

AMENDMENTS 001-117

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

Report

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Liability for defective products

A9-0291/2023

Proposal for a directive (COM(2022)0495 – C9-0322/2022 – 2022/0302(COD))

Amendment 1**Proposal for a directive****Recital 1***Text proposed by the Commission*

(1) Council Directive 85/374/EEC³⁹ 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, and that entail a differing degree of protection of the consumer against damage to health or property caused by such products.

³⁹ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States

Amendment

(1) Council Directive 85/374/EEC³⁹ 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, and that entail a differing degree of protection of the consumer against damage to health or property caused by such products, **and is aimed at providing compensation for such damage.**

³⁹ 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).

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(OJ L 210, 7.8.1985, p. 29).

Amendment 2

Proposal for a directive

Recital 3

Text proposed by the Commission

(3) Directive 85/374/EEC 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, *including AI*. 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.

Amendment

(3) Directive 85/374/EEC *has been an effective and important instrument, but it has emerged that it* 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 *the development of which has* 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 a level playing field with legal certainty, while avoiding disproportionate costs and risks for microenterprises, small-sized businesses and start-ups.*

Amendment 3

Proposal for a directive
Recital 4

Text proposed by the Commission

(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 and to reflect recent case law of the Court of Justice of the European Union.

Amendment

(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, ***a revision is necessary to complement national laws on extra-contractual liability, and to provide for compensation and a high level of protection for persons injured by defective products. Furthermore,*** there is a need to clarify basic notions and concepts to ensure coherence and legal certainty and ***a level playing field in the internal market, and*** to reflect recent case law of the Court of Justice of the European Union.

Amendment 4

Proposal for a directive
Recital 5

Text proposed by the Commission

(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.

Amendment

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

Amendment 5

Proposal for a directive
Recital 6

Text proposed by the Commission

(6) In order to ensure the Union's product liability regime is comprehensive,

Amendment

(6) In order to ensure the Union's product liability regime is comprehensive

no-fault liability for defective products should apply to all movables, including when they are integrated into other movables or installed in immovables.

and easy and effective to apply, no-fault liability for defective products should apply to all movables, including ***software, irrespective of the mode of supply and including*** when they are integrated into other movables or installed in immovables.

Amendment 6

Proposal for a directive Recital 8

Text proposed by the Commission

(8) In order to create a genuine internal market with a high and uniform level of consumer protection, and to reflect the case law of the Court of Justice, Member States should not ***be***, 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.

Amendment

(8) In order to create a genuine internal market with a high and uniform level of consumer protection, 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. ***For matters other than those provided for under this Directive, national procedural rules should apply in so far as they do not undermine the effectiveness and objectives of the system of product liability provided for under this Directive.***

Amendment 7

Proposal for a directive Recital 9

Text proposed by the Commission

(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 defectiveness of a product, for example liability based on warranty or on fault. ***This includes the provisions of the [AI Liability***

Amendment

(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 defectiveness of a product, for example liability based on warranty or on fault. Such provisions, which also serve to attain

Directive .../... of the European Parliament and of the Council], which lays down common rules on the disclosure of information and the burden of proof in the context of fault-based claims for damages caused by an AI system. Such provisions, which also serve to attain inter alia the objective of effective protection of consumers, should remain unaffected by this Directive.

inter alia the objective of effective protection of consumers, should remain unaffected by this Directive.

Amendment 8

Proposal for a directive Recital 10

Text proposed by the Commission

(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 consumers in the pharmaceutical sector is already attained. The right to make such claims should remain unaffected by this Directive.

Amendment

(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 consumers in the pharmaceutical sector is already attained ***in those Member States. When it comes to harm suffered due to pharmaceuticals that are not defective, all Member States cover basic losses through national health systems or social security schemes. To cover further losses, some Member States have created special insurance schemes for pharmaceuticals, under which victims of harm are able to get compensation if, despite being non-defective, the pharmaceutical product nonetheless caused harm, without any need to prove fault or defectiveness.*** The right to make such claims should remain unaffected by this Directive. ***Amendments to those special national liability systems, health systems and social security schemes as well as the possible introduction of insurance schemes should not be precluded. However, such amendments***

should not undermine the effectiveness and objectives of the system of product liability provided for under this Directive.

Amendment 9

Proposal for a directive

Recital 12

Text proposed by the Commission

(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 or accessed through cloud technologies. The source code of software, however, is not to be considered as a product for the purposes of this Directive as this is pure information. The developer or producer of software, including AI system providers within the meaning of [Regulation (EU) .../... (AI Act)], should be treated as a manufacturer.

Amendment

(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 ***or may be provided as one or more services***, and is capable of causing damage through its execution. ***The risk of damage is proportionate to the extent to which software is essential to the functioning of a product into which it is integrated or with which it is interconnected, and in how far it contributes to one or more of the functions of the product, or in how far its absence would prevent the product from performing one or more of its functions. In particular where software that ordinarily and of itself does not pose a significant risk of damage is included in a product with higher safety expectations, the assessment of defectiveness leading to damage should take the original intent of the software producer into account.*** 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 or accessed through ***a communication network or cloud technologies, or supplied through a software as-a-service model.***

The source code of software, however, is not to be considered as a product for the purposes of this Directive as this is pure information. The developer or producer of software, including AI system providers within the meaning of [Regulation (EU) .../... (AI Act)] ***and deployers that make substantial modifications to software,*** should be treated as a manufacturer.

Amendment 10

Proposal for a directive

Recital 12 a (new)

Text proposed by the Commission

Amendment

(12a) Software in its own right, where specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, should qualify as a medical device, while software intended for general purposes, even when used in a healthcare setting, or software intended for lifestyle and well-being purposes should not be considered a medical device. The qualification of software, either as a device or an accessory, should be independent of the software's location or the type of interconnection between the software and a device.

Amendment 11

Proposal for a directive

Recital 12 b (new)

(12b) Individual natural persons who are typically employed in the context of a non-personal professional activity related to the development, manufacturing, production or design of a product and do not exert control over the manufacturing, integration, placing on the market or putting into service of the product should not be considered manufacturers in the meaning of this Directive.

Amendment 12

Proposal for a directive Recital 13

(13) 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***. This is in particular the case for software, including its source code and modified versions, that is openly shared and freely accessible, usable, modifiable and redistributable. 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.

(13) In order not to hamper innovation or research, this Directive should not apply to free and open-source software ***in accordance with the conditions laid down under this Directive***. This is in particular the case for software, including its source code and modified versions, that is openly shared and freely accessible, usable, modifiable and redistributable. ***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 relies on public licences that guarantee the freedom to run, copy, distribute, study, change and improve the software. In order to ensure that innovation and research are not hindered, this Directive should not impact the use of such public licences.*** 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, the Directive should apply.

Amendment 13

Proposal for a directive Recital 13 a (new)

Text proposed by the Commission

Amendment

(13a) A manufacturer should be allowed to decide to integrate free and open-source software as a component of a product or authorise its integration, interconnection or supply by a third party, which should then, in the interest of legal certainty, be considered to be modifications under the manufacturer's control. In such cases, if the product is placed on the market or put into service in the course of a commercial activity, this Directive should apply, meaning that in that case the manufacturer of the product could be held liable for damage arising from a defect in the free and open source software. However, it should not be possible to hold the developer or producer of the free and open-source software liable for such damage unless the software is supplied to the manufacturer of the product for payment or for personal data other than data exclusively for improving the security, compatibility or interoperability of the software.

Amendment 14

Proposal for a directive Recital 14

Text proposed by the Commission

Amendment

(14) Digital manufacturing files, which contain the functional information

(14) 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 consumer protection in cases where such files are defective. For the avoidance of doubt, it should also be clarified that electricity **is a product**.

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 consumer protection in cases where such files are defective. For the avoidance of doubt, it should also be clarified that **raw materials and electricity are products. Products that are digital manufacturing files, which are licensed under free and open-source licenses, should be treated analogously to how free and open-source software products are treated.**

Amendment 15

Proposal for a directive Recital 15

Text proposed by the Commission

(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, for example the continuous supply of traffic data in a navigation system. 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, in the sense that they are supplied by the manufacturer itself or that the manufacturer **recommends** them or otherwise influences their supply by a third party.

Amendment

(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, for example the continuous supply of traffic data in a navigation system. **The relevant functions that should be considered for the purposes of this Directive are those that have been attributed to the product by its manufacturer or the functions that an average person would reasonably expect the product to have in light of the description of the product provided by the manufacturer.** 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, in the sense that they are supplied by the manufacturer itself or that the manufacturer **authorises** them or otherwise influences their supply by a third party.

Amendment 16

Proposal for a directive Recital 15 a (new)

Text proposed by the Commission

Amendment

(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. 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 decides to supply software updates or upgrades, or authorises or consents to the supply thereof by a third party.

Amendment 17

Proposal for a directive Recital 16

Text proposed by the Commission

Amendment

(16) In recognition of the growing relevance and value of intangible assets, ***the loss or*** corruption of data, such as ***content*** deleted from a hard drive, should also be compensated, ***including*** the cost of recovering or restoring the data. As a

(16) In recognition of the growing relevance and value of intangible assets, ***economic loss due to the destruction or irreversible*** corruption of data, such as ***digital files*** deleted from a hard drive, should also be compensated, ***when***

result, the protection of consumers 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 **loss or** corruption of data.

Nevertheless, compensation for infringements of Regulation (EU) 2016/679 of the European Parliament and of the Council⁴¹, Directive 2002/58/EC of the European Parliament and of the Council⁴², Directive (EU) 2016/680 of the European Parliament and of the Council⁴³ and Regulation (EU) 2018/1725 of the European Parliament and of the Council⁴⁴ is not affected by this Directive.

consumers cannot access data in the way they could before the damage and they have to pay a price for recovering and restoring that data. This should include, where relevant, the cost of recovering or restoring the data. As a result, the protection of consumers 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 irreversible** corruption of data. **However, in order to avoid the potential risk of litigation in an excessive number of cases, the destruction or irreversible corruption of data should not be compensated if the economic value of the damage is below EUR 1 000.**

Nevertheless, **destruction or irreversible 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 Council⁴¹, Directive 2002/58/EC of the European Parliament and of the Council⁴², Directive (EU) 2016/680 of the European Parliament and of the Council⁴³ and Regulation (EU) 2018/1725 of the European Parliament and of the Council⁴⁴ is not affected by this Directive. **Destruction or corruption of data does not automatically result in a material loss for the victim if, for example, 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. In line with the principle of contributory negligence, it should be possible to reduce or disallow an economic operator's liability where the persons who have suffered the loss or damage themselves have negligently contributed to the cause of the damage, for example if it can be reasonably expected that certain digital files are**

regularly backed up in a second location.

⁴¹ 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).

⁴² 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).

⁴³ 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.

⁴⁴ 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.

⁴¹ 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).

⁴² 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).

⁴³ 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.

⁴⁴ 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.

Amendment 18

Proposal for a directive Recital 17

Text proposed by the Commission

(17) In the interests of legal certainty, it should be clarified that personal injury includes medically recognised damage to psychological health.

Amendment

(17) In the interests of legal certainty, it should be clarified ***that Member States should provide*** that personal injury includes medically recognised damage to psychological health, ***certified by a court ordered medical expert, including psychologists, and limited to serious adverse effects on the victim's psychological integrity of such gravity or intensity that it affects the victim's general state of health and cannot be resolved without therapy or medical treatment, taking , in particular, the International Classification of Diseases of the World Health Organisation into account.***

Amendment 19

**Proposal for a directive
Recital 18**

Text proposed by the Commission

(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 data loss or corruption***, rules on calculating compensation ***should be laid down by Member States. Furthermore, this Directive should not affect national rules relating to non-material damage.***

Amendment

(18) While Member States should provide full, ***proportionate*** and proper compensation for all material losses resulting from death, or personal injury, or damage to or destruction of property, ***Member States should ensure that their national rules on calculating compensation allow for injured persons to obtain full and proper compensation from the economic operator who is ultimately liable or from any other relevant party.***

Amendment 20

**Proposal for a directive
Recital 19**

Text proposed by the Commission

(19) In order to protect consumers, 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 consumers, property used exclusively for professional purposes should be excluded from its scope.

Amendment

(19) In order to protect consumers, 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 consumers, property used exclusively for professional purposes should be excluded from its scope.

However, several Member States provide for the possibility to extend consumer protection rules to other weaker parties, such as microenterprises as defined in Commission Recommendation 2003/361/EC^{1a}. Member States should therefore be encouraged to compensate damage to property used exclusively for professional purposes by microenterprises.

^{1a} Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

Amendment 21

**Proposal for a directive
Recital 20**

Text proposed by the Commission

(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

Amendment

(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.

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. *Neither the collaborative development of free and open-source software nor making such software available on open repositories should constitute placing on the market or putting into service. A commercial activity within the understanding of making available on the market might, however, be characterised by monetisation or paid software updates, unless that serves only to recover actual costs, or by the use of personal data for reasons other than exclusively for improving the security, compatibility or interoperability of the software. Occasional supplies by charities or hobbyists should not be considered as taking place in a business-related context.*

Amendment 22

Proposal for a directive Recital 20 a (new)

Text proposed by the Commission

Amendment

(20a) Products which are not intended to be placed on the market or to be put into service, due to them, for example, being intended only for personal use or for use only in a controlled and confined setting, but which appear on the market or are put into service after, for example, being stolen, should be excluded from the scope of this Directive.

Amendment 23

Proposal for a directive Recital 20 b (new)

(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 national consumer protection authorities and bodies provide all relevant information and tailored guidance to affected consumers to enable them to effectively exercise their right to compensation in accordance with this Directive. National consumer protection agencies and bodies should regularly exchange relevant information they become aware of and closely cooperate with market surveillance authorities.

Amendment 24

Proposal for a directive Recital 22

(22) In order to protect the health and property of consumers, the defectiveness of a product should be determined by reference not to its fitness for use but to the lack of the safety ***that the public at large*** is entitled to expect. The assessment of defectiveness should involve an objective analysis 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***, the objective characteristics and the properties of the product in question as well as the specific requirements of the

(22) In order to protect the health and property of consumers, the defectiveness of a product should be determined by reference not to its fitness for use but to the lack of the safety ***an average person*** is entitled to expect ***or that is required under Union or national law***. The assessment of defectiveness should involve an objective analysis and not refer to the safety that any particular person is entitled to expect. The safety that ***an average person*** is entitled to expect should be assessed by taking into account, inter alia, ***reasonably foreseeable use, the presentation***, the objective characteristics and the properties 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.

product in question as well as the specific requirements of the group of users for whom the product is intended. ***In addition, the compliance with relevant product safety requirements laid down in Union and national law should be taken into account, in particular if non-compliance increased the risk of the product causing damage of the type suffered by the injured person and that risk has materialised. Economic operators should not be liable, however, if they prove that the damage suffered by the injured person would also have occurred if the relevant mandatory requirements under Union or national law had been complied with.*** 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.

Amendment 25

Proposal for a directive Recital 23

Text proposed by the Commission

(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 effects of other products on the product in question. The effect on a product's safety of its ability to learn after ***deployment*** 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

Amendment

(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. The effect on a product's safety of its ability to learn 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

behaviour. 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.

algorithms are designed in such a way as to prevent hazardous product behaviour. ***In particular where software that ordinarily and of itself does not pose a significant risk of damage is included in a product with higher safety expectations, such as in case of life-sustaining medical devices as defined in Article 2, point (1), of Regulation (EU) 2017/745 of the European Parliament and of the Council^{1a}, the assessment of defectiveness leading to damage should take the original intent of the developer or manufacturer of the software into account.*** 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 ***where the product does not fulfil safety-relevant cybersecurity requirements laid down in Union or national law.***

^{1a} ***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).***

Amendment 26

Proposal for a directive Recital 24

Text proposed by the Commission

(24) In order to reflect the relevance of product safety and market surveillance legislation for determining the level of safety that ***the public at large*** is entitled to expect, it should be clarified that safety requirements, including safety-relevant cybersecurity requirements, and interventions by regulatory 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.

Amendment

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

Amendment 27

Proposal for a directive
Recital 25

Text proposed by the Commission

(25) In the interests of consumer choice and in order to encourage innovation, 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.

Amendment

(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 ***previous*** 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.

Amendment 28

Proposal for a directive
Recital 28

(28) Online selling has grown consistently and steadily, creating new business models and new actors in the market such as online platforms. *[Regulation [.../.../...] on a Single Market for Digital Services (Digital Services Act)]* and *[Regulation [.../.../...] 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 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 the Digital Services Act. However, the Digital Services Act 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. 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.

(28) Online selling has grown consistently and steadily, creating new business models and new actors in the market such as online platforms. ***Regulations (EU) 2022/2065^{1a} and (EU) 2023/988^{1b} of the European Parliament and of the Council*** 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 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 the Digital Services Act. However, the Digital Services Act 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. 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.

^{1a} 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).

^{1b} 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).

Amendment 29

Proposal for a directive Recital 29

Text proposed by the Commission

(29) In the transition from a linear to a circular economy, products are designed to be more durable, reusable, repairable 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.⁴⁷ . In addition, products allow for modifications through changes to software, including upgrades. When a product is modified substantially outside the control of the original manufacturer, it is considered to be a new product and 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

Amendment

(29) In the transition from a linear to a circular economy, products are designed to be more durable, reusable, repairable 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.⁴⁷ . In addition, products allow for modifications through changes to software, including upgrades. When a product is modified substantially outside the control of the original manufacturer, it is considered to be a new product and it should be possible to hold the person that made the substantial modification liable as a manufacturer of the modified product, **and subject to the same obligations of a manufacturer**, since under relevant Union legislation they are

requirements. Whether a modification is substantial is determined according to criteria set out in relevant Union and national safety legislation, ***such as modifications that*** change the original intended functions or affect the product's compliance with applicable safety requirements. In the interests of a fair apportionment of risks in the circular economy, an economic operator 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.

responsible for the product's compliance with safety requirements. ***However, those requirements should only apply with respect to the modified part of the product, provided that the modification does not affect the product as a whole. Therefore, the liability of the person that made the substantial modification should be limited to the modified part of the product when the modification does not have an impact on the product as a whole.*** Whether a modification is substantial is determined according to criteria set out in relevant Union ***law, including Regulation (EU) 2023/988***, and national ***product*** safety legislation. Modifications ***should be considered substantial, for instance, if they*** change the original intended functions or affect the product's compliance with applicable safety requirements. In the interests of a fair apportionment of risks in the circular economy, an economic operator 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. ***In particular the provision of third-party software updates or upgrades after a manufacturer has ceased to provide support for a product can have very positive effects for the environment by contributing to the repairability and longevity of such a product and should not be disproportionately or negatively affected by this Directive.***

⁴⁷ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A new

⁴⁷ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A new

Amendment 30

Proposal for a directive Recital 29 a (new)

Text proposed by the Commission

Amendment

(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 should be able to use existing national sectorial compensation schemes or establish new ones under national law, which should not be funded by public revenues, to appropriately compensate injured persons who suffered damage caused by defective products.

Amendment 31

Proposal for a directive Recital 30

Text proposed by the Commission

Amendment

(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. 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

(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. It should be possible for Member States to empower national consumer protection bodies to represent the interests of consumers in the process of gathering the evidence necessary to***

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.

prove the defectiveness of a product, the damage caused by the defective product and the causal link between the two. 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. The Commission Impact Assessment Report accompanying the proposal for this Directive highlighted the fact that the most frequent reasons to reject claims relate to the proof of the defect and its link with the damage, which together account for 53 % of the cases of rejection. On the other hand, the 2018 Commission Evaluation of Council Directive 85/374/EEC assessed that around 60 % of the claims for defective products were successful from 2000 to 2016.

Amendment 32

Proposal for a directive Recital 31

Text proposed by the Commission

(31) ***It is therefore necessary to facilitate claimants' access to evidence to be used*** in legal proceedings, ***while ensuring that such access is limited to that which*** is necessary and proportionate, and that ***confidential information and*** trade secrets are protected. Such evidence should also include documents that have to be created ex novo by the defendant by compiling or classifying the available evidence.

Amendment

(31) Therefore, in legal proceedings ***to adjudicate on compensation for damage caused by a defective product, at the request of a claimant who has presented facts and evidence sufficient to support the plausibility of the claim for compensation, national courts should be able to order the defendant to disclose relevant evidence that is at its disposal, in accordance with national procedural law. At the request of the defendant, national courts should also be able to order the claimant to disclose relevant evidence that***

is at its disposal, in accordance with national procedural law. The requested disclosure of evidence should be limited to what is necessary and proportionate, and should be carried out in such a way as to ensure that trade secrets, in line with the Directive (EU) 2016/943 of the European Parliament and of the Council^{1a}, are protected. Such evidence should also include documents that have to be created ex novo by the defendant by compiling or classifying the available evidence. Taking in consideration the complexity of certain types of data, especially those from digital products, the evidence to be disclosed should be delivered in an easily accessible and easily understandable manner.

^{1a} 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).

Amendment 33

Proposal for a directive Recital 31 a (new)

Text proposed by the Commission

Amendment

(31a) This Directive should not affect national law relating to the pre-trial disclosure of evidence.

Amendment 34

Proposal for a directive Recital 32

(32) In respect of trade secrets within the meaning of Directive (EU) 2016/943 *of the European Parliament and of the Council*⁴⁸, 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.

⁴⁸ *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, national courts should be empowered to take *all necessary* measures to ensure *their* confidentiality 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, *including the amount of damage*, 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.

Amendment 35

Proposal for a directive Recital 33

(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 legislative and mandatory safety requirements have been adopted in order to protect consumers and the public from the risk of harm. 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 normal use, since it is unnecessarily burdensome to require a claimant to prove defectiveness when the circumstances are such that its existence is undisputed.

(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 legislative and mandatory safety requirements have been adopted in order to protect consumers and the public 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 normal use, since it is unnecessarily burdensome to require a claimant to prove defectiveness when the circumstances are such that its existence is undisputed.

Amendment 36

Proposal for a directive Recital 34

(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 light of the technical or scientific complexity of the case, to prove its defectiveness or the causal link, or both. In such cases, requiring proof would undermine the effectiveness of the right to compensation. Therefore, given that manufacturers have expert knowledge and are better informed than the injured person, **it should be for them to rebut the presumption**. 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

(34) National courts should also **alleviate the burden of proving** 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 **and taking all relevant circumstances of the case into account**, it would be excessively difficult for the claimant, in light of the technical or scientific complexity of the case, to prove its defectiveness or the causal link, or both. In such cases, requiring proof would undermine the effectiveness of the right to compensation. Therefore, given that manufacturers have expert knowledge and are better informed than the injured person, **the claimant should be required to establish on the basis of relevant evidence that it is possible that the product contributed to the damage and, where the claimant's difficulties relate to proving defectiveness, that it is possible that the product was defective, or where the claimant's difficulties relate to proving the causal link, that its defectiveness is a possible 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 **substantiated advice from experts in the relevant field**, the complex nature of the product 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

establish the causal link. The defendant should have the possibility to contest the existence of excessive difficulties.

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 the existence of excessive difficulties *for example by demonstrating that the claimant has sufficient evidence to prove the defectiveness of the product or the causal link between its defectiveness and the damage, or both. In such a case, the defectiveness of the product or the causal link between its defectiveness and the damage, or both, should not be presumed.*

Amendment 37

Proposal for a directive Recital 35

Text proposed by the Commission

Amendment

(35) In order to maintain a fair apportionment of risk, and to avoid a reversal of the burden of proof, a claimant should nevertheless, in order to benefit from the presumption, be required to demonstrate, on the basis of sufficiently relevant evidence, 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.

deleted

Amendment 38

Proposal for a directive
Recital 36

Text proposed by the Commission

(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 ***mandatory regulations*** was the very reason for the product's defectiveness.

Amendment

(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.

Amendment 39

Proposal for a directive
Recital 36 a (new)

Text proposed by the Commission

Amendment

(36a) In order not to hamper innovation in the software sector and acknowledging the challenges developers of software could be facing with respect to the rules laid down under this Directive, software manufacturers should be exempted from liability if another economic operator is liable under this Directive for damage caused by that software, and, at the time of the placing on the market of that software, that manufacturer was 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, falls within the category of microenterprises or small enterprises within the meaning of Article 2(1) of that

Amendment 40

Proposal for a directive

Recital 38

Text proposed by the Commission

(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 Council⁴⁹, manufacturers should also be liable for damage caused by 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.

Amendment

(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 **security** 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 Council⁴⁹, manufacturers should also be liable for damage caused by their failure to supply 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 **updates or upgrades** 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 ***insofar as that can be reasonably expected by the owner in terms of their technical capabilities and the knowledge required to be able to perform such update or upgrade.***

⁴⁹ 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).

⁴⁹ 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).

Amendment 41

Proposal for a directive Recital 39

Text proposed by the Commission

(39) In the interests of a fair apportionment of risks, **manufacturers** 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 **manufacturer** in question, while the product was within their control was such that the existence of defectiveness could not be discovered.

Amendment

(39) In the interests of a fair apportionment of risks, **economic operators** should also be exempted from liability if they prove that the **general** 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 their control was such that the existence of defectiveness could not be discovered.

Amendment 42

Proposal for a directive Recital 40

Text proposed by the Commission

(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

Amendment

(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 consumer protection, all parties should be held liable jointly and severally in such situations.

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 consumer protection, all parties should be held liable jointly and severally in such situations, ***with compensation mechanisms allowing the injured person to be compensated for the relevant damage.***

Amendment 43

Proposal for a directive Recital 41

Text proposed by the Commission

(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 as a result of such acts or omissions. 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.

Amendment

(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 ***an average person*** is entitled to expect, the liability of the economic operator should not be reduced, ***excluded 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, ***including where the injured person failed to install updates or upgrades provided by the economic operator that would have mitigated or avoided the damage.***

Amendment 44

Proposal for a directive
Recital 43

Text proposed by the Commission

(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 limitation period should be **15** years in cases where the symptoms of a personal injury are, according to medical evidence, slow to emerge.

Amendment

(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 limitation period should be **30** years in cases where the symptoms of a personal injury are, according to medical evidence, slow to emerge.

Amendment 45

Proposal for a directive
Recital 45

Text proposed by the Commission

(45) In order to facilitate harmonised interpretation of this Directive by national courts, Member States should be required to publish relevant court judgments on product liability.

Amendment

(45) In order to facilitate harmonised interpretation of this Directive by national courts, Member States should be required to publish relevant court judgments on product liability. ***Furthermore, the Commission should set up and maintain an easily accessible and publicly available database containing such judgments as well as judgments delivered by the Court of Justice of the European Union in relation to proceedings launched pursuant to this Directive.***

Amendment 46

Proposal for a directive Article 1 – title

Text proposed by the Commission

Amendment

Subject matter

Subject matter **and objective**

Amendment 47

Proposal for a directive Article 1 – paragraph 1

Text proposed by the Commission

Amendment

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

This Directive lays down common rules on the liability of economic operators for damage suffered by natural persons caused by defective products **and is aimed at ensuring that such persons are entitled to compensation.**

Amendment 48

Proposal for a directive Article 1 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The objective of this Directive is to contribute to the proper functioning of the internal market, while ensuring a high level of consumer protection, and to remove divergences between the legal systems of Member States related to the liability of economic operators for damage suffered by natural persons caused by defective products.

Amendment 49

Proposal for a directive
Article 2 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. This Directive does not apply to free and open-source software, unless such software is offered in exchange for a price or for personal data not exclusively used for improving the security, compatibility or interoperability of that software.

Amendment 50

Proposal for a directive
Article 2 – paragraph 3 – point b

Text proposed by the Commission

Amendment

(b) national rules concerning the right of contribution or recourse between two or more economic operators that are jointly and severally liable pursuant to Article 11 or in a case where the damage is caused both by a defective product and by an act or omission of a third party as referred to in Article 12;

deleted

Amendment 51

Proposal for a directive
Article 4 – paragraph 1 – point 1

Text proposed by the Commission

Amendment

(1) ‘product’ means all movables, even if integrated into another movable or into an immovable. ‘Product’ includes electricity, digital manufacturing files and software;

(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;

Amendment 52

Proposal for a directive
Article 4 – paragraph 1 – point 2

Text proposed by the Commission

(2) ‘digital manufacturing file’ means a digital version or a digital template of a movable;

Amendment

(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;***

Amendment 53

Proposal for a directive
Article 4 – paragraph 1 – point 3

Text proposed by the Commission

(3) ‘component’ means any item, whether tangible or intangible, or any related service, that is integrated into, or inter-connected with, ***a*** product by the manufacturer of that product or within that manufacturer’s control;

Amendment

(3) ‘component’ means any item, whether tangible or intangible, ***including embedded software, raw materials*** or any related service, that is integrated into, or inter-connected with ***another*** product by the manufacturer of that product or ***by a third party*** within that manufacturer’s control;

Amendment 54

Proposal for a directive
Article 4 – paragraph 1 – point 5

Text proposed by the Commission

(5) ‘manufacturer’s control’ means that the manufacturer of a product authorises a) the integration, inter-connection or supply by a third party of a component including software updates or upgrades, or b) the modification of the product;

Amendment

(5) ‘manufacturer’s control’ means that the manufacturer of a product ***performs or, with respect to the actions of a third party, explicitly*** authorises ***or consents to*** a) the integration, inter-connection or supply by a third party of a component including ***the specific*** software updates or upgrades, or b) the modification of the product, ***including***

substantial modifications;

Amendment 55

Proposal for a directive

Article 4 – paragraph 1 – point 6

Text proposed by the Commission

Amendment

**(6) ‘damage’ means material losses
resulting from:** *deleted*

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

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

(i) the defective product itself;

**(ii) a product damaged by a defective
component of that product;**

**(iii) property used exclusively for
professional purposes;**

**(c) loss or corruption of data that is not
used exclusively for professional
purposes;**

Amendment 56

Proposal for a directive

Article 4 – paragraph 1 – point 7 a (new)

Text proposed by the Commission

Amendment

**(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;**

Amendment 57

Proposal for a directive
Article 4 – paragraph 1 – point 9

Text proposed by the Commission

Amendment

(9) ‘**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;

deleted

Amendment 58

Proposal for a directive
Article 4 – paragraph 1 – point 10

Text proposed by the Commission

Amendment

(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;

(10) ‘putting into service’ means the first use of a product **by the end user** 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;

Amendment 59

Proposal for a directive
Article 4 – paragraph 1 – point 11 – introductory part

Text proposed by the Commission

Amendment

(11) ‘manufacturer’ means any natural or legal person who **develops, manufactures or produces a product or has a product designed or manufactured, or who markets that product under its name or trademark or who develops, manufactures or produces a product for its own use;**

(11) ‘manufacturer’ means any natural or legal person who:

Amendment 60

Proposal for a directive

Article 4 – paragraph 1 – point 11 – point a (new)

Text proposed by the Commission

Amendment

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

Amendment 61

Proposal for a directive

Article 4 – paragraph 1 – point 11 – point b (new)

Text proposed by the Commission

Amendment

(b) has a product designed or manufactured, or who markets that product under its name or trademark, thereby presenting itself as a manufacturer; or

Amendment 62

Proposal for a directive

Article 4 – paragraph 1 – point 11 – point c (new)

Text proposed by the Commission

Amendment

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

Amendment 63

Proposal for a directive

Article 4 – paragraph 1 – point 12

Text proposed by the Commission

Amendment

(12) ‘authorised representative’ means any natural or legal person established within the Union who has received a

(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;

written mandate from a manufacturer to act on its behalf in relation to specified tasks
for the purposes of this Directive;

Amendment 64

Proposal for a directive

Article 4 – paragraph 1 – point 17

Text proposed by the Commission

(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)*⁵⁴.

Amendment

(17) ‘online platform’ means online platform as defined in Article 3, point (i), of Regulation (EU) **2022/2065**;

⁵⁴ +**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.

Amendment 65

Proposal for a directive

Article 4 – paragraph 1 – point 17 a (new)

Text proposed by the Commission

Amendment

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

Amendment 66

Proposal for a directive

Article 4 – paragraph 1 – point 17 b (new)

Text proposed by the Commission

Amendment

(17b) ‘substantial modification’ means a modification to a product, made after the product 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 such change being foreseen in the manufacturer’s initial risk assessment of the product; and

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

Amendment 67

Proposal for a directive

Article 5 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) a person acting on behalf of one or more injured persons in accordance.

(b) a person acting on behalf of one or more injured persons in accordance ***with Union or national law.***

Amendment 68

Proposal for a directive

Article 5 a (new)

Text proposed by the Commission

Amendment

Article 5a

Damage

1. For the purpose of this Directive, ‘damage’ means material losses resulting from:

(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 of that product that is integrated into, or inter-connected with, a product by the manufacturer of that product within that manufacturer’s control;

(iii) property used exclusively for professional purposes.

(c) destruction or irreversible corruption of data that are not used for professional purposes, provided that the material loss exceeds EUR 1 000.

2. This Article shall not affect national rules relating to non-material damage as well as those relating to the compensation of damage under other liability regimes.

Amendment 69

Proposal for a directive Article 5 b (new)

Text proposed by the Commission

Amendment

Article 5b

Guidance

1. Member States shall ensure that the competent national consumer protection authorities provide information and tailored guidance to consumers to enable them to effectively exercise their right to

compensation in accordance with Article 5.

2. Member States shall ensure that market surveillance authorities regularly exchange relevant information with national consumer protection agencies and bodies to ensure a high level of consumer protection and that national consumer protection agencies and bodies regularly exchange relevant information at their disposal.

Amendment 70

Proposal for a directive Article 6 – paragraph -1 (new)

Text proposed by the Commission

Amendment

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

Amendment 71

Proposal for a directive Article 6 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. A product *shall be considered defective when it does not provide the safety which the public at large is entitled to expect, taking* all circumstances into account, including *the following*:

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

Amendment 72

Proposal for a directive Article 6 – paragraph 1 – point a

Text proposed by the Commission

- (a) the ***presentation*** of the product, including the instructions for installation, use and maintenance;

Amendment

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

Amendment 73

Proposal for a directive

Article 6 – paragraph 1 – point b

Text proposed by the Commission

- (b) the reasonably ***foreseeable use and misuse*** of the product;

Amendment

- (b) the reasonably ***foreseeable use*** of the product, ***taking into account the expected lifespan of the product***;

Amendment 74

Proposal for a directive

Article 6 – paragraph 1 – point c

Text proposed by the Commission

- (c) the effect on the product of any ability to ***continue to learn*** after ***deployment***;

Amendment

- (c) the effect on the product of any ability to ***acquire new features or knowledge*** after ***it is placed on the market or put into service***;

Amendment 75

Proposal for a directive

Article 6 – paragraph 1 – point d

Text proposed by the Commission

- (d) the effect ***on the product of*** other products ***that*** can reasonably be expected

Amendment

- (d) the effect ***that*** other products ***might have on the product to be assessed, where, at the time of placing on the market or***

*to be used together with **the product**,*

putting into service, it can reasonably be expected that the product will be used together with other products, including the interconnection of those products;

Amendment 76

Proposal for a directive

Article 6 – paragraph 1 – point f

Text proposed by the Commission

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

Amendment

(f) **relevant** product safety requirements, including safety-relevant cybersecurity requirements ***laid down in Union or national law, that are intended to protect against the risk of the damage that has occurred;***

Amendment 77

Proposal for a directive

Article 6 – paragraph 1 – point g

Text proposed by the Commission

(g) any intervention by a regulatory authority or by an economic operator referred to in Article 7 relating to product safety;

Amendment

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

Amendment 78

Proposal for a directive

Article 6 – paragraph 1 – point h

Text proposed by the Commission

(h) ***the specific expectations of the end-users for whom the product is intended.***

Amendment

deleted

Amendment 79

Proposal for a directive

Article 7 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Member States shall ensure that, where a defective component has caused the product to be defective, the manufacturer of a defective component can also be held liable for the same damage.

Amendment

Member States shall ensure that, where a defective component has caused the product to be defective, the manufacturer of a defective component can also be held liable for the same damage, ***unless the defect 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.***

Amendment 80

Proposal for a directive

Article 7 – paragraph 2

Text proposed by the Commission

2. Member States shall ensure that, where the manufacturer of the defective product is established outside the Union, the importer of the defective product ***and*** the authorised representative of the manufacturer can be held liable for damage caused by that product.

Amendment

2. Member States shall ensure that, where the manufacturer of the defective product ***or component*** is established outside the Union, the importer of the defective product ***or component and, where applicable,*** the authorised representative of the manufacturer can be held liable for damage caused by that product.

Amendment 81

Proposal for a directive

Article 7 – paragraph 3

Text proposed by the Commission

3. Member States shall ensure that, where the manufacturer of the defective

Amendment

3. Member States shall ensure that, where the manufacturer of the defective

product is established outside the Union and neither of the economic operators referred to in paragraph 2 is established in the Union, the fulfilment service provider can be held liable for damage caused by the defective product.

product is established outside the Union and neither of the economic operators referred to in paragraph 2 is established in the Union, the fulfilment service provider can be held liable for damage caused by the defective product ***or, where applicable, component.***

Amendment 82

Proposal for a directive Article 7 – paragraph 4

Text proposed by the Commission

4. Any natural or legal person that modifies a product ***that has already been placed*** on the market or put into service shall be considered a manufacturer of the product for the purposes of paragraph 1, ***where the modification is considered substantial under relevant Union or national rules on product safety and is undertaken outside the original manufacturer's control.***

Amendment

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 put into service shall be considered a manufacturer of the product for the purposes of paragraph 1.

Amendment 83

Proposal for a directive Article 7 – paragraph 6

Text proposed by the Commission

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 manufacturer, importer or distributor, provided that the conditions of Article 6(3) set out in Regulation (EU).../... ***of the European Parliament and of the Council on a Single Market for Digital Services (Digital Services Act)***⁺ are fulfilled.

Amendment

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 manufacturer, importer or distributor, provided that the conditions of Article 6(3) set out in Regulation (EU) ***2022/2065*** are fulfilled.

⁺ **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.

Amendment 84

Proposal for a directive Article 7 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

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 shall not be funded by public revenues, to appropriately compensate injured persons who suffered damage caused by defective products.

Amendment 85

Proposal for a directive Article 8 – paragraph 1

Text proposed by the Commission

Amendment

1. Member States shall ensure that ***national courts are empowered, upon request of an injured person*** claiming compensation for damage caused by a defective product (***‘the claimant’***) who has presented facts and evidence sufficient to support the plausibility of the claim for compensation, ***to*** order the defendant to

1. Member States shall ensure that ***in proceedings for*** claiming compensation for damage caused by a defective product, ***at the request of a*** claimant who has presented facts and evidence sufficient to support the plausibility of the claim for compensation, ***national courts may*** order the defendant to disclose relevant evidence

disclose relevant evidence that is at its disposal.

that is at its disposal, ***subject to the conditions set out in this Article.***

Amendment 86

Proposal for a directive Article 8 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Member States shall ensure that, if requested by the defendant, national courts are able to order the claimant to disclose relevant evidence that is at its disposal, subject to the same conditions that apply to the disclosure of evidence by the defendant set out in this Article.

Amendment 87

Proposal for a directive Article 8 – paragraph 3

Text proposed by the Commission

Amendment

3. When determining whether the disclosure ***is*** 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 within the meaning of Article 2, point 1, of Directive (EU) 2016/943.

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 trade secrets within the meaning of Article 2, point 1, of Directive (EU) 2016/943 ***and the need to prevent non-specific searches for information, which is unlikely to be of relevance for the parties to the procedure.***

Amendment 88

Proposal for a directive Article 8 – paragraph 4

Text proposed by the Commission

4. Member States shall ensure that, where a defendant is ordered 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 the legal proceedings.

Amendment

4. Member States shall ensure that, where a defendant is ordered to disclose information that is a trade secret or an alleged trade secret, national courts ***take*** 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.

Amendment 89

**Proposal for a directive
Article 8 – paragraph 4 a (new)**

Text proposed by the Commission

Amendment

4a. Member States shall ensure that, where a party is ordered to disclose information, the information is presented without undue delay to the other party in an easily accessible and easily understandable manner.

Amendment 90

**Proposal for a directive
Article 8 – paragraph 4 b (new)**

Text proposed by the Commission

Amendment

4b. This Article does not affect national law relating to the pre-trial disclosure of evidence.

Amendment 91

**Proposal for a directive
Article 9 – paragraph 2 – point b**

Text proposed by the Commission

(b) the claimant establishes that the product does not comply with mandatory safety requirements laid down in Union law or national law that are intended to protect against the risk of the damage *that has occurred*; or

Amendment

(b) the claimant establishes 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 ***or reduce*** the risk ***of the occurrence*** of the damage ***suffered by the injured party***; or

Amendment 92

**Proposal for a directive
Article 9 – paragraph 2 – point c**

Text proposed by the Commission

(c) the claimant establishes that the damage was caused by an obvious malfunction of the product during normal use or under ordinary circumstances.

Amendment

(c) the claimant establishes that the damage was caused by an obvious malfunction of the product during normal use ***as intended by the manufacturer*** or under ordinary circumstances.

Amendment 93

**Proposal for a directive
Article 9 – paragraph 3**

Text proposed by the Commission

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.

Amendment

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 typically consistent with the defect in question, ***or where the product belongs to the same production series as a product already proven to be defective.***

Amendment 94

Proposal for a directive

Article 9 – paragraph 4 – subparagraph 1 – introductory part

Text proposed by the Commission

Where a national court ***judges that the claimant faces excessive difficulties, due to technical or scientific complexity, to prove*** the defectiveness of the product or the causal link between its defectiveness and the damage, or both, ***the defectiveness of the product or causal link between its defectiveness and the damage, or both, shall be presumed where the claimant has demonstrated, on the basis of sufficiently relevant evidence, that:***

Amendment

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

Amendment 95

Proposal for a directive

Article 9 – paragraph 4 – subparagraph 1 – point a

Text proposed by the Commission

(a) the product ***contributed to*** the damage; and

Amendment

(a) ***the national court considers that the claimant faces excessive difficulties, 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

Amendment 96

Proposal for a directive

Article 9 – paragraph 4 – subparagraph 1 – point b

Text proposed by the Commission

(b) it is ***likely*** that the product ***was*** defective or that its defectiveness is a ***likely*** cause of the damage, or both.

Amendment

(b) ***the claimant establishes, on the basis of relevant evidence, that*** it is ***possible*** that the product ***contributed to the damage, and it is possible that the product*** is defective or that its defectiveness is a ***possible*** cause of the damage, or both.

Amendment 97

Proposal for a directive

Article 9 – paragraph 4 – subparagraph 2

Text proposed by the Commission

The defendant shall have the right to contest the existence of excessive difficulties or the **likelihood** referred to in the first subparagraph.

Amendment

The defendant shall have the right to contest the existence of excessive difficulties or the **possibility** referred to in the first subparagraph.

Amendment 98

Proposal for a directive

Article 10 – paragraph 1 – point a (new)

Text proposed by the Commission

Amendment

(aa) in the case of a manufacturer of software that, at the time of the placing on the market of that software, the manufacturer was 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, provided that another economic operator is liable under this Directive for damage caused by that software;

Amendment 99

Proposal for a directive

Article 10 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

(b) in the case of **a distributor or an online platform acting as** a distributor, that it did not make the product available on the market;

Amendment 100

Proposal for a directive

Article 10 – paragraph 1 – point c

Text proposed by the Commission

(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;

Amendment

(c) that, **having regard to the circumstances**, 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, **provided that that defectiveness did not result from any update or supply under the control of that economic operator and was not due to the failure of that economic operator to provide an update as required by Union or national law**;

Amendment 101

Proposal for a directive

Article 10 – paragraph 1 – point d

Text proposed by the Commission

(d) that the defectiveness is due to compliance of the product with **mandatory regulations issued by public authorities**;

Amendment

(d) that the defectiveness is due to compliance of the product with **legal requirements and that the economic operator exercised all reasonable due care required in the circumstances**;

Amendment 102

Proposal for a directive Article 10 – paragraph 1 – point e

Text proposed by the Commission

(e) ***in the case of a manufacturer, that*** 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;

Amendment

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

Amendment 103

Proposal for a directive Article 10 – paragraph 2 – point b

Text proposed by the Commission

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

Amendment

(b) software, including software updates or upgrades ***for the reasonably expected lifespan of the product***; or

Amendment 104

Proposal for a directive Article 10 – paragraph 2 – point c

Text proposed by the Commission

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

Amendment

(c) the lack of software updates or upgrades necessary to maintain safety ***for the reasonably expected lifespan of the product***.

Amendment 105

Proposal for a directive Article 11 – paragraph 1

Text proposed by the Commission

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.

Amendment

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.

Amendment 106

**Proposal for a directive
Article 12 – paragraph 1**

Text proposed by the Commission

1. Member States shall ensure that the liability of an economic operator is not reduced when the damage is caused both by the defectiveness of a product and by an act or omission of a third party.

Amendment

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, ***excluded or disallowed*** when the damage is caused both by the defectiveness of a product and by an ***event outside the control of the economic operator, such as one attributable to an*** act or omission of a third party.

Amendment 107

**Proposal for a directive
Article 12 – paragraph 2**

Text proposed by the Commission

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.

Amendment

2. ***Without prejudice to the compensation mechanisms provided under this Directive***, 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, *including when the injured person does not install updates or upgrades provided by the economic operator that would have mitigated the defect,*

Amendment 108

Proposal for a directive Article 12 a (new)

Text proposed by the Commission

Amendment

Article 12a

Right of recourse

1. Where more than one economic operator is liable for the same damage, any economic operator that has compensated the injured person or was ordered to do so by an enforceable judgment shall have a right of recourse against any other jointly and severally liable economic operator. Member States shall lay down the conditions for exercising such right of recourse which shall not be less favourable to the claimant than in comparable national cases.

2. National courts may, where appropriate, apply Article 9(2) to (5) in cases in which the right of recourse is exercised.

Amendment 109

Proposal for a directive Article 14 – paragraph 2

Text proposed by the Commission

Amendment

2. Member States shall ensure that the rights conferred upon the injured person pursuant to this Directive are extinguished

2. Member States shall ensure that the rights conferred upon the injured person pursuant to this Directive are extinguished

upon the expiry of a limitation period of 10 years from the date on which the actual defective product which caused the damage was placed on the market, put into service or substantially modified as referred to in Article 7(4), unless a claimant has, in the meantime, initiated proceedings before a national court against an economic operator that can be held liable pursuant to Article 7.

upon the expiry of a limitation period of 10 years from the date on which the actual defective product, ***or the last update or supply under the control of the manufacturer***, which caused the damage was placed on the market, put into service or substantially modified as referred to in Article 7(4), ***or in case of an update or upgrade, should have been made available on the market in order to bring it into conformity with applicable product safety requirements under Union or national law***, unless a claimant has, in the meantime, initiated proceedings before a national court against an economic operator that can be held liable pursuant to Article 7. ***A software update or upgrade and related services which do not amount to a substantial modification under Article 7(4) shall not trigger or restart the limitation period.***

Amendment 110

Proposal for a directive Article 14 – paragraph 3

Text proposed by the Commission

3. By way of exception from paragraph 2, where an injured person has not been able to initiate proceedings within 10 years due to the latency of a personal injury, the rights conferred upon the injured person pursuant to this Directive shall be extinguished upon the expiry of a limitation period of **15** years.

Amendment 111

Proposal for a directive Article 15 – paragraph 2

Amendment

3. By way of exception from paragraph 2, where an injured person, ***despite exercising all due care***, has not been able to initiate proceedings within 10 years due to the latency of a personal injury, the rights conferred upon the injured person pursuant to this Directive shall be extinguished upon the expiry of a limitation period of **30** years.

Text proposed by the Commission

2. The Commission **may** set up and maintain a publicly available database containing the judgments referred to in paragraph 1.

Amendment

2. The Commission **shall** set up and maintain a ***an easily accessible and*** publicly available database containing the judgments referred to in paragraph 1. ***This database shall contain, in addition to the judgements referred to in paragraph 1, the judgments delivered by the Court of Justice of the European Union relating to proceedings launched pursuant to this Directive.***

Amendment 112

**Proposal for a directive
Article 16 – paragraph 1**

Text proposed by the Commission

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, review the application of this Directive and submit a report to the European Parliament, to the Council and to the European Economic and Social Committee.

Amendment

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, review 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:***

Amendment 113

**Proposal for a directive
Article 16 – paragraph 1 – point a (new)**

Text proposed by the Commission

Amendment

(a) the costs entailed by this Directive for economic operators as a percentage of their operation costs;

Amendment 114

Proposal for a directive
Article 16 – paragraph 1 – point b (new)

Text proposed by the Commission

Amendment

(b) the net benefit of this Directive or its qualified estimation for consumers;

Amendment 115

Proposal for a directive
Article 16 – paragraph 1 – point c (new)

Text proposed by the Commission

Amendment

(c) a comparison of the protection provided by this Directive with the protection provided in relevant third countries belonging to the Organisation for Economic Co-operation and Development and world leading economies;

Amendment 116

Proposal for a directive
Article 16 – paragraph 1 – point d (new)

Text proposed by the Commission

Amendment

(d) the availability of insurance and other products to cover the risks of economic operators related to this Directive.

Amendment 117

Proposal for a directive
Article 16 – paragraph 1 a (new)

The Commission shall clearly specify the methodologies used for calculation of any qualified estimation contained in the report referred to in paragraph 1. The Commission shall gather information for that report without increasing the reporting obligations of 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.