Council of the European Union
General Secretariat

Interinstitutional files:
2022/0302 (COD)

Brussels, 08 December 2023

WK 16587/2023 INIT

LIMITE

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WORKING DOCUMENT

From: To:	General Secretariat of the Council Delegations
N° Cion doc.:	ST 13134 2022 + ADD 1 - ADD 4
Subject:	Proposal for a Directive of the European Parliament and of the Council on liability for defective products - Recitals

Delegations will find in Annex a table with the position of the Parliament and of the Council on the recitals of the review of the Product Liability Directive and, in the third column of the table, compromise proposals prepared by the Commission, as well as some comments explaining those compromise proposals.

EP Mandate	Council Mandate	Draft Suggestions
(1) Council Directive 85/374/EEC[1] 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***. 1. Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).	(1) **In order to improve the proper functioning of the internal market, it is necessary to ensure that competition is not distorted and the movement of goods is not obstructed.** Council Directive 85/374/EEC[1] 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~~**. Greater harmonisation of the common rules on liability for defective products laid down in that Directive should further contribute to the achievement of these objectives, while entailing an increased** degree of protection of ~~the consumer against damage to~~**consumers' and other natural persons'** health or property**.** ~~caused by such products.~~ 1. **[1]** Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).	(1) **In order to improve the proper functioning of the internal market, it is necessary to ensure that competition is not distorted and the movement of goods is not obstructed.** Council Directive 85/374/EEC[1] 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~~**. Greater harmonisation of the common rules on liability for defective products laid down in that Directive should further contribute to the achievement of these objectives, while entailing an increased** degree of protection of ~~the consumer against damage to~~**consumers' and other natural persons'** health or property**.** ~~caused by such products.~~
	Recital 2	
(2) Liability without fault on the part of the relevant economic operator remains the sole means of adequately solving the problem of a	(2) Liability without fault on the part of the relevant economic operator remains the sole means of adequately solving the problem of a	(2) Liability without fault on the part of the relevant economic operator remains the sole means of adequately solving the problem of a

Commented [A1]: This is now in article 1.

Commented [A2]: This sentence reflects the part in Art.1 that EP whished to have.

fair apportionment of the risks inherent in modern technological production.	fair apportionment of the risks inherent in modern technological production.	fair apportionment of the risks inherent in modern technological production.
	Recital 3	
(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 ~~*have*~~***has*** led to ~~*inconsistences*~~***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***, 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***.	(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 inconsistences 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.	(3) Directive 85/374/EEC **has been an effective and important instrument, but** needs to be revised in light of developments related to new technologies, including artificial intelligence (AI), new circular economy business models and new global supply chains, which have led to inconsistencies and legal uncertainty, in particular as regards the meaning of the term 'product'. Experience gained from applying Directive 85/374/EEC has also shown that injured persons face difficulties obtaining compensation due to restrictions on making compensation claims and due to challenges in gathering evidence to prove liability, especially in light of increasing technical and scientific complexity. This includes claims for damages related to new technologies~~,~~ ~~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**, and that all businesses benefit from more legal certainty and a level playing field.**

Commented [A3]: To wait on the final decision on the exemption.

	Recital 4	
(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.	(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.	(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**,** concepts to ensure coherence and legal certainty**, a level playing field in the internal market** and to reflect recent case law of the Court of Justice of the European Union.
	Recital 5	
(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.	(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.	(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.
	Recital 6	
(6) In order to ensure the Union's product liability regime is comprehensive ***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	(6) In order to ensure **that** the Union's product liability regime is comprehensive, no-fault liability for defective products should apply to all movables, including when they are integrated into other movables or installed in immovables.	(6) In order to ensure **that** the Union's product liability regime is comprehensive, no-fault liability for defective products should apply to all movables, **including software,** including when they are integrated into other movables or installed in immovables.

Commented [A4]: This is inaccurate as the revision complements its own regime not other systems.

Objectives are perhaps sufficiently reflected elsewhere, including in Art. 1 now.

Commented [A5]: Meaning of "effective to apply" not clear. Suggest to stick with comprehensive, which is the idea behind "all".

Commented [A6]: The mode of supply is already mentioned in recital 12

are integrated into other movables or installed in immovables.		
	Recital 7	
(7) Liability for defective products should not apply to damage arising from nuclear accidents, in so far as liability for such damage is covered by international conventions ratified by Member States.	(7) Liability for defective products should not apply to damage arising from nuclear accidents, in so far as liability for such damage is covered by international conventions ratified by Member States.	(7) Liability for defective products should not apply to damage arising from nuclear accidents, in so far as liability for such damage is covered by international conventions ratified by Member States.
	Recital 8	
(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. ***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.***	(8) In order to create a genuine internal market with a high and uniform level of ~~consumer protection~~**protection for natural persons**, 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.	(8) In order to create a genuine internal market with a high and uniform level of **protection of consumers and other natural persons**, and to reflect the case law of the Court of Justice, Member States should not, in respect of matters within the scope of this Directive, maintain or introduce more, or less, stringent provisions than those laid down in this Directive.
	Recital 9	
(9) Under the legal systems of Member States an injured person may have a claim for damages on the basis of contractual liability	(9) Under the legal systems of Member States an injured person may have a claim for damages on the basis of contractual liability	(9) Under the legal systems of Member States an injured person may have a claim for damages on the basis of contractual liability

Commented [A7]: It is not clear what we are referring to here? Is it meant to cover the same as CSL recital 31a?

Commented [A8]: This is a clarification of the status quo added by Council on art.2

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 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.	or on grounds of non-contractual liability that do not concern the **manufacturer's liability for** defectiveness of a product~~,~~ **as established in this Directive. This concerns** for example liability based on warranty or on fault**, or strict liability of operators for damages caused by the properties of an organism, resulting from genetic engineering. This also** ~~. This~~ includes the provisions of the [AI Liability 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 **and other natural persons**, should remain unaffected by this Directive.	or on grounds of non-contractual liability that do not concern the **manufacturer's liability for** defectiveness of a product, **as established in this Directive. This concerns** for example liability based on warranty or on fault**, or strict liability of operators for damages caused by the properties of an organism, resulting from genetic engineering. ~~This also~~** ~~*This includes the provisions of the [AI Liability 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 **and other natural persons**, should remain unaffected by this Directive.
	Recital 10	
(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***	(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~~**natural persons** in the pharmaceutical sector is already attained. The right to make such claims should remain unaffected by this Directive. **Furthermore, amendments to such special liability systems should not be precluded as long as they do not undermine the effectiveness of**	(10) In certain Member States, injured persons may be entitled to make claims for damages caused by pharmaceutical products under a special national liability system, with the result that effective protection of **natural persons** in the pharmaceutical sector is already attained. The right to make such claims should remain unaffected by this Directive. **Furthermore, amendments to such special liability systems should not be precluded as long as they do not undermine the effectiveness of the system of liability**

Commented [A9]: This is outside of the scope of the Directive. This recital should be only about the specific liability regime that predates the PLD.

The last part of EP text is reflected in CSL text.

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.***	**the system of liability provided for in this Directive or its objectives.**	**provided for in this Directive or its objectives.**
	Recital 11	
(11) Decision No 768/2008/EC[1] of the European Parliament and of the Council lays down common principles and reference provisions intended to apply across sectoral product legislation. In order to ensure consistency with such legislation, it is appropriate to align certain provisions of this Directive, in particular the definitions, to that Decision. _____ 1. Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products.	(11) Decision No 768/2008/EC[1] of the European Parliament and of the Council lays down common principles and reference provisions intended to apply across sectoral product legislation. In order to ensure consistency with such legislation, it is appropriate to align certain provisions of this Directive, in particular the definitions, to that Decision. _____ 1. Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products.	(11) Decision No 768/2008/EC[1] of the European Parliament and of the Council lays down common principles and reference provisions intended to apply across sectoral product legislation. In order to ensure consistency with such legislation, it is appropriate to align certain provisions of this Directive, in particular the definitions, to that Decision.
	Recital 12	

Commented [A10]: This is a confusion of the compensation funds that may exist at national level, which are not related to liability claims.

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

Commented [A11]: This recital doesn't reflect anymore the EP mandate on software. Also, the PLD is not a risk-based legislation, since the damage has already occurred.

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.		
	Recital 12a	
(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.		
	Recital 12b	
(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		

Commented [A12]: Deployer is not a notion under the PLD, and when it comes to substantial modification the definition already refers to the relevant piece of legislation.

Commented [A13]: This recital shouldn't be integrated into the PLD - it tries to define a notion that is of MDR. Under the PLD, medical devices are products or components and are not referred to with other terms.

No longer in line with EP mandate on software. The purpose of a piece of software is not relevant for liability purposes.

Commented [A14]: Purpose of recital not entirely clear.

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.		
	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*~~***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~~*, and is therefore supplied in the*~~	(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**, since products so developed or supplied are by definition not placed on the market**. 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. **If, however, free and open-source software supplied outside the course of a commercial activity is subsequently integrated by a manufacturer as a component into a product that is placed on the market, it would be possible to hold that manufacturer liable for damage caused by the defectiveness of such software, while not the manufacturer of the software itself because they would have not**	(13) **Free and open-source software, where the source code is openly shared and users can freely access, use, modify and redistribute the software or modified versions thereof, can contribute to research and innovation on the market. Such software is subject to licences that allow anyone the freedom to run, copy, distribute, study, change and improve the software.** In order not to hamper innovation or research, this Directive should not apply to free and open-source software developed or supplied outside the course of a commercial activity, ***since products so developed or supplied are by definition not placed on the market***. ~~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.

Commented [A15]: COM input 10.11

~~*course of a commercial activity*~~, the Directive should apply.	**fulfilled the conditions of placing a product or component on the market.**	
	Recital 13a	
(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, inter-connection 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.		(13a) ***If~~, however,~~ free and open-source software supplied outside the course of a commercial activity is subsequently integrated by a manufacturer as a component into a product that is placed on the market, it would be possible to hold that manufacturer liable for damage caused by the defectiveness of such software, while not the manufacturer of the software itself because they would have not fulfilled the conditions of placing a product or component on the market.***
	Recital 14	
(14) Digital manufacturing files, which contain the functional information necessary to produce a tangible item by enabling the	(14) **Whereas digital files as such are not products under this Directive,** digital manufacturing files, which contain the	(14) **Whereas digital files as such are not products under this Directive,** digital manufacturing files, which contain the

Commented [A16]: COM Input 10.11 - the text comes from CSL recital 13 that has been split in two and explains the same as EP recital 13a.

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 ~~*is a product*~~***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***.	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~~**the** protection **of natural persons** in cases where such files are defective. For **example, a defective computer-assisted-design (CAD) file used to create a 3D-printed good that causes harm should give rise to liability under this Directive. For** the avoidance of doubt, it should also be clarified that ~~electricity is a product~~**raw materials, such as gas and water, and electricity are products**.	functional information necessary to produce a tangible item by enabling the automated control of machinery or tools, such as drills, lathes, mills and 3D printers, should be considered as products, in order to ensure **the** protection **of natural persons** in cases where such files are defective. For **example, a defective computer-assisted-design (CAD) file used to create a 3D-printed good that causes harm should give rise to liability under this Directive,** ***when they are supplied or developed in the course of a commercial activity*****. For** the avoidance of doubt, it should also be clarified that **raw materials, such as gas and water, and electricity are products**.
	Recital 15	
(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	(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~~	(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~~

Commented [A17]: This last part is reflected now in the italic text.

Commented [A18]: This is not aligned anymore with EP and CSL mandate on the definition of related service.

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*~~***authorises*** them or otherwise influences their supply by a third party.	~~that the manufacturer recommends them or otherwise influences their supply by a third party~~**. Examples of such related services include the continuous supply of traffic data in a navigation system, a health monitoring service that relies on sensors of a physical product to track the user's physical activity or health metrics, a temperature control service that monitors and regulates the temperature of a smart fridge, or a voice assistant service, which allows control of one or more products by using voice commands. However, internet access services should not be treated as related services, since they cannot be considered as part of the product and it would be unreasonable to make manufacturers liable for harm caused by shortcomings in such services. Nevertheless, a product that relies on such services and that fails to maintain safety in the event of a loss of connectivity could be found to be defective under this Directive**.	~~that the manufacturer recommends them or otherwise influences their supply by a third party~~**. Examples of such related services include the continuous supply of traffic data in a navigation system, a health monitoring service that relies on sensors of a physical product to track the user's physical activity or health metrics, a temperature control service that monitors and regulates the temperature of a smart fridge, or a voice assistant service, which allows control of one or more products by using voice commands. [However, internet access services should not be treated as related services, since they cannot be considered as part of the product and it would be unreasonable to make manufacturers liable for harm caused by shortcomings in such services. Nevertheless, a product that relies on such services and that fails to maintain safety in the event of a loss of connectivity could be found to be defective under this Directive.]**
	Recital 15a	
(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		

Commented [A19]: CSL proposal of 28.11 - This needs to be aligned once the discussions on related services are closed.

Commented [A20]: Propose to take over CSL recital 15a, as it is the same as EP but bring a clarity of when it's not under the manufacturer's control. In line with previous discussions.

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

	(15b) In addition, once a product has been placed on the market, it should be considered to be within the manufacturer's control in so far as the manufacturer retains the technical ability to supply software updates or upgrades itself or via a third party.	**(15b) In addition, once a product has been placed on the market, it should be considered to be within the manufacturer's control in so far as the manufacturer retains the technical ability to supply software updates or upgrades itself or via a third party.**
	Recital 16	
(16) In recognition of the growing relevance and value of intangible assets, ~~*the loss or*~~ ***economic loss due to the destruction or irreversible*** corruption of data, such as ~~*content*~~***digital files*** deleted from a hard drive, should also be compensated, ~~*including*~~***when 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 ~~*loss or*~~***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***	(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 result, the protection of ~~consumers~~**natural persons** requires compensation for material losses resulting not only from death or personal injury, such as funeral or medical expenses or lost income, and from damage to property, but also for loss or corruption of data. Nevertheless, compensation for infringements of Regulation (EU) 2016/679 of the European Parliament and of the Council[1], Directive 2002/58/EC of the European Parliament and of the Council[2], Directive (EU) 2016/680 of the European Parliament and of the Council[3] and Regulation (EU) 2018/1725 of the European Parliament and of the Council[4] is not affected by this Directive. _____ 1. **[1]** Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the	

Commented [A21]: This is aligned with the new structure and definition of manufacturer's control.

Commented [A22]: Depends on outcome of trilogue.

or breaches of data protection rules, and compensation for infringements of Regulation (EU) 2016/679 of the European Parliament and of the Council[1], Directive 2002/58/EC of the European Parliament and of the Council[2], Directive (EU) 2016/680 of the European Parliament and of the Council[3] and Regulation (EU) 2018/1725 of the European Parliament and of the Council[4] 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.***	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). 2. **[2]** Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (OJ L 201, 31.7.2002, p. 37). 3. **[3]** Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA, OJ L 119, 4.5.2016, p. 89. 4. **[4]** Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39.	
1. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (OJ L 119, 4.5.2016, p. 1). 2. Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (OJ L 201, 31.7.2002, p. 37).		

3. Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA, OJ L 119, 4.5.2016, p. 89. 4. Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39.		
	Recital 17	
(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***.	(17) In the interests of legal certainty, it should be clarified that personal injury includes medically recognised damage to psychological health.	(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. ***This should be certified by an independent*** ~~court ordered~~ medical expert, including psychologists, and limited ***to damage that*** ~~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~~***, taking into account, inter alia,*** the International Classification of Diseases of the World Health Organisation into account.
	Recital 18	

Commented [A23]: CSL proposed text on 23.11

(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*** ~~*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*~~***allow for injured persons to obtain full and proper compensation from the economic operator who is ultimately liable or from any other relevant party***.	(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, **compensation of non-material losses resulting from the damages covered by** this Directive**, such as pain and suffering,** should ~~not affect national rules relating to non-material damage~~**be provided in so far as they are compensable under national law**.	
	Recital 18a	
	(18a) Types of damage other than those provided for in this Directive, such as pure economic loss, privacy infringements or discrimination, should not by themselves trigger liability under this Directive. However, this Directive should not affect the right to compensation for any damages, including non-material, under other liability regimes.	**(18a) Types of damage other than those provided for in this Directive, such as pure economic loss, privacy infringements or discrimination, should not by themselves trigger liability under this Directive. However, this Directive should not affect the right to compensation for any damages, including non-material, under other liability regimes.**
	Recital 19	
(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	(19) In order to protect **natural persons** ~~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	(19) In order to protect **natural persons**, damage to any property owned by a natural person should be compensated. Since property is increasingly used for both private and professional purposes, it is appropriate to provide for the compensation of damage to

Commented [A26]: To be decided on final agreement on art.5a

Commented [A24]: This is the general principle of liability the compensation should, as much as possible, put the victim in the situation before the damage "full and proper compensation". The compensation is of the actual damages suffered, therefore nothing to do with "proportionate".

It is also not aligned with EP last part which omits "proportionate".

Commented [A25]: This is a repetition of what the recital already says, thus CSL text is enough.

Commented [A27]: Proposed to take over CSL recital, as it looks aligned with EP mandate.

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).***	appropriate to provide for the compensation of damage to such mixed-use property. In light of this Directive's aim to protect **natural persons** ~~consumers~~, property used exclusively for professional purposes should be excluded from its scope.	such mixed-use property. In light of this Directive's aim to protect **natural persons**, property used exclusively for professional purposes should be excluded from its scope.
	Recital 20	
(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. ***Neither the collaborative development of free and open-source software nor making such software available on open repositories should constitute***	(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.	(20) This Directive should apply to products placed on the market or, where relevant, put into service in the course of a commercial activity, whether in return for payment or free of charge, for example products supplied in the context of a sponsoring campaign or products manufactured for the provision of a service financed by public funds, since this mode of supply still has an economic or business character. ***The concept of putting into service is relevant for products that are not placed on the market prior to their first***

Commented [A28]: Member States do extend the PLD to B2B cases, not SMEs. For the second part, it's better to not introduce an "encourage" clause here, while there is no corresponding article in the operative part.

Commented [A30]: Text proposed for alignement with Article 4.10 (COM Input 27.11)

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.		***use, as can be the case in the field of lifts, machinery or medical devices.***
	Recital 20a	
(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.		
	Recital 20b	
(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		(20b) ***In order to better enable persons injured by defective products to effectively exercise their right to compensation under this Directive,*** ~~Taking into account~~ ***in particular in light of*** the increased complexity of products, of business models and of supply chains~~, and considering that the~~

Commented [A29]: This discussion on OSS should be taken over in recital 13 upon final agreement between EP and Council.

Commented [A31]: Not in line with the definition (in EP mandate) of manufacturer:

LINE 11: manufactures or produces a product for its own use

Commented [A32]: This is covered in the exemption in Art. 10.1.a, where the manufacturer did not intend to place the product on the market.

Commented [A33]: COM Input 17.11

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.		~~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~~ ***encourage*** competent national consumer protection authorities ~~and bodies~~ ***to*** provide all relevant information and ~~tailored~~ guidance to affected consumers ***concerning their rights and the various means of seeking redress*** ~~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.~~
	Recital 20a	
	(20a) In so far as national law provides, the right to compensation for injured persons should apply both to direct victims, who suffer damage directly caused by a defective product, and to indirect victims, who suffer damage as a result of the direct victim's damage.	**(20a) In so far as national law provides, the right to compensation for injured persons should apply both to direct victims, who suffer damage directly caused by a defective product, and to indirect victims, who suffer damage as a result of the direct victim's damage.**
	Recital 21	
(21) This Directive should not affect the various means of seeking redress at national level, whether through court proceedings, non-court solutions, alternative dispute resolution or representative actions under Directive (EU) 2020/1828[1] of the European	(21) This Directive should not affect the various means of seeking redress at national level, whether through court proceedings, non-court solutions, alternative dispute resolution or representative actions under Directive (EU) 2020/1828[1] of the European	(21) This Directive should not affect the various means of seeking redress at national level, whether through court proceedings, non-court solutions, alternative dispute resolution or representative actions under Directive (EU) 2020/1828[1] of the European

Commented [A34]: This is a clarification of the status quo added by CSL of Art.5.

Parliament and of the Council or under national collective redress schemes. _____ 1. Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC (OJ L 409, 4.12.2020, p. 1).	Parliament and of the Council or under national collective redress schemes. _____ 1. Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC (OJ L 409, 4.12.2020, p. 1).	Parliament and of the Council or under national collective redress schemes. _____ 1. Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC (OJ L 409, 4.12.2020, p. 1).
	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*~~***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 ~~*the public at large*~~***an average person*** is entitled to expect should be assessed by taking into account, inter alia, ~~*the intended purpose*~~***reasonably foreseeable use, the presentation***, the objective characteristics and the properties of the product in question 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.***	(22) In order to protect the health and property of ~~consumers~~**natural persons**, the defectiveness of a product should be determined by reference not to its fitness for use but to the lack of the safety that 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 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.	**(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 that ***~~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 ***of the safety that the public at large is entitled to expect,*** and not refer to the safety that any particular person is entitled to expect. The safety that ~~**an average person**~~ ***the public at large*** is entitled to expect should be assessed by taking into account, inter alia, ***the intended purpose,*** **reasonably foreseeable use, the presentation,** the objective characteristics and the properties of the product in question***, including its expected lifespan,*** as well as the specific requirements of the group of users for whom the product is intended. Some products, such as life-sustaining medical devices, entail an especially high risk of damage to people and therefore give rise to particularly high safety expectations. In order to take such

Commented [A35]: COM input 22.11

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

Commented [A36]: Text clarifying some elements Article 6.1

	from lack of concentration or the foreseeable behaviour of certain user groups such as children.	**from lack of concentration or the foreseeable behaviour of certain user groups such as children.**
	Recital 23	
(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 ~~*deployment*~~***it is placed on the market or put into service*** should also be taken into account, to reflect the legitimate expectation that a product's software and underlying algorithms are designed in such a way as to prevent hazardous product behaviour. 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	(23) In order to reflect the increasing prevalence of inter-connected products, the assessment of a product's safety should also take into account the **reasonably foreseeable** effects of other products on the product in question**, for example within a smart home system**. The effect on a product's safety of its ability to learn after ~~deployment~~**it is placed on the market or put into service** should also be taken into account, to reflect the legitimate expectation that a product's software and underlying algorithms are designed in such a way as to prevent hazardous product behaviour**. As such, a manufacturer that designs a product with the ability to develop unexpected behaviour remains responsible for behaviour that causes harm**. In order to reflect that in the digital age many products remain within the manufacturer's control beyond the moment at which they are placed on the market, the moment in time at which a product leaves the manufacturer's control should also be taken into account in the assessment of a product's safety. A product can also be found to be defective on account of its cybersecurity vulnerability.	

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).***		
		New Recital 24a
		In order to reflect the nature of products whose very purpose is to prevent damage, such as a warning mechanism like a smoke alarm, it should be clarified that the assessment of such a product's safety should also take into account its failure to fulfil that purpose.
	Recital 24	
(24) In order to reflect the relevant of product safety and market surveillance legislation for determining the level of safety that ~~*the public at large*~~***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	(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	(24) In order to reflect the relevance of product safety and market surveillance legislation for determining the level of safety that ***a person*** ~~***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 **competent** authorities, such as issuing product recalls, or by economic operators themselves, should also be taken

Commented [A37]: Text proposed for Art.6(i) (COM Input 27.11)

Commented [A38]: Adapted with proposed wording for Art.6 and recital (COM Input 22.11) if agreed.

Commented [A39]: Adapted with agreed LINE 110.

also be taken into account in that assessment. ~~*Such*~~***Voluntary*** interventions should, however, not of themselves create a presumption of defectiveness.	themselves create a presumption of defectiveness.	into account in that assessment. ~~***Voluntary:***~~ ***Such*** interventions should, however, not of themselves create a presumption of defectiveness.
	Recital 25	
(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.	(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.	(25) In the interests of consumer choice and in order to encourage innovation, ***research and easy access to new technologies,*** the existence, or subsequent placing, on the market of a better product should not in itself lead to the conclusion that a product is defective. Equally, the supply of updates or upgrades to a product should not in itself lead to the conclusion that a previous version of the product is defective.
	Recital 26	
(26) The protection of the consumer requires that any manufacturer involved in the production process can be made liable, in so far as their product or a component supplied by them is defective. Where a manufacturer integrates a defective component from another manufacturer into a product, an injured person should be able to seek compensation for the same damage from either the manufacturer of the product or from the manufacturer of the component.	(26) The protection of ~~the consumer~~**natural persons** requires that any manufacturer involved in the production process can be made liable, in so far as their product or a component supplied by them is defective. **This includes any person who presents themselves as the manufacturer by affixing, or authorising a third party to affix, their name, trademark or other distinguishing feature, since by doing so they give the impression that they are involved in the production process or assume the responsibility for it.** Where a manufacturer integrates a defective component from another	

Commented [A40]: Propose to revert back to original wording, as nowhere it is referred voluntary intervention.

	manufacturer into a product, an injured person should be able to seek compensation for the same damage from either the manufacturer of the product or from the manufacturer of the component. **Where a component is integrated into a product outside of the control of the product manufacturer, an injured person should be able to seek compensation from the component manufacturer in so far as the component itself is a product under this Directive.**	
	Recital 27	
(27) In order to ensure that injured persons have an enforceable claim for compensation where a manufacturer is established outside the Union, it should be possible to hold the importer of the product and the authorised representative of the manufacturer liable. Practical experience of market surveillance has shown that supply chains sometimes involve economic operators whose novel form means that they do not fit easily into the traditional supply chains under the existing legal framework. Such is the case, in particular, with fulfilment service providers, which perform many of the same functions as importers but which might not always correspond to the traditional definition of importer in Union law. In light of the role of fulfilment service providers as economic operators in the product safety and market surveillance framework, in particular in Regulation (EU) 2019/1020 of the European	(27) In order to ensure that injured persons have an enforceable claim for compensation where a manufacturer is established outside the Union, it should be possible to hold the importer of the product and the authorised representative of the manufacturer**, appointed for the purpose of specified tasks under product safety and market surveillance legislation,** liable. Practical experience of market surveillance has shown that supply chains sometimes involve economic operators whose novel form means that they do not fit easily into the traditional supply chains under the existing legal framework. Such is the case, in particular, with fulfilment service providers, which perform many of the same functions as importers but which might not always correspond to the traditional definition of importer in Union law. ~~In light of the role of fulfilment service providers~~**Fulfilment service providers play an increasingly**	(27) In order to ensure that injured persons have an enforceable claim for compensation where a manufacturer is established outside the Union, it should be possible to hold the importer of the product and the authorised representative of the manufacturer **[, appointed for the purpose of specified tasks under product safety and market surveillance legislation,]** liable. Practical experience of market surveillance has shown that supply chains sometimes involve economic operators whose novel form means that they do not fit easily into the traditional supply chains under the existing legal framework. Such is the case, in particular, with fulfilment service providers, which perform many of the same functions as importers but which might not always correspond to the traditional definition of importer in Union law. ~~In light of the role of fulfilment service providers~~**Fulfilment**

Commented [A41]: To be aligned upon final agreement on the article on Authorised representative.

Parliament and of the Council[1], it should be possible to hold them liable, but given the subsidiary nature of that role, they should be liable only where no importer or authorised representative is based in the Union. In the interests of channelling liability in an effective manner towards manufacturers, importers, authorised representatives and fulfilment service providers, it should be possible to hold distributors liable only where they fail to promptly identify a relevant economic operator based in the Union. 1. Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).	**significant role** as economic operators **enabling and facilitating access to the Union market for products from third countries. This shift in relevance is already reflected** in the product safety and market surveillance framework, in particular in Regulation (EU) 2019/1020 of the European Parliament and of the Council[1] **and [General Product Safety Regulation]. Therefore**, it should be possible to hold them liable, but given the subsidiary nature of that role, they should be liable only where no importer or authorised representative is based in the Union. In the interests of channelling liability in an effective manner towards manufacturers, importers, authorised representatives and fulfilment service providers, it should be possible to hold distributors liable only where they fail to promptly identify a relevant economic operator based in the Union. 1. Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).	**service providers play an increasingly significant role** as economic operators **enabling and facilitating access to the Union market for products from third countries. This shift in relevance is already reflected** in the product safety and market surveillance framework, in particular in Regulation (EU) 2019/1020 of the European Parliament and of the Council[1] **and [General Product Safety Regulation]. Therefore**, it should be possible to hold them liable, but given the subsidiary nature of that role, they should be liable only where no importer or authorised representative is based in the Union. In the interests of channelling liability in an effective manner towards manufacturers, importers, authorised representatives and fulfilment service providers, it should be possible to hold distributors liable only where they fail to promptly identify a relevant economic operator based in the Union. 1. Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).
	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*~~	(28) Online selling has grown consistently and steadily, creating new business models and new actors in the market such as online platforms. ~~[~~Regulation ~~[…/…]~~ **(EU) 2022/2065** on a Single Market for Digital	

~~*Act)] and [Regulation […/…] on General Product Safety]*~~ ***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	Services (Digital Services Act)~~]~~[1] of the European Parliament and of the Council 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~~**Regulation (EU) 2022/2065** . However, ~~the Digital Services Act~~**Regulation (EU) 2022/2065** establishes that online platforms that allow consumers to conclude distance contracts with traders are not exempt from liability under consumer protection law where they present the product or otherwise enable the specific transaction in question in a way that would lead an average consumer to believe that the product is provided either by the online platform itself or by a trader acting under its authority or control. In keeping with this principle, when online platforms do so present the product or otherwise enable the specific transaction, it should be possible to hold them liable, in the same way as distributors under this Directive. 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	

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).***	platform fails to promptly identify a relevant economic operator based in the Union. _____ **1. 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).**	
	Recital 29	
(29) In the transition from a linear to a circular economy,– products are designed to be more durable, reusable, reparable and upgradable. The Union is also promoting innovative and sustainable ways of production and consumption that prolong the functionality of products and components, such as remanufacturing, refurbishment and repair.[1]. 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***	(29) In the transition from a linear to a circular economy,– products are designed to be more durable, reusable, reparable and upgradable. The Union is also promoting innovative and sustainable ways of production and consumption that prolong the functionality of products and components, such as remanufacturing, refurbishment and repair.[1] ~~. 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~~**and is thereafter made available on the market or put into service**, it is considered to be a new product**. Where the modification is made outside the control of the original manufacturer,** ~~and~~ it	(29) …. Whether a modification is substantial is determined according to criteria set out in relevant Union and national safety legislation, ***which typically refer to*** ~~such as~~ modifications that change the original intended functions ***in such a way that changes or creates a new hazard or increases the level or risk,*** ~~or~~ ***thus affecting*** the product's compliance with applicable safety requirements. ….

Commented [A42]: (COM Input 27.11) This extract is subject to the overall recital once agreed.

obligations of a manufacturer, since under relevant Union legislation they are 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*** ~~***, 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. ***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***	should be possible to hold the person that made the substantial modification liable as a manufacturer of the modified product, since under relevant Union legislation they are responsible for the product's compliance with safety requirements. Whether a modification is substantial is determined according to criteria set out in relevant Union and national safety legislation, such as modifications that change the original intended functions or affect the product's compliance with applicable safety requirements. **Where a substantial modification is carried out by the original manufacturer, or within its control, and where such a substantial modification makes the product defective, that manufacturer should not be able to avoid liability by arguing that the defect came into being after it originally placed the product on the market or put it into service.** In the interests of a fair apportionment of risks in the circular economy, an economic operator **other than the original manufacturer** that makes a substantial modification should be exempted from liability if it can prove that the damage is related to a part of the product not affected by the modification. Economic operators that carry out repairs or other operations that do not involve substantial modifications should not be subject to liability under this Directive. _____ 1. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A new Circular Economy Action Plan for a	

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. 1. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A new Circular Economy Action Plan for a cleaner and more competitive Europe, COM/2020/98 final.	cleaner and more competitive Europe, COM/2020/98 final.	
	Recital 29a	
(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.		
	Recital 29a	
	(29a) Since products also allow for modifications through changes to software, including upgrades, the same principles of substantial modification should apply. Where a substantial modification is made through a software update or upgrade, or due to the continuous learning of an AI	**(29a) Since products also allow for modifications through changes to software, including upgrades, the same principles of substantial modification should apply. Where a substantial modification is made through a software update or upgrade, or due to the continuous learning of an AI**

Commented [A43]: Hold until agreement is found on the fund article

Commented [A44]: Text clarifying when a substantial modification is placed on the market, subject to agreement to overall definition of substantial modification.

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

Commented [A45]: Hold until agreement is found on the fund article

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.		
	Recital 31	
(31) ~~*It is therefore necessary to facilitate claimants' access to*~~***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***~~*to be used in legal proceedings, while ensuring that such access is limited to that which*~~ 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]***~~*, that confidential information and trade secrets*~~ are protected. Such evidence	(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.	(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. ***In assessing the request for disclosure of evidence it should be ensured that such access is limited to that which is necessary and proportionate, inter alia to avoid non-specific searches for information that are not relevant to the proceedings, and to protect [confidential information and] trade secrets in accordance with Union and national law.***

Commented [A46]: The reference to the IA is only made in COM explanatory memorandum, the recitals are not right place for this.

Commented [A47]: For Article 8(1)and(2) - (COM Input 22.11)

To be finalised upon final agreement on article 8. Further discussions needed.

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

Commented [A48]: This is part of council recital 31a if agreed.

Commented [A49]: CSL text is also aligned with EP Mandate (Article 8(6) and recital 31a)

	Recital 32	
(32) In respect of trade secrets within the meaning of Directive (EU) 2016/943 ~~*of the European Parliament and of the Council*~~[~~1~~], national courts should be empowered to take ~~*specific*~~***all necessary*** measures to ensure ~~*the*~~***their*** 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***, 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. _____ ~~*1. Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).*~~	(32) In respect of trade secrets within the meaning of Directive (EU) 2016/943 of the European Parliament and of the Council[1], 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. _____ 1. 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).	
	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***, 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.	(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~~**natural persons** 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~~**reasonably foreseeable** use, since it is unnecessarily burdensome to require a claimant to prove defectiveness when the circumstances are such that its existence is undisputed.	(33) It is also necessary to alleviate the claimant's burden of proof provided that certain conditions are fulfilled. Rebuttable presumptions of fact are a common mechanism for alleviating a claimant's evidential difficulties, and allow a court to base the existence of defectiveness or causal link on the presence of another fact that has been proven, while preserving the rights of the defendant. In order to provide an incentive to comply with the obligation to disclose information, national courts should presume the defectiveness of a product where a defendant fails to comply with such an obligation. Many mandatory safety requirements have been adopted in order to protect **consumers and natural persons** from the risk of harm, ***including under Regulation (EU) 2023/988***. In order to reinforce the close relationship between product safety rules and liability rules, non-compliance with such requirements should also result in a presumption of defectiveness. This includes cases in which a product is not equipped with the means to log information about the operation of the product as required under Union or national law. The same should apply in the case of obvious malfunction, such as a glass bottle that explodes in the course **of reasonably foreseeable use**, since it is unnecessarily burdensome to require a claimant to prove defectiveness when the circumstances are such that its existence is undisputed. ***Reasonably foreseeable use covers the use for which a product is***

Commented [A50]: Taken from the Blue Guide (interpretative guide for single market legislation).

(COM Input 22.11)

		intended in accordance with the information provided by the manufacturer or economic operator placing it on the market, the ordinary use as determined by the design and construction of the product, and the conditions of use which can be reasonably foreseen, if such use could result from lawful and readily predictable human behaviour.
	Recital 33a	
	(33a) Similarly, where it has been established that the product is defective and the kind of damage that occurred is, based primarily on other similar cases, typically caused by the defectiveness in question, the claimant should be spared from fully proving the causal link and its existence should be presumed.	**(33a) Similarly, where it has been established that the product is defective and the kind of damage that occurred is, based primarily on other similar cases, typically caused by the defectiveness in question, the claimant should be spared from fully proving the causal link and its existence should be presumed.**
	Recital 34	
(34) National courts should also ~~*presume*~~***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	(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~~**particular due to** the technical or scientific complexity of the case, to prove its defectiveness or the causal link, or both. **They should do so taking into account all the circumstances of the case.** In such cases, requiring **the usual standard of** proof **as**	

Commented [A51]: CSL text relates to Art.9(3) which is similar to EP text. To be agreed.

Commented [A52]: **Depends on the outcome of the trilogue**

the effectiveness of the right to compensation. Therefore, given that manufacturers have expert knowledge and are better informed than the injured person, ~~it~~***the claimant*** should be ~~*for them to rebut the presumption*~~***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 ~~*the complex nature of the product, such as an innovative medical device;*~~***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 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	**required under national law, which often calls for a high degree of probability,** would undermine the effectiveness of the right to compensation. Therefore, given that manufacturers have expert knowledge and are better informed than the injured person, ~~it~~**and in order to maintain a fair apportionment of risk while avoiding a reversal of the burden of proof, the claimant** should be ~~for them to rebut the presumption~~**required to prove only that it is likely that, where the claimant's difficulties relate to proving defectiveness, the product was defective, or that, where the claimant's difficulties relate to proving the causal link, its defectiveness is a likely cause of the damage**. Technical or scientific complexity should be determined by national courts on a case-by-case basis, taking into account various factors. Those factors should include the complex nature of the product, such as an innovative medical device; the complex nature of the technology used, such as machine learning; the complex nature of the information and data to be analysed by the claimant; and the complex nature of the causal link, such as a link between a pharmaceutical or food product and the onset of a health condition, or a link that, in order to be proven, would require the claimant to explain the inner workings of an AI system. The assessment of excessive difficulties should also be made by national courts on a case-by-case basis. While a claimant should provide arguments to demonstrate excessive difficulties, proof of such difficulties should not be required. For	

example, in a claim concerning an AI system, the claimant should, for the court to decide that excessive difficulties exist, neither be required to explain the AI system's specific characteristics nor how these characteristics make it harder to establish the causal link. The defendant should have the possibility to contest 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***.	example, in a claim concerning an AI system, the claimant should, for the court to decide that excessive difficulties exist, neither be required to explain the AI system's specific characteristics nor how these characteristics make it harder to establish the causal link. The defendant should have the possibility to contest **all elements, including** the existence of excessive difficulties.	
	Recital 35	
deleted	*deleted*	
	Recital 36	
(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*~~***legal requirements***	(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~~**legal requirements**	(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~~ **legal requirements**

was the very reason for the product's defectiveness.	was the very reason for the product's defectiveness.	was the very reason for the product's defectiveness.
	Recital 36a	
(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 Annex.		
	Recital 37	
(37) The moment of placing on the market or putting into service is normally the moment at which a product leaves the control of the manufacturer, while for distributors it is the moment when they make the product available on the market. Therefore manufacturers should be exempted from	(37) The moment of placing on the market or putting into service is normally the moment at which a product leaves the control of the manufacturer, while for distributors it is the moment when they make the product available on the market. Therefore manufacturers should be exempted from	(37) The moment of placing on the market or putting into service is normally the moment at which a product leaves the control of the manufacturer, while for distributors it is the moment when they make the product available on the market. Therefore manufacturers should be exempted from

Commented [A53]: Depends on the outcome of the trilogue

liability where they prove that it is probable that the defectiveness that caused the damage did not exist when they placed the product on the market or put it into service or that it came into being after that moment. However, since digital technologies allow manufacturers to exercise control beyond the moment of placing the product on the market or putting into service, manufacturers should remain liable for defectiveness that comes into being after that moment as a result of software or related services within their control, be it in the form of upgrades or updates or machine-learning algorithms. Such software or related services should be considered within the manufacturer's control where they are supplied by that manufacturer or where that manufacturer authorises them or otherwise influences their supply by a third party.	liability where they prove that it is probable that the defectiveness that caused the damage did not exist when they placed the product on the market or put it into service or that it came into being after that moment. However, since digital technologies allow manufacturers to exercise control beyond the moment of placing the product on the market or putting into service, manufacturers should remain liable for defectiveness that comes into being after that moment as a result of software or related services within their control, be it in the form of upgrades or updates or machine-learning algorithms. Such software or related services should be considered within the manufacturer's control where they are supplied by that manufacturer or where that manufacturer authorises them or otherwise ~~influences~~**consents to** their supply by a third party. **For example, if a smart television is presented as including a video application, but the user is required to download the application from a third party's website after purchase of the television, the television manufacturer should still be liable, alongside the manufacturer of the video application, for damage caused by any defectiveness of the video application, even though the defectiveness came into being only after the television was placed on the market.**	liability where they prove that it is probable that the defectiveness that caused the damage did not exist when they placed the product on the market or put it into service or that it came into being after that moment. However, since digital technologies allow manufacturers to exercise control beyond the moment of placing the product on the market or putting into service, manufacturers should remain liable for defectiveness that comes into being after that moment as a result of software or related services within their control, be it in the form of upgrades or updates or machine-learning algorithms. Such software or related services should be considered within the manufacturer's control where they are supplied by that manufacturer or where that manufacturer authorises them or otherwise ~~influences~~**consents to** their supply by a third party. **For example, if a smart television is presented as including a video application, but the user is required to download the application from a third party's website after purchase of the television, the television manufacturer should still be liable, alongside the manufacturer of the video application, for damage caused by any defectiveness of the video application, even though the defectiveness came into being only after the television was placed on the market.**
	Recital 38	

Commented [A54]: EP text is not aligned with its current notion of manufacturer's control that speaks about "consents" and not anymore "influences".

Commented [A55]: This is an example concerning consent, needs to be aligned once the definition on manufacturer's control is agreed.

(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*~~***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 Council[1] , 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*~~***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***. 1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on	(38) The possibility for economic operators to avoid liability by proving that a defect came into being after they placed the product on the market or put it into service should also be restricted when a product's defectiveness consists in the lack of software updates or upgrades necessary to address cybersecurity vulnerabilities and maintain the product's safety. Such vulnerabilities can affect the product in such a way that it causes damage within the meaning of this Directive. In recognition of manufacturers' responsibilities under Union law for the safety of products throughout their lifecycle, such as under Regulation (EU) 2017/745 of the European Parliament and of the Council[1], manufacturers should also **not be exempted from liability**~~**be liable**~~ for damage caused by their **defective product when the defectiveness resided in their** failure to supply software security updates or upgrades that are necessary to address the product's vulnerabilities in response to evolving cybersecurity risks. Such liability should not apply where the supply or installation of such software is beyond the manufacturer's control, for example where the owner of the product does not install an update or upgrade supplied for the purpose of ensuring or maintaining the level of safety of the product. **This Directive does not itself impose any obligation to provide updates or upgrades to a product.** 1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC,	

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).	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).	
	Recital 39	
(39) In the interests of a fair apportionment of risks, ~~*manufacturers*~~***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 ~~*manufacturer*~~***economic operator*** in question, while the product was within their control was such that the existence of defectiveness could not be discovered.	(39) In the interests of a fair apportionment of risks, ~~manufacturers~~**economic operators** should also be exempted from liability if they prove that the state of scientific and technical knowledge, determined with reference to the most advanced level of objective knowledge accessible and not to the actual knowledge of the manufacturer in question, while the product was within their control was such that the existence of defectiveness could not be discovered.	(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** ~~manufacturer~~ in question, while the product was within the~~ir~~ **manufacturer's** control was such that the existence of defectiveness could not be discovered.
	Recital 40	
(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***, with***	(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~~**the** protection **of natural persons**, all parties	

Commented [A56]: EP addition, important to understand how this would affect the existing scope of the development risk defense as included in the current PLD.

compensation mechanisms allowing the injured person to be compensated for the relevant damage.	should be held liable jointly and severally in such situations.	
	Recital 41	
(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*~~***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.	(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~~**protecting natural persons**, 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.	
	Recital 42	
(42) The objective of consumer protection would be undermined if it were possible to	(42) The objective of ~~consumer protection~~**protecting natural persons** would	(42) The objective of **protecting natural persons** would be undermined if it were

limit or exclude an economic operator's liability through contractual provisions. Therefore no contractual derogations should be permitted. For the same reason, it should not be possible for provisions of national law to limit or exclude liability, such as by setting financial ceilings on an economic operator's liability.	be undermined if it were possible to limit or exclude an economic operator's liability through contractual provisions. Therefore no contractual derogations should be permitted. For the same reason, it should not be possible for provisions of national law to limit or exclude liability, such as by setting financial ceilings on an economic operator's liability.	possible to limit or exclude an economic operator's liability through contractual provisions. Therefore no contractual derogations should be permitted. For the same reason, it should not be possible for provisions of national law to limit or exclude liability, such as by setting financial ceilings on an economic operator's liability.
	Recital 43	
(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~~ ***30*** years in cases where the symptoms of a personal injury are, according to medical evidence, slow to emerge.	(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~~**expiry** period should be ~~15~~**20** years in cases where the symptoms of a personal injury are, according to medical evidence, slow to emerge.	(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~~**expiry** period should be ~~15~~**[20/30]** years in cases where the symptoms of a personal injury are, according to medical evidence, slow to emerge
	Recital 44	
(44) Since substantially modified products are essentially new products, the limitation period should restart after a product has been substantially modified, for example as a result	(44) Since substantially modified products are essentially new products, ~~the limitation~~**a new expiry** period should ~~restart~~**start to run** after a product has been substantially	(44) Since substantially modified products are essentially new products, **a new expiry** period should **start to run** after a product has been substantially modified **and has**

Commented [A57]: CSL structure of article 14 and 14a was agreed, therefore the wording to use is expiry here.

Commented [A58]: This will depend on the final outcome

Commented [A59]: CSL text and is also in line with EP Mandate on Art.14(2)

of remanufacturing, that modify a product in such a way that its compliance with the applicable safety requirements may be affected.	modified **and has subsequently been made available on the market or put into service**, for example as a result of remanufacturing~~, that modify a product in such a way that its compliance with the applicable safety requirements may be affected~~**. Updates or upgrades that do not amount to a substantial modification of the product do not affect the expiry period that applies to the original product**.	**subsequently been made available on the market or put into service**, for example as a result of remanufacturing**. Updates or upgrades that do not amount to a substantial modification of the product do not affect the expiry period that applies to the original product**.
	Recital 44a	
	(44a) The possibility offered to an economic operator to free itself from liability, if it proves that the state of scientific and technical knowledge at the time when the product was placed on the market, put into service or in the period in which the product was within the manufacturer's control was not such as to enable the existence of a defect to be discovered, could be deemed in certain Member States to limit unduly the protection of natural persons. It should therefore be possible for a Member State to introduce new measures, including amending existing ones, extending liability in such situations to specific types of products, if it is deemed necessary, proportionate and justified by public interest objectives, such as those within the meaning of the Treaty on the Functioning of the European Union, namely public policy, public security and public health.	

Commented [A60]: Text on updates in line with agreed text in Art. 14a.1

Commented [A61]: Depending on final outcome on Art.-15.
Also, this recital would need to be realigned with recital 39.

	To ensure transparency and legal certainty for economic operators operating across the Union, the use of such a derogation from the development risk defence should be notified to the Commission, who should then inform the other Member States. In order to facilitate a coherent approach across Member States and consistency with the objectives of the Directive, the Commission should be able to issue a non-binding opinion on the proposed measure. In order to allow time for such an opinion, the Member State concerned should hold the proposed measure in abeyance for 6 months following its notification to the Commission, unless the Commission issues an opinion earlier. Such opinions should be issued after close cooperation between the Member State concerned and the Commission, taking into account any views of other Member States. In the interest of legal certainty and to facilitate continuity of arrangements under Directive 85/374/EEC, it should also be possible for a Member State to maintain existing derogations from the development risk defence in its legal system.	
	Recital 45	
(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***	(45) In order to facilitate **the** harmonised interpretation of this Directive by national courts, Member States should be required to publish ~~relevant~~ **final** court judgments on product liability **under this Directive,**	(45) In order to facilitate **the** harmonised interpretation of this Directive by national courts, Member States should be required to publish **[final]** court judgments on product liability **under this Directive[, meaning**

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.	**meaning those judgments that cannot be, or can no longer be, appealed. In order to limit administrative burden, Member States should be required only to publish judgments of national courts of appeal or of the highest instance**.	**those judgments that cannot be, or can no longer be, appealed. In order to limit administrative burden, Member States should be required only to publish judgments of national courts of appeal or of the highest instance.]**
		NEW RECITAL 45a
		To increase the understanding of how this Directive is applied at national level, for the benefit of, inter alia, the public, legal practitioners, academia and Member States, the Commission should set up and maintain an easily accessible and publicly available database containing the relevant judgments, as well as references to relevant judgments delivered by the Court of Justice of the European Union.
	Recital 46	
(46) The Commission should carry out an evaluation of this Directive. Pursuant to paragraph 22 of the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making[1], that evaluation should be based on the five criteria of efficiency, effectiveness, relevance, coherence and EU value added and should provide the basis for impact assessments of possible further measures. For reasons of legal certainty, this Directive should not apply to products placed or put	(46) The Commission should carry out an evaluation of this Directive. Pursuant to paragraph 22 of the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making[1], that evaluation should be based on the five criteria of efficiency, effectiveness, relevance, coherence and EU ~~value~~ added **value** and should provide the basis for impact assessments of possible further measures. For reasons of legal certainty, this Directive should not apply to products placed **on the**	(46) The Commission should carry out an evaluation of this Directive. Pursuant to paragraph 22 of the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making[1], that evaluation should be based on the five criteria of efficiency, effectiveness, relevance, coherence and EU added value and should provide the basis for impact assessments of possible further measures. For reasons of legal certainty, this Directive should not apply to products placed on the Union market or put into service before the

Commented [A62]: Need to align depending final agreement on article 15, whether or not including first instance courts.

Commented [A63]: COM Input 29.11 based on EP recital 45

into service on the Union market before the date of its transposition. It is necessary to provide for transitional arrangements in order to ensure continued liability under Directive 85/374/EEC for damage that caused by defective products which have been placed on the market or put into service before that date. _____ 1. Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016 (OJ L 123, 12.5.2016, p. 1).	**Union market** or put into service ~~on the Union market~~ before the date of its ~~transposition~~**application**. It is necessary to provide for transitional arrangements in order to ensure continued liability under Directive 85/374/EEC for damage ~~that~~ caused by defective products which have been placed on the market or put into service before that date. _____ 1. Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016 (OJ L 123, 12.5.2016, p. 1).	date of its application. It is necessary to provide for transitional arrangements in order to ensure continued liability under Directive 85/374/EEC for damage caused by defective products which have been placed on the market or put into service before that date. ***In its evaluation report, the Commission should provide the methodology of the calculation used in its evaluation.*** **The Commission should gather** ***all relevant information in a way that avoids overregulation and administrative burden for Member States and*** **economic operators, using information from all relevant and reliable sources, including Union institutions, bodies, offices and agencies, national competent authorities and internationally recognised bodies and organisations**.
	Recital 47	
(47) Since the objectives of this Directive, namely to ensure the functioning of the internal market, undistorted competition and a high level of consumer protection, cannot be sufficiently achieved by the Member States due to the Union-wide nature of the market in goods but can rather, by reason of the harmonising effect of common rules on liability, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this	(47) Since the objectives of this Directive, namely to ensure the functioning of the internal market, undistorted competition and a high level of ~~consumer~~ protection **for natural persons**, cannot be sufficiently achieved by the Member States due to the Union-wide nature of the market in goods but can rather, by reason of the harmonising effect of common rules on liability, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out	(47) Since the objectives of this Directive, namely to ensure the functioning of the internal market, undistorted competition and a high level of protection **for consumers and for natural persons**, cannot be sufficiently achieved by the Member States due to the Union-wide nature of the market in goods but can rather, by reason of the harmonising effect of common rules on liability, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out

Commented [A64]: Addition reflecting EP Art.16 (COM Input 22.11)

Directive does not go beyond what is necessary in order to achieve those objectives,	in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives,	in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives,