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ELI Draft of a Revised Product Liability Directive

Draft Legislative Proposal of the European Law Institute

**PRODUCT
LIABILITY**



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The European Law Institute

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Executive Summary

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 (the 1985 PLD)¹ has been the basis for product liability in the EU for almost four decades. Its technology-neutral and cross-sectoral approach has made it rather resilient to many developments, but digitalisation, and in particular the increasing interaction between, and gradual merging of, tangible and purely digital items means that the 1985 PLD is no longer fit to protect consumers and other victims of harm caused by unsafe products. In January 2021, the ELI published the 'Guiding Principles for Updating the EU Product Liability Directive for the Digital Age',² authored by Christian Twigg-Flesner, which set out concrete propositions for updating the EU Product Liability Directive with a view to adapting it to the digital age. In autumn 2021, the European Commission launched a public consultation on 'Adapting liability rules to the digital age and Artificial Intelligence', in which the ELI participated. A small working group, tasked with drafting the 'ELI Response to the European Commission's Public Consultation on Civil Liability',³ led by Bernhard A Koch, produced recommendations on the way forward and answered the questions specifically posed by the European Commission. As the group had to submit the Response by 10 January 2022 and was working under great time pressure, a tentative full draft for a new Directive that had been produced internally by a member of the group (Christiane Wendehorst) could not be discussed and integrated into ELI's Response. However, upon the initiative of ELI bodies, the group reconvened in spring 2022 in order to discuss the tentative full draft and develop it further. Bernhard A Koch and Jean-Sébastien Borghetti were asked to lead the Project Team, which again had to work under considerable time pressure, as Reporters. After taking on board very helpful guidance from Advisors and ELI bodies, the Project Team submitted the ELI Draft of a Revised Product Liability Directive (hereinafter the ELI Draft PLD) to the ELI Council, which approved it on 5 July 2022.

The following Draft for a possible revision of the 1985 PLD is indeed very tentative in nature and merely intended as a toolbox and possible source of inspiration. It was drafted in full recognition of current plans by the European Commission to amend the 1985 PLD. The text below was nevertheless completed in order to provide a coherent and consistent model that can also serve as a point of reference for a future debate and ELI's future work on a possible reform at the level of the EU institutions.

¹ The 1985 PLD refers to the consolidated text of the Council Directive 85/374/EEC of 25 July 1985, as amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 amending Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products; Official Journal of the European Union (OJ) L141/42 <<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31999L0034&from=EN>>.

² European Law Institute, Guiding Principles for Updating the Product Liability Directive for the Digital Age (ELI Innovation Paper Series, 2021) <https://europeanlawinstitute.eu/fileadmin/user_upload/p_eli/Publications/ELI_Guiding_Principles_for_Updating_the_PLD_for_the_Digital_Age.pdf>.

³ European Law Institute, European Commission's Public Consultation on Civil Liability. Adapting Liability Rules to the Digital Age and Artificial Intelligence (Response of the European Law Institute, 2022) <https://europeanlawinstitute.eu/fileadmin/user_upload/p_eli/Publications/Public_Consultation_on_Civil_Liability.pdf>.

The ELI Draft of a Revised Product Liability Directive is characterised by the following considerations:

- Adaptation, in terms of concepts and terminology, to modern product safety legislation, in particular the Medical Device Regulation⁴ and the Proposal for a General Product Safety Regulation,⁵ as well as to the Digital Content Directive⁶ and Sale of Goods Directive⁷;
- Flexibility as to some important policy choices, such as the extension to self-standing digital content and possibly digital services (which the authors would recommend), liability for damage to purely digital assets (which the authors would likewise recommend), liability for data leakage, and any special role of artificial intelligence (AI);
- Taking on board a range of suggestions made in the 2019 Expert Group Report,⁸ including on technological and commercial units as well as on the burden of proof, and in the ELI Guiding Principles⁹ as well as the ELI Consultation Response;¹⁰
- Including provisions on refurbished products and on safety-relevant modifications, in line with formulations in the Medical Device Regulation and the Proposal for a General Product Safety Regulation as well as recent developments of the circular economy;
- Subsidiary liability of online marketplaces that have enabled the making available of the product on the Union market (inspired by the draft Digital Services Act);¹¹ and
- Including a chapter on liability for non-compliance with duties under product safety and market surveillance law (in order to provide better consistency between these areas of the law and a level playing-field through full harmonisation).

⁴ 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/EE [2017] Official Journal of the European Union (OJ) L117/1 <<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745>>.

⁵ Proposal for a Regulation of the European Parliament and of the Council on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council [2021] COM/2021/346 final <<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0346>>.

⁶ Directive (EU) 2019/770 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the supply of digital content and digital services [2019] OJ L136/1 <<https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32019L0770>>.

⁷ Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC OJ L136/28 [2019] <<https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32019L0771>>.

⁸ European Commission, Directorate-General for Justice and Consumers, Liability for artificial intelligence and other emerging digital technologies, Publications Office, 2019, <<https://data.europa.eu/doi/10.2838/573689>>.

⁹ See n 1.

¹⁰ See n 2.

¹¹ Proposal for a Regulation of the European Parliament and of the Council on a Single Market For Digital Services (Digital Services Act) and amending Directive 2000/31/EC [2020] COM/2020/825 final <<https://eur-lex.europa.eu/legal-content/en/TXT/?uri=COM%3A2020%3A825%3AFIN>>.

Table of Contents

Acknowledgements	5
Executive Summary	6
Table of Contents	8
Proposal for a Directive on Liability for Defective Products	9
Chapter I: General Provisions	10
Article 1: Subject Matter	10
Article 2: Scope	10
Article 3: Definitions	11
Article 4: Level of Harmonisation	15
Chapter II: Strict Liability for Harm Caused by Defective Products	16
Article 5: Right to Compensation	16
Article 6: Relevant Harm	16
Article 7: Defective Products	18
Article 8: Liable Economic Operators	20
Article 9: Burden of Proof	21
Article 10: Defences	23
Chapter III: Liability for Non-compliance with Obligations Under Product Safety and Market Surveillance Law	24
Article 11: Right to Compensation	24
Article 12: Burden of Proof	27
Chapter IV: General Provisions on Liability	28
Article 13: Joint and Several Liability, Reduction and Exclusion of Liability	28
Article 14: Right of Recourse	28
Article 15: Mandatory Nature	29
Article 16: Liability Caps	29
Article 17: Limitation Period	29
Chapter V: Final Provisions	32
Article 18: Repealing of Council Directive 85/374/EEC	32
Article 19: Transposition	32
Article 20: Review	32
Article 21: Entering into Force	32
Article 22: Addressees	32
Annex I	32

Proposal for a Directive on Liability For Defective Products

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on liability for defective products, repealing Council Directive 85/374/EEC

Chapter I: General Provisions

Article 1

Subject Matter

This Directive lays down a harmonised regime of liability for defective products. It complements Union and Member State law on product safety and market surveillance as well as on extra-contractual liability, providing for compensation and a high level of protection for the victims of unsafe products. It shall also encourage investment in innovation and enhancement of product safety.

Article 2

Scope

1. This Directive shall apply to products as defined in Article 3(1) that were made available on the market, whether new, used, repaired or reconditioned.
2. This Directive shall not apply to services other than digital services within the scope of Directive (EU) 2019/770, regardless of whether digital forms or means are used by the service provider to produce the output of the service or to deliver or transmit it to the addressee.
3. This Directive is without prejudice to the rules laid down by Union or Member State law on liability based on grounds of attribution other than the making available on the market of a defective product or the failure to comply with obligations under product safety or market surveillance law, such as contractual liability, fault liability, or strict liability of the operator of a device.

Comment

Article 2 sets out the scope of application of the ELI Draft PLD. Its scope is confined to the types of products within Article 3(1).

It is inherent in the overall scheme of the ELI Draft PLD that liability only arises once a product has been made available on the market by the producer. This would

exclude from its scope products which have not been made available on the market by the producer, eg, because they have been stolen at a point when they were not yet intended to be made available on the market, or because they were intended for use only in a controlled and confined setting (such as a medical trial). See also the definition of 'finished product' in Article 3(4), which refers expressly to a product which has been made available on the market 'with the assent of its producer'. Article 2 only mentions the making available on the market, but not the putting into service (see, by contrast, Article 1 of the *Proposal for a Regulation on Machinery Products*,¹² COM(2021) 202 final).

The ELI Draft PLD does not apply to services, which reflects the scope of the 1985 PLD (see case C-65/20 *VI v Krone*, paragraph 27). The issues associated with liability for services differ from those relevant for strict liability for defective products and cannot be addressed within the scope of this Draft Directive. Previous efforts to introduce a Council Directive on the Liability of Suppliers of Services (91/C269/14) were unsuccessful, and reforming the 1985 PLD is not the right context within which to revisit this issue.

However, in one respect, services are not excluded: the definition of 'product' in Article 3(1) extends to digital products, defined as digital content and digital services within the scope of Directive (EU) 2019/770 (DCD). Digital services are distinct from non-digital services and often not clearly distinguishable from digital content, so their inclusion within the scope of the ELI Draft PLD is appropriate; moreover, as the ELI Draft PLD applies to products with digital elements, and such digital elements can take the form of a digital service, digital services cannot be excluded from the scope of the ELI Draft PLD. For the sake of clarification, it should be stressed that reference to the DCD does not include reference to contract law in a more general manner. For example, for the purposes of the ELI Draft PLD, the classification of the contract under which the defective product was supplied is not relevant because liability under the ELI Draft PLD does not arise from a contract, but from the fact that a product was defective and caused relevant harm.

¹² Proposal for a Regulation of the European Parliament and of the Council on machinery products COM/2021/202 final [2021] <<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0202>>.

It was already the case under the 1985 PLD that rights under liability systems in national law based on non-contractual or contractual liability, or special liability systems in existence when the 1985 PLD was notified would be unaffected (Article 13 of the 1985 PLD). In short, liability systems for anything other than strict liability for relevant harm caused by a defective product are outside the scope of the ELI Draft PLD (cf European Court of Justice (ECJ) cases C-327/05 Commission v Denmark; C-183/00 María Victoria González Sánchez v Medicina Asturiana SA). This approach continues in the ELI Draft PLD. However, to create more of a level playing field within Europe, the restriction in Article 13 of the 1985 PLD to liability regimes already in existence at a particular point in time should be reconsidered. Under Article 2(3) ELI Draft PLD, such regimes could not remain in force insofar as they establish liability based on the product's defectiveness. However, they might contain procedural or other rules, which would not be affected by the ELI Draft PLD, for example, on the burden of proof (subject to Article 9) or discovery measures.

Article 3

Definitions

For the purposes of this Directive the following definitions apply:

1. 'Product' means:
 - (a) any tangible movable item, with or without a digital element, whether incorporated into or coupled with another movable or immovable item or not;
 - (b) any digital product.
2. 'Digital product' means digital content and digital services within the scope of Directive (EU) 2019/770.
3. 'Digital element' means any digital product or digital service that is incorporated into, or is inter-connected with, a tangible movable item in such a way that the absence of such digital product would prevent the item from performing the functions ascribed to the item by or with the consent of its producer.
4. (a) 'Finished product' means any product which is made available on the market by, or with the assent of, its producer for use without further modifications by another producer. This includes products which have undergone a process of professional refurbishment once they are made available on the market again by the refurbisher.
 - (b) A product which needs to be assembled or installed or which requires the installation of a digital element is a finished product where assembly or installation is to be undertaken by the end user or by a distributor or under the latter's control before it reaches the end user.
 - (c) A digital product or a product with a digital element is a finished product notwithstanding the subsequent provision of an authorised update.
5. 'Component' means any raw material or product that is incorporated into, or coupled with, a finished product.
6. 'Authorised update' means an update to a finished digital product (paragraph (2)) or to a digital element (paragraph (3)) of a finished product which is made available by or with the consent of the producer of the digital element or of the producer of the finished product.
7. 'Making available on the market' means any supply of a product for distribution, consumption or use on the market in the course of a commercial activity, whether in return for payment or free of charge.
8. 'Producer' means a natural or legal person who:
 - (a) manufactures, produces, develops, or fully refurbishes a finished product;
 - (b) has a product developed, manufactured, produced, or fully refurbished and markets it under their name or trademark, thereby presenting themselves as a producer;
 - (c) manufactures, produces, develops, or fully refurbishes a component.
9. 'Authorised representative' means any natural or legal person established within the Union who has been appointed by a producer to act on their behalf for the purpose of Union product safety or market surveillance legislation.
10. 'Importer' means any natural or legal person established within the Union who first makes a product from a third country available on the Union market.

11. 'Distributor' means any natural or legal person in the supply chain, other than the producer, the importer, or the authorised representative, who makes a product available on the market.
12. 'Online marketplace' means an online platform which allows users to conclude distance contracts with traders.
13. 'Fulfilment service provider' means any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services, parcel delivery services and any other postal services or freight transport services.
14. 'Economic operator' means the producer, the authorised representative, the fulfilment service provider, or any other natural or legal person who is subject to obligations in relation to the development or manufacture of products or to making them available on the market.
15. 'End user' means any natural or legal person residing or established in the Union, to whom a product has been made available.
16. 'Victim' means any natural or legal person having suffered relevant harm within the meaning of Article 6, either as an end user or as a third party ('innocent bystander').
17. 'European standard' means a European standard as defined in Article 2(1) point (b) of Regulation (EU) No 1025/2012.

Comment

This Article provides definitions under the ELI Draft PLD. Some of these definitions are based on the 1985 PLD, whereas others are new. Several new definitions were required in order to extend the scope of the ELI Draft PLD to the digital realm and to cover novel means of supplying and utilising new types of products, such as smart products combining a physical item with digital elements.

Product, Digital Product, Digital Element (nos 1–3)

The core definition of a product is that it is a tangible movable item. This was already the position under the original Directive (Article 2 of the 1985 PLD), as was the clarification that a tangible movable item was still within the definition of a product where it had been

incorporated into another movable or immovable. This scope has been retained for the ELI Draft PLD.

However, this scope has been broadened in the ELI Draft PLD in that the definition of product not only covers the situation where a tangible movable item has been incorporated into another movable or immovable, but also where it has been coupled with another (eg, multiple products coupled with one another as part of a smart home system).

A key objective the ELI Draft PLD is to update the 1985 PLD for the digital age. The definition of product has therefore been extended to clarify that products with a digital element are covered, and that it includes digital products. The first, mostly clarificatory, extension of the definition is that it confirms explicitly that products with a digital element are covered (see [ELI Innovation Paper, Guiding Principle 4](#); [Consultation Response](#), p 12). This extension prompts several additional issues, such as the implications of updates to the digital element, which are addressed in other Articles of this Directive (see Articles 10 and 17). A separate definition of 'digital element' is provided in Article 3(3). This definition is based on the definition of 'goods with digital element' in Article 2(3) DCD. Accordingly, a digital element is digital content or a digital service which is integral to the functionality of the tangible movable item with which it is connected or into which it has been incorporated. Given that the respective definition in the DCD can rely on the functions owed by a seller under a contract, while product liability applies irrespective of any contract, there has to be a link between the relevant function and the producer, ie, the function must be one that has been ascribed to the item by its producer or that an end user would reasonably expect in the light of the description of the product type provided by the producer. It would, for instance, cover an operating system for a smartphone, but it would not include an online banking app which has been installed on that smartphone by its owner. The latter would be a 'digital product' in its own right.

*A further extension of the notion of product is the inclusion of 'digital product'. The notion of a 'digital product' is used as an umbrella term to cover both digital content and digital services, as defined in the DCD, and excluding digital content and digital services excluded by Article 3(5) DCD from the scope of the DCD. The ELI Draft PLD ensures consistency in the use of new terminology in the *acquis* by cross-referring to existing definitions rather than proposing separate standalone definitions. This will mean that any interpretation of either term by the Court of Justice of the European*

Union (CJEU) would not only apply within the context of the DCD, but also to the notion of ‘digital product’ in the ELI Draft PLD.

The definitions of digital product and digital element do not explicitly refer to AI or AI systems. The notion of ‘digital product’ already covers AI because the broad definition of ‘digital content’ already includes AI. The Project Team discussed whether to include AI (systems) separately in the definition of product and concluded that this would not be necessary because it would not add anything of substance. It should therefore be assumed that digital product and digital element both include AI systems.

This definition does not make express reference to electricity, unlike the 1985 PLD, but it can be assumed to be within its scope. A more difficult issue is the inclusion of animals, human organs, or blood within the definition. Although this is likely to be answered in the affirmative, it is open for further debate whether these should be included expressly in this definition.

Finished Product (no 4)

The 1985 PLD made reference to a ‘finished product’ (Recitals and Article 3(1) of the 1985 PLD) but left this undefined. The ELI Draft PLD includes a definition of ‘finished product’. A product qualifies as a finished product once it has been made available on the market. ‘Making available on the market’ is defined in Article 3(7) and explained below. Importantly, only a product which was made available on the market with the assent of its producer falls within this definition. This excludes instances where a product has somehow reached a person who was harmed by a defect at a time when its producer had not assented to it being made available on the market.

A finished product must have been made available on the market for use and not require any further modification by another producer, such as its incorporation as a component into another product.

An important innovation in the definition of ‘finished product’ is the express inclusion of products which have undergone a process of professional refurbishment and have been made available on the market again by the refurbisher. It is increasingly the case that products which had already been supplied to, and used by, an end user are completely overhauled (refurbished) and made available again on the market. Refurbishment is likely to become more prevalent in the future as concerted efforts to promote product sustainability are pursued.

As refurbishment, unlike simple repair or a regular service, effectively involves a complete overhaul of the product in question, the latter should be treated once again as a finished product when it is made available on the market again by the refurbisher.

Furthermore, point (b) of the definition of ‘finished product’ clarifies that products which need to be assembled, installed or which require the installation of a digital element are nevertheless finished products if assembly or installation is to be carried out either by the end user, or by, or under the control of, a distributor before it reaches the end user. For the purposes of the ELI Draft PLD, ‘distributor’ has been defined broadly (Article 3(11)) to include any party in the supply chain other than the producer who makes the product available on the market. In practical terms, the ‘distributor’ carrying out the installation or assembly in the situation covered by this definition will usually be the final contractual seller or supplier of the product in question. In effect, this situation mirrors the approach taken under the Sale of Goods Directive (2019/771; SGD) in respect of goods to be installed.

Finally, point (c) of the definition clarifies that, in the case of a digital product or product with a digital element, the fact that the digital aspect is subject to updating does not alter the fact that such a product is to be treated as a finished product within point (a). Otherwise, the regular provision of authorised updates could remove such products from the definition of ‘finished product’ altogether and thereby lead to the evasion of other provisions of the ELI Draft PLD.

Component (no 5)

Although the 1985 PLD referred to ‘components’ as well as finished products, this term had also not been defined. For the sake of clarity, a definition has been introduced into the ELI Draft PLD. ‘Component’ covers both raw materials and products which are incorporated into, or coupled with, a finished product. Such a finished product may itself subsequently become a component of another finished product into which it is incorporated after it has been made available on the market.

Authorised Update (no 6)

It is in the nature of digital products and products with digital elements that they can be updated to improve functionality or to remove ‘bugs’ in codes. Elsewhere in the ELI Draft PLD, the implications of updates on the system of liability are addressed. For the purposes of the ELI Draft PLD, updates are relevant where they are

authorised, ie, where the update in question has been made available by, or with the consent of, the producer. Liability arising in connection with updates should be limited to those instances where the updates are within a degree of control of the producer of the digital product or of the finished product with a digital element.

This excludes updates which are supplied by third parties and cannot be attributed to the producer from the notion of 'authorised update'. Where a third party provides an update without the producer's consent, the producer should not be at risk of liability if the result of the update is to render a product defective where it subsequently causes harm. Instead, in such a situation, the third party would be treated as the producer of a separate digital product, the update, and would be liable separately if the update is defective and causes relevant harm.

Making Available on the Market (no 7)

It was already the case under the 1985 PLD that a criterion was needed to fix the point for defining the producer's liability. The 1985 PLD referred to 'putting the product into circulation'. This Directive refers instead to making a product available on the market. Once a product has been supplied for distribution, consumption, or use, it is regarded as having been made available on the market. This definition is based on the definition of this term in Article 3(1) of the *Market Surveillance Regulation*¹³ (2019/1020; MSR).

An essential element of this definition is that the product must have been supplied in the course of a commercial activity, reflecting a limitation already inherent in the 1985 PLD. It would not, for instance, cover the supply of a 3D-printed product made by a private individual at home.

However, it is irrelevant for the purposes of establishing whether the supply of the product occurred in the course of a commercial activity that the supply was in return for payment or free of charge. Whether a product was supplied in the course of a commercial activity therefore has to be determined on the basis of other factors, such as the fact that the supply is part of the producer's business activities.

Producer (no 8)

Under the liability system introduced by the 1985 PLD, liability is placed on the producer of the defective product. The definition of 'producer' in the 1985 PLD was broad, covering not only the manufacturer of a finished product, but also a producer of raw materials, the manufacturer of component parts, and a person presenting themselves as a producer by putting their name or trademark on the product ('own-brander').

This broad approach has been carried through into this Draft Directive, albeit with some modifications. Some of these modifications are needed to reflect the broader scope of the ELI Draft PLD compared to the 1985 PLD, particularly in respect of digital products/elements and the express inclusion of refurbished products. Thus, a producer is a natural or legal person who manufactures, produces, develops, or fully refurbishes a finished product or a component. Furthermore, the 'own-brander' situation is also retained, with an enhanced wording (Article 3(8) point (b)).

It is important that this definition is read in light of the definitions of 'finished product' and 'component part'. Both ultimately relate to the making available of a product on the market. Therefore, a producer involved in research and development, or a designer, who is not involved in producing a 'finished product' as defined for the purposes of the ELI Draft PLD, would not be a producer within this definition.

Furthermore, building on the exclusion of services, and in line with case C-65/20 VI v Krone, the provision of a service which includes the supply of a product (eg, a lawyer who has drafted a memo on paper or on a digital file) would also not be a 'producer'.

Online Marketplace (no 12)

For the purposes of the ELI Draft PLD, a simple definition of 'online marketplace' has been included. In essence, it covers those platforms which enable users of such platforms (whether consumers or businesses) to conclude contracts with traders. It therefore only includes platforms on which B2C or B2B contracts can be concluded, but not P2P contracts.

¹³ 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 [2019] OJ L169/1 <<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32019R1020>>.

This definition is shorter than the definition of ‘online marketplace’ used in Article 2(1) point (n) of the *Unfair Commercial Practices Directive*¹⁴ (2005/29/EC; UCPD), which defines ‘online marketplace’ as ‘a service using software, including a website, part of a website or an application, operated by or on behalf of a trader which allows consumers to conclude distance contracts with other traders or consumers.’ Although the definition in the UCPD is more extensive, it does not differ significantly in substance from the definition in Article 3(12) of the ELI Draft PLD. The key criterion is the ability to conclude contracts with traders offering products via the online platform.

Article 3(14) of the Proposal for a General Product Safety Regulation (COM(2021) 346 final; ‘Proposed GPSR’) defines ‘online marketplace’ as ‘a provider of an intermediary service using software, including a website, part of a website or an application, operated by or on behalf of a trader, which allows consumers to conclude distance contracts with other traders or consumers for the sale of products covered by this Regulation’. Again, the focus is on the conclusion of distance contracts, but here, it only includes those marketplaces which facilitate B2C and P2P contracts, but not B2B contracts.

Victim (no 16)

A definition of ‘victim’ has been included to clarify the scope of the ELI Draft PLD. Thus, it includes both natural and legal persons who have suffered relevant harm (as defined in Article 6 of the ELI Draft PLD), either as an ‘end user’ (as defined in Article 3(15), see below) or as a third party, ie, an innocent bystander.

Definitions Adopting Definitions in Other Measures

There are several terms which were used in the 1985 PLD, but which had not been properly defined. Since its adoption in 1985, many of these terms have been defined in related EU legislation, and in order to ensure coherence between related instruments, the ELI Draft PLD borrows a number of definitions used elsewhere. Several terms defined in Article 3 of the ELI Draft PLD either directly follow or are substantively identical to the definitions of these terms in Article 3 MSR. This is the

case for the definitions of ‘authorised representative’ (Article 3(12) MSR), ‘importer’ (Article 3(9) MSR), ‘distributor’ (Article 3(10) MSR), and ‘fulfilment service provider’ (Article 3(11) MSR). Furthermore, the definition of ‘economic operator’ is based on Article 3(13) MSR but has been worded differently for the specific context of the ELI Draft PLD.

The definition of ‘end user’ is based on the definition of the same term in Article 3(16) of the proposed GPSR, but it omits the words ‘either as a consumer outside of any trade, business, craft, or profession or as a professional end user in the course of its industrial or professional activities’. The additional words in the proposed GPSR definition seem otiose and are therefore not needed for the purposes of the ELI Draft PLD. Furthermore, ‘European standard’ follows the wording of Article 3(17) of the proposed GPSR.

Article 4

Level of Harmonisation

1. Member States shall not maintain or introduce, in their national law, provisions diverging from those laid down in this Directive, including more or less stringent provisions to ensure a different level of compensation for victims, unless otherwise provided for in this Directive.
2. Unless a matter has been addressed by this Directive, Member States are free to apply their general rules and principles of non-contractual liability to liability under this Directive, or any special rules and principles.
3. This Directive shall not affect any rights which a victim may have according to law that remain unaffected by this Directive according to Article 2(3).

¹⁴ Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council [2005] OJ L149/22 <<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32005L0029>>.

Chapter II: Strict Liability for Harm Caused by Defective Products

Article 5

Right to Compensation

Victims of relevant harm (Article 6) caused by a defective product (Article 7) shall be entitled to receive compensation from the liable economic operators (Article 8) under the conditions laid down in this Chapter.

Article 6

Relevant Harm

1. Relevant harm means any of the following:
 - (a) death or personal injury, including damage to psychological health, that has materialised, or is likely to materialise, in a recognised state of illness;
 - (b) damage to tangible property, other than the defective product itself;
 - (c) damage to files;
 - (d) leakage of personal or other data.
2. This Article shall be without prejudice to Member State law relating to non-economic harm, in particular pain and suffering, resulting from relevant harm within the meaning of paragraph (1), and to harm suffered by third parties as a consequence of the immediate victim's death or personal injury within the meaning of paragraph (1) point (a). The conditions, in particular time limits, for reparation of loss or damage laid down by Member State law must not be less favourable than those relating to comparable domestic claims and must not be so framed as to make it virtually impossible or excessively difficult to obtain reparation.
3. The conditions under which third parties can claim compensation for harm suffered by the immediate victim shall be determined by Member State law.

Comment

Article 6 defines the types of harm and losses that can be compensated under the ELI Draft PLD, as does Article 9 of the 1985 PLD.

Primary Harm (paragraph (1))

Paragraph (1) restrictively sets the types of primary harm that can give rise to reparation under the ELI Draft PLD. There are four types.

The first one is death or personal injury (paragraph 1 point (a)). Product liability as a specific branch of the law was born out of the need to better protect victims of personal injuries caused by manufactured products, and harm consisting in death or personal injury has always stood at the heart of product liability. Paragraph (1) point (a) makes it clear that personal injury does not refer only to bodily injuries but also includes damage to psychological health, as has been explicitly recognised in several Member States. There are psychological diseases as there are physical ones, and there is no reason why the rules on product liability should protect only physical health, and not psychological health, especially as the two can be closely connected or intertwined.

Paragraph (1) point (a) also specifies that personal injury need not have materialised in a recognised state of illness, even though this will generally be the case. It is enough if the injury is likely to materialise in a recognised state of illness. This can be the case, for example, where someone has been contaminated by the HIV virus but has not (yet) developed any associated disease or condition. This can also be the case, as in cases C-503/13 and C-504/13 *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt – Die Gesundheitskasse and Betriebskrankenkasse RWE*, where someone was implanted with a defective defibrillator and the product, though still functioning, must be replaced; or where a woman received a breast implant presenting an inevitable risk of rupture and needs to have it removed.

An injury 'likely to materialise' is an objective standard. It is not the same thing as the subjective fear of falling ill, which may or may not be grounded on objective and

convincing elements. For example, the fear, however sincere, of developing an illness caused by exposure to magnetic waves cannot qualify as an 'injury likely to materialise' if there is no convincing scientific evidence suggesting that such exposure may indeed cause an illness of that type.

The Draft does not define the notion of 'recognised state of illness'. There exist different classifications of diseases that have achieved broad international recognition, such as the International Classification of Diseases (ICD) published by the World Health Organization (WHO), or the Diagnostic and Statistical Manual of Mental Disorders (DSM) of the American Psychiatric Association. National courts may wish to refer to them, but it is not for the ELI Draft PLD to define what is a disease or illness from a medical point of view.

The second type of primary harm that calls for reparation under the ELI Draft PLD is damage to tangible property, other than the defective product itself. The exclusion of damage to the defective product itself has been carried over from the 1985 PLD. Such damage is better handled through the rules of sales law, including (but not exclusively) those of the SGD. However, it should be stressed that, if damage has been caused to a finished product by a defect in a component or digital element of that product, the component or digital element then constitutes the 'defective product' within the meaning of Article 6(1) point (b) and the owner of the finished product can then turn to the producer, or any other person liable under Article 8 of the ELI PLD Draft, to be compensated for that damage caused to the finished product. For example, if a phone catches fire due to a defect in its battery, and the phone thereby causes damage to a bystander, that bystander can seek compensation for their harm both from the producer of the phone (the finished product) and from the producer of the battery (a component), who are jointly and severally liable under Article 13. The owner of the phone, on the other hand, cannot seek compensation for the loss of their phone from the producer of the phone under the ELI PLD Draft, but they can seek compensation for it from the producer of the battery (who will not have to compensate the loss of the battery itself, however). The same would be true, of course, if the defect in the finished product were caused not by a physical component but by a digital element of the finished product.

Tangible property should be understood as including live animals. The classification of animals as items of property has now been challenged in several legal

systems and the Draft does not take a position as to whether an animal constitutes a 'thing' that can be the subject of a property right. It simply wishes to make clear that animals are protected under the ELI Draft PLD.

In its current state, Article 9 of the 1985 PLD only covers 'damage to, or destruction of, any item of property other than the defective product itself, with a lower threshold of 500 ECU, provided that the item of property: (i) is of a type ordinarily intended for private use or consumption, and (ii) was used by the injured person mainly for his own private use or consumption.' The Draft has abandoned both the threshold and the exclusion of 'professional property'.

The threshold appears as an unnecessary source of complication. Various Member States have analysed it differently, but its practical relevance is in any case limited. It was intended to limit litigations and to avoid courts being flooded with low-value claims, but even in countries with a comparatively low average income, product liability claims are seldom filed for amounts of only a few hundred euros, or the equivalent thereof. It is therefore simpler to do without the threshold altogether.

The exclusion of damage to property used for professional purposes was justified when product liability was understood as a consumer protection tool. However, the ECJ has clearly taken the position that consumer protection is not the ratio legis behind the 1985 PLD (see cases C-183/00; C-52/00; C-154/00). Besides, given the ELI Draft PLD's objective to harmonise the law across Europe, damage caused to tangible goods intended for a professional use should not be left aside in view of its practical importance. To include such damage obviously extends the scope of liability as compared to the 1985 PLD. However, producers and other potentially liable persons can purchase insurance.

The third type of primary harm covered by paragraph (1) is damage to files. 'Files' must be understood here as digital files, ie, as data that can be read by computers or other similar instruments. Files can contain words, figures, photos, etc. In practice, including damage to files among the types of primary harm covered by the ELI Draft PLD means that digital assets are protected by the instrument. This is in line with the inclusion of digital products in the notion of product in Article 3(1). However, the destruction or damaging of a file will not automatically result in a loss for the victim. It is possible, for example, that the victim will have a copy of the file or can retrieve the destroyed or damaged file. In such

cases, the actual loss will not be the value of the file or of its content but may be the cost of retrieving it or the loss resulting from the file being temporarily unavailable.

Leakage of personal or other data is the fourth type of primary harm recognised by paragraph (1). Such harm may be recognised regardless of whether the defective product's aim was precisely to protect data from leakage. Of course, paragraph (1) point (d) applies without prejudice to Article 82 of the General Data Protection Regulation¹⁵ (Regulation (EU) 2016/679; GDPR) on the liability of the controller or processor of data.

Consequential Harm (paragraphs 2 and 3)

When primary harm of a kind covered at paragraph (1) has been caused by a product's defect, in the sense of Article 7, the victim will be entitled to reparation under the ELI Draft PLD. In practice, the victim will normally seek to be compensated for the losses resulting from the primary harm. For example, in the case of personal injury, the victim may seek reimbursement of the costs of medical treatment and loss of revenues during the time when they were not able to work. In all Member States, the law normally allows for the compensation of economic losses, ie, incurred expenditure or lost profits, resulting from primary harm, subject to the existence of a sufficient causal link between the latter and the former. National rules should apply when determining and delineating compensable economic losses resulting from primary harm covered by the ELI Draft PLD. The only requirement is that the 'equivalence principles' stated by the ECJ in several cases (see, eg, cases C-261/95 at 27; C-295/04 at 62) be applied: these losses are to be treated like similar losses in purely domestic claims.

On the other hand, Member States have diverging rules on the issue of non-economic losses, such as pain and suffering, resulting from primary harm. While most of them now accept that non-economic losses can be compensated at least in some cases, some do not, and national laws further diverge as to the types of primary harm that may give rise to non-economic losses and as to the identification and measure of such losses. As Article 9(2) of the 1985 PLD currently does, Article 6(2) of the ELI Draft PLD therefore leaves it to Member States to decide if, and to what extent, non-economic losses resulting from primary harm listed at paragraph (1)

may be compensated. Here again, the equivalence principle must apply, whereby non-economic losses, if compensable, must be compensated under the same conditions as in purely domestic claims.

Paragraph (2) formulates the same rule for losses suffered by third parties as a result of the primary harm (sometimes referred to as 'ricochet losses'). Many Member States do not allow for the compensation of such losses in liability claims, in which case they should not be compensated in product liability claims either. On the other hand, in those countries where such losses may be compensated, the equivalence principle must apply.

Losses that are not the consequence of a primary harm listed at paragraph (1) cannot be compensated under the ELI Draft PLD. This is the case especially for pure economic losses. However, according to the solution set by the ECJ in case C-285/08 *Moteurs Leroy Somer v Dalkia France and Ace Europe*, Member States should be allowed to provide for a system of liability corresponding to that established by the ELI Draft PLD for such losses, and more generally for types of harm not covered at paragraph (1).

Article 7

Defective Products

1. A product is defective if, under normal or reasonably foreseeable conditions of use or misuse, including the expected life-span of the product, it does not provide the safety which it should provide according to its design or which a person is entitled to expect, considering in particular the standard of safety required by applicable rules of Union or Member State law on product safety.
2. In assessing the safety of a product, the following aspects shall be taken into account:
 - (a) the characteristics of the product, including its design, technical features, composition, packaging, instructions for assembly, use, installation, and maintenance;

¹⁵ 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 (General Data Protection Regulation) [2016] OJ L119/1 <<https://eur-lex.europa.eu/eli/reg/2016/679/oj>>.

(b) the effect on other products as well as the effect that other products might have on the product, where it is reasonably foreseeable that it will be used with other products, including by interconnecting multiple products;

(c) the presentation of the product, the labelling, any warnings and instructions for its safe use and disposal, and any other indication or information regarding the product;

(d) the appearance of the product;

(e) the categories of end users or other parties at risk when using the product, in particular vulnerable persons such as children, older people, and persons with disabilities;

(f) the appropriate security features necessary to protect the product against external influences, including by malicious third parties, when such an influence might have an impact on the safety of the product;

(g) the evolving, learning and predictive functionalities of a product.

Comment

The concepts of 'defect' and 'defective product' are central to the application of the Directive. The defectiveness of a product is a basic premise for the producer's liability – the producer is not obliged to compensate any damage caused by the product, but only for damage caused by the defectiveness of the product. This is particularly important in the case of those products whose use inherently involves a risk of harm (such as medicines, chemicals, cars, etc). In the event of damage, in order to obtain compensation, the injured party must show that the damage occurred because the product was defective.

The definition of defect adopted in Article 7(1) of the Draft corresponds in principle to the definition in Article 6(1) of the 1985 PLD, retaining the phrase 'safety which ... a person is entitled to expect'. It is therefore based on a test of legitimate expectations as to safety. This is not a subjective expectation – the actual beliefs of the victim or others about what level of safety a product should provide. Such subjective expectations may be one-sided or unrealistic, leading to an excessive burden of liability on the manufacturer and consequently reducing the availability of certain products on the market. What is meant is an objectively justified level of expectation as

to the safety of a product (as expressed by the phrase 'entitled to expect').

The ELI Draft PLD does not explicitly define this required level of safety (just as the 1985 PLD did not do so), because it is not possible to determine it in the abstract for all types of products. This is particularly the case for so-called design and information defects, for which it is necessary to determine in concreto what safety features of a given product were warranted or what information should have been provided to the user.

However, the ELI Draft PLD clearly establishes that a product is already defective for the reason that its safety properties are worse than they should be according to the product design (so-called manufacturing defects). There is then no need to examine whether the design itself and the information about the product provided a sufficient level of safety.

Compared to the 1985 PLD, the ELI Draft PLD clarifies the legitimate expectations test as much as possible while maintaining the generic approach (not differentiating between product types).

Firstly, the safety features of a product should be related to its normal use and to those uses (correct or incorrect) which the manufacturer should have foreseen.

Secondly, it is reasonable to expect a product to retain the required safety characteristics throughout its expected lifetime.

Thirdly, EU and national product safety legislation contribute to determining the required level of safety. Everyone is entitled to expect a product to comply with the legal safety standards applicable to it, and failure to meet this expectation constitutes a product defect. It must be emphasised that product safety law is not invoked here as a defence for the manufacturer, but as a benchmark for the legitimate expectations of the public. The manufacturer may not exempt itself from liability by proving the product's compliance with legal safety requirements, and it cannot escape liability if non-compliance with those requirements caused the damage. Product safety law is, however, only one of the criteria shaping legitimate safety expectations. It is not applicable where the law does not regulate specific products or their particular properties. Notwithstanding the fact that a product meets legal standards, it can still be found to be defective (eg, when legal requirements are out-dated or incomplete).

In addition, Article 7(2) of the ELI Draft PLD contains additional guidance to assist in investigating the defectiveness of a particular product. Most of these points are self-explanatory. However, a few are worth mentioning:

- the product as a whole is assessed – its design, materials, manufacturing, packaging and presentation to the customer, instructions and other information made available to users;
- the foreseeable interaction of the product with other products should be taken into account (which is of particular importance in the Internet of Things (IoT) context);
- the required level of safety should be determined taking into account the particular characteristics of typical users or other persons foreseeably coming into contact with the product and thus being exposed to risks – if these persons are below average in terms of intellectual skills, physical fitness, prudence, etc, the product should also be safe for them, even if it is safe for the general public;
- the assessment of the defectiveness of a product which, by reason of its characteristics or its intended use, is liable to external interference (whether in the form of manipulation of the physical form of the product or of cybersecurity threats) should also cover its susceptibility or resistance to such interference;
- if a product is designed in such a way that the manufacturer envisages the possibility of its properties being changed in the future (through data collection, learning, etc), this possibility and its limits are themselves relevant for assessing whether the product is safe; therefore, if the design of the product has made it possible for it to acquire dangerous properties in the future, the product must be considered defective.

As to proving the defectiveness of a product, see Article 9.

Article 8

Liable Economic Operators

1. The parties primarily liable for the relevant harm caused by a defective product are:
 - (a) the producer of the finished product; and
 - (b) if the producer is located outside the Union, the importer and the producer's authorised representative also.

2. (a) If, in cases covered by point (b) of paragraph (1), both an importer as well as an authorised representative are established within the Union, they are jointly and severally liable with the producer of the finished product.
3. (b) If, in cases covered by point (b) of paragraph (1), neither an authorised representative nor an importer exists in the Union or cannot be identified, but where there exists an online marketplace where such an online marketplace presents the product or otherwise enables the specific transaction at issue in a way that would lead a consumer to believe that the product that is the object of the transaction is provided either by the online marketplace itself or by a trader who is acting under its authority or control, the online marketplace will be deemed an economic operator which has enabled the making available of the product on the Union market, and shall also be liable.
4. Any producer of a defective component or digital element shall also be liable if the defect in the component or digital element has caused the defect in the finished product, unless the defect is attributable to the design of the product into which the component or digital element has been incorporated or to the instructions given by the producer of that product.
5. Where the producer or, in the case of a producer located outside the Union, a party referred to in point (b) of paragraph (1) and in paragraph (2), cannot be identified, each distributor shall be treated as the producer unless the distributor informs the victim, within a reasonable time, of the identity of the producer or, in the case of a producer located outside the Union, a party referred to in point (b) of paragraph (1), or of the party who supplied the distributor with the product.

Comment

This provision must be read in conjunction with the relevant definitions in Article 3: 'economic operator', 'producer', 'importer', 'distributor', 'authorised representative', 'online marketplace', and 'fulfilment provider'.

Article 8 sets out a cascade scheme for the liability of the economic operators engaged in manufacturing, developing, or making the product available on the

market. It corresponds to Article 3 of the 1985 PLD, but it aims at adapting the provision to the structure of modern distribution models and making-available-on-the-market practices.

The producer is, as in the current legal regime, the primary liable economic operator for the harm caused by a defective product. If the producer is located outside the Union, the importer and the producer's authorised representative shall also be liable. *Vis-à-vis* the injured person, if both an importer and an authorised representative are established in the Union, they shall be jointly and severally liable, without prejudice to a subsequent recourse action to be exercised by the payor against any of the other primarily liable economic persons.

Paragraph (2) point (b) represents a novelty and adds a significant innovation to the current legal regime by addressing the relevant role of online marketplaces in making products available on the market. The provision applies where neither an authorised representative nor an importer in the Union exists or can be identified, but the product is deemed to have been made available on the market through an online marketplace as defined by the provision. In such a case, the online marketplace is liable, provided that the following conditions are met:

- First, the online marketplace is subject to the Digital Services Act (COM/2020/825 final; DSA). Pursuant to Article 3(12) of the ELI Draft PLD, an 'online marketplace' is an online platform which allows users to conclude distance contracts with traders. Thus, the definition of 'online marketplace' is built on the concept of 'online platform' pursuant to the DSA but shall cover both B2C and B2B online marketplaces here.
- Second, such an online marketplace presents the product or otherwise enables the specific transaction at issue in a way that would lead a consumer to believe that the product that is the object of the transaction is provided either by the online marketplace itself or by a trader who is acting under its authority or control. This condition follows the exception to the liability exemption of hosting services providers (precisely, such an online marketplace) as provided for by Article 5(3) of the DSA.

While paragraph (1) refers to the producer of the finished product, paragraph (3) addresses the liability of the producer of a component, pursuant to the definition

of 'producer' as per Article 3. The proposed provision also adds a relevant innovation by addressing not only tangible components but also digital elements. In the ELI Draft PLD, the producer of a defective component or digital element shall also be liable if the defect in the component or digital element has caused the defect in the finished product, unless the defect is attributable to the design of the product into which the component or digital element has been incorporated or to the instructions given by the producer of that product. The second part of the provision incorporates the defence that is currently provided for by Article 7 point (f) PLD.

Accordingly, a party who has suffered harm has to prove two links of causation. First, the injured person must prove the causal relationship between the defect and the damage. Second, and additionally, as far as this paragraph is concerned, the victim must prove *vis-à-vis* the producer of the component or digital element that the defect in the component or digital element caused the defect in the finished product.

Paragraph (4) adds a 'last-resort' layer of liability in case none of the primarily liable economic operators described in the previous paragraphs can be identified – the producer, or, when the producer is established outside the Union, the importer, the authorised representative or the online marketplace. In such a case, each economic operator involved in making the product available on the market (the distributor) shall be treated as the producer unless that economic operator informs the injured person, within a reasonable time, of the identity of the producer or, in the case of a producer located outside the Union, of a party referred to in point (b) of paragraph (1) – the importer or the authorised representative – or of the party who supplied that economic operator with the product.

Article 9

Burden of Proof

1. The party who has suffered the relevant harm has to prove that this harm was caused by a defect of the product.
2. Member States shall ensure in their national laws that requirements for proving the defect and causation are not too onerous for a victim, in order not to undermine the purpose of this Directive as referred to in Article 1. In doing so, they shall take into account at least the following factors:

- (a) the likelihood that the product at least contributed to the relevant harm;
 - (b) the likelihood that the relevant harm was caused either by the product or by some other cause attributable to the defendant;
 - (c) the risk of a known defect within the product if it would be excessively difficult to prove a defect in a particular item;
 - (d) asymmetry in the parties' access to information about processes within the defendant's sphere that may have contributed to the harm and to data collected and generated by the product or by a connected service. Any producer of a defective component or digital element shall also be liable if the defect in the component or digital element has caused the defect in the finished product, unless the defect is attributable to the design of the product into which the component or digital element has been incorporated or to the instructions given by the producer of that product.
3. The burden of proving a defect or causation within the meaning of paragraph (1) shall shift to the defendant where:
- (a) there is an obligation under Union or Member State law to equip a product with means of recording information about the operation of the product (logging by design) if such an obligation has the purpose of establishing whether a risk exists or has materialised, and where the product fails to be equipped with such means, or where the economic operator controlling the information fails to provide the victim with reasonable access to the information; or
 - (b) the following types of provisions or legally binding standards exist and the product fails to conform to those provisions or standards in relation to the risk or risk category that has potentially materialised:
 - (i) relevant Union or Member State product safety law, including on cybersecurity, together with implementing acts adopted in accordance with such law;
 - (ii) relevant European standards or, in the absence of European standards, health and

safety requirements laid down in the law of the Member State where the product is made available on the market.

Comment

Article 9(1) of the ELI Draft PLD corresponds to the content of Article 4 of 1985 PLD. The essential elements of liability – defect of the product, damage, and causal link between the two – must be proven by the victim.

What is new, however, is that Member States are required to ensure that the applicable procedural rules do not place an unreasonable burden on the victim, which would make their protection illusory (Article 9(2) of the ELI Draft PLD). The ELI Draft PLD therefore provides for a relaxation of the burden of proof of defect and causation (but not of damage) but leaves the national legislator free to choose the technique to achieve this (lowering of the standard of proof, presumption, right to information, etc), as this belongs to the sphere of civil procedure in which the EU legislator should not interfere without necessity. The ELI Draft PLD identifies several circumstances that justify an easement of proof for the injured party. These relate to the likelihood of causation; the likelihood of a defect where it would be difficult to establish (see cases C-504/13 and C-504/13, Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt – Die Gesundheitskasse and Betriebskrankenkasse RWE); and the unequal access of the parties to relevant information (which is particularly relevant in relation to digital products and products using digital content). In addition to these factors – specific to product liability – national case law may have developed other methods to mitigate the victim's evidentiary burden in damages disputes. One typical example is the lowering in practice of the requirements to prove causation in certain cases of severe personal injury.

The second novelty in the ELI Draft PLD is the reversal of the burden of proof of defect or causation. The Draft provides for this in two situations. The first is a breach by the manufacturer of its duty to ensure that information about the product's performance is recorded, or a refusal to provide the injured party with such information. The reversal of the burden of proof here is based on the logic of adverse inference – the facts (defect or causation), which the manufacturer, in violation of its obligation, prevented from being examined, are deemed established unless the defendant proves their falsity. The other

situation is the product's failure to meet requirements set by law or legally binding standards. Non-compliance with legally binding safety requirements determines the defectiveness of the product (Article 7(1) of the ELI Draft PLD), whereas, if the damage matches the typical effects of the materialisation of the very risk the law was designed to protect against, the injured party does not have to prove the existence of a causal connection between the defect and the damage in this particular case, but the defendant has to prove its non-existence.

Article 10

Defences

An economic operator within the meaning of Article 8 shall not be liable under Article 5 if they prove that the defective product was not a finished product or that the defect which caused the damage:

- (a) neither existed at the time when they made the product available on the market, nor originated in any authorised update, nor was due to their failure to provide an update as required by Union or Member State safety laws; or
- (b) is due to compliance with mandatory legal requirements or with mandatory regulations issued by public authorities; or
- (c) could not have been discovered with the scientific and technical knowledge available at the time they made the product or the last authorised update available on the market.

Comment

Defences in General

The defences at present provided by Article 7 of the 1985 PLD are mostly retained (though with a caveat concerning the development risk defence, see below). However, the wording of Article 7 of the 1985 PLD need not be copied into this text entirely as some of the matters are already addressed elsewhere in the ELI Draft PLD, making a duplication here redundant.

Whereas Article 7 point (a) of the 1985 PLD provides that the producer shall not be liable if he proves that he did not put the product into circulation, the ELI Draft PLD provides that an economic operator is not liable if they proves that the defective product was not a finished

product. This is because liability of the producer under the ELI Draft PLD only arises if harm is caused by a 'finished product' (Article 8), which is defined by Article 3(4) point (a) as a 'product which is made available on the market by, or with the assent of, its producer'. 'Making available on the market' is in turn further defined as a 'commercial activity' at Article 3(7). Article 10 therefore makes it clear that it is not for the victim to demonstrate that the product that caused their harm was a finished product. Rather, it is for the economic operator to prove that the product had not been made available on the market by or with the assent of its producer or that it was not intended for use without modifications by another producer (in which case it was not a finished product under Article 3(4) point (a)), or that the product was not supplied in the course of a commercial activity (in which case it was not made available on the market according to Article 3(4)). This latter point covers Article 7 point (c) of the 1985 PLD.

Article 7 point (f) of the 1985 PLD is now addressed by Article 8(3).

The proposed points (a) and (b) of Article 10 mirror the current Article 7 points (b) and (d) of the 1985 PLD respectively. The only necessary modification concerns the reference to updates in the language of point (a) above. A defect may be introduced after the initial distribution of the product via an update provided by or with the assent of the producer, which is why the crucial point in time of this defence must be adjusted accordingly.

Development Risk Defence

The development risk defence in point (c) is and always has been highly disputed (see, eg, Key Finding 14 of the 2019 Expert Group Report). Both previous ELI publications on the topic raised doubts at least with respect to the current wording of Article 7 point (e) of the 1985 PLD. 'If the development risks defence were to be retained, its scope in respect of goods with digital elements, digital products, and AI should be reconsidered and the focus on the point at which a product is "put into circulation" changed.' (ELI Guiding Principles p 11, similarly ELI Consultation Response p 18). Also, the 'scientific and technical knowledge available at the time' needs to be specified further in light of the accessibility of information (including foreign language information) online today as compared to 1985.

Chapter III: Liability for Non-compliance with Obligations under Product Safety and Market Surveillance Law

Article 11

Right to Compensation

1. Without prejudice to liability under Article 5, a victim of relevant harm within the meaning of Article 6 or of pure economic loss caused by a defective product within the meaning of Article 7 shall be entitled to receive compensation from an economic operator where:
 - (a) that economic operator failed to comply with its obligations under Union or Member State product safety or market surveillance law, a list of which is attached in Annex I to this Directive;
 - (b) one of the specific purposes of the obligation referred to under point (a) is to prevent harm of the type suffered by the victim;
 - (c) the failure to comply with the obligation has specifically enhanced the risk of causing harm of the relevant type suffered by the victim, and that risk has materialised.
2. The economic operator shall not be liable under paragraph (1) if that economic operator proves that:
 - (a) the harm would also have been caused if the obligation referred to under point (a) of paragraph (1) had been complied with; or
 - (b) the economic operator was not able to comply with the obligations referred to in paragraph (1) due to an impediment beyond their control and which they could not reasonably be expected to have avoided or overcome.
3. Article 6(2) and (3) shall apply accordingly with regard to compensation for non-economic harm and harm suffered by third parties.

Comment

While Chapter II deals with strict liability for defective products, which applies irrespective of whether the producer or other economic operator has breached any particular obligations, Chapter III deals with liability for failure to comply with obligations under product safety or market surveillance law.

General Purpose of Chapter III and its Relationship to Chapter II

There is no equivalent to Chapter III in the 1985 PLD. Rather, liability for non-compliance with market surveillance and similar obligations was formerly dealt with under national tort law, such as under general rules of liability for negligence or under rules that attach liability to a particularly unlawful behaviour. The fact that the 1985 PLD did not cover non-compliance with post-market product monitoring obligations was one of the main reasons why it was essential to allow claims under national tort law in parallel to claims under harmonised product liability law. This has led to a fragmentation of the Internal Market, with the extent to which victims of harm were able to get compensation depending, to a significant extent, on the applicable national law. If the ELI Draft PLD is to achieve a higher degree of harmonisation among Member States and more of a level playing field within the Union, efforts should also be made to harmonise liability for breach of obligations under product safety and market surveillance law. At the same time, Chapter III serves to enhance consistency of the acquis by clarifying how non-compliance with obligations under other Union law can translate into private law liability.

Chapter III does not mention fault as a requirement, but liability is excluded, inter alia, where the non-compliance was due to an impediment beyond the defendant's control, which is a test also used in other

contexts (such as Article 79 United Nations Convention on Contracts for the International Sale of Goods¹⁶ (CISG) or Article 7.1.7 UNIDROIT Principles of International Commercial Contracts¹⁷ (PICC)) and which moves liability under Chapter III at least close to fault liability. Chapter III may become relevant for victims in particular where the defendant has a defence under Chapter II but not under Chapter III. For example, if the defect was due to compliance with mandatory legal requirements or with mandatory regulations issued by public authorities, but, when the problem became apparent and publicly known, the producer failed to take any corrective measures as required by the Proposed GPSR, then Article 10 point (b) would shield the producer from liability under Chapter II, but the producer could still be liable under Chapter III.

Even more importantly, Chapter III may be relevant for victims where economic operators other than the producer violated a specific obligation they have under relevant product safety or market surveillance legislation but would not be jointly and severally liable under Chapter II. For example, if the operator of an online marketplace received an order under Article 14(4) point (k) MSR from the competent authority to remove content referring to an unsafe product from an online interface, but failed to comply with that order, which is why the victim was able to buy the unsafe product via the online marketplace and suffered harm, then the victim has a claim both against the producer under Chapter II and against the operator of the online marketplace under Chapter III even where the requirements of Article 8(2) point (b) are not met.

Requirements of Liability (paragraph 1)

The types of harm for whose infliction victims may seek recovery under Chapter III include the types for which recovery can already be sought under Chapter II and which are listed in Article 6. However, Chapter III goes

one step further and also includes pure economic loss. This means pure economic loss as the primary harm inflicted (eg, where a security gap in software enables malicious third parties to steal virtual currencies), not consequential economic loss (eg a doctor's bill which the victim had to pay after treatment for bodily injury), as the latter is covered more generally. It should be stressed that recovery for pure economic loss can only be based on Chapter III where all the other requirements of Chapter III are met, including, for instance, that the clear and specific purpose of the obligation that was breached was to prevent this type of primary harm from occurring.

As to the relevant obligations, New Legislative Framework (NLF) legislation typically includes at least one Chapter on obligations of economic operators, in particular producers, but also authorised representatives, importers, distributors or, more recently, operators of online marketplaces. As far as Union law is concerned, Annex I to this Draft Directive would include a list of relevant Union product safety and market surveillance legislation. This list would cover 'horizontal' legislation, such as the Proposed GPSR or the MSR as well as 'sectoral' legislation, such as the proposed Machinery Regulation¹⁸ (COM(2021) 202 final). It will also cover 'semi-horizontal' legislation such as the Radio Equipment Directive¹⁹ 2014/53/EU and its implementing acts, the proposed Artificial Intelligence Act²⁰ (see COM(2021) 206 final; AIA) or the future Cyber Resilience Act. It may be worth mentioning, given that there has been much debate about the absence of liability provisions in the AIA Proposal, that Chapter III would provide that 'missing link'.

As far as listed Union legislation is not directly applicable in the Member States, the relevant rules of law would follow from Member State law, and Annex I could provide that Member States may apply Chapter III also

¹⁶ UN Convention on Contracts for the International Sale of Goods (2010) <https://uncitral.un.org/sites/uncitral.un.org/files/media-documents/uncitral/en/19-09951_e_ebook.pdf>.

¹⁷ UNIDROIT Principles of International Commercial Contracts (2016) <<https://www.unidroit.org/wp-content/uploads/2021/06/Unidroit-Principles-2016-English-bl.pdf>>.

¹⁸ See n 11.

¹⁹ Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC [2014] OJ L153/62 <<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014L0053>>.

²⁰ Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts COM/2021/206 final [2021] <<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0206>>.

to Member State product safety law in particular sectors (to be determined). Needless to say, failure to comply with orders issued by competent authorities under the listed legislation counts as failure to comply with the legislation itself.

The obligations resulting from product safety or market surveillance law are manifold, ranging from ensuring conformity with essential safety requirements in the first place, to monitoring the product, to taking corrective measures in case safety issues arise (eg, an over-the-air update or product recall), to cooperating with market surveillance authorities. In principle, breach of any such obligation could potentially result in harm to victims. In order to provide for appropriate boundaries of liability, however, breach of only such obligations whose specific purpose it is to prevent harm of the type suffered by the victim should lead to liability under Chapter III. For example, the duty of post-market monitoring of product safety and of taking appropriate corrective measures is clearly and specifically aimed at preventing harm that could be caused by an unsafe product and, thus, if a victim suffers bodily injury as a result, the victim could raise a claim based on Chapter III. By contrast, the primary purpose of a manufacturer's obligation to indicate their name, registered trade name and their postal and electronic address on the product is primarily to facilitate effective market surveillance and law enforcement. While this obligation may, indirectly, also aim at preventing bodily injury from occurring, this is not the specific aim of the obligation.

In a similar vein, liability under Chapter III is justified only where the failure to comply with the obligation has specifically enhanced the risk of causing harm of the relevant type suffered by the victim, and that risk has materialised. For example, if an e-scooter is recalled by the producer because of a problem with the speed control mechanism, and if a distributor that would have been under an obligation to immediately stop further sales of that e-scooter fails to comply with that obligation, continuing to sell the e-scooter to customers, then a customer who bought the e-scooter after the recall and suffered bodily injury in an accident caused by speeding as a result of the defect may sue the distributor

under Chapter III (subject to contributory negligence, etc). However, where the customer suffered property damage because the e-scooter's battery caught fire, this should not lead to liability of the distributor because the failure to comply has not specifically enhanced the risk that ultimately materialised.

Defences (paragraph 2)

In the light of the different nature of liability under Chapter III as compared with liability under Chapter II, the defences available to a defendant under Article 11(2) are also different as compared with the defences available under Article 10. The first defence available to a defendant is absence of causation in the sense that the harm would also have materialised if the obligation in question had been complied with.

The second defence available to a defendant is force majeure or hardship, which has been formulated along the lines we find in other international legislation or soft law, in particular in Article 79 CISG, Article 7.1.7 PICC and Article 8:108 *Principles of European Contract Law*²¹ (PECL) as well as the relevant provision in the *Draft Common Frame of Reference*²² (DCFR). While certainly not being identical with the requirement of (presumed) fault, this defence makes liability under Chapter III similar to liability for presumed fault in that it allows the defendant to escape liability by demonstrating that it was not able to comply with the relevant obligations due to an impediment beyond its control which it could not reasonably be expected to have avoided or overcome.

In the event of doubt, and considering the specific context of non-contractual liability, case law and doctrinal analysis that has evolved in other contexts may provide guidance on how to interpret this defence.

Non-economic Harm and Harm Suffered by Third Parties (paragraph 3)

As concerns compensation for non-economic harm and harm suffered by third parties, the rules in Article 6(2) and (3) apply accordingly, ie, whether and under what conditions such compensation is due is largely a matter for Member State law to determine.

²¹ Principles of European Contract Law (PECL) <https://www.trans-lex.org/400200/_/pecl/>.

²² Christian von Bar, Eric Clive and Hans Schulte-Nölke (eds), *Draft Common Frame of Reference (DCFR) - Outline Edition (2009)* <https://www.trans-lex.org/400725/_/outline-edition/>.

Article 12

Burden of Proof

1. In cases covered by Article 11, the victim has to prove that their damage was caused by a defect of the product within the meaning of Article 7 and that the requirements under paragraph (1) points (b) and (c) of Article 11 are met. It is for the defendant to prove that their obligations resulting from product safety or market surveillance law were complied with.
2. Article 9(2) to (3) shall apply accordingly with regard to proving defect and causation.

Comment

The distribution of the burden of proof for liability under Chapter III is largely identical to the distribution of the burden of proof under Chapter II (see Article 9). This includes any alleviations or shifts of the burden of proof under Article 9(2) and (3).

Consistent with Article 9, the victim must also prove the other positive requirements of liability listed in Article 11(1), with one important exception: the burden of proof with regard to compliance with obligations resulting from product safety or market surveillance law is on the defendant. Placing the burden of proof with regard to compliance on the defendant is in line with a general principle according to which the burden of proof should lie with the party that has more or less exclusive control of the relevant information. For example, while it would be extremely onerous for the victim to prove that no proper post-market monitoring took place on the part of the producer, it should be relatively easy for the producer to demonstrate the concrete arrangements made in terms of post-market product safety monitoring, in particular as the producer should keep appropriate records of such activities anyway.

Needless to say, the defendant only has to provide proof with regard to obligations where non-compliance could potentially give rise to a claim under Article 11. Member States will have appropriate mechanisms in place to deal with abusive litigation techniques (eg, claimants forcing the defendant to give proof of compliance obviously unrelated to the harm caused in order to gain access to trade secrets or to reach a settlement for the mere nuisance factor).

Chapter IV: General Provisions on Liability

Article 13

Joint and Several Liability, Reduction and Exclusion of Liability

1. Where more than one economic operator is liable for compensation of the same relevant harm suffered by a victim, the latter can claim compensation from each of them. Overall, the victim can only recover for the total relevant harm suffered.
2. The liability of an economic operator shall not be excluded or reduced where the harm is caused both by a defect in the product and an event attributable to a third party.
3. The conditions under which liability may be reduced or excluded where conduct attributable to the victim contributed to the harm shall be determined by Member State law. These conditions must not be less favourable to the victim than those relating to similar domestic claims.

Comment

Article 13(1) of the ELI Draft PLD incorporates the solution of Article 5 of the 1985 PLD. Unlike Article 5, however, it does not mention the right of recourse, which is addressed in Article 14 of the ELI Draft PLD.

Paragraph (2) copies the essence of Article 8(1) of the 1985 PLD.

The relevance of contributory conduct from within the victim's own sphere shall be determined by Member State law in the same way as other tort claims are regulated in this matter (paragraph (3)).

Article 14

Right of Recourse

1. Where more than one economic operator is liable for compensation of the same relevant harm suffered by a victim, any economic operator that has indemnified the victim or was ordered to do so by an enforceable judgment has a right

of recourse against another jointly and severally liable economic operator. Member States shall provide the conditions for exercising such right of recourse, which must not be less favourable to the claimant than in comparable domestic cases.

2. Article 9(2) and (3) shall apply as appropriate when claiming such right of recourse against any other jointly and severally liable economic operator.

Comment

Article 14 of the ELI Draft PLD aims at ensuring that there is a valid and effective right of recourse, where economic operators are jointly and severally liable. At the same time, it confirms the principle of joint and several liability when several economic operators are held liable, formulated at Article 13 (see also Article 8(2) point (b)).

Pursuant to Article 8(3), any producer of a defective component or digital element shall also be liable towards the victim if the defect in the component or digital element caused the defect in the finished product. Such producer shall, therefore, be held jointly and severally liable with the producer of the finished product.

The present Article shall further apply to any circumstances where several economic operators may be held (primarily) liable for having jointly made a defective product available on the market. For example, if Companies A and B have concluded a joint venture to bring on the market a new bottle stopper that would revolutionise the serving of wine for private users, ensuring no air would affect the wine quality once the bottle has been opened, and if both Company A and Company B jointly make the finished product available on the market, then, if some devices do not work properly and if some consumers have had prestigious bottles of wine totally or partially turned into vinegar, the victims may file a claim either against Company A or Company B for the entire loss suffered. And if it appears that a strategic component of the product that should ensure the vacuum process, manufactured by Company C, does not function properly, the victim can file a claim against either Company A, Company B or Company C for the entire loss suffered.

Article 14 does not intend to provide for an autonomous ground for the right of recourse. It is only imposed on the Member States to ensure that such right of recourse exists and is effective. The ground for it might often be based on a contractual relationship, given that the producer of a defective component will have provided such component pursuant to a contract concluded with the producer of the finished product. The features of such right of recourse may therefore be dependent on the contractual provisions of such contract between the economic operators. Pursuant to Article 15, terms limiting or excluding liability under the PLD are unenforceable only in the relationship between the economic operator and the victim; therefore, the right of recourse can be contractually organised or even excluded.

In some Member States, recourse may also be grounded in tort or on unjust enrichment or *negotiorum gestio*. This Article does not intend to impose one ground over the other for Member States but aims at ensuring that an effective right of recourse exists.

This provision does not determine whether the jointly and severally liable economic operators are or are not jointly and severally liable when one of them has a right of recourse against the other. Most Member States provide that the other economic operators are not jointly and severally liable when the right of recourse is exerted against them by another economic operator; the latter must then ask for the maximum share from each of them. For example, if Company A was ordered to indemnify the victim for the loss suffered, it then has a right of recourse against Company C whose vacuum system did not work properly and was the cause of the defect in the finished product. This right of recourse is based on the contract of sale that was concluded between Company C and the joint venture of Company A and B. Contractual clauses may have restricted this right of recourse or set some requirements for it.

Article 14(2) deals with the burden of proof. While it is important that the liability of the economic operator seeking recourse (which was established by the victim) and the liability of the operator at which the recourse is directed (which is to be established by the other operator) should not be established on the basis of significantly different probatory rules, it is also necessary to take into account the fact that an economic operator may not need the same kind of help as Article 9(2) and (3) intends to provide to the victim. Accordingly, paragraph (2) provides for the application of Article 9(2) and (3) to recourse claims 'as appropriate'. It seems preferable to

grant judges some discretion in this respect, rather than to set hard and fast rules that could not be adapted to the great variety of situations where a right of recourse may be exercised.

Article 15

Mandatory Nature

The liability of an economic operator arising from this Directive may not, in relation to the victim, be limited or excluded by a contractual term limiting the liability of that economic operator or exempting that economic operator from liability.

Article 16

Liability Caps

Member States may provide that the total liability of economic operators resulting from identical products with the same defect shall be limited to an amount which may not be less than [amount adapted to enhanced risks and inflation].

Comment

Article 16 in essence mirrors current Article 16(1) of the 1985 PLD by giving Member States the option to determine a maximum amount of compensation (at present no less than 70 million ECU). Only Germany and Spain have taken advantage of that option so far, and it is doubtful whether such a provision is truly needed, considering that the insurance industry in all other Member States seem to cope with no such caps.

Article 17

Limitation Period

1. Member States shall provide in their legislation that a limitation period of three years shall apply to proceedings for the recovery of compensation as provided for in this Directive. The limitation period shall begin to run from the day on which the victim became aware, or should reasonably have become aware, of the harm, the defect and the identity of the liable economic operator.
2. Member States shall provide in their legislation that compensation for harm other than that referred to in Article 6(1) point (a) can no longer

be recovered from the liable economic operator after ten years from the day on which:

- (a) they made the actual product which caused the harm available on the market;
 - (b) the last authorised update for this product was made available;
 - (c) they should have made available or authorised an update for this product in order to bring it into conformity with product safety requirements under Union or Member State law but failed to do so; whichever is the latest. The ten-year limitation period shall not apply if the defect was inherent in or caused by machine learning or similar further developments of a digital product or of a digital element of a product and the liable economic operator cannot prove that this defect was not attributable to the product as made available on the market or as subsequently modified by an authorised update.
3. The right of recourse amongst jointly and severally liable economic operators shall not be affected by the above limitation periods. Instead, Member States shall provide in their legislation that a limitation period of one year shall apply to proceedings for the recovery of a contribution as provided for in Article 14. This limitation period shall begin to run from the day on which the economic operator seeking recourse agreed to or was ordered by an enforceable judgment to indemnify the victim, or from the day they became aware, or should reasonably have become aware, of the identity of the other liable economic operator, whichever is later.
 4. The laws of Member States regulating suspension or interruption of a limitation period shall not be affected by this Directive.

Comment

The 1985 PLD rules on time limitations in Articles 10 and 11 need to be reconsidered in part.

The first paragraph of Article 10 of the 1985 PLD as it stands has been included in the ELI Draft PLD (paragraph (1)) as it still seems acceptable for all Member States, despite differing time limits in their tort law regimes. Equally, Article 10(2) of the 1985 PLD has been retained in paragraph (4) of this Article.

The extinction of rights foreseen by the current Article 11 of the 1985 PLD is alien to the laws of all Member States, however, and needs to be reduced to mere prescription.

The ten-year period of Article 11 of the 1985 PLD can no longer apply to bodily harm (at least not without further qualifications) in light of the Howald Moor ruling of the ECtHR (nos 52067/10 and 41072/11). It is proposed to abolish all upper time limits to death or personal injury claims (which would have come in addition to the three-year limitation suggested by paragraph (1) here that already provides adequate protection of the defendant's interests, particularly in light of the claimant's burden of proof). This is in line with jurisdictions such as the Czech Republic, France, the Netherlands, or Poland. Alternatively, a 30-year long-stop period for bodily harm and death may be considered, as suggested by Article III-7:307 DCFR.

The ensuing question of when the suggested long-stop limitation period of ten years for losses other than death or personal injury shall start and how long it shall last is addressed by paragraph (2). In light of the relevance of updates, extending the control of the producer over the product and thereby their potential liability, it is necessary to focus not only on the moment when the defective product was first made available on the market, but also on any subsequent updates the producer himself made available or which were made available with his consent. If they failed to make such updates available despite a legal obligation to do so, the hypothetical date when such updates would have been due shall be used instead. While this extends the overall time period for which the producer may have to account for product defects, one has to bear in mind that the claimant still needs to prove all elements of the claim as foreseen by Article 9, which will be more difficult the more time has passed since the damage was caused.

Due to the special nature of machine learning software, a reversal of the burden of proof is proposed regarding the expiration of the ten-year long-stop period.

Paragraph (3) foresees a one-year limitation period for recourse claims. This period will normally run from the day on which the economic operator seeking recourse agreed to indemnify the victim or was ordered to do so by an enforceable judgment. By taking the time of agreement to indemnify and not the time of indemnification, one ensures that the start of the limitation period cannot be indefinitely delayed.

However, to file such a recourse, the economic operator has to know the identity of at least one other economic operator that is jointly and severally liable. The limitation period cannot begin to run beforehand, given that the purpose of such limitation period is to ensure that the economic operator who must pay will pursue their rights within a reasonable period of time, not waiting for too long if they are aware of all the elements required to bring his claim, including the identity of the jointly and severally liable economic operator. If the first economic operator remains idle and does not look for the identity of that second economic operator, the ELI PLD Draft provides for normative knowledge. In most cases, however, the identity of at least one other economic operator will be known from the beginning; this will be the case where the operator has a contractual relationship with another economic operator.

Chapter V: Final Provisions

Article 18

Repealing of Council Directive 85/374/EEC

Council Directive 85/374/EEC is repealed.

Article 19

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by *[the date of ...after the entry into force]* at the latest. They shall apply these laws, regulations and administrative provisions to all products made available on the market on or after *[the date of ... after the entry into force]*.
2. The liability of an economic operator shall not be excluded or reduced where the harm is caused both by a defect in the product and an event attributable to a third party.
3. The conditions under which liability may be reduced or excluded where conduct attributable to the victim contributed to the harm shall be determined by Member State law. These conditions must not be less favourable to the victim than those relating to similar domestic claims.

ANNEX I

Comment

Annex I shall provide a list of relevant Union or Member State product safety or market surveillance law as referred to in Article 11(1) point (a).

Article 20

Review

The Commission shall, not later than on *[the date of five years after entry into force]* review the application of this Directive and submit a report to the European Parliament and the Council.

Article 21

Entering into Force

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

Article 22

Addressees

This Directive is addressed to the Member States.

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