of the Council or under national collective redress schemes.

(22) In order to protect the health and property of ▌ ***natural persons***, the defectiveness of a product should be determined by reference not to its fitness for use but to the lack of the safety that ***that a person*** ▌ is entitled to expect ***or that is required under Union or national law***. The assessment of defectiveness should involve an objective analysis ***of the safety that the public at large is entitled to expect,*** and not refer to the safety that any particular person is entitled to expect. The safety that the public at large is entitled to expect should be assessed by taking into account, inter alia, the intended purpose, ***reasonably foreseeable use, the presentation,*** the objective characteristics and the properties of the product in question***, including its expected lifespan,*** as well as the specific requirements of the group of users for whom the product is intended. Some products, such as life-sustaining medical devices, entail an especially high risk of damage to people and therefore give rise to particularly high safety expectations. In order to take such expectations into account, it should be possible for a court to find a product defective without establishing its actual defectiveness, where it belongs to the same production series as a product already proven to be defective.

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[8] Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC (OJ L 409, 4.12.2020, p. 1).

(22a) The assessment of defectiveness should take into account the product's presentation. However, warnings or other information provided with a product cannot by themselves make an otherwise defective product safe, since defectiveness is determined only by reference to the safety that the public at large is entitled to expect. Therefore, liability under this Directive cannot be circumvented simply by listing all conceivable side effects of a product. When determining the defectiveness of a product, its reasonably foreseeable use should also encompass misuse that is not unreasonable under the circumstances, such as the foreseeable behaviour of a user of machinery resulting from lack of concentration or the foreseeable behaviour of certain user groups such as children.

(23) In order to reflect the increasing prevalence of inter-connected products, the assessment of a product's safety should also take into account the ***reasonably foreseeable*** effects of other products on the product in question***, for example within a smart home system***. The effect on a product's safety of its ability to learn ***or acquire new features*** after ▌ ***it is placed on the market or put into service*** should also be taken into account, to reflect the legitimate expectation that a product's software and underlying algorithms are designed in such a way as to prevent hazardous product behaviour. ***As such, a manufacturer that designs a product with the ability to develop unexpected behaviour remains responsible for behaviour that causes harm.*** In order to reflect that in the digital age many products remain within the manufacturer's control beyond the moment at which they are placed on the market, the moment in time at which a product leaves the manufacturer's control should also be taken into account in the assessment of a product's safety. A product can also be found to be defective on account of its cybersecurity vulnerability***, for example where the product does not fulfil safety-relevant cybersecurity requirements***.

(23a) In order to reflect the nature of products whose very purpose is to prevent damage, such as a warning mechanism like a smoke alarm, it should be clarified that the assessment of such a product's safety should also take into account its failure to fulfil that purpose.

(24) In order to reflect the relevance of product safety and market surveillance legislation for determining the level of safety that ▌ ***a person*** is entitled to expect, it should be clarified that ***relevant product*** safety requirements, including safety-relevant cybersecurity requirements, and interventions by ▌ ***competent*** authorities, such as issuing product recalls, or by economic operators themselves, should also be taken into account in that assessment. Such interventions should, however, not of themselves create a presumption of defectiveness.

(25) In the interests of consumer choice and in order to encourage innovation, ***research and easy access to new technologies,*** the existence, or subsequent placing, on the market of a better product should not in itself lead to the conclusion that a product is defective. Equally, the supply of updates or upgrades to a product should not in itself lead to the conclusion that a previous version of the product is defective.

(26) The protection of ▌ ***natural persons*** requires that any manufacturer involved in the production process can be made liable, in so far as their product or a component supplied by them is defective. ***This includes any person who presents themselves as the manufacturer by affixing, or authorising a third party to affix, their name, trademark or other distinguishing feature, since by doing so they give the impression that they are involved in the production process or assume the responsibility for it.*** Where a manufacturer integrates a defective component from another manufacturer into a product, an injured person should be able to seek compensation for the same damage from either the manufacturer of the product or from the manufacturer of the component. ***Where a component is integrated into a product outside of the control of the product manufacturer, an injured person should be able to seek compensation from the component manufacturer in so far as the component itself is a product under this Directive.***

(27) In order to ensure that injured persons have an enforceable claim for compensation where a manufacturer is established outside the Union, it should be possible to hold the importer of the product and the authorised representative of the manufacturer***, appointed for the purpose of specified tasks under Union legislation, for example product safety and market surveillance legislation,*** liable. Practical experience of market surveillance has shown that supply chains sometimes involve economic operators whose novel form means that they do not fit easily into the traditional supply chains under the existing legal framework. Such is the case, in particular, with fulfilment service providers, which perform many of the same functions as importers but which might not always correspond to the traditional definition of importer in Union law. ▌***Fulfilment service providers play an increasingly significant role*** as economic operators ***enabling and facilitating access to the Union market for products from third countries. This shift in relevance is already reflected*** in the product safety and market surveillance framework, in particular in Regulation (EU) 2019/1020 of the European Parliament and of the Council[9] ***and General Product Safety Regulation. Therefore***, it should be possible to hold them liable, but given the subsidiary nature of that role, they should be liable only where no importer or authorised representative is based in the Union. In the interests of channelling liability in an effective manner towards manufacturers, importers, authorised representatives and fulfilment service providers, it should be possible to hold distributors liable only where they fail to promptly identify a relevant economic operator based in the Union.

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[9] Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).

(28) Online selling has grown consistently and steadily, creating new business models and new actors in the market such as online platforms. ▌Regulation ▌ ***(EU) 2022/2065*** on a Single Market for Digital Services (Digital Services Act) ▌ ***[10]of the European Parliament and of the Council and*** Regulation ▌ ***(EU) 2023/988[11] of the European Parliament and of the Council*** on General Product Safety ▌ regulate, inter alia, the responsibility and accountability of online platforms with regard to illegal content, including products. When online platforms perform the role of manufacturer, importer***, authorised representative, fulfilment service providers*** or distributor in respect of a defective product, they should be liable on the same terms as such economic operators. When online platforms play a mere intermediary role in the sale of products between traders and consumers, they are covered by a conditional liability exemption under ▌ ***Regulation (EU) 2022/2065***. However, ▌ ***Regulation (EU) 2022/2065*** establishes that online platforms that allow consumers to conclude distance contracts with traders are not exempt from liability under consumer protection law where they present the product or otherwise enable the specific transaction in question in a way that would lead an average consumer to believe that the product is provided either by the online platform itself or by a trader acting under its authority or control. In keeping with this principle, when online platforms do so present the product or otherwise enable the specific transaction, it should be possible to hold them liable, in the same way as distributors under this Directive***. Therefore, provisions of this Directive relating to distributors should apply analogously to such online platforms***. That means that they would be liable only when they do so present the product or otherwise enable the specific transaction, and only where the online platform fails to promptly identify a relevant economic operator based in the Union.

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10 ***Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 1).***

11 ***Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L 135, 23.5.2023, p. 1).***

(29) In the transition from a linear to a circular economy, products are designed to be more durable, reusable, reparable and upgradable. The Union is also promoting innovative and sustainable ways of production and consumption that prolong the functionality of products and components, such as remanufacturing, refurbishment and repair.[12] ▌When a product is modified substantially ▌ ***and is thereafter made available on the market or put into service***, it is considered to be a new product***. Where the modification is made outside the control of the original manufacturer,*** ▌ it should be possible to hold the person that made the substantial modification liable as a manufacturer of the modified product, since under relevant Union legislation they are responsible for the product's compliance with safety requirements. Whether a modification is substantial is determined according to criteria set out in relevant Union and national ***product*** safety legislation, ***including Regulation (EU) 2023/988. Where no such criteria are laid down in respect of the product in question,*** ▌ modifications that change the original intended functions or affect the product's compliance with applicable safety requirements ***or change its risk profile should be considered to be substantial modifications. Where a substantial modification is carried out by the original manufacturer, or within its control, and where such a substantial modification makes the product defective, that manufacturer should not be able to avoid liability by arguing that the defect came into being after it originally placed the product on the market or put it into service***. In the interests of a fair apportionment of risks in the circular economy, an economic operator ***other than the original manufacturer*** that makes a substantial modification should be exempted from liability if it can prove that the damage is related to a part of the product not affected by the modification. Economic operators that carry out repairs or other operations that do not involve substantial modifications should not be subject to liability under this Directive.

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[12] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A new Circular Economy Action Plan for a cleaner and more competitive Europe, COM/2020/98 final.

(29a) Where victims fail to obtain compensation because no economic operator is liable under this Directive or because the liable economic operators are insolvent or have ceased to exist, Member States can use existing national sectorial compensation schemes or establish new ones under national law to appropriately compensate injured persons who suffered damage caused by defective products. It is for Member States to decide whether such compensation schemes are funded in whole or in part from public or private revenues.

(29b) Since products also allow for modifications through changes to software, including upgrades, the same principles of substantial modification should apply. Where a substantial modification is made through a software update or upgrade, or due to the continuous learning of an AI system, the substantially modified product should be considered to be made available on the market or put into service at the time the modification is actually made.

(30) In light of the imposition on economic operators of liability irrespective of fault, and with a view to achieving a fair apportionment of risk, the injured person claiming compensation for damage caused by a defective product should bear the burden of proving the damage, the defectiveness of a product and the causal link between the two***, in accordance with the standard of proof applicable under national law***. Injured persons, are, however, often at a significant disadvantage compared to manufacturers in terms of access to, and understanding of, information on how a product was produced and how it operates. This asymmetry of information can undermine the fair apportionment of risk, in particular in cases involving technical or scientific complexity.

(31) It is therefore necessary to facilitate claimants' access to evidence to be used in legal proceedings ▌***. Such evidence should also include documents that have to be created ex novo by the defendant by compiling or classifying the available evidence. In assessing the request for disclosure of evidence it should be ensured*** that such access is limited to that which is necessary and proportionate, ▌***inter alia to avoid non-specific searches for information that are not relevant to the proceedings, and to protect*** confidential information***, such as information falling within the scope of legal professional privilege*** and trade secrets ▌***in accordance with Union and national law, in particular with Directive (EU) 2016/943 of the European Parliament and of the Council[13]. Taking into consideration the complexity of certain types of evidence, for example*** evidence ***relating to digital products, it*** should ▌***be possible for national courts to require such evidence to be presented in an easily accessible and easily understandable manner, subject to conditions***.

(31a) This Directive harmonises rules on disclosure of evidence only in so far as such matters are regulated by it. Matters not regulated include rules on disclosure of evidence (i) regarding pre-trial procedures, (ii) on how specific a request for evidence must be, (iii) in relation to third parties, (iv) in cases of declaratory actions and (v) sanctions against non-compliance with obligations to disclose evidence.

(31b) In light of the fact that defendants might also need access to evidence at the disposal of the claimant in order to counter a claim for compensation under this Directive, defendants should also have the possibility to access evidence. Similarly to a disclosure requested by the claimant, when assessing the request for disclosure of evidence of the defendant it should be ensured that such access is limited to that which is necessary and proportionate, inter alia to avoid non-specific searches for information that are not relevant to the proceedings, and to protect confidential information.

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[13] Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).

(32) In respect of trade secrets within the meaning of Directive (EU) 2016/943 of the European Parliament and of the Council[14], national courts should be empowered to take specific measures to ensure the confidentiality of trade secrets during and after the proceedings, while achieving a fair and proportionate balance between the interest of the trade-secret holder to secrecy and the interest of the injured person. This should include at least measures to restrict access to documents containing trade secrets or alleged trade secrets and access to hearings to a limited number of people, or allowing access to redacted documents or transcripts of hearings. When deciding on such measures, national courts should take into account: (i) the need to ensure the right to an effective remedy and to a fair trial; (ii) the legitimate interests of the parties and, where appropriate, of third parties; and (iii) any potential harm for either of the parties, and, where appropriate, for third parties, resulting from the granting or rejection of such measures.

[14] Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).

(33) It is also necessary to alleviate the claimant's burden of proof provided that certain conditions are fulfilled. Rebuttable presumptions of fact are a common mechanism for alleviating a claimant's evidential difficulties, and allow a court to base the existence of defectiveness or causal link on the presence of another fact that has been proven, while preserving the rights of the defendant. In order to provide an incentive to comply with the obligation to disclose information, national courts should presume the defectiveness of a product where a defendant fails to comply with such an obligation. Many ▌ mandatory safety requirements have been adopted in order to protect consumers and ▌ ***natural persons*** from the risk of harm***, including under Regulation (EU) 2023/988***. In order to reinforce the close relationship between product safety rules and liability rules, non-compliance with such requirements should also result in a presumption of defectiveness. This includes cases in which a product is not equipped with the means to log information about the operation of the product as required under Union or national law. The same should apply in the case of obvious malfunction, such as a glass bottle that explodes in the course of ▌ ***reasonably foreseeable*** use, since it is unnecessarily burdensome to require a claimant to prove defectiveness when the circumstances are such that its existence is undisputed. ***Reasonably foreseeable use covers the use for which a product is intended in accordance with the information provided by the manufacturer or economic operator placing it on the market, the ordinary use as determined by the design and construction of the product, and the conditions of use which can be reasonably foreseen, if such use could result from lawful and readily predictable human behaviour.***

(33a) Similarly, where it has been established that the product is defective and the kind of damage that occurred is, based primarily on other similar cases, typically caused by the defectiveness in question, the claimant should be spared from fully proving the causal link and its existence should be presumed.

(34) National courts should also presume the defectiveness of a product or the causal link between the damage and the defectiveness, or both, where, notwithstanding the defendant's disclosure of information, it would be excessively difficult for the claimant, in ▌ ***particular due to*** the technical or scientific complexity of the case, to prove its defectiveness or the causal link, or both. ***They should do so taking into account all the circumstances of the case.*** In such cases, requiring ***the usual standard of*** proof ***as required under national law, which often calls for a high degree of probability,*** would undermine the effectiveness of the right to compensation. Therefore, given that manufacturers have expert knowledge and are better informed than the injured person, ▌ ***and in order to maintain a fair apportionment of risk while avoiding a reversal of the burden of proof, the claimant*** should be ▌ ***required to prove only that it is likely that, where the claimant's difficulties relate to proving defectiveness, the product was defective, or that, where the claimant's difficulties relate to proving the causal link, its defectiveness is a likely cause of the damage***. Technical or scientific complexity should be determined by national courts on a case-by-case basis, taking into account various factors. Those factors should include the complex nature of the product, such as an innovative medical device; the complex nature of the technology used, such as machine learning; the complex nature of the information and data to be analysed by the claimant; and the complex nature of the causal link, such as a link between a pharmaceutical or food product and the onset of a health condition, or a link that, in order to be proven, would require the claimant to explain the inner workings of an AI system. The assessment of excessive difficulties should also be made by national courts on a case-by-case basis. While a claimant should provide arguments to demonstrate excessive difficulties, proof of such difficulties should not be required. For example, in a claim concerning an AI system, the claimant should, for the court to decide that excessive difficulties exist, neither be required to explain the AI system's specific characteristics nor how these characteristics make it harder to establish the causal link. The defendant should have the possibility to contest ***all elements, including*** the existence of excessive difficulties.

▌

(36) In the interest of a fair apportionment of risk, economic operators should be exempted from liability if they can prove the existence of specific exonerating circumstances. They should not be liable where they can prove that a person other than themselves has caused the product to leave the manufacturing process against their will or that compliance with ▌***legal requirements*** was the very reason for the product's defectiveness.

(37) The moment of placing on the market or putting into service is normally the moment at which a product leaves the control of the manufacturer, while for distributors it is the moment when they make the product available on the market. Therefore manufacturers should be exempted from liability where they prove that it is probable that the defectiveness that caused the damage did not exist when they placed the product on the market or put it into service or that it came into being after that moment. However, since digital technologies allow manufacturers to exercise control beyond the moment of placing the product on the market or putting into service, manufacturers should remain liable for defectiveness that comes into being after that moment as a result of software or related services within their control, be it in the form of upgrades or updates or machine-learning algorithms. Such software or related services should be considered within the manufacturer's control where they are supplied by that manufacturer or where that manufacturer authorises them or otherwise ▌***consents to*** their supply by a third party. ***For example, if a smart television is presented as including a video application, but the user is required to download the application from a third party's website after purchase of the television, the television manufacturer should still be liable, alongside the manufacturer of the video application, for damage caused by any defectiveness of the video application, even though the defectiveness came into being only after the television was placed on the market.***

(38) The possibility for economic operators to avoid liability by proving that a defect came into being after they placed the product on the market or put it into service should also be restricted when a product's defectiveness consists in the lack of software updates or upgrades necessary to address cybersecurity vulnerabilities and maintain the product's safety. Such vulnerabilities can affect the product in such a way that it causes damage within the meaning of this Directive. In recognition of manufacturers' responsibilities under Union law for the safety of products throughout their lifecycle, such as under Regulation (EU) 2017/745 of the European Parliament and of the Council[15], manufacturers should also ***not be exempted from liability*** ▌ for damage caused by their ***defective product when the defectiveness resided in their*** failure to supply software security updates or upgrades that are necessary to address the product's vulnerabilities in response to evolving cybersecurity risks. Such liability should not apply where the supply or installation of such software is beyond the manufacturer's control, for example where the owner of the product does not install an update or upgrade supplied for the purpose of ensuring or maintaining the level of safety of the product. ***This Directive does not itself impose any obligation to provide updates or upgrades to a product.***

(39) In the interests of a fair apportionment of risks, ▌ ***economic operators*** should also be exempted from liability if they prove that the state of scientific and technical knowledge, determined with reference to the most advanced level of objective knowledge accessible and not to the actual knowledge of the ▌ ***economic operator*** in question, while the product was within ▌ ***the manufacturer's*** control was such that the existence of defectiveness could not be discovered.

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[15] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

(40) Situations may arise in which two or more parties are liable for the same damage, in particular where a defective component is integrated into a product that causes damage. In such a case, the injured person should be able to seek compensation both from the manufacturer that integrated the defective component into its product and from the manufacturer of the defective component itself. In order to ensure ▌ ***the*** protection ***of natural persons***, all parties should be held liable jointly and severally in such situations.

(40a) A high degree of innovation is needed particularly in the software sector. With a view to supporting the innovative capacity of micro and small enterprises that produce software, it should be possible for such enterprises to contractually agree with manufacturers that integrate their software into a product, that the latter would not seek recourse from the software manufacturer in the event of a defective software component causing harm. Such contractual agreements, already used in some Member States, should be allowed, since the overall manufacturer is in any event liable for any defectiveness in the product, including in components. However, liability towards an injured person should never be limited or excluded by such a contractual agreement.

(41) Situations may arise in which the acts and omissions of persons other than a potentially liable economic operator contribute, in addition to the defectiveness of the product, to the cause of the damage suffered, such as a third party exploiting a cybersecurity vulnerability of a product. In the interests of consumer protection, where a product is defective, for example due to a vulnerability that makes the product less safe than the public at large is entitled to expect, the liability of the economic operator should not be reduced ***or disallowed*** as a result of such acts or omissions ***by a third party***. However, it should be possible to reduce or disallow the economic operator's liability where injured persons themselves have negligently contributed to the cause of ***the damage, for example where the injured person negligently failed to install updates or upgrades provided by the economic operator that would have mitigated or avoided*** the damage.

(42) The objective of ▌***protecting natural persons*** would be undermined if it were possible to limit or exclude an economic operator's liability through contractual provisions. Therefore no contractual derogations should be permitted. For the same reason, it should not be possible for provisions of national law to limit or exclude liability, such as by setting financial ceilings on an economic operator's liability.

(43) Given that products age over time, and that higher safety standards are developed as the state of science and technology progresses, it would not be reasonable to make manufacturers liable for an unlimited period of time for the defectiveness of their products. Therefore, the liability should be subject to a reasonable length of time, that is 10 years following placing on the market, without prejudice to claims pending in legal proceedings. In order to avoid unreasonably denying the possibility of compensation, the ▌***expiry*** period should be ▌***25*** years in cases where the symptoms of a personal injury are, according to medical evidence, slow to emerge.

(44) Since substantially modified products are essentially new products, ▌***a new expiry*** period should ▌***start to run*** after a product has been substantially modified ***and has subsequently been made available on the market or put into service***, for example as a result of remanufacturing ▌***. Updates or upgrades that do not amount to a substantial modification of the product do not affect the expiry period that applies to the original product***.

(44a) The possibility offered to an economic operator to free itself from liability, if it proves that the state of scientific and technical knowledge at the time when the product was placed on the market, put into service or in the period in which the product was within the manufacturer's control was not such as to enable the existence of a defect to be discovered, could be deemed in certain Member States to limit unduly the protection of natural persons. It should therefore be possible for a Member State to introduce new measures, including amending existing ones, extending liability in such situations to specific types of products, if it is deemed necessary, proportionate and justified by public interest objectives, such as those within the meaning of the Treaty on the Functioning of the European Union, namely public policy, public security and public health. To ensure transparency and legal certainty for economic operators operating across the Union, the use of such a derogation from the development risk defence should be notified to the Commission, who should then inform the other Member States. In order to facilitate a coherent approach across Member States and consistency with the objectives of the Directive, the Commission should be able to issue a non-binding opinion on the proposed measure. In order to allow time for such an opinion, the Member State concerned should hold the proposed measure in abeyance for 6 months following its notification to the Commission, unless the Commission issues an opinion earlier. Such opinions should be issued after close cooperation between the Member State concerned and the Commission, taking into account any views of other Member States. In the interest of legal certainty and to facilitate continuity of arrangements under Directive 85/374/EEC, it should also be possible for a Member State to maintain existing derogations from the development risk defence in its legal system.

(45) In order to facilitate ***the*** harmonised interpretation of this Directive by national courts, Member States should be required to publish ***final*** court judgments on product liability ***under this Directive, meaning those judgments that cannot be, or can no longer be, appealed. In order to limit administrative burden, Member States should be required only to publish judgments of national courts of appeal or of the highest instance.***

(45a) To increase the understanding of how this Directive is applied at national level, for the benefit of, inter alia, the public, legal practitioners, academia and Member States, the Commission should set up and maintain an easily accessible and publicly available database containing the relevant judgments, as well as references to relevant judgments delivered by the Court of Justice of the European Union.

(46) The Commission should carry out an evaluation of this Directive. Pursuant to paragraph 22 of the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making[16], that evaluation should be based on the five criteria of efficiency, effectiveness, relevance, coherence and EU ***added*** value ▌ and should provide the basis for impact assessments of possible further measures. For reasons of legal certainty, this Directive should not apply to products placed ▌ on the Union market ***or put into service*** before the date of its transposition. It is necessary to provide for transitional arrangements in order to ensure continued liability under Directive 85/374/EEC for damage ▌ caused by defective products which have been placed on the market or put into service before that date. ***In its evaluation report, the Commission should provide the methodology of the calculation used in its evaluation. The Commission should gather all relevant information in a way that avoids overregulation and administrative burden for Member States and economic operators, using information from all relevant and reliable sources, including Union institutions, bodies, offices and agencies, national competent authorities and internationally recognised bodies and organisations.***

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16 Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016 (OJ L 123, 12.5.2016, p. 1).

(47) Since the objectives of this Directive, namely to ensure the functioning of the internal market, undistorted competition and a high level of ▌ protection ***for natural persons***, cannot be sufficiently achieved by the Member States due to the Union-wide nature of the market in goods but can rather, by reason of the harmonising effect of common rules on liability, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

General provisions

Article 1

Subject matter *and objective*

This Directive lays down common rules on the liability of economic operators for damage suffered by natural persons caused by defective products ***and on compensation for such damage***.

The objective of this Directive is to contribute to the proper functioning of the internal market, while ensuring a high level of protection of consumers and other natural persons.

Article 2

Scope

1. This Directive shall apply to products placed on the market or put into service after [OP, please insert the date: ▌ ***24*** months after entry into force].

1a. This Directive does not apply to free and open-source software that is developed or supplied outside the course of a commercial activity.

2. This Directive shall not apply to damage arising from nuclear accidents in so far as liability for such damage is covered by international conventions ratified by Member States.

3. This Directive shall not affect:

(a) the applicability of Union law on the protection of personal data, in particular Regulation (EU) 2016/679, Directive 2002/58/EC, and Directive (EU) 2016/680;

▌

(c) any rights which an injured person may have under national rules concerning contractual liability or concerning non-contractual liability on grounds other than the defectiveness of a product ***as provided for in this Directive***, including national rules implementing Union law ▌;

(d) any rights which an injured person may have under any special liability system that existed in national law on 30 July 1985.

Article 3

Level of harmonisation

Member States shall not maintain or introduce, in their national law, provisions diverging from those laid down in this Directive, including more, or less, stringent provisions to achieve a different level of ▌***protection for consumers and other natural persons***, unless otherwise provided for in this Directive.

Article 4

Definitions

For the purpose of this Directive, the following definitions shall apply:

(1) 'product' means all movables, even if integrated into ***or inter-connected with*** another movable or into an immovable. 'Product' includes electricity, digital manufacturing files***, raw materials*** and software;

(2) 'digital manufacturing file' means a digital version or a digital template of a movable***, which contains the functional information necessary to produce a tangible item by enabling the automated control of machinery or tools***;

(3) 'component' means any item, whether tangible or intangible, ***raw materials*** or any related service, that is integrated into, or inter-connected with a product ▌;

(4) 'related service' means a digital service that is integrated into, or inter-connected with, a product in such a way that its absence would prevent the product from performing one or more of its functions;

(5) ‘manufacturer’s control’ means that ▌*:*

(a) the manufacturer of a product performs or, with respect to actions of a third party, authorises or consents to:

(i) the integration, inter-connection or supply of a component including software updates or upgrades; or

(ii) the modification of the product, including substantial modifications;

(b) the manufacturer of a product has the ability to supply software updates or upgrades itself or via a third party.

▌

(7) ‘data’ means data as defined in Article 2, point (1), of Regulation (EU) 2022/868 of the European Parliament and of the Council[17];

[17] Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) (OJ L 152, 3.6.2022, p. 1).

(7a) 'making available on the market' means any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(8) 'placing on the market' means the first making available of a product on the Union market;

▌

(10) 'putting into service' means the first use of a product in the Union in the course of a commercial activity, whether in return for payment or free of charge, in circumstances in which the product has not been placed on the market prior to its first use;

(11) 'manufacturer' means any natural or legal person who ▌***:***

(a) develops, manufactures or produces a product; or

(b) has a product designed or manufactured, or who, by putting its name, trademark or other distinguishing features on that product, presents itself as its manufacturer; or

(c) develops, manufactures or produces a product for its own use;

(12) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks;

(13) ‘importer’ means any natural or legal person ▌ who places a product from a third country on the Union market;

(14) ‘fulfilment service provider’ means any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching of a product, without having ownership of the product, with the exception of postal services as defined in Article 2, point (1), of Directive 97/67/EC of the European Parliament and of the Council[18], of parcel delivery services as defined in Article 2, point (2), of Regulation (EU) 2018/644 of the European Parliament and of the Council[19], and of any other postal services or freight transport services;

(15) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

(16) ‘economic operator’ means the manufacturer of a product or component, the provider of a related service, the authorised representative, the importer, the fulfilment service provider or the distributor;

(17) ‘online platform’ means online platform as defined in Article 2, point (h), of Regulation (EU)…/… of the European Parliament and of the Council on a Single Market for Digital Services (Digital Services Act)[20].

(17a) ‘trade secret’ means a trade secret as defined in Article 2, point (1), of Directive (EU) 2016/943;

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18 Directive 97/67/EC of the European Parliament and of the Council of 15 December 1997 on common rules for the development of the internal market of Community postal services and the improvement of quality of service (OJ L 15, 21.1.1998, p. 14).

19 Regulation (EU) 2018/644 of the European Parliament and of the Council of 18 April 2018 on cross-border parcel delivery services (OJ L 112, 2.5.2018, p. 19).

20 +OP: Please insert in the text the number of the Directive contained in document PE-CONS 30/22 (2020/0361(COD)) and insert the number, date, title and OJ reference of that Directive in the footnote.

(17b) 'substantial modification' means a modification of a product after it has been placed on the market or put into service:

(a) that is considered substantial under relevant Union or national rules on product safety; or

(b) where relevant Union or national rules lay down no threshold on what is to be considered substantial modification, that:

(i) changes the product's original performance, purpose or type, without this being foreseen in the manufacturer's initial risk assessment; and

(ii) changes the nature of the hazard, creates a new hazard or increases the level of risk;

CHAPTER II

Specific provisions on liability for defective products

Article 5

Right to compensation

1. Member States shall ensure that any natural person who suffers damage caused by a defective product ('the injured person') is entitled to compensation in accordance with the provisions set out in this Directive.

2. Member States shall ensure that claims for compensation pursuant to paragraph 1 may also be brought by:

(a) a person that succeeded, or was subrogated, to the right of the injured person by virtue of ***Union or national*** law or contract; or

(b) a person acting on behalf of one or more injured persons ▌***by virtue of*** Union or national law.

Article 5a

Damage

1. The right to compensation under Article 5 shall apply in respect of only the following types of damage:

(a) death or personal injury, including medically recognised damage to psychological health;

(b) damage to, or destruction of, any property, except:

(i) the defective product itself;

(ii) a product damaged by a defective component that is integrated into, or inter-connected with, a product by the manufacturer of that product or within that manufacturer's control; and

(iii) property used exclusively for professional purposes; and

(c) destruction or corruption of data that is not used for professional purposes

2. The right to compensation shall cover all material losses resulting from the damage referred to in paragraph 1. The right to compensation shall also cover non-material losses resulting from the damage referred to in paragraph 1, in so far as they are compensable under national law.

3. This Article does not affect national law relating to the compensation of damages under other liability regimes.

Article 6

Defectiveness

-1. ***A product shall be considered defective when it does not provide the safety that a person is entitled to expect or that is required under Union or national law.***

1. ▌ ***In assessing the defectiveness of a product, all circumstances shall be taken*** into account, including ▌ :

(a) the presentation ***and the characteristics*** of the product, including ***its labelling, design, technical features, composition, packaging and*** the instructions for ***assembly,*** installation, use and maintenance;

(b) the reasonably foreseeable use ▌ of the product;

(c) the effect on the product of any ability to continue to learn ***or aquire new features*** after ▌ ***it is placed on the market or put into service***;

(d) the ***reasonably foreseeable*** effect on the product of other products that can ▌ be expected to be used together with the product***, including by means of interconnection***;

(e) the moment in time when the product was placed on the market or put into service or, where the manufacturer retains control over the product after that moment, the moment in time when the product left the control of the manufacturer;

(f) ***relevant*** product safety requirements, including safety-relevant cybersecurity requirements;

(g) any ***recall of the product or any other relevant*** intervention by a ▌ ***competent*** authority or by an economic operator referred to in Article 7 relating to product safety;

(h) the specific ▌***needs*** of the ▌***group of users*** for whom the product is intended***;***

(ha) in the case of a product whose very purpose is to prevent damage, any failure of the product to fulfil that purpose.

2. A product shall not be considered defective for the sole reason that a better product, including updates or upgrades to a product, is already or subsequently placed on the market or put into service.

Article 7

Economic operators liable for defective products

-1. Member States shall ensure that the following economic operators are liable for damage pursuant to this Directive:

(a) the manufacturer of the defective product;

(b) the manufacturer of a defective component, where that component has been integrated into, or inter-connected with, the product within the manufacturer's control has caused the product to be defective, and without prejudice to the liability of the manufacturer under point (a); and

(c) in the case of a manufacturer of a product or a component established outside the Union, and without prejudice to its own liability:

(i) the importer of the defective product or component;

(ii) the authorised representative of the manufacturer; and

(iii) where there is no importer established within the Union or authorised representative, the fulfilment service provider.

The liability of the manufacturer under the first subparagraph, point (a) shall also cover any damage caused by a defective component if it was integrated into, or inter-connected with, the product within that manufacturer's control.

▌

4. Any natural or legal person that ***substantially*** modifies a product ***outside the manufacturer's control and thereafter makes it available*** ▌ on the market or ▌ ***puts it*** into service shall be considered a manufacturer of the product for the purposes of paragraph 1 ▌ .

5. Member States shall ensure that**,** where ▌ ***an economic operator*** under paragraph **-**1 ▌ established ▌ ***in*** the Union ▌ cannot be identified, each distributor of the ***defective*** product ▌ ***is*** liable where:

   (a) the ▌ ***injured person*** requests that distributor to identify ▌ ***an*** economic operator ▌ ***as referred to in paragraph -1 and established in the Union, or its own*** distributor ***who supplied it with that*** ▌ product; and

(b) ▌ ***that*** distributor fails to identify ▌ ***an*** economic operator or ▌ ***its own distributor, as referred to in point (a),*** within ▌ ***one*** month of receiving the request ***referred to in point (a)***.

6. Paragraph 5 shall also apply to any provider of an online platform that allows consumers to conclude distance contracts with traders and that is not a**n economic operator** ▌ , provided that the conditions ▌ set out in ▌ ***Article 6(3) of Regulation (EU*)** ▌ ***2022/2065*** are fulfilled.

6a. Where victims fail to obtain compensation because none of the economic operators referred to in paragraphs 1 to 6 can be held liable under this Directive, or because the liable economic operators are insolvent or have ceased to exist, Member States may use existing national sectorial compensation schemes or establish new ones under national law, which should preferably not be funded by public revenues, to appropriately compensate injured persons who suffered damage caused by defective products.

Article 8

Disclosure of evidence

1. Member States shall ensure that ▌ , upon request of an injured person ***who is*** claiming compensation ***in proceedings before a national court*** for damage caused by a defective product ('the claimant') ***and*** who has presented facts and evidence sufficient to support the plausibility of the claim for compensation, ▌ ***the defendant is required*** to disclose relevant evidence that is at its disposal***, subject to the conditions set out in this Article***.

1a. Member States shall ensure that, upon request of a defendant who has presented facts and evidence sufficient to demonstrate its need for evidence for the purposes of countering a claim for compensation, the claimant is required, in accordance with national law, to disclose relevant evidence that is at its disposal

2. Member States shall ensure that ▌ the disclosure of evidence ***pursuant to paragraph 1 and in accordance with national law is limited to what is necessary and proportionate*** ▌ .

3. When determining whether the disclosure ***requested by a party is necessary and*** ▌ proportionate, national courts shall consider the legitimate interests of all parties, including third parties concerned, in particular in relation to the protection of confidential information and trade secrets ▌ .

4. Member States shall ensure that, where a defendant is ▌ ***required*** to disclose information that is a trade secret or an alleged trade secret, national courts are empowered, upon a duly reasoned request of a party or on their own initiative, to take the specific measures necessary to preserve the confidentiality of that information when it is used or referred to in the course of ***and after*** the legal proceedings.

4a. Member States shall ensure that, where a party is required to disclose evidence, national courts are empowered, upon a duly reasoned request of the counterpart or where the national court deems it pertinent and in accordance with national law, to require the evidence to be presented in an easily accessible and easily understandable manner, if such presentation is deemed proportionate by the national court in terms of costs and effort for the required party.

4b. This Article does not affect national rules relating to the pre-trial disclosure of evidence, where such rules exist.

Article 9

Burden of proof

1. Member States shall ensure that a claimant is required to prove the defectiveness of the product, the damage suffered and the causal link between the defectiveness and the damage.

2. The defectiveness of the product shall be presumed, where any of the following conditions are met:

   (a) the defendant has failed to ▌ disclose relevant evidence ▌ pursuant to Article 8(1);

   (b) the claimant ▌ ***demonstrates*** that the product does not comply with mandatory ***product*** safety requirements laid down in Union law or national law that are intended to protect against the risk of the damage ▌ ***suffered by the injured person***; or

   (c) the claimant ▌ ***demonstrates*** that the damage was caused by an obvious malfunction of the product during ▌ ***reasonably foreseeable*** use or under ordinary circumstances.

3. The causal link between the defectiveness of the product and the damage shall be presumed, where it has been established that the product is defective and the damage caused is of a kind typically consistent with the defect in question.

4. ▌ A national court ▌ ***shall presume*** the defectiveness of the product or the causal link between its defectiveness and the damage, or both, ***where, despite the disclosure of evidence in accordance with Article 8 and taking into account all relevant circumstances of the case*** ▌ :

(a) the ▌ ***claimant faces excessive difficulties, in particular due to technical or scientific complexity to be able to prove the defectiveness of the product or the causal link between its defectiveness and*** the damage***, or both***; and

(b) ***the claimant demonstrates that*** it is likely that the product ▌ ***is*** defective or that ▌ ***there is a causal link between the defectiveness and*** the damage, or both.

▌

5. The defendant shall have the right to rebut any of the presumptions referred to in paragraphs 2, 3 and 4.

Article 10

Exemption from liability

1. An economic operator referred to in Article 7 shall not be liable for damage caused by a defective product if that economic operator proves any of the following:

(a) in the case of a manufacturer or importer, that it did not place the product on the market or put it into service;

(b) in the case of a distributor, that it did not make the product available on the market;

(c) that it is probable that the defectiveness that caused the damage did not exist when the product was placed on the market, put into service or, in respect of a distributor, made available on the market, or that this defectiveness came into being after that moment;

(d) that the defectiveness is due to compliance of the product with ▌ ***legal requirements;***

(e) ▌ the objective state of scientific and technical knowledge at the time when the product was placed on the market, put into service or in the period in which the product was within the manufacturer's control was not such that the defectiveness could be discovered;

(f) in the case of a manufacturer of a defective component referred to in Article ▌ ***7(-1), first*** subparagraph***, point (b)***, that the defectiveness of the product is attributable to the design of the product in which the component has been integrated or to the instructions given by the manufacturer of that product to the manufacturer of the component; or

(g) in the case of a person that modifies a product as referred to in Article 7(4), that the defectiveness that caused the damage is related to a part of the product not affected by the modification.

2. By way of derogation from paragraph 1, point (c), an economic operator shall not be exempted from liability, where the defectiveness of the product is due to any of the following, provided that it is within the manufacturer's control:

(a) a related service;

(b) software, including software updates or upgrades; ▌

(c) the lack of software updates or upgrades necessary to maintain safety***; or***

(ca) a substantial modification.

CHAPTER III

General provisions on liability

Article 11

Liability of multiple economic operators

1. ***Without prejudice to national law concerning the right of contribution or recourse,*** Member States shall ensure that where two or more economic operators are liable for the same damage pursuant to this Directive, they can be held liable jointly and severally.

1a. ***A manufacturer that integrates software as a component in a product shall not have a right to recourse against the manufacturer of a defective software component that causes damage, where:***

a) ***the software component manufacturer was, at the time of the placing on the market of the software, a microenterprise or a small enterprise, meaning an enterprise that, when assessed together with all of its partner enterprises and linked enterprises within the meaning of Article 3 of the Annex to Recommendation 2003/361/EC, if any, is a microenterprise as defined in Article 2(3) of that Annex or a small enterprise as defined in Article 2(2) of that Annex; and***

b) ***the manufacturer integrating the software as a component in a product has contractually agreed with the component manufacturer to waive that right.***

Article 12

Reduction of liability

1. ***Without prejudice to national law concerning the right of contribution or recourse,*** Member States shall ensure that the liability of an economic operator is not reduced ***or disallowed*** when the damage is caused both by the defectiveness of a product and by an act or omission of a third party.

2. The liability of an economic operator may be reduced or disallowed when the damage is caused both by the defectiveness of the product and by the fault of the injured person or any person for whom the injured person is responsible.

Article 12a

Right of recourse

Where more than one economic operator is liable for the same damage, the economic operator that has compensated the injured person shall be entitled to pursue remedies against the other economic operators liable under Article 7, in accordance with national law.

Article 13

Exclusion or limitation of liability

Member States shall ensure that the liability of an economic operator pursuant to this Directive is not, in relation to the injured person, limited or excluded by a contractual provision or by national law.

Article 14

Limitation periods

1. Member States shall ensure that a limitation period of ▌***three*** years applies to the initiating of proceedings for claiming compensation for damage falling within the scope of this Directive. The limitation period shall begin to run from the day on which the injured person became aware, or should reasonably have become aware, of all of the following:

(a) the damage;

(b) the defectiveness;

(c) the identity of the relevant economic operator that can be held liable for the damage in accordance with Article 7.

2. The laws of Member States regulating suspension or interruption of the limitation period referred to in ▌***paragraph 1*** shall not be affected by this Directive.

Article 14a

Expiry period

▌***1***. Member States shall ensure that the ▌***injured person is no longer entitled to compensation*** pursuant to this Directive ▌ upon the expiry of a ▌ period of 10 years ▌ , unless ▌***that injured person*** has, in the meantime, initiated proceedings ▌ against an economic operator that can be held liable pursuant to Article 7.

The period shall run from:

(a) the date on which the actual defective product which caused the damage was placed on the market or put into service; or

(b) in the case of substantially modified products , the date the product was made available on the market or put into service subsequent to the substantial modification.

▌ ***2***. By way of exception from paragraph ▌ ***1***, where an injured person has not been able to initiate proceedings within 10 years due to the latency of a personal injury, the ▌ ***injured person shall no longer be entitled to compensation*** pursuant to this Directive ▌ upon the expiry of a ▌ period of ▌ ***25*** years***, unless that injured person has, in the meantime, initiated proceedings against an economic operator that can be held liable pursuant to Article 7***.

CHAPTER IV

Final provisions

Article -15

Derogation from development risk defence

1. Member States may, by way of derogation from Article 10(1), point (e), maintain in their legal systems existing measures to the effect that economic operators are to be liable even if they prove that the state of scientific and technical knowledge at the time when the product was placed on the market, put into service or in the period in which the product was within the manufacturer's control was not such that the defectiveness could be discovered.

Any Member State wishing to maintain measures in accordance with this paragraph shall notify the text of the measure to the Commission no later than [24 months after entry into force]. The Commission shall inform the other Member States thereof.

2. ***Member States may, by way of derogation from Article 10(1), point (e), introduce or amend in their legal systems a measure to the effect that economic operators are to be liable even if they prove that the state of scientific and technical knowledge at the time when the product was placed on the market, put into service or in the period in which the product was within the manufacturer's control was not such that the defectiveness could be discovered.***

3. ***Such a measure as referred to in paragraph 2 shall be:***

   (a) limited to specific categories of products;

   (b) justified by public interest objectives; and

   (c) proportionate in that it is suitable for securing the attainment of the objective pursued and does not go beyond what is necessary to attain that objective.

4. ***Any Member State wishing to introduce or amend a measure as referred to in paragraph 2 shall notify the text of the proposed measure to the Commission and shall provide a justification of how the measure complies with paragraph 3. The Commission shall inform the other Member States thereof.***

5. ***The Commission may, within 6 months, issue an opinion on the text and the justification, taking into account any observations received from other Member States.***

   The Member State concerned shall hold the proposed measure in abeyance for 6 months following its notification to the Commission, unless the Commission issues its opinion earlier.

Article 15

Transparency

1. Member States shall publish, in an easily accessible and electronic format, any final judgment delivered by their national courts ***of appeal or of the highest instance*** in relation to proceedings launched pursuant to this Directive ▌. The publication shall be made ▌ ***in accordance with national law***.

2. The Commission ▌ ***shall*** set up and maintain ▌ ***an easily accessible and*** publicly available database containing the judgments referred to in paragraph 1.

Article 16

Review

The Commission shall by [OP, please insert the date: 6 years after the date of entry into force of this Directive], and every 5 years thereafter, ▌ ***evaluate*** the application of this Directive and submit a report to the European Parliament, to the Council and to the European Economic and Social Committee ***including information about: the cost and benefits of the Directive, comparison with OECD countries and availability of product liability insurance***.

Article 17

Repeal and transitional provision

1. Directive 85/374/EEC is repealed with effect from [OP, please insert the date: ▌ ***24*** months after the date of entry into force of this Directive]. However, it shall continue to apply with regard to products placed on the market or put into service before that date.

2. References to Directive 85/374/EEC shall be construed as references to this Directive and shall be read in accordance with the correlation table set out in the Annex to this Directive.

Article 18

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [OP, please insert the date: ▌***24*** months after entry into force of this Directive]. They shall forthwith communicate to the Commission the text of those provisions.

   When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 19

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the ***Official Journal of the European Union.***

Article 20

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	**For the Council**
The President	**The President**

ANNEX

CORRELATION TABLE

Directive 85/374/EEC	This Directive
Article 1	Article 1
	Article 2(1a)
-	Article 3
Article 2	Article 4, point (1)
-	Article 4, points (2) to (5), and (7) to **(17b)**
Article 3(1) and (2)	Article 4, point (11)
-	Article 5
Article 3(3)	Article 7(5)
-	Article 7(-1)**,** (4), (6) **and (6a)**
-	Article 8
Article 4	Article 9(1)
-	Article 9(2) **to (5)**
Article 5	Article 11(1)
	Article 11(1a)
Article 6	Article 6
Article 7	Article 10
Article 8	Article 12
	Article 12a
Article 9, first paragraph, point (a)	Article **5a**, **paragraph 1,** point (a)
Article 9, first paragraph, point (b)	Article **5a**, **paragraph 1,** point (b)
-	**Article 5a, paragraph 1, point (c)**

□	**Article 5a, paragraph 2**
Article 9, second paragraph	**Article 5a, paragraph 3**
Article 10	Article 14 □
Article 11	Article 14**a**(**1** □)
-	Article 14**a**(□ **2**)
Article 12	Article 13
-	Article 15
Article 13	Article 2(3), points (c) and (d)
-	Article 2(3), point□ (a) ▌
Article 14	Article 2(2)
-	**Article -15(1)**
Article 15(1), point (b)	**Article -15(2)**
Article 15(2) and (3)	**Article -15(3) to (5)**
Article 16	-
Article 17	Article 2(1)
-	Article 16
-	Article 17
Article 18	-
Article 19	Article 18(1)
Article 20	Article 18(2)
Article 21	-
-	Article 19
Article 22	Article 20