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Review article

PRODUCT LIABILITY REFORM IN THE EU*

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ABSTRACT

Following a long discussion among professionals, academics and competent authorities, at the end of September 2022, the European Commission published the Proposal for a directive on liability for defective products. In a practical sense, the most significant innovations in the Proposal are the expansion of the definitions of fundamental terms, such as product, producer, defect and damage, and the new provisions that should make it easier for the injured person to initiate proceedings and prove the fulfillment of the conditions for establishing the strict liability of the producer. The reform has several specific goals: to ensure that the liability rules reflect the nature and risks of products in the digital age and circular economy; to ensure that there is always a business based in the EU that can be held liable for defective products purchased directly from manufacturers outside the EU; to ease the burden of proof in complex cases, for example when the damage originates from pharmaceutical products, medical devices and products with a digital component, in which the injured person usually lacks the scientific and technological knowledge and information necessary to prove the existence of defect and the causal link; to ease restrictions on claims (by abolishing the rule that prevents compensation of property damage valued below EUR 500); and to ensure legal certainty by better aligning the rules on product liability with new product safety rules, and by codifying relevant case law. From the producer's standpoint, all of the changes that have been proposed will lead to an increase in the risk of their liability, which may further cause the rise in liability insurance premiums for the producers. It is reasonable to expect the producers to pass the increased costs of their liability risk on to the consumers.

***Keywords*:** *Circular economy, Digitalization, Product liability reform, Proposal for a directive on liability for defective products (2022)*

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1. THE CURRENT EU RULES ON PRODUCT LIABILITY

There are a number of social, political and legal reasons to base liability for a defective product on an objective principle and for them to be considered cumulatively: the producer is best informed about all the characteristics of their product; they reap the economic benefit of placing the product on the market; the producer can socialize the risk of the damage and liability, i.e., pass on the risk to the buyers by increasing the price of the product; the producer can take out liability insurance; the likelihood of damage increases when a product is widely used, which also applies to the scope of the damage that may occur for a large number of potential injured persons.[1]

Of course, general rules on strict liability for defective products are not necessarily limited to damage caused by consumer goods. Product liability may apply also to damage from any object of property, provided that the object was defective, regardless of whether it was produced by craft or industry. However, certain products intended for widespread use and consumption create conditions for the occurrence of serial damage, whose wide spread – which usually entails a large number of injured persons – may create social and economic problems on a new scale.[2]

The development of product liability, as a specific form of strict (or objective) liability, was promoted in Europe and North America by a tragedy that occurred in the 1960s, by the widespread use of thalidomide (sold under brand names such as Thalidomid, Contergan and Kevadon), a pharmaceutical with a teratogenic effect.[3] The Grünenthal company developed a drug that, among other uses, was prescribed as an antiemetic, especially to women suffering from serious morning sickness during the first trimester of pregnancy. The application of this drug led to the birth of several thousand infants with serious deformities. This event stepped up the work at the European Convention on Products Liability in regard to Personal Injury and Death, adopted by the Council of Europe in 1977.[4] The

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1 Koch, B. A.; Koziol, H., *Comparative Conclusions*, in: Bernhard A. Koch; Helmut Koziol (eds.), Unification of Tort Law: Strict Liability, Kluwer, The Hague, 2002, pp. 402–403.

2 Markovits, Y., *La Directive C.E.E. du 25 juillet 1985 sur la responsabilité du fait des produits défectueux*, L.G.D.J., Paris, 1990, pp. 1–2.

3 Stapleton, J., *Product Liability*, Butterworths, London 1994, pp. 5, 66–67; Cane, P.; Atiyah P., *Atiyah's Accidents, Compensation and the Law*, C.U.P., Cambridge 2013, p. 103; Howells, G. G.; Ramsay, I. M.; Wilhelmsson, T., *Handbook of Research on International Consumer Law*, Elgar, Cheltenham 2010, p. 237. See also: Bernstein A., *Formed by Thalidomide: Mass Torts as a False Cure for Toxic Exposure*, Columbia Law Review, Vol. 97, No. 7, 1997, pp. 2153–2176; Korzec, R., *Dashing Consumer Hopes: Strict Products Liability and the Demise of the Consumer Expectations Test*, Boston College International and Comparative Law Review, Vol. 20, No. 2, 1997, p. 227.

4 Convention européenne sur la responsabilité du fait des produits en cas de lésions corporelles ou de décès, Strasbourg, 27. I 1977, Série des traités européens – n° 91, [https://rm.coe.int/1680077328],

Convention then served as a historical model for the adoption of the Product Liability Directive (hereafter: the Directive or PLD).[5]

The Directive is a maximum directive, meaning that the Member State cannot provide consumers greater protection than the protection granted by the Directive.[6] The aim of maximum directives is not only to protect the consumer, but also to level the terms under which producers are exposed to liability while operating within the internal market. However, there have been critics who have pointed out that such a maximum, i.e., full harmonization, only limits the protection that the consumer may already enjoy according to national rules of certain European states, and that a visible improvement for the European producers is not achieved.[7]

Since the Directive stipulates full harmonization, the EU Member States do not have the freedom to provide greater or lesser protection to the injured person than that imperatively prescribed by the Directive. They are also required to fully harmonize their national law with the requirements of the Directive, and they are free to independently regulate issues not covered by the Directive,[8] of course, in such a manner as not to be in contravention with other requirements placed before them by EU law. Regardless of the question of whether it is justified to reduce the protection enjoyed by consumers in some countries, the maximum harmonization in the domain of consumer rights levels the operating conditions regarding the liability of the producers and reduces the risk that is created for producers arising from the variance in national liability rules.

The Directive rules have been transposed into the national laws of all the Member States and many states that aspire to EU membership. In brief, these rules stipulate that the producer is liable for damage caused by defective products according to

accessed 29 March 2023.

5 Directive 85/374/EEC concerning liability for defective products [1985], OJ L 210, amended by Directive 1999/34/EC concerning liability for defective products [1999], OJ L 141. For a detailed overview and analysis of the Directive see: Micklitz, H. W., *Liability for defective products and services*, in: Micklitz, H. W.; Reich, N.; Rott, P.; Tonner, K. (eds.), European Consumer Law, Intersentia, Cambridge–Antwerp–Portland 2014, p. 239 ff. On the relationship between the Strasbourg Convention and the Directive see: Markovits, Y., 54 ff.

6 CJEU took this stance on at least three occasions (Case C-52/00 *Commission v France* [2000], ECLI:EU:C:2002:252; Case C-154/00 *Commission v Greece* [2000], ECLI:EU:C:2002:254; Case C-183/00 *González Sánchez v Medicina Asturiana* [2000], ECLI:EU:C:2002:255).

7 Schmid, C., *The Instrumentalist Conception of the Acquis Communautaire in Consumer Law*, in: Grundmann, S.; Schauer, M. (eds.), The Architecture of European Codes and Contract Law, Kluwer, Alphen aan den Rijn 2006, pp. 265–267.

8 For example, the Directive does not regulate liability for non-material damage caused by a defective product, nor the liability for damage caused to the product itself; these matters are freely regulated by the Member States. This stems from the provisions in Art. 9 PLD.

the objective principle, i.e. regardless of the producer's fault.[9] The injured person bears the burden of proof of the damage, the defectiveness of the product, and the causal links between the defectiveness and the suffered damage.

Any movable, including movables incorporated into another movable or into an immovable, is considered a product. Electricity is also a product. Defectiveness exists if the product does not provide the level of safety that is expected given the circumstances of the specific case, including advertisement and use of the product that could be reasonably expected at the time when the product was put into circulation. The fact that a higher quality product was marketed subsequently is not reason enough to consider that the product has a defect.

In contrast to product liability in the US, the Directive does not differentiate between design, manufacturing and instruction or warning defects.[10] The same is true for most statutes on product liability in Europe. However, some national courts do make such distinction, and apply different tests to determine the existence of manufacturing defects, on the one hand, and the existence of design and instruction defects, on the other.[11]

Damage entails material damage due to death or personal injury, as well as damage to, or destruction of any item of property that is commonly used for private use or consumption, and that was in fact predominantly used by the injured person for her own private use or consumption. The Directive does not affect national rules on non-material damage. The damage to, or destruction of the defective product itself does not qualify as damage under PLD, and it is generally considered to be better regulated by contract law. The lower threshold of producer's liability is EUR 500, meaning that the injured person has no right to compensation for the first EUR 500 of damage, and if the damage is greater, the producer is required to provide compensation for everything over that sum.

One of the ways that the producer can be exempt from liability is that they prove that the state of scientific and technical knowledge at the time when the product

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9 In detail: Fairgrieve D.; Howells G.; Møgelvang-Hansen P.; Straetmans G.; Verhoeven D.; Machnikowski, P.; Janssen A.; Schulze R., *Product Liability Directive*, in: Machnikowski P. (ed.), European Product Liability. An Analysis of the State of the Art in the Era of New Technologies, Intersentia, Cambridge – Antwerp – Portland, 2017, pp. 17–108.

10 Reimann, M., *Product Liability*, in: Bussani, M.; Sebok A. J. (eds.), Comparative Tort Law, Edward Elgar Publishing, Cheltenham – Northampton MA, 2021, pp. 236 ff; Wuyts, D., *The Product Liability Directive – More than two Decades of Defective Products in Europe*, Journal of European Tort Law, Vol. 5, No. 1, 2014, p. 10.

11 Santos Silva M. *et al.*, *Relevance of Risk-benefit for Assessing Defectiveness of a Product: A Comparative Study of Thirteen European Legal Systems*, European Review of Private Law, Vol. 29, No. 1, 2021, p. 127. The CJEU can make a binding decision only on whether such test is permitted or not. *Ibidem*., p. 128.

was put on the market was not such as to enable the existence of the defect to be discovered (Art. 7 (1)(e) PLD).[12] In other words, the Member State is free to stipulate that the producer will not be held liable for damage caused by a defect that was not discoverable, based on the most advanced objective knowledge, at the time when the product was put into circulation. If this is stipulated, the Member State effectively passes the development risks to the consumers, which is, at least in theory, supposed to accelerate innovation.[13]

In recent decades there has been a lively discussion on the need to revise the rules of the Directive, i.e., to regulate the product liability domain in a new and contemporary manner. In the years of the Commission's reluctance to engage in a revision of the Directive, some legal scholars have contemplated the use of alternative 'soft law' techniques for promoting greater certainty as to the meaning of some key provisions of the Directive.[14]

In late September 2022 the European Commission finally adopted and published the Proposal for a Directive on liability for defective products (hereafter: the Proposal or DPLD).[15] Therefore, this paper has two aims: (1) to review the reasons why it is necessary to amend the EU rules on product liability, and (2) to examine the prospective new rules proposed by the European Commission.

2. REASONS FOR REFORMING PRODUCT LIABILITY IN THE EU

2.1. Technological development: digital and circular economy

The Product Liability Directive has successfully harmonized the internal regulations of the EU Member States concerning liability for defective products.[16] Clear legal and political reasons for this were pointed out back in 1985: the harmoni-

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12 The transposition of this provision is not mandatory, as per Art. 15 (1)(b) PLD.

13 Mildred, M., *The development risk defence*, in: Fairgrieve, D. (ed.), *Product Liability in Comparative Perspective*, C.U.P., Cambridge 2005, pp. 167–168; Koch, B. A., *The development risk defence of the EC Product Liability Directive*, Pharmaceuticals Policy and Law, Vol. 20, No. 1–4, 2018, pp. 163–176; Karanikić, M., *Development Risks*, Anali Pravnog fakulteta u Beogradu, Vol. 54, No. 3, 2006, pp. 117–148.

14 Fairgrieve D.; Howells G.; Pilgerstorfer M., *The Product Liability Directive: Time to get Soft?*, Journal of European Tort Law, Vol. 4, No. 1, 2013, pp. 1–33.

15 Proposal for a Directive on liability for defective products, COM(2022) 495. This document contains the Explanatory Memorandum and text of the Proposal for a Directive on liability for defective products.

16 European Commission, Report on the Application of the Council Directive 85/374/EEC concerning liability for defective products, COM/2018/246 final, p. 8.

zation of national regulations on product liability is necessary in order to ensure equal operating terms in the internal market, free competition, equal conditions for movement of goods, and equal level of consumer protection. Furthermore, under conditions of contemporary scientific and technological development, fair appointment of risk of damage caused by the defectiveness of products can be achieved only if the producer is held liable objectively, i.e., regardless of their own fault.

The Directive has been in force for more than 35 years and during that time it has been amended only once, in 1999, following the epidemic of Bovine Spongiform Encephalopathy, also known as Mad Cow Disease. At the time it was necessary for the European legislator to expand the definition of "product" in order to extend the scope of the objective liability of the producer to include primary agricultural products (products of the soil, of livestock farming and of fisheries) and game. It is understood that the amended definition of 'product' also encompasses genetically modified seeds and other genetically modified organisms.[17] In all other matters the Directive has retained its original form.

The Directive was generally appraised as a 'good thing from the consumer perspective': without this instrument it is unlikely that all Member States would have introduced strict liability and certainly it would not have come about in so coherent a form.[18]

However, there have been numerous social, political, economic and technological changes since the adoption of the Directive, which have created the need to update the existing liability regime, as well as political pressure to do so, primarily in a manner that the rules on liability better correspond to the new conditions of the circular and digital economy. The general digitalization of society has enabled the efficient exchange of information and application of modern technologies in product manufacturing and distribution. The aim of a circular economy is for products and materials to remain in use for as long as possible, i.e., to reduce waste accumulation through the reuse, repair, and recycling of products.[19]

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17 See answers to parliamentary questions P-2383/00, E-2685/00, and E-1724/98, to the European Commission, available at:
[http://europarl.europa.eu], Accessed 29 March 2023.

18 See, instead of many others, Howells G., *Product liability – a history of harmonisation*, in: Fairgrieve D. (ed.), Product Liability in Comparative Perspective, C.U.P., Cambridge, 2005, pp. 215–216.

19 On this path the Commission adopted a new highly-ambitious strategy for economic development, in which the EU "aims to transform the EU into a fair and prosperous society" with a competitive economy and completely green economic growth (without net emissions of greenhouse gases in 2050 and economic growth decoupled from resource use). The European Green Deal, COM/2019/640 final. Of

This brings up the question who should be considered the manufacturer of the modified products, the products that are refurbished and adapted beyond the producer's control, the products with high degree of autonomy, and also those with strong service components. Another aspect to be taken into account are multi-actor and global value chains, as well as the instances of direct online sales from third countries. In addition, many new products can not be used as standalone items, but must be connected to other products or integrated into a system.

In cases of damage caused by defects in complex products like medical devices, pharmaceutical products and products with digital components, the burden of proof is correspondingly very complex, and costs seem to be unevenly distributed between consumers and producers. On top of that, the general and sectoral rules and regulations on product safety and market control have advanced, and so the liability regimes should readjust, to create a more coherent system.

2.2. Practical problems with the application of the existing rules

In the process of evaluating the Directive, which preceded the adoption of the Proposal, it was determined that the existing rules created numerous practical problems for the circular and digital economy.[20]

The Directive was adopted far before the digital revolution, so it is now difficult to apply its provisions to products the likes of which did not exits, and especially to software and products such as smart devices and autonomous vehicles, which cannot function without software and connected digital services. It is also unclear who should be liable for damage caused by the defectiveness of a product that has been modified, or its digital component has been replaced or updated.

The EU consumers are increasingly buying products online directly from the non-EU countries, which means that there is no person established in the EU (producer, importer, distributor, retailer) that could be effectively held liable for damage in accordance with the Directive. The Directive originates from the time when supply chains were mostly organized as 'pipelines', and now we also have digital markets, with online platforms as key players, and new supply chains that directly connect EU consumers with non-EU traders.[21] The regulatory response

course, it is debatable whether it is possible to *globally* decouple economic growth from resource use in such a short period of time (or at all).

[20] All according to: Executive Summary of the Impact Assessment Report, accompanying the Proposal for a Directive on liability for defective products, SWD/2022/317 final.

[21] Busch C., *When Product Liability Meets the Platform Economy: A European Perspective on Oberdorf v. Amazon*, Journal of European Consumer and Market Law, Vol. 8, No. 5, 2019, p. 174.

to this development in the EU has been direct regulation via product safety rules and market surveillance, which should be supplemented by expanding the application of product liability rules to online marketplaces.[22] At this point, online marketplaces are effectively outside the scope of PLD, and the very use of these platforms can make it harder for injured parties to establish liability of other participants in the supply chain under PLD.[23]

Furthermore, according to the Directive, the burden of proof of the existence of defect, and that of the causal link between the defect and the inflicted damage, falls on the injured person. However, the Directive does not define the standard of proof, which causes divergence in the levels of consumer protection within the EU.[24]

It may be very difficult, if not impossible, for the injured person to prove the existence of the defectiveness and causal link in complex situations, for example, when the damage is caused by pharmaceutical products, or products based on machine learning and artificial intelligence, or products with a digital component in general. In such cases the injured person usually does not have technical knowledge and sufficient information on the product necessary to prove the causal link, and the provisions of the Directive do not require the producer to grant access to such information, nor do they allow for the burden of proof to be shifted to the producer in national law.

Finally, the position of the injured person is also inferior because the obligation of the producer to provide compensation in any case expires ten years from the date that the product was put on the market, as well as that, according to the Directive, the producer is not liable for the first EUR 500 of the damages.

At first glance it might seem that the ten-year prescription period is more than sufficient to exercise the right to compensation for damage caused by a defective product. However, if the defectiveness causes a delayed harmful effect, then even a much shorter period, which would not start until the damage occurred, would be more favorable for the injured person than such a long period that starts as soon as the item is put on the market. For example, the harmful effects of a defective pharmaceutical product may become pronounced several years after the use of this product. For the injured person it may be more beneficial for the right to

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22 Busch, C., Rethinking Product Liability Rules for Online Marketplaces: A Comparative Perspective, 10 February 2021,
[https://ssrn.com/abstract=3784466], Accessed 12 May 2023, *passim*.

23 Ulfbeck V.; Verbruggen P., *Online Marketplaces and Product Liability: Back to the Where We Started?*, European Review of Private Law, Vol. 30, No. 6, 2022, p. 998.

24 Wuyts, *op. cit.* note 10, 23 ff.

compensation to expire five years from the occurrence of the damage, rather than ten years from the time that the drug was put into circulation.

2.3. The role of the courts

Scientific and technological development has made possible new situations and disputes regarding issues that could previously not have been imagined. In order to resolve them, it is necessary for the courts to creatively interpret the old stipulations of the Directive. The courts have done so with variable success. We will present two examples.

In the first one, the ruling of the Court of Justice of the European Union (CJEU) in the Case *Boston Scientific*[25] drew great attention from the legal scholars and professionals, and from the medical industry.[26] At the time the CJEU introduced the concept of 'potential defect' into the domain of product liability, in connection with implantable medical devices, such as pacemakers and cardioverter defibrillators. The CJEU held that an implantable medical device may be classified as defective, on the sole basis that it belongs to a group of products, or to a production series, which has a potential defect, without need to establish that the medical device in the very case has such a defect. In addition, the damage caused by a surgical operation for the replacement of a defective implantable medical device constitutes 'damage caused by death or personal injuries' for which the producer is liable, if such an operation is necessary to overcome the defect in the product in question.

In other words, where an implantable medical device belongs to an abnormally hazardous production series, the device in question should be classified as 'defective' for the mere fact that the existence of a defect in the implanted product can only be established by removing the device from the human body, or in some

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[25] Joined Cases C–503/13 *Boston Scientific Medizintechnik v Die Gesundheitskasse*, and C–504/13 *Boston Scientific Medizintechnik v. Betriebskrankenkasse* [2015] ECLI:EU:C:2015:148.

[26] Van Leeuwen B., Verbruggen P., *Resuscitating EU Product Liability Law? Contemplating the effects of Boston scientific medizintechnik*, European Review of Private Law, Vol. 23, No. 5, 2015, pp. 899–915; Verdure C., *Arrêt Boston Scientific Medezintechnik : l'appréciation du 'défaut' dans le cadre de la Directive relative aux produits défectueux*, Journal de droit européen, Vol. 240, 2015, pp. 242–244; Reich N., *Produkthaftungsrecht: Haftung für potenziell fehlerhaftes Medizinprodukt*, Europäische Zeitschrift für Wirtschaftsrecht, No. 8, 2015, pp. 318–320; Büyüksagis E., *Et si Dr House évoquait le défaut potentiel de votre pacemaker...*, Aktuelle juristische Praxis, No. 1, 2016, pp. 14–22; Büyüksagis E., *La responsabilité du fait des produits 'défectueux sans défaut' : l'arrêt Boston Scientific du 5 mars 2015*, Droit de la consommation, No. 1, 2016, pp. 15–30; Karanikić Mirić, M., *Odgovornost proizvođača za potencijalni defekt*, in: Ignjatović, Đ. (ed.), Kaznena reakcija u Srbiji, Vol. VIII, Pravni fakultet Univerziteta u Beogradu, Belgrade, 2018, pp. 194–213.

other way involving a violation of the bodily integrity of the patient. Furthermore, the costs of the surgical replacement of a potentially defective implantable medical device qualify as 'damage', provided that such a surgical operation is required for removing the defect. When it comes to the safety standard, it has been pointed out in the literature that while the Directive focuses on 'the safety which a person is entitled to expect', after the *Boston Scientific* such standard shall be understood as safety which 'the public at large is entitled to expect', and it is for the court to decide to which expectations the general public is entitled.[27]

In the second example, the *Sanofi Pasteur* case,[28] the CJEU held that, where medical research neither establishes, nor rules out the existence of a causal link between the administering of the vaccine and the occurrence of the victim's disease, i.e. in the absence of scientific consensus, the courts of the Member States may allow plaintiffs to use circumstantial evidence to prove vaccine harms. However, the courts cannot reverse the burden of proof set in the Directive (as per Art. 4 PLD, the injured person is required to prove the damage, the defect and the causal relationship between defect and damage), nor can they introduce irrebuttable presumption at the expense of vaccine producers.

In certain complex situations it may be practically impossible for the injured person to prove the existence of the causal link between the defect and the damage. In *Sanofi Pasteur*, there was no scientific evidence that either confirms, or refutes the existence of the causal link between the vaccine against hepatitis B and multiple sclerosis. The rule that medical causation can only be proven by scientific evidence would in such cases infringe on the effectiveness and frustrate the purpose of product liability, which includes fair apportionment of development risks and protection of consumer health and safety.

According to CJEU, the principle of effectiveness requires that national evidentiary rules do not render practically impossible or excessively difficult for the injured person to prove causation. Procedural position of the injured person is unjustifiably difficult, if the single admissible proof of causation is nothing less than conclusive scientific research. In the absence of such proof, the injured party may be allowed, by the national rules of evidence, to submit other relevant pieces of evidence, which, when presented together, can confirm that it is more likely that the disease was caused by the administered vaccine than by any other cause. Unlike the vaccine producer, which is not only able to, but is also required to carry out or finance medical studies concerning the side effects of his products, the injured

[27] Santos Silva *et al.*, *op. cit.* note 11, pp. 126–127.

[28] Case C–621/15 *N.W v Sanofi Pasteur* [2017], ECLI:EU:C:2017:484.

party regularly has neither the knowledge, nor the financial means to provide scientific evidence of causation.[29]

The CJEU has repeatedly emphasized that the Directive is fully harmonizing. PLD undeniably aims to create a level playing field, *i.e.* to remove obstacles to the functioning of the internal market, even to the detriment of consumers. This comes from the idea that the applied method of harmonization is determined by the legal grounds for the Directive (Art. 100 of the Rome Treaty (EEC)).[30] However, within this scope, the Directive is meant to ensure protection for the victims of product-related accidents, and so the trend has been noted in the recent CJEU case law to foster the position of the consumer.[31] Moreover, the Court has expressly endorsed the regulatory role of the Directive, especially in relation to implantable medical devices, and has openly interpreted product liability law under the Directive as an additional instrument of product safety regulation.[32]

2.4. Public discussion on the need to modernize the Directive

Competent institutions and the professional and scientific communities have discussed for a long time the needs and ways for the existing rules on product liability to be adapted to the new social circumstances, primarily the processes and effects of the new digital technologies and the green transition.[33]

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29 Karanikić Mirić, M., *Odgovornost proizvođača vakcine u praksi Evropskog suda pravde*, Srpska politička misao, No. 4, 2017, pp. 137–159. Also see: Haertlein L., *Immunizing Against Bad Science: The Vaccine Court and the Autism Test Cases*, Law and Contemporary Problems, Vol. 75, No. 2, 2012, pp. 211–232; Stapleton, J, *Scientific and Legal Approaches to Causation*, in: Freckelton I., Mendelson D. (eds.), *Causation in Law and Medicine*, Aldershot, Ashgate, 2002, pp. 14–37; Stratton K., Ford A., Rusch E., Wright Clayton E. (eds.), *Adverse Effects of Vaccines: Evidence and Causality: Consensus Study Report*, National Academies of Sciences, Engineering, and Medicine, Washington, 2012.

30 Machnikowski P., *Conclusions*, in: Machnikowski P. (ed.), European Product Liability. An Analysis of the State of the Art in the Era of New Technologies, Intersentia, Cambridge – Antwerp – Portland, 2017, pp. 680–681.

31 Verheyen T., *Full Harmonization, Consumer Protection and Products Liability: A Fresh Reading of the Case Law of the ECJ*, European Review of Private Law, Vol. 26, No. 1, 2018, pp. 119–140; noting at p. 140 that this trend benefits the injured consumers at the detriment of consumers as a class that suffer from increased prices.

32 Reich, N., *Product Liability and Beyond: An Exercise in 'Gap-Filling'*, European Review of Private Law, Vol. 24, No. 3/4, 2016, pp. 624–627.

33 See for example: European Parliament resolution with recommendations to the Commission on a civil liability regime for artificial intelligence, 2020/2014(INL); Commission Staff Working Document, Liability for emerging digital technologies, SWD/2018/137 final; European Commission, Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, COM/2020/64 final.

For example, in January 2021, the European Law Institute (ELI) published a document titled Guiding Principles for Updating the Product Liability Directive for the Digital Age,[34] which states that the aims of the modernization of the Directive should: simplify the mechanism for exercising the right to compensation; establish a balance between protecting the injured person on one hand, and encouraging innovation and use of digital technologies, on the other; align the rules on product liability with the rules on other forms of liability, as well as insurance and other forms of compensation. Furthermore, it is necessary to expand the notions of 'producer' (to include parties that oversee and update digital content and digital services, as well as to online platforms with an active role in distribution); 'product' (to include items with a digital component, digital content and digital services that are delivered as 'digital products'); 'defect' (bearing in mind the specific characteristics of digital components and products); and 'damage' (so as to also encompass damage to and destruction of digital data, products and components). Also, the burden of proof and defenses available to a producer should be adapted to the specific conditions in the digital environment. Furthermore, the recourse claims between liable parties and their statutes of limitation should be regulated, since the Directive makes no mention of them.[35]

On the official side, the European Commission has submitted regular five-year reports to the EU Council and the European Parliament on the application of the Directive,[36] carried out a formal evaluation of the Directive[37] based on an extensive study that it had commissioned, and organized public consultations. Furthermore, it has formed an expert group for the domain of liability and new

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[34] ELI, *Guiding Principles for Updating the Product Liability Directive for the Digital Age*, Vienna 2021, [https://europeanlawinstitute.eu/fileadmin/user_upload/p_eli/Publications/ELI_Guiding_Principles_for_Updating_the_PLD_for_the_Digital_Age.pdf], Accessed 29 March 2023. Furthermore, upon publication of DPLD, ELI published general feedback consisting of comments to selected articles of the Proposal. See: ELI, European Commission's Proposal for a Revised Product Liability Directive. Feedback of the European Law Institute (hereafter: ELI Feedback), Vienna 2023, [https://www.europeanlawinstitute.eu/fileadmin/user_upload/p_eli/Publications/ELI_Feedback_on_the_EC_Proposal_for_a_Revised_Product_Liability_Directive.pdf], Accessed 29 March 2023.

[35] In addition to these guiding principles, ELI also published its draft of the new directive on product liability. See: *ELI Draft of a Revised Product Liability Directive*, Draft Legislative Proposal, Vienna 2022, [http://europeanlawinstitute.eu/fileadmin/user_upload/p_eli/Publications/ELI_Draft_of_a_Revised_Product_Liability_Directive.pdf], Accessed 29 March 2023.

[36] The fifth report was submitted in 2018: Report from the Commission on the Application of the Directive on liability for defective products, COM/2018/246 final.

[37] Commission Staff Working Document, Evaluation of Council Directive on liability for defective products, SWD/2018/157 final, accompanying the Report from the Commission on the Application of the Directive on liability for defective products, COM/2018/246 final.

technologies,[38] and published a report on product safety and liability for defective products in the context of artificial intelligence, the Internet of Things, and robotics.[39]

Finally, the Commission has launched proceedings for revising the rules on product liability, in the direction that is suitable for the development of the circular and digital economy, and on 28 September 2022 adopted and published its Proposal for a Directive on liability for defective products.[40]

2.5. Official explanation of the Proposal for a Directive on product liability

The need to revise the rules on product liability in EU law is linked to practical problems that may arise when some of the old rules are applied to certain new situations. Bearing this in mind, the European Commission has formulated the general and the particular objectives of the planned revision, in the Explanatory Memorandum accompanying the Proposal.[41]

The general objective, i.e., the purpose of product liability, remains the same, and in this respect the Proposal does not differ from the Directive: it is still necessary to ensure the functioning of the internal market and a high level of protection of consumers' health and property. However, the Proposal also contains some specific, particular objectives, whose achievement would call for amendments to the existing legal regime, by adapting the old rules to the new political, social, economic and technological conditions. The European Commission has formulated these specific objectives as follows.

First, it is necessary to ensure that the rules of product liability reflect the nature and risks of products in the digital age and circular economy. Second – and much more concretely – it is necessary to ensure that there is always a business

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38 Expert Group on Liability and New Technologies, *Liability for artificial intelligence and other emerging digital technologies*, Publications Office, 2019, doi/10.2838/573689, accessed 29 March 2023. Also see the critical analysis: Bertolini, A.; Episcopo, F., *The Expert Group's Report on Liability for Artificial Intelligence and Other Emerging Digital Technologies: A critical assessment*, European Journal of Risk Regulation, Vol. 12, No. 3, 2021, pp. 644–659.

39 European Commission, Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, COM/2020/64 final, [https://*eur-lex.europa.eu*], Accessed 10 October 2022.

40 For more information on the ongoing process visit: European Commission, *Adapting liability rules to the digital age, circular economy and global value chains*, [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-adapting-liability-rules-to-the-digital-age-and-artificial-intelligence_en], Accessed 29 March 2023.

41 See: FN 16 here.

established in the EU that can be effectively held liable for defective products that consumers purchase directly from manufacturers outside EU. Namely, in the present situation, when consumers increasingly purchase goods directly from non-EU countries, it may be that there is no producer, retailer, importer or distributor based in the EU, to whom the consumer could address his claim for compensation.

Third, it is necessary to ease the burden of proof for the injured person in complex cases, and also to ease restrictions on making claims, while ensuring a fair balance between the legitimate interests of manufacturers, injured persons and consumers in general. Fourth, it is necessary to harmonize the rules on liability for defective products with the newer rules on product safety and to codify the PLD related case law.

3. THE PROPOSAL FOR A DIRECTIVE ON LIABILITY FOR DEFECTIVE PRODUCTS

3.1. The most significant innovations

In the practical sense, the most significant novelties in DPLD are the expansions of the definitions of the fundamental terms, such as 'product', 'producer', 'defect' and 'damage', and the changes intended to facilitate the submission of claim and evidentiary requirements for the injured person.

Also significant is the Commission's proposal to set the level of harmonization at maximum, by expressly prescribing that Member States may not maintain or introduce provisions in their national laws that diverge from the Proposal: neither more, nor less stringent national provisions from those laid down in the Proposal may be permitted (Art. 3 DPLD). So far, maximum harmonization has only been the position of the CJEU on PLD,[42] and now the Commission proposes codification of that position, i.e. explicit clarification that DPLD should operate as instrument of full or maximum harmonization. In addition to not being modifiable by national regulations, the proposed rules would also not be modifiable through contracts: product liability cannot be excluded nor limited by contract, according to the explicit letter of the Proposal (Art. 13 DPLD).

Member States will be required to harmonize their national legislation with DPLD within twelve months of its adoption. PLD will remain in effect during the transition, and subsequently only for products that have been put into service or placed on the market prior to DPLD coming into effect (Art. 17 DPLD).

[42] See: FN 7 here.

3.1.1. The notions of 'product' and 'damage'

First of all, DPLD proposes the notion of 'product' to be expanded to include software as a standalone digital product, or as a digital component of a product, regardless of how it is delivered or used (e.g. on a device, in a cloud, online).[43] The term 'product' should also include digital manufacturing files, i.e. the files that contain functional information for the production of movables. These are digital versions or digital templates of movables, that allow automated control of machines and tools, such as drills, lathes, mills and 3D printers, which produce tangible items according to those instructions (Art. 4 (1)(1–2) DPLD). It would be beneficial to expressly define the exemption for free or open-source software, and not only in Recital 13.

Commentators have pointed out that it is unclear whether or not the revised product liability rules apply to so-called digital product passports (DPPs) and the information these files contain. DDPs are electronic files that change during the lifecycle of the product, and provide product information throughout the value chain. These information concern sustainability, responsible sourcing and manufacturing, environmental and recyclability attributes of the product, but may also relate to it's composition and performance, and if defective, they may cause damage.[44]

ELI proposes to expressly state in DPLD that software as a service is also a 'product', and disapproves of DPLD being silent on whether or not 'product' includes waste, or products based on human body parts, such as blood, cells, or tissue.[45] Others have noted that there are products that merely convey information, and products which use information in their operation, and maintained that where the product is merely a medium, strict liability should not apply. The same goes if the product is digitally stored information. An error in the information constitutes a defect only if such error affects the operation of the product.[46]

In any case, the current revision of product liability rules should be used, among other things, to settle the ongoing debates on whether certain objects qualify as

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43 Mere information supplied in digital form is presently excluded from the notion of 'product'. Case C–65/20 *Krone* [2021], ECLI:EU:C:2021:471.

44 Dheu O.; De Bruyne J.; Ducuing C, The European Commission's Approach To Extra-Contractual Liability and AI – A First Analysis and Evaluation of the Two Proposals, pp. 39-40, 6 October 2022, [https://ssrn.com/abstract=4239792], Accessed 12 May 2023.

45 ELI Feedback, p. 11–12.

46 Machnikowski P., *Product Liability for Information products?: The CJEU Judgment in VI/KRONE–Verlag Gesellschaft mbH & Co KG, 10 June 2021 [C-65/20]*, European Review of Private Law, Vol. 30, No. 1, 2022, p. 200.

'products' and fall within the scope of the Directive. It should also be stated clearly that 'product' includes both goods produced on an industrial scale, and goods produced individually.

Furthermore, DPLD proposes to expand the term 'damage' so as to explicitly include material losses from 'medically recognized harm to psychological health', as well as 'loss or corruption of data that is not used exclusively for professional purposes'. It would be good to clarify that data loss includes leakage.[47] Also, it is explicitly stated in Recital 18 of the Proposal that DPLD should not affect national rules relating to non-material damage. Therefore, liability for non-material losses can be freely regulated by national laws.

The Proposal enumerates the types of material losses that are recoverable under DPLD. Further express clarification that other material losses are excluded, and that Members States may not regulate liability for those losses as they wish, would be welcome, in order to preserve one of the purposes of this instrument, and that is to limit the financial impact of product liability for the producers.[48] Damage to the defective product itself is excluded, which confirms the existing law. However, damage caused to a product by a defective component of that product should be covered by product liability rules. This is one of the sound critiques of the DPLD.[49]

DPLD leaves to Member States to lay down the rules on calculating compensation. Moreover, the opportunity is missed to address the consequences of the potential insolvency of the liable party, which may leave the victim without compensation, and to examine the possibility of introducing mandatory liability insurance for the manufacturers in some instances.[50]

3.1.2. The notion of 'defect'

DPLD expands and clarifies the notion of 'defectiveness' (Art. 6). It lays down that a product is considered defective if it does not provide the safety that the public at large is entitled to expect,[51] taking all circumstances into account, including the advertisement, instructions for installation, use and maintenance; the reasonably

47 ELI Feedback, p. 13.

48 ELI Feedback, p. 12–13.

49 ELI Feedback, p. 13.

50 Dheu; De Bruyne ; Ducuing, *op.cit.*, note 44 pp. 38–39.

51 In the time of COVID-19 pandemic, legal scholars concluded that producing in an emergency will not by itself provide a defense to product liability, though it might be a factor to be taken into account, for instance, in the sense that 'where regulatory demands are reduced and the processes accelerated, then the entitled expectations of safety might also be lowered'. Fairgrieve D.; Feldschreiber P.; Howells G.;

foreseeable use and misuse of the product; the moment in time when the product was placed on the market or put into service or, where the manufacturer retains control over the product after that moment, the moment in time when the product left the control of the manufacturer.

Furthermore, DPLD prescribes that in assessing whether the product is defective, also taken into consideration will be the specific expectations of the end-users for whom the product is intended; the effect on the product of any ability to continue to learn after deployment, i.e. the machine-learning capability of the product after being put into service; the effect on the product of other products that can reasonably be expected to be used together with the product; product safety requirements, including safety-relevant cybersecurity requirements; subsequent interventions by the producer or regulatory authorities, such as product recall for insufficient safety; significant subsequent modifications that affect the safety of the product.

However, the specific safety expectations of end-users themselves may be lowered due to their lack of knowledge or cognitive deficits.[52] It was pointed out by the commentators that the objective expectations, i.e. reasonable safety expectations of the public at large, should prevail in that case. This is especially true for children as end-users.

In contrast, there is a growing gap between the common expectations about the safety of the new technologies and their actual safety. In other words, the safety expectations of the public at large about the innovative products may be set at unrealistic levels, which may hamper technological development and obstruct access to the new technologies for EU consumers.[53] It has been pointed out that the public at large may easily have safety expectations for modern products which would be considered unrealistic by experts in the given field. Therefore, it would be advisable to stipulate the criteria that control whether a given expectation of safety is reasonable or justified, and consequently to what level of safety the public at large is entitled.[54]

Furthermore, in *Boston Scientific* (para. 42) the Court held that a fair apportionment of the risks inherent in modern technological production between the in-

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Pilgerstorfer M., *Products in a Pandemic: Liability for Medical Products and the Fight against COVID-19*, European Journal of Risk Regulation, Vol. 11, No. 3, 2020, p. 597.

52 ELI Feedback, p. 16.

53 Santos Silva M. *et al.*, *op. cit.* note 11, pp. 130–131.

54 For instance, the number of accidents involving autonomous vehicles is not significant in relation to the distance travelled, and yet each accident is perceived as confirmation that these vehicles lack in safety. *Ibidem*., p. 130.

jured person and the producer needs to be ensured, bearing in mind the abnormal potential for damage which some products might cause to the person concerned. In the same CJEU case, AG Bot stated that a product should be deemed unsafe if it creates the risk of 'an abnormal, unreasonable character exceeding the normal risks inherent in its use' (para. 30). The Court relied on the principle of fair apportionment of risks, and on the concept of abnormal potential for damage, to clarify the criterion of defectiveness.[55] It seems that DPLD would benefit from enriching the standard of defectiveness in a comparable manner.

The new expanded DPLD definition addresses the control the producer sometimes retains over the product after putting it into circulation, the ability of the product to evolve after being put into service, and the ability of the product to connect and function together with other products. Still, the critics have stated that allowing the defectiveness to be inferred from a product recall may discourage manufacturers from voluntarily recalling products of unsatisfactory quality.[56]

3.1.3. The notion of 'manufacturer'

DPLD stipulates a circle of potentially liable persons to be significantly expanded, compared to the existing liability regime, to include, for example, producers of software and providers of related services, representatives of the non-EU producers, importers, fulfilment service providers, product refurbishers, which all should increase the likelihood of the injured person exercising their right to compensation. The genus-term that covers all potentially liable persons in DPLD is 'economic operator' (Art. 4 (1)(16)).

The PLD notion of 'producer' is substituted in DPLD by a broader notion of 'manufacturer'. For instance, only the latter includes a person who produces a product for their own use. Also, the notion of 'manufacturer' may include providers of software and digital services, as well as online marketplaces. The manufacturer of a defective component can also be held liable for the same damage, along with the manufacturer of the final product, and the component means any tangible or intangible item or a related service, whose integration and interconnection with the product was carried out or approved by the product manufacturer.

Where the manufacturer of the defective product is established outside the EU, the importer of the defective product and the authorized representative of the

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55 Fairgrieve D.; Pilgerstorfer, M., *European Product Liability after Boston Scientific: An Assessment of the Court's Judgment on Defect, Damage and Causation*, European Business Law Review, Vol. 28, No. 6, 2017, pp. 882, 887 and *passim*.

56 ELI Feedback, p. 16.

manufacturer will be held liable for damage caused by that product. And if the product is purchased directly from manufacturers outside the EU, the fulfilment service provider will be liable for damage caused by the defective product. The fulfilment service provider means any natural or legal person facilitating fulfillment of the manufacturer's obligations towards the consumer, by offering, in the course of their commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching of a product, without having ownership of the product, and with the exception of postal services and freight transport services.

Furthermore, the person that modifies the product that has already been put into service or on the market is liable for damage like the manufacturer, provided that the modification was significant and that it was carried out outside of the control of the manufacturer. However, this person may be exempt from liability if it proves that the modification did not affect the part of the product that contains the defect (Art. 10 (1)(g) DPLD).

To sum up, the aim of the proposed system is to ensure that there is always a person established in the EU that can be held liable for defective products purchased directly from the manufacturers outside the EU. If the manufacturer is established outside EU, liability for the defective product sits with the importer, or with the manufacturer's representative based in the EU, and if they do not exist (e.g. the consumer has procured the product online directly from a non-EU trader), then the fulfilment service provider will be held liable, namely any person that in the course of their profession enables the non-EU retailer to fulfill his obligation towards the EU consumer.

If there is no one who is established in the EU who could be liable in this order, every distributor that fails to identify the person who supplied the defective product, within a month of receiving such request from the injured person, will be held liable. For instance, an online platform which has enabled the consumer to conclude distance contract with the non-EU trader may be held liable, irrespective of whether or not the platform qualifies as producer, importer, or distributor (Art. 7 (5–6) DPLD). Their liability is not restricted to the distribution of digital products.

The Proposal even makes it possible for the manufacturer to be liable for the defect that did not exist at the time when the product was put into service or on the market, if that defect came into being due to the conducting or failure to conduct any subsequent action, which was conducted or should have been con-

ducted within the control of the manufacturer (the related service, or software installation, functioning, update or upgrade).[57]

The benefits of increased compensation for consumers represent a cost to manufacturers. The expansion of circle of potentially liable persons may lead to an increase in liability insurance premiums, which, according to some predictions, is expected to especially impact the operation of small and medium-sized businesses, more so than it would influence the large companies. Namely, small and medium-sized businesses have fewer resources for legal counsel, and less ability to absorb costs.[58]

Viewed more widely, if legal position of the injured persons truly improves, i.e., if it becomes easier for them to exercise their right to compensation, the risk for the manufacturers will also increase, and they will consequently increase the price of products.[59] In other words, the manufacturers will try to pass the risk insurance premium to the consumers. A separate issue is whether or not the manufacturers will actually obtain liability insurance, i.e., whether or not they will use the increase in the price of product to finance such insurance. By passing on the risk insurance premium to consumers, manufacturers will ultimately disperse (socialize) all the risks for which they are presently not liable, but would be liable according to DPLD.

3.1.4. Restrictions on claims and burden of proof

The Proposal improves legal position of the injured person by removing the Directive's rule according to which the damage must exceed EUR 500 in order for the injured person to make a compensation claim, i.e., according to which the claimant is always liable for the first EUR 500 of damage (Art. 9 (1)(b) PLD). The original purpose of this lower limit was to prevent the filing of small claims, i.e., to unburden the courts. However, most consumer disputes are small claims cases. Elimination of the said limit, together with the improved collective redress mechanisms, vastly improves the concurrent resolution of a large number of small claims.

The Proposal also improves the position of the injured person in the evidentiary proceedings, by relocating the burden of proof to manufacturer in certain cases. As

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[57] This is the case when the defect is due to a related service, or software, or lack of software updates or upgrades necessary to maintain safety, provided that they were within the manufacturer's control (Art. 10 (2) pertaining to Art. 10 (1)(c) DPLD).

[58] Executive Summary of the Impact Assessment Report, accompanying the Proposal for a Directive on liability for defective products, SWD/2022/317 final.

[59] Polinsky, A. M.; Shavell S., *The Uneasy Case for Product Liability*, Harvard Law Review, Vol. 123, No. 6/2010, pp. 1467–1469., 1472.

mentioned above, the Directive presently states – and the Member States are not allowed to stipulate differently – that the injured person bears the burden of proof that all the conditions for determining the producer's liability have been met. This means that the injured person must prove the damage, the defect, and the causal link between the defect and the damage (Art. 4 PLD). The Directive does not require the producers of exceptionally complex products, such as pharmaceutical products, medical devices and products with digital components, to share technical information about their products to the injured person, so the latter may try to prove causal link.

Unlike the Directive, the Proposal contains special rules on disclosure of evidence (Art. 8 DPLD). Namely, if the injured person presents facts and evidence sufficient to support the plausibility of the claim for compensation, the defendant will be ordered to disclose relevant evidence that is at its disposal, to the extent necessary and proportionate to support the said claim. When determining whether the disclosure is proportionate, the legitimate interests of all parties are considered, including third parties concerned, in particular in relation to the protection of confidential information and trade secrets. And where the defendant is ordered to disclose a trade secret or an alleged trade secret, the specific measures must be taken in order to preserve the confidentiality of the disclosed information.

The Proposal includes the same basic rule on the burden of proof as the Directive: the injured person must prove the defectiveness of the product, the damage suffered and the causal link between the defectiveness and the damage. The existence of the causal link is not presumed in the Directive nor in the Proposal. However, according to the Directive the rule applies without exception, while the Proposal prescribes numerous situations in which, by way of exception, it is presumed that the defectiveness or the causal link exist (Art. 9 DPLD). These presumptions are rebuttable.

First, the defectiveness is presumed if the manufacturer has failed to disclose relevant evidence, as ordered by the court. Second, the defectiveness is presumed if the injured person establishes that the product does not comply with mandatory safety requirements that are intended to protect against the risk of the damage that has occurred. And third, the defectiveness is also presumed if the injured person establishes that the damage was caused by an obvious malfunction of the product during normal use or under ordinary circumstances.

The causal link between the defectiveness of the product and the damage is presumed, where the injured person establishes that the product is defective and the damage caused is of a kind typically consistent with the defect in question. In

addition, where the court determines that the injured person faces excessive difficulties, due to technical or scientific complexity, to prove the defectiveness or the causal link, or both, then the defectiveness or the causal link, or both will be presumed, on condition that the injured person demonstrates, on the basis of sufficiently relevant evidence, that the product contributed to the damage and that it is likely that the product was defective, or that its defectiveness is a likely cause of the damage, or both.

The new possibility to rebuttably presume the defectiveness, or the causal link, or both, in cases where proving either one of them, or both, is excessively difficult for the injured person that lacks the necessary scientific or technical data or expertise – clearly addresses the situations illustrated above, in *Boston Scientific* and *Sanofi Pasteur*.[60]

The proposed rules greatly empower the injured person in the evidentiary proceedings. In the case of damage caused by especially complex products, whose comprehension requires specific technical or scientific knowledge, the presumption would not apply only to the causal link, but also to the existence of the defect. If the injured person proves that the product contributed to the damage, and that it was likely that the cause of the damage was a defect whose existence has not been proven, then it would be up to the producer to refute either of the two presumptions, i.e. to prove that the product is not defective or that the fact that it is defective was not the cause of the damage.

The proposed DPLD rules on limitation periods are the same as in the Directive. However, DPLD introduces one new provision: where an injured person has not been able to initiate proceedings within a limitation period of 10 years due to the latency of a personal injury, the limitation period will extend to 15 years from the date on which the product was placed on the market, put into service or substantially modified (Art. 14 (3) DPLD). The rights of the injured person will be extinguished upon expiry of that period.

3.1.5. Multiple liable persons and multiple causes of damage

Where two or more persons are liable for the same damage caused by defectiveness of the same product, they will be held jointly and severally liable. The Directive contains the same rule (Art. 5 PLD and Art. 11 DPLD).

The recourse claims are not addressed in DPLD, which means that they can be freely regulated by national laws. However, the various stages of modern produc-

[60] See: FNs 20 and 23 here.

tion regularly involve a number of producers, and the new technologies often merge or connect different elements and devices into one complex item. Therefore, it would be sensible to determine the principles for recourse claims among the enterprises involved in production processes.

Sometimes the damage is caused both by the defectiveness of the product and by the act or omission of a third party. DPLD clarifies that contribution from a third party to the occurrence of damage may not be the reason to reduce liability of manufacturer (Art. 12 (1) DPLD). In such cases the third party and the manufacturer will be held jointly and severally liable.

Finally, when the cause of the damage is both the defectiveness of the product and the fault of the injured person, or a person for whom the injured person is responsible, the manufacturer's liability may be reduced or disallowed (Art. 12 (2) DPLD). The contributory act or omission of that person is not sufficient; what is required is their fault.

3.2. Product liability reform as part of broader legislative activity in the EU

Together with DPLD, the Commission adopted and published another instrument: the Proposal for a Directive on adapting non-contractual civil liability rules to artificial intelligence (hereafter: DAILD).[61]

DAILD is a minimum directive intended to regulate non-contractual fault-based civil liability for damage caused by an artificial intelligence system (AI system). AI system means software that is developed with one or more of the techniques and approaches including machine learning, logic- and knowledge-based approaches, statistical approaches, Bayesian estimation, search and optimization methods, and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with.[62]

DPLD and DAILD should be complementary in an effort to adapt the rules on product liability to the conditions and needs of the digital age, circular economy

[61] Proposal for a Directive on adapting non-contractual civil liability rules to artificial intelligence (*AI Liability Directive*), COM(2022) 496.

[62] Art. 2 (1)(1) of DAILD takes this definition from yet another novel instrument, Proposal for a Regulation on artificial intelligence (*Artificial intelligence act*), COM/2021/206 final.

and global value chains.[63] Moreover, they are systemically linked to other legislative and policy initiatives of the EU, primarily in the domains of product safety, circular economy business models, cybersecurity and collective redress mechanisms.

For example, the recently adopted rules on representative actions, i.e. the legal actions brought by representative entities, for the protection of the collective interests of consumers,[64] together with the proposed suppression of the lower threshold for consumer product liability claims (Art. 4(6)(b) DPLD), which is presently set at EUR 500 (Art. 9 (b) PLD), could substantially ease the simultaneous submission of a large number of small consumer claims in damages. And, taking into account the proposal to alleviate the burden of proof for injured persons and to adjust evidentiary rules to better suit their interests (Art. 8 and Art. 9 DPLD), a significant improvement may be expected in the procedural position of a large number of claimants.

Furthermore, the proposed expansion of the definitions of 'product', 'producer', 'defect' and 'damage' could lead to the increase in the number and the total sum of compensation claims. From the producers' standpoint, the proposed product liability reform will increase the risk of their liability, so it is reasonable to expect that the producers will try to socialize that risk, i.e. to pass the increased costs of their liability risk on to the consumers.

Looking at all these processes, the impression is that after decades of talks on the deficiencies of the existing liability regime, steps are now being taken toward the effective tightening of the product liability rules. However, it should also be expected that the increase of the risk premium born by producers will be dispersed, to a certain extent, to the injured persons and consumers at large.

3.3. Some remaining observations

Apart from the specific issues that have already been raised here, such as the need to clarify certain terms in DPLD, and to address the consequences of potential

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63 The different stages of the production process, i.e. the design, production and marketing of many products, now involve a chain of activities divided among enterprises located across different countries. For example, a smart phone assembled in China includes graphic design elements from the United States, computer code from France, silicon chips from Singapore, and precious metals from Bolivia. Throughout this process, all countries involved retain some value and benefit from the export of the final product. OECD, *The trade policy implications of global value chains,* [www.oecd.org/trade/topics/global-value-chains-and-trade], Accessed 29 March 2023.

64 Directive 2020/1828 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC, *OJ L* 409.

insolvency of the liable person, or to regulate recourse claims between liable parties and their statutes of limitation, there are some general observations that can be made with regard to the proposed changes.

First of all, DPLD extends the scope of strict liability for defective products by expanding the fundamental notions of product, producer, defect and damage. It has been pointed out that the same results with at least some of these notions could have been achieved by extensive interpretation of the existing provisions of PLD. And while the courts may develop a concept incrementally, the legislative intervention bears the risk of going too far.[65]

For example, DPLD expands the circle of potentially liable persons to producers of software and providers of related services, representatives of the non-EU producers, fulfilment service providers, product refurbishers and online platforms.[66] Consequently, the regime of product liability will suddenly surpass the scope of what has been so far considered 'production' or 'manufacturing'.[67]

It is important at this point to carefully analyze the potential consequences of such expansions, and to examine whether the rules on product liability should be used in a more balanced manner as an instrument for regulating the effects of new technologies,[68] especially if the risk premium born by producers will be dispersed to the consumers at large.

Second, DPLD recognizes that property is increasingly used for both private and professional purposes, and provides for the compensation of damage to such mixed-use property, but still excludes property used exclusively for professional purposes. The rationale for this exclusion is that the aim of the Directive is to protect consumer (Recital 19 DPLD). However, EU rules on product liability

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65 Wagner G., *Liability Rules for the Digital Age*, Journal of European Tort Law, Vol. 13, No. 3, 2022, p. 203. Wagner offers an example: The expansion of the concept of product to also include software should start from standard software, which is distributed 'like a product', while bespoke software could continue to be treated as a service for the time being (p. 203). Others have noticed that expanding the notion 'product' so as to include digital content requires a revision of PLD, especially because PLD is based on the assumption that putting a product on the market is a one-off act of the producer. Machnikowski P., *Product Liability for Information products?: The CJEU Judgment in VI/KRONE–Verlag Gesellschaft mbH & Co KG, 10 June 2021 [C-65/20]*, pp. 199–200.

66 They have already been called 'a parade of new defendants'. Wagner, *op. cit*. note 66, p. 212.

67 Dheu; De Bruyne; Ducuing, *op. cit*. note 45, p. 35.

68 The US litigation crisis showed how, together with other features of the US legal system (such as contingency fees, class actions, and punitive damages), the burden of product liability could become so high as to make some products uninsurable. Fairgrieve D. et al., *Product Liability Directive*, in: Machnikowski P. (ed.), European Product Liability. An Analysis of the State of the Art in the Era of New Technologies, p. 25.

also aspire to remove obstacles to the functioning of the internal market. Besides, some national regimes of product liability are not historically rooted in the policy of consumer protection. Therefore, it may be time to consider removing this particular restriction, and to protect all property under DPLD, irrespective of its use and purpose.[69]

Third, a sound proposal has been made to include the rules on liability for failure to comply with obligations under product safety and market surveillance law, in order to provide better consistency with product liability and to create more of a level playing field.[70] It seems that this idea should have been given more attention.

4. CONCLUSION

The ongoing product liability reform in the EU aims to accommodate the existing rules to the new digital technologies, circular economy business models and global value chains. Last year, following a long discussion among professionals, academics and competent authorities, the European Commission published the Proposal for a directive on liability for defective products. The Commission proposes, among other things, the broader concepts of product, producer, defect and damage; addresses the need to ease the burden of proof for consumers; cancels the EUR 500 minimum threshold for consumer claims in damages; introduces new liabilities for online marketplaces and product refurbishers, and strict liability for software and digital services that affect how the product works. This includes cybersecurity and connectivity risks. The reform also plans to compel producers to disclose information where the injured person demonstrates plausibility of their claim for compensation, and aims to ensure that injured persons receive due compensation for defective products procured directly from the non-EU countries.

Having all that in mind, DPLD surely represents a significant step forward in the protection of persons injured by product safety defects. However, there is still some room for improvements, as summed up in this paper, such as, to harmonize the recourse claims between liable parties and their statutes of limitation; to clarify certain terms (for instance, to expressly include waste and products based on human cells and tissue in products, to stipulate an explicit exception for free or open-source software, to clearly state whether an error in the information is a defect if that information does not affects the operation of the product); to stipulate the criteria which control whether a given expectation of safety is reasonable or justi-

[69] Wagner proposes the same. See: Wagner, *op. cit*. note 65, pp. 219–220.

[70] Art. 11 and 12, ELI Draft of a Revised Product Liability Directive.

fied; to clearly state that material losses are recoverable only if they are enumerated in DPLD, etc.

Finally, on a general level, and having in mind that the manufacturers will pass the increased costs of their liability risk on to the consumers at large, it seems that the aim to always have a business established in the EU that can be held liable for defective products, on the one hand, should be carefully balanced, on the other hand, against the rest of conceivable consequences of the proposed vast expansion of the circle of liable persons

REFERENCES

BOOKS AND ARTICLES

1. Bernstein A., *Formed by Thalidomide: Mass Torts as a False Cure for Toxic Exposure*, Columbia Law Review, Vol. 97, No. 7, 1997, pp. 2153–2176
2. Bertolini, A., Episcopo, F., *The Expert Group's Report on Liability for Artificial Intelligence and Other Emerging Digital Technologies: A critical assessment*, European Journal of Risk Regulation, Vol. 12, No. 3, 2021, pp. 644–659
3. Busch C., *When Product Liability Meets the Platform Economy: A European Perspective on Oberdorf v. Amazon*, Journal of European Consumer and Market Law, Vol. 8, No. 5, 2019, pp. 173–174
4. Büyüksagis E., *Et si Dr House évoquait le défaut potentiel de votre pacemaker...*, Aktuelle juristische Praxis, No. 1, 2016, pp. 14–22
5. Büyüksagis E., *La responsabilité du fait des produits 'défectueux sans défaut' : l'arrêt Boston Scientific du 5 mars 2015*, Droit de la consommation, No. 1, 2016, pp. 15–30
6. Cane, P., Atiyah P., *Atiyah's Accidents, Compensation and the Law*, C.U.P., Cambridge 2013
7. Fairgrieve D., Feldschreiber P., Howells G., Pilgerstorfer M., *Products in a Pandemic: Liability for Medical Products and the Fight against COVID-19*, European Journal of Risk Regulation, Vol. 11, No. 3, 2020, pp. 565–603
8. Fairgrieve D., Howells G., Møgelvang-Hansen P., Straetmans G., Verhoeven D., Machnikowski, P., Janssen A., Schulze R., *Product Liability Directive*, in: Machnikowski P. (ed.), European Product Liability. An Analysis of the State of the Art in the Era of New Technologies, Intersentia, Cambridge – Antwerp – Portland, 2017, pp. 17–108
9. Fairgrieve D., Howells G., Pilgerstorfer M., *The Product Liability Directive: Time to get Soft?*, Journal of European Tort Law, Vol. 4, No. 1, 2013, pp. 1–33
10. Fairgrieve D., Pilgerstorfer, M., *European Product Liability after Boston Scientific: An Assessment of the Court's Judgment on Defect, Damage and Causation*, European Business Law Review, Vol. 28, No. 6, 2017, pp. 879–910
11. Haertlein L., *Immunizing Against Bad Science: The Vaccine Court and the Autism Test Cases*, Law and Contemporary Problems, Vol. 75, No. 2, 2012, pp. 211–232
12. Howells G., *Product liability – a history of harmonisation*, in: Fairgrieve D. (ed.), Product Liability in Comparative Perspective, C.U.P., Cambridge, 2005, pp. 202–217

13. Howells, G. G., Ramsay, I. M., Wilhelmsson, T., *Handbook of Research on International Consumer Law*, Elgar, Cheltenham 2010
14. Karanikić Mirić, M., *Odgovornost proizvođača vakcine u praksi Evropskog suda pravde (Liability of Vaccine Manufacturers in ECJ Practice)*, Srpska politička misao, No. 4, 2017, pp. 137–159
15. Karanikić Mirić, M., *Odgovornost proizvođača za potencijalni defekt (Product Liability For Potential Defect)*, in: Ignjatović, Đ. (ed.), Kaznena reakcija u Srbiji, Vol. VIII, Pravni fakultet Univerziteta u Beogradu, Belgrade, 2018, pp. 194–213
16. Karanikić Mirić, M., *Reforma odgovornosti za proizvod s nedostatkom u pravu Evropske unije (Product Liability Reform in the EU)*, in: Lilić, S., Perspektive implementacije evropskih standarda u pravni sistem Srbije, Vol. XII, Pravni fakultet Univerziteta u Beogradu, Belgrade, 2022, pp. 96–116
17. Karanikić, M., *Development Risks*, Anali Pravnog fakulteta u Beogradu, Vol. 54, No. 3, 2006, pp. 117–148
18. Koch, B. A., *The development risk defence of the EC Product Liability Directive*, Pharmaceuticals Policy and Law, Vol. 20, No. 1–4, 2018, pp. 163–176
19. Koch, B. A., Koziol, H., *Comparative Conclusions*, in: Koch, B. A., Koziol, H. (eds.), Unification of Tort Law: Strict Liability, Kluwer, The Hague, 2002, pp. 395–435
20. Korzec, R., *Dashing Consumer Hopes: Strict Products Liability and the Demise of the Consumer Expectations Test*, Boston College International and Comparative Law Review, Vol. XX, No. 20, 1997, pp. 227–249
21. Machnikowski P., *Conclusions*, in: Machnikowski P. (ed.), European Product Liability. An Analysis of the State of the Art in the Era of New Technologies, Intersentia, Cambridge – Antwerp – Portland, 2017, pp. 669–705
22. Machnikowski P., *Product Liability for Information products?: The CJEU Judgment in VI/KRONE–Verlag Gesellschaft mbH & Co KG*, 10 June 2021 [C-65/20], European Review of Private Law, Vol. 30, No. 1, 2022, pp. 191–200
23. Markovits, Y., *La Directive C.E.E. du 25 juillet 1985 sur la responsabilité du fait des produits défectueux*, L.G.D.J., Paris, 1990
24. Micklitz, H. W., *Liability for defective products and services*, in: Micklitz, H. W.; Reich, N.; Rott, P.; Tonner, K. (eds.), European Consumer Law, Intersentia, Cambridge–Antwerp–Portland 2014, pp. 239–284
25. Mildred, M., *The development risk defence*, in: Fairgrieve, D. (ed.), Product Liability in Comparative Perspective, C.U.P., Cambridge 2005, pp. 167–184
26. Polinsky, A. M., Shavell S., *The Uneasy Case for Product Liability*, Harvard Law Review, Vol. 123, No. 6/2010, pp. 1437–1492
27. Reich N., *Produkthaftungsrecht: Haftung für potenziell fehlerhaftes Medizinprodukt*, Europäische Zeitschrift für Wirtschaftsrecht, No. 8, 2015, pp. 318–320
28. Reich, N., *Product Liability and Beyond: An Exercise in 'Gap-Filling'*, European Review of Private Law, Vol. 24, No. 3/4, 2016, pp. 619–644
29. Reimann, M., *Product Liability*, in: Bussani, M., Sebok A. J. (eds.), Comparative Tort Law, Edward Elgar Publishing, Cheltenham – Northampton MA, 2021, pp. 236–262

30. Santos Silva M., Fairgrieve D., Machnikowski P., Borghetti J.-S., Keirse A., Del Olmo P., Rajneri E., Schmon C., Ulfbeck, V., Vallone V., Zech H., *Relevance of Risk-benefit for Assessing Defectiveness of a Product: A Comparative Study of Thirteen European Legal Systems*, European Review of Private Law, Vol. 29, No. 1, 2021, pp. 91–132
31. Schmid, C., T*he Instrumentalist Conception of the Acquis Communautaire in Consumer Law*, in: Grundmann, S.; Schauer, M. (eds.), The Architecture of European Codes and Contract Law, Kluwer, Alphen aan den Rijn 2006, pp. 255–270
32. Stapleton, J., *Scientific and Legal Approaches to Causation*, in: Freckelton I., Mendelson D. (eds.), Causation in Law and Medicine, Aldershot, Ashgate, 2002, pp. 14–37
33. Stapleton, J., *Product Liability*, Butterworths, London 1994
34. Stratton K., Ford A., Rusch E., Wright Clayton E. (eds.), *Adverse Effects of Vaccines: Evidence and Causality: Consensus Study Report*, National Academies of Sciences, Engineering, and Medicine, Washington, 2012
35. Ulfbeck V., Verbruggen P., *Online Marketplaces and Product Liability: Back to the Where We Started?*, European Review of Private Law, Vol. 30, No. 6, 2022, pp. 975–998.
36. Van Leeuwen B., Verbruggen P., *Resuscitating EU Product Liability Law? Contemplating the effects of Boston scientific medizintechnik*, European Review of Private Law, Vol. 23, No. 5, 2015, pp. 899–915
37. Verdure C., *Arrêt Boston Scientific Medezintechnik : l'appréciation du 'défaut' dans le cadre de la Directive relative aux produits défectueux*, Journal de droit européen, Vol. 240, 2015, pp. 242–244
38. Verheyen T., Full Harmonization, Consumer Protection and Products Liability: A Fresh Reading of the Case Law of the ECJ, European Review of Private Law, Vol. 26, No. 1, 2018, pp. 119–140
39. Wagner G., *Liability Rules for the Digital Age*, Journal of European Tort Law, Vol. 13, No. 3, 2022, pp. 191–243
40. Wuyts, D., *The Product Liability Directive – More than two Decades of Defective Products in Europe*, Journal of European Tort Law, Vol. 5, No. 1, 2014, pp. 1–34

COURT OF JUSTICE OF THE EUROPEAN UNION

1. Opinion of Advocate General Bot in Joined Cases C-503/13 and C–504/13, *Boston Scientific* [2014], ECLI:EU:C:2014:2306
2. Case C–154/00 *Commission of the European Communities v Hellenic Republic* [2002], ECR I–03879, ECLI:EU:C:2002:254
3. Case C–183/00 *María Victoria González Sánchez v Medicina Asturiana SA* [2002], ECR I-03901, ECLI:EU:C:2002:255
4. Case C–52/00 *Commission of the European Communities v French Republic* [2002], ECR I–03827, ECLI:EU:C:2002:252
5. Case C–621/15 *N. W and Others v Sanofi Pasteur MSD SNC and Others* [2017], ECLI:EU:C:2017:484
6. Case C–65/20 *VI v KRONE Verlag Gesellschaft mbH & Co KG* [2021], ECLI:EU:C:2021:471

7. Joined Cases C–503/13 *Boston Scientific Medizintechnik v AOK Sachsen-Anhalt – Die Gesundheitskasse*, and C–504/13 *Boston Scientific Medizintechnik v. Betriebskrankenkasse RWE* [2015], ECLI:EU:C:2015:148.

EU LAW AND OFFICIAL DOCUMENTS

1. Directive 2020/1828 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC [2020], OJ L 409
2. Directive 85/374/EEC concerning liability for defective products [1985], OJ L 210, amended by Directive 1999/34/EC concerning liability for defective products [1999], OJ L 141 (*PLD*)
3. European Parliament resolution with recommendations to the Commission on a civil liability regime for artificial intelligence, 2020/2014(INL)
4. Evaluation of Council Directive on liability for defective products, SWD/2018/157 final
5. Executive Summary of the Impact Assessment Report, accompanying the Proposal for a Directive on liability for defective products, SWD/2022/317 final
6. Liability for emerging digital technologies, SWD/2018/137 final
7. Proposal for a Directive on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive), COM(2022) 496 (*DAILD*)
8. Proposal for a Directive on liability for defective products, COM(2022) 495 (*DPLD*)
9. Proposal for a Regulation on artificial intelligence (Artificial intelligence act), COM/2021/206 final
10. Report from the Commission on the Application of the Directive on liability for defective products, COM/2018/246 final
11. Report on the Application of the Council Directive 85/374/EEC concerning liability for defective products, COM/2018/246 final
12. Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, COM/2020/64 final
13. The European Green Deal, COM/2019/640 final
14. Treaty of Rome establishing the European Community [1957]

WEBSITE REFERENCES

1. Answers to parliamentary questions P–2383/00, E–2685/00, and E–1724/98, to the European Commission,
[http://europarl.europa.eu], Accessed 29 March 2023
2. Busch, C., *Rethinking Product Liability Rules for Online Marketplaces: A Comparative Perspective* (February 10, 2021),
[https://ssrn.com/abstract=3784466], Accessed 12 May 2023
3. Convention européenne sur la responsabilité du fait des produits en cas de lésions corporelles ou de décès, Strasbourg, 27. I 1977, Série des traités européens – n° 91,
[https://rm.coe.int/1680077328], Accessed 29 March 2023

4. Dheu O., De Bruyne J., Ducuing C, *The European Commission's Approach To Extra-Contractual Liability and AI – A First Analysis and Evaluation of the Two Proposals* (6 October 2022), [https://ssrn.com/abstract=4239792], Accessed 12 May 2023
5. European Commission, *Adapting liability rules to the digital age, circular economy and global value chains*, [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-adapting-liability-rules-to-the-digital-age-and-artificial-intelligence_en], Accessed 29 March 2023
6. European Law Institute, ELI Draft of a Revised Product Liability Directive, Draft Legislative Proposal, Vienna 2022, [http://europeanlawinstitute.eu/fileadmin/user_upload/p_eli/Publications/ELI_Draft_of_a_Revised_Product_Liability_Directive.pdf], Accessed 29 March 2023
7. European Law Institute, European Commission's Proposal for a Revised Product Liability Directive. Feedback of the European Law Institute, Vienna 2023, [https://www.europeanlawinstitute.eu/fileadmin/user_upload/p_eli/Publications/ELI_Feedback_on_the_EC_Proposal_for_a_Revised_Product_Liability_Directive.pdf], Accessed 29 March 2023 (*ELI Feedback*)
8. European Law Institute, Guiding Principles for Updating the Product Liability Directive for the Digital Age, Vienna 2021, [https://europeanlawinstitute.eu/fileadmin/user_upload/p_eli/Publications/ELI_Guiding_Principles_for_Updating_the_PLD_for_the_Digital_Age.pdf], Accessed 29 March 2023
9. Expert Group on Liability and New Technologies, *Liability for artificial intelligence and other emerging digital technologies*, Publications Office, 2019, [https://data.europa.eu/doi/10.2838/573689], Accessed 29 March 2023
10. OECD, *Global value chains and trade*, [www.oecd.org/trade/topics/global-value-chains-and-trade], Accessed 29 March 2023