

Presumed Product Defect – the New Dimensions of the European Product Liability Reform

ABSTRACT: *The question of whether the Product Liability Directive¹ (PLD) can fulfil its original purpose and function effectively today has been raised several times. In 1985, the community legislator introduced and popularised a set of rules that created the objective liability of the producer. Since the PLD was adopted, the technological environment has changed radically. Moreover, the small number of product liability cases before the courts (at both the EU and national levels) suggests that the instrument has not achieved, or has not fully achieved, the breakthrough for which it was designed. In response, the Commission of the European Union adopted an important package of proposals in September 2022. A reformed Draft of the Product Liability Directive (hereinafter: Draft, Draft Directive)², as well as a Draft directive to harmonise artificial intelligence with tort (non-contractual) liability, the so-called AI Liability Directive³, was adopted. After an introductory summary of the PLD's current concepts, this study analyses the product liability regime from a sustainability perspective, by contrasting the shortcomings of the current regulatory framework with the novelties of the draft package, particularly in terms of the burden of proof and producer exemption.*

KEYWORDS: *product liability, burden of proof, exemption, development risk*

- 1 The Council Directive of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC).
- 2 Proposal for a Directive of the European Parliament and of the Council on liability for defective products, 26.06.2023.
- 3 Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive) 28.06.2023.

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1. Introduction

For nearly four decades since its creation in 1985, the Product Liability Directive (PLD) has ensured that victims of damage caused by defective products (covered by the objective scope of the PLD) could bring direct, non-contractual tort claims against producers. At the time of its creation, the PLD was a pioneering instrument, since continental law did not have a similar instrument for the enforcement of claims in the area of private law.

Article I of the PLD states, with noble simplicity, that the producer shall be liable for damage caused by a defect in his product. A product is defective if it does not provide the safety normally expected, particularly in terms of its presentation, reasonably foreseeable use, and the time the product was put into circulation.⁴ The date of putting the product into circulation is particularly important. On the one hand, this marks the beginning of the limitation period for the producer's liability for the product; on the other hand, it is relevant that the product cannot be considered defective simply because, after putting it into circulation, an improved product was placed on the market.⁵ The term "damage" means the death, personal injury, or damage to the health of the injured party and the damage caused by a defective product in any item of property with a lower threshold of 500 ECU⁶, if the property is for personal use and private consumption and was also used by the injured person for his own private use or consumption.⁷ Examining the concept of a product in the PLD, it could be concluded that the subject of a product liability's "legal relationship" could be movable property only. Real estate does not fall within the scope of product liability; however, movable property, which later becomes a component part of another thing (such as real estate), retains the character of a product, so that product liability could be applied to components⁸

In the event of a defective product causing damage, a claim for damages could be made against the manufacturer of the product. The producer of a product is the person or legal person who produces the final product, raw material, sub-product, as well as the person or legal person who identifies himself as the producer of the product with his name and trademark placed on the product.⁹ It is a multi-step and multi-player process before the producer's product ultimately reaches the consumer. To facilitate the enforcement of injured parties' claims, the EU legislator

4 Article 6 of the PLD.

5 Article 6(2) of the PLD.

6 After the replacement of the European Currency Unit (ECU) by the Euro, it has been 500 EUR since 1 January 1999.

7 Article 9 of the PLD.

8 Shapo (1993), p. 281 and Article 2 of the PLD.

9 Article 3 of the PLD.

assumes as a guarantee rule that, in case of difficulty or even unidentifiability of the manufacturer, the distributor's so-called subsidiary liability comes into view. Under Article 3(3) of the Directive, all suppliers and importers shall be treated as producers until they inform the injured party through a request about the producer within a reasonable time.¹⁰ The liability of the importer or distributor is only potential, as he can “release” from the legal relationship of product liability by naming the manufacturer.

The concepts contained in the PLD, which were unambiguous in 1985, have now become somewhat questionable, as the technological environment to which the PLD's legal framework was adapted has changed considerably and is still undergoing rapid development-oriented changes. Today's products could be modified, repaired, and refurbished to an increasing extent, essentially without the producer having any influence on it. Several modern products could hardly be included in the 1985 product definition, the existence of which, if not completely stretches the current product definition of the Directive, certainly broadens it considerably.¹¹ In addition to the ability of products to innovate, the increasing autonomy of products due to artificial intelligence is a challenge. In a significantly changing technological environment, product liability jurisprudence (including trends in national and domestic product liability court cases) is pointing towards the need for a possible product liability reform. The lack of product liability court cases (mainly in domestic courts) indicates that the instrument has not yet achieved the breakthrough that the EU legislator intended, although the Commission has assessed it as an effective instrument for the enforcement of claims in the course of periodic reviews.¹² The burden of proof on the injured party, the shifting of the burden of development risk to the injured party, and, in this context, the very limited professional and financial means available for proof on the side of the injured party and the almost unlimited means available on the side of the producer, may create a disproportionate situation. In such a situation, the injured party, overestimating all this, may decide to opt for a different basis for asserting his claim instead of product liability. Consequently, the question often arises whether the European product liability regime should be amended.¹³

10 In this respect, Act X of 1993 on Product Liability gave a deadline of 30 days for the distributor. (4 § (2) as in the case of the regulations currently in force. (Act V of the 2013 Civil Code of Hungary 6: 553. § (4)).

11 For example, the dilemma of whether to categorise software as a service or as a product, in which the Commission ultimately opted for the latter, is worth mentioning. See Kóhidi and Somkutas, 2017, and Fuglinszky, 2015.

12 See: European Commission: Liability for defective products, 7.

13 See for example, Navas, 2020, p. 77–84, Risso, 2019, p. 201–233 and Williams and Fox, 2019.

In response to these changes, the Commission launched a review of the PLD in 2018.¹⁴ The review will include a multi-stage assessment of whether the Directive remains effective in achieving its original objectives, whether it is efficient, coherent with EU law, and functionally covers the scope of technological changes.¹⁵ To examine the impact of modern technologies on the liability regime, the Commission has also set up a specific liability group to explore in detail the effects of these changes.¹⁶ Similar to the review taking place within the Commission, the European Law Institute has identified the main areas for the revision of the Directive as well.¹⁷ The document identifies areas for possible review in nine guiding principles, including the need to redefine products in light of digital technology and the possibilities for reassessing product failure. This review reached an important milestone on 28 September 2022, when the Commission adopted two major draft documents on this subject, already set out in the abstract. The AI Liability Directive sets out the harmonisation of AI and tort liability in the event of non-compliance or breach of the conditions and requirements set out in the Draft AI Regulation adopted on 21 April 2021 (hereinafter, the AI Liability Directive)¹⁸. While the AI Regulation provides a framework for the use of AI and related services by defining the concept of an AI system¹⁹ and setting out the obligations for providers of high-risk AI systems²⁰, the AI Liability Directive aligns the liability issues arising in this context with tort liability rules and sets out the specific conditions for enforcement. Due to space constraints, the AI Regulation and the AI Liability Directive is not discussed in detail in this paper. Instead, I focus on the provisions of the Draft Product Liability Directive. In this context, the paper focuses on the development risk, which is already a crucial point of product liability, as a case of the exemption of the producer and the burden of proof on the injured party. The Draft Directive introduces decisive changes to the current regulatory principles, including a presumption of the existence of a product defect under certain conditions.

14 Evaluation of 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, 05.07.2023.

15 Report from the Commission to the Council, the European Parliament and the European Economic and Social Committee on the application of Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. 05.07.2023.

16 See also on p. 10.

17 Twigg and Flesner, 2022.

18 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, 28.06.2023.

19 Article 3(1) of the AI Regulation.

20 Articles 6-28 of the AI Regulation.

2. Areas for Review

In this chapter, I address the issues of producer exemption and proof of harm, which are the most critical areas in product liability. In these areas, the imbalance of power between producers and potential victims, in most cases, the consumers, could be most pronounced, and would be significantly affected by a possible product liability reform. In the relationship between producers and victims, it is clear that the party/parties harmed by product damage is/are at a disadvantage compared to producers with incomparably more economic resources. Noteworthy from the point of view of the balance of power between the injured party and the producer is the rule that the burden of proving the defect and damage and the causal link between them lies with the injured party.²¹ In terms of the burden of proof on the injured party, the Civil Code Act V of 2013 (hereinafter, Civil Code), Section 6:554 § (3), which states that ‘the burden of proof of the defect of the product lies with the injured party’, also has a similar provision. The burden of proving harm in product defect cases, which is problematic in some cases²², could make it difficult to enforce claims in the technological complexity of modern products.²³ However, the European legislator is attempting to compensate for the already vulnerable situation of the victim by introducing some rules in the field of product liability regulation that are favourable to the victim. One example is the provision on the exclusion and limitation of liability, according to which the producer may neither exclude nor limit his liability towards the injured party.²⁴ A similar rule, which is favourable to the injured party, is that the legislator sets a limitation period of three years²⁵ – although shorter than the general five years – for the injured party to bring a claim, while at the same time the legislator extends the liability of the producer and sets it at 10 years from the date of placing the product on the market.²⁶

The strict and objective institution of product liability, in terms of the exclusion of limitation of liability and somewhat relaxing the strictness of the time limit for the producer's liability, which is set at 10 years from the date of placing the product on the market, allows the producer to be exempted in many cases. For example, the producer is exempted if he proves that he did not place the product on the market, that he did not manufacture or market the product for non-commercial purposes, or that the defect that caused the damage was not present at the time of placing the product on the market or arose subsequently, and that the defect results from compliance with mandatory rules adopted by the public authorities, in the case of

21 Fazekas, 2007, p. 118 and Article 4 of the PLD.

22 Kóhidi, 2010, p. 305–316.

23 Amato, 2019, p. 77–95.

24 Article 12 of the PLD.

25 Article 10 of the PLD, Civil Code 6:558 § (1).

26 Fazekas, 2007, p. 118, Article 11 of the PLD, Civil Code 6:558 § (3).

the producer of a component part, where the defect results from the design of the product in which the component part is incorporated or the defect is attributable to instructions given by the producer of the product.²⁷ Similarly, Section 7(1) of Act X of 1993 on Product Liability defines the scope of the producer's exemption and defines in Section 6:555 § (1) a)-e) The Civil Code. This list is a taxonomy, since, in the spirit of maximum harmonisation, the omission of any ground for exemption, or the extension of such grounds, thereby making them more burdensome for the producer and more favourable to the injured party, would be contrary to Community law.²⁸

Article 13 of the PLD provides that 'this Directive shall not affect any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive is notified'. The PLD is generally considered a consumer protection directive and therefore seemed to fit well into the range of consumer protection directives in Community law with minimum harmonisation requirements.²⁹ Consumer directives in Community law mainly set minimum standards³⁰, and the so-called minimum clause gives the national legislator the power to adopt rules that are more favourable to consumers than the requirements of the directive.³¹ It is this "consumer protection character," as well as the unaffectedness of the injured party's contractual, non-contractual, or special liability claims existing at the time of notification of the Directive, as reflected in Article 13, which may lead to the erroneous conclusion that the PLD is also to be understood as a minimum harmonisation requirement.³² The problem of harmonisation of national law in light of Article 13 of the PLD was resolved by the Court of Justice of the European Union (hereinafter, ECJ) in three judgments published on the same day in 2002, which also highlighted the need for maximum harmonisation obligations in terms of product liability. In *Commission v. France*, the ECJ ruled that a national measure allowing claims for damage to property below the threshold of €500 on the basis of product liability was contrary to Community law. The legislation also extended the strict product liability rules to the distributor and further tightened the scope of the producer's exemption, with an additional exclusion of liability only if the producer has taken all necessary measures to prevent or avoid the damage caused by the defective product.³³ In *Commission v. Greece*, the ECJ also found that the measure, which did not contain the €500 threshold, was contrary to

27 Article 7(a) to (f) of the PLD.

28 Machnikowski, 2016, p. 28.

29 Menyhárd, 2010, p. 19–24.

30 Menyhárd, 2000, p. 24–25.

31 Menyhárd, 2010, p. 19–24.

32 Fuglinszky, 2015, p. 589.

33 Judgment of 25 April 2002 in Case 52/00 *Commission v. France*.

Community law.³⁴ In the *González Sánchez* case, the ECJ examined, in the context of Article 13 of the PLD, whether that Article excludes or limits the rights of the injured party under pre-existing contractual or non-contractual liability rules. In the underlying case, the plaintiff received a blood transfusion at the defendant's medical institution and was then infected with the hepatitis C virus. The plaintiff based his claim on an objective form of liability, independent of fault, which was already in force in Spanish law prior to the harmonisation of the PLD. The defendant contested the applicability of the law that favoured the injured party.³⁵ In its judgment, the ECJ explained that the rule in Article 13 does not affect the pre-existing rights of the injured party under other legal rules on contractual or non-contractual liability, but that this exclusion only applies to claims other than those based on warranty or fault and to liability rules of a sectoral nature.³⁶ The ECJ has therefore taken the firm view that, in cases falling within the scope of the PLD, the Article does not allow for the application of forms of liability that are more favourable to the injured party than those provided for in the PLD. In the light of the case-law of the ECJ, it may be concluded that the PLD was adopted in the spirit of maximum harmonisation, under which any derogation from its rules, whether positive or negative, would be contrary to Community law.

In the case of Hungary, the Civil Code. 6:555 § (3) excludes the possibility of exemption from the development risk³⁷ in the event of damage caused by the use of the medicinal product in accordance with the prescription. However, this provision is not in breach of Community law, since the PLD expressly states that, 'where a Member State has already introduced specific liability rules to protect consumers in the field of medicinal products, claims may still be brought on the basis of those rules'.³⁸ In Hungary, such a special liability rule is provided for in Act XCV of 2005 on Medicinal Products for Human Use and other Acts amending the Acts regulating the pharmaceutical market and its Article 21a), b) which provides for the application of the provisions of the Civil Code on damages and product liability, with the exceptions provided for in this Act, to liability for death, disability or damage to health in the event of death or disability caused by the use of medicinal products, and to liability for material damage resulting from non-material damage.

From the cases of exemption, point (e), the case of development risk as a ground for exemption should be highlighted, as it could be said without exaggeration that it is one of the most controversial elements of product liability regulation. Under this ground for exemption, the producer is exempted from product liability claims even

34 Judgment of 25 April 2002 in Case 154/00 *Commission v Greece*.

35 Judgment of 25 April 2002 in Case 183/00 *González Sánchez*.

36 *Ibid*, Menyhárd, 2010, p. 23 and Fuglinszky, 2015, p. 589.

37 Fazekas, Menyhárt, Kóhidi, 2017, p. 280, and Osztoivits, 2014, p. 283.

38 Preamble paragraph 13 of the PLD.

if he proves that the defect was not detectable by the state of scientific and technical knowledge at the time he placed the product on the market. The mentioned exemption, known in the relevant literature³⁹ as development risk or the so-called state-of-the-art clause. It is most commonly referred to in the literature as development risk or state-of-the-art defence/state-of-the-art clause, or also as development risk and state-of-the-art exemption. In addition to the state-of-the-art exemption, the term “development risk” is used several times in the present study to name the exemption, on the grounds that development risk is more widely used and generally accepted in the scientific literature to specify the exemption. Given that the relevant documents (drafts, opinions, position papers) produced in the course of the PLD’s drafting,⁴⁰ as well as the Commission reports⁴¹ resulting from the periodic reviews of the PLD, also use the term development risk as a designation of the exemption. This is why this study also uses the designation of the exemption under the name of development risk.

The reasoning behind development risk is that if the legislator were to place the risk of development on the producer in a one-to-one relationship (not regulated as an exemption), producers would become disinterested in innovation and product development. By keeping the development risk on the producer’s side, it would not be economically profitable to develop newer products, since each product could involve the possibility of potential (damage) claims. Placing the development risk on the producer’s side, or on the side of the consumer, is no longer a purely legal and legislative issue, but also an economic issue of economic efficiency.

39 Inter alia: Fuglinkszky, 2015, p. 655, Wellmann (ed.), 2018, p. 658, Fairgrieve, 2005, p. 320, Machinowsky (ed.), 2016, p. 75, Koziol, Green and Lunney, 2017, p. 542, Fazekas, 2007, p. 119, Fazekas, 2022, p. 142, Surányi, 1994, p. 22, Fairgrieve and Goldberg, 2020, p. 484.

40 Opinion of the Economic and Social Committee, in: Official Journal of the European Communities, C 114, Volume 22, 1979, Document C:1979:114:TOC, COM1976, 372, 17, Opinion of the European Parliament, in: Official Journal of the European Communities, C 127, Volume 22, 1979, Document C:1979:127:TOC, Official Journal of the European Communities, C 127, 21 May 1979, 62.

41 First Report on the Application on the Council Directive on the Approximation of Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, 1995, Brussels, COM (95) 617; Report from the Commission on the Application of Directive 85/374 on Liability for Defective Products, 2001, Brussels, COM (2000) 893; Third report on the application of Council Directive on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC of 25 July 1985, amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999); Fourth report on the application of 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 amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999., Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Application of the Council Directive on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products (85/374/EEC), COM/2018/246.

This exemption could be put in parallel with the PLD's and the other most controversial rule of the European product liability regime, namely the rule imposing the burden of proof on the injured party. Under Article 4 of the PLD, the burden of proving the damage, the defect and the causal link between the defect and the damage lies on the injured party. From the point of view of the injured party, this unfavourable rule of evidence and the reference to state-of-the-art as an exemption – which inevitably leaves much room for manoeuvre – *ad absurdum* may render the whole product liability regime irrelevant. This justifies the essentiality of the review, and foresees the reconsideration of the producer's exemption about development risk and to work out a more proportionate allocation of the burden of proof.

3. The Presumed Product Defect

The Draft Directive puts the provisions on evidence on completely new grounds and thus seeks to alleviate some of the burden of proof on victims in the context of development risk. In this respect, an article with a completely new meaning would be added to the PLD, which is titled "Disclosure of Evidence" in the Draft. In this Article, the EU legislator would regulate the scenario where an injured party (plaintiff) claiming damages for harm caused by a defective product has already presented sufficient facts and evidence to establish the credibility of the claim for damages, he or she may be entitled to have the defendant ordered by the court to disclose the available evidence upon request.⁴² The question may arise as to what effect such a change in the burden of proof in a case of necessity and the imposition of the obligation to provide and disclose evidence on defendants would have on the practice of national courts. Undoubtedly, compliance with this obligation on defendants is not negligible from a data protection perspective, since the obligation on defendants to disclose evidence may also concern data covered by the obligation of business secrets. In paragraph 2 of the same Article, the Draft relaxes what at first sight appears to be a strict rule for the defendant by limiting the disclosure of evidence⁴³ to what is necessary and proportionate to support the plaintiff's claim and by making the interest of the third party concerned in the protection of confidential information and business secrets subject to examination by the national court in this context.⁴⁴ To safeguard business secrets and confidential information, the Draft further provides that when using data and information in this field in court proceedings, the court shall, upon reasoned request from the parties, order

⁴² Article 8 (1) of the Draft.

⁴³ Article 8 (2) of the Draft.

⁴⁴ Article 8 (3) of the Draft.

the parties to take special measures to preserve confidentiality, i.e. to use closed processing.⁴⁵

Article 9(1) of the Draft takes over, almost unchanged, the provision of the current Article 4 of the PLD, according to which the burden of proving the damage, the defect, and the causal link between the defect and the damage lies with the injured party. In this respect, no radical change could yet be mentioned in relation to the current rules. The novelties appear as from Article 9(2) of the Draft. Unlike the current rules, Article 9(2) of the Draft sets out the conditions under which the product is presumed to be defective or faulty. The presumption of defectiveness is established by the Draft in the event of a defendant's failure to provide evidence, as set out in Article 8, or in the event of successful proof by the plaintiff. Thus, the product is presumed defective when the defendant has failed to comply with the obligation to provide relevant evidence, the plaintiff proves that the product does not comply with mandatory safety requirements under EU or national law designed to protect against the risk of damage, or the plaintiff proves that the damage was caused by an apparent failure of the product in the normal course of its use or under normal circumstances.⁴⁶

The Draft goes beyond the mere presumption of product defect and extends it to the causal link between product defect and damage, where it is established that the product is defective and the damage is of a nature that is typically compatible with the defect in question (for example, in the case of digital products, digital manufacturing files).⁴⁷ Contrary to the main rule in Article 4 of the PLD currently in force and Article 9(1) of the Draft, by proving the defect of the product and the likelihood of the typicality of the resulting damage, the injured party no longer has to prove causation, since it must be presumed.

4. Conclusions

Based on the rules of the Draft discussed above, we can conclude that the EU legislator from four decades of practice has recognised the most problematic areas of product liability law, that is, the disproportionality between the burden of proof on the injured party and the burden of proof on the producer's side of proving that the defect cannot be detected in the state of scientific and technical knowledge. This unequal situation is compounded by the fact that the professional and financial means available for proof are very limited on the injured party's side and almost unlimited on the producer's side. In response to these circumstances, the EU legislator could alleviate the burden

⁴⁵ Article 8 (4) of the Draft.

⁴⁶ Article 9 (2) (a) to (c) points of the Draft.

⁴⁷ Article 9 (3) of the Draft.

of proof on the injured party by establishing a legal presumption of the existence of a product defect on the one hand, and of a causal link between the product defect and the damage suffered from it on the other. To alleviate the excessive difficulties of proof on the plaintiff's side, the Draft would allow the court to have the discretion to presume the causal link between the defect and the damage, or both, if the technical or scientific complexity of proving the defectiveness of the product creates excessive difficulties for the plaintiff. This would require that the plaintiff prove/make probable that the product contributed to the damage and that it is likely that the product was defective or that the damage was likely caused by the defectiveness of the product.⁴⁸ As a rebuttable presumption in the nature of a *presumptio iuris*, the Draft would allow the defendant to challenge the existence of excessive difficulties of proof on the side of the plaintiff and to rebut any of the presumptions set out in paragraphs (2), (3), and (4) of Article 9.⁴⁹ By applying these rules, the substantive law would regulate and sanction the defendant with the plaintiff's "claim of necessity"⁵⁰ if the defendant breaches its obligation to provide evidence in connection with the successful evidentiary proceedings and fails to rebut the presumption of product defect and causation in this context.

48 Article 9 (4) (a) to (b) points of the Draft.

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

(a) the defendant has failed to comply with an obligation to disclose relevant evidence at its disposal pursuant to Article 8(1); (b) the claimant establishes that the product does not comply with mandatory safety requirements laid down in Union law or national law that are intended to protect against the risk of the damage that has occurred; or (c) the claimant establishes that the damage was caused by an obvious malfunction of the product during normal use or under ordinary circumstances." (Article 9(2) paragraph of the Draft), "The causal link between the defectiveness of the product and the damage shall be presumed, where it has been established that the product is defective and the damage caused is of a kind typically consistent with the defect in question." (Article 9(2) paragraph of the Draft), "Where a national court judges that the claimant faces excessive difficulties, due to technical or scientific complexity, to prove the defectiveness of the product or the causal link between its defectiveness and the damage, or both, the defectiveness of the product or causal link between its defectiveness and the damage, or both, shall be presumed where the claimant has demonstrated, on the basis of sufficiently relevant evidence, that: (a) the product contributed to the damage; and (b) it is likely that the product was defective or that its defectiveness is a likely cause of the damage, or both.' (Article 9(2) paragraph of the Draft).

50 Section 184 § (1) of Act CXXX of 2016 on the Code of Civil Procedure provides for a party in a state of necessity, in which case the court may accept the facts of the case as true if it has no doubts as to their truth. The presumptions appearing in the Draft may not result in a one-to-one situation of necessity to prove a claim (with regard to the entire right, the claim for damages), since the situation of necessity to prove under the Code of Civil Procedure refers to the information necessary for the assertion of the so-called secondary facts (see Miczán, 2018, p. 26), the plaintiff must have the information concerning the primary, disputed right; however, this may be reduced to the proof of product damage in certain cases, in accordance with the new rules of evidence appearing in the Draft.

The Draft Directive, which was developed during the revision of the PLD and adopted in September 2022, is a striking testimony that the EU legislator has recognised the gaps and problematic areas in the European regulation of product liability. By rethinking the burden of proof for the injured party and creating a presumption of a causal link between the product defect and the damage, the legislator would reverse the logic of the current rules on proof, and would relieve the plaintiff who provides evidence of the full burden of proof of the development risk (currently imposed on him). However, the extent to which the new rules set out in the draft would facilitate the efficient handling of product liability claims. Would evidence or even counter-evidence in the course of the evidentiary procedure to prove presumptions based on probability and their rebuttal not further complicate the whole legal procedure and create additional obstacles to the effective and smooth enforcement of claims by product liability victims against producers?

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