

Relevance of Risk-benefit for Assessing Defectiveness of a Product: A Comparative Study of Thirteen European Legal Systems

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Abstract: Under Council Directive 85/374/EEC, liability of a producer crucially depends upon the proof of a product’s defectiveness. This central notion of the Directive has however long been the source of debate regarding the extent to which it is grounded in a solely safety-based approach, or whether a risk-benefit approach may be admitted. The defectiveness concept is now subject to a growing body of case law. This article examines how the courts in a selection of Member States (MS) approach the notion of defect and take account of risk-benefit considerations in determining whether a product is defective. It aims, first, at lowering the level of complexity which was added to the definition of *defect* in the Directive by the discretion given to national courts on the applicable standard of liability. Second, it means to show the real level and scope of harmonization of the product liability law in the EU by revealing differences that still exist in the interpretation of seemingly harmonized laws. Third, it aims to contribute to the clarification of whether the risk-benefit test is compliant with the spirit of the Directive, and thereby informing policy makers at a time where the guidelines of interpretation of the Directive are being prepared.

Résumé: En vertu de la directive 85/374/CEE du Conseil, la responsabilité d’un producteur dépend essentiellement de la preuve de la défectuosité de son produit. Cette notion centrale de la directive donne lieu depuis longtemps à des discussions sur le point de savoir si elle repose sur une approche uniquement fondée sur la sécurité ou si une approche en termes de bilan bénéfiques/risques peut être admise. Le concept de défectuosité fait désormais l’objet d’une jurisprudence importante et croissante. Cet article examine la manière dont les juridictions d’une sélection d’États membres abordent la notion de défaut et prennent en compte les considérations tirées d’une analyse bilan bénéfiques/risques pour déterminer si un produit est défectueux. Il vise, en premier lieu, à réduire la complexité qui a été ajoutée à la définition du défaut dans la directive

* All co-authors except Vera Vallone are members of the Product Liability Directive formation of the EC’s Expert Group on Liability and New Technologies. The views expressed in this article should not be understood as those of the Expert Group / or of the European Commission, but solely those of the co-authors personally. The authors are grateful to Max Tipp McKnight and Henriikka Malmi for the editorial assistance. A final version of this contribution was submitted on 31 August 2020. Emails: m.santossilva@maastrichtuniversity.nl, d.fairgrieve@BIICL.ORG, piotr.machnikowski@uwr.edu.pl, Jean-Sebastien.Borghetti@u-paris2.fr, a.l.m.keirse@uu.nl, olmo@der-pr.uc3m.es, erajneri@hotmail.it, christoph@eff.org, vibe.ulfbeck@jur.ku.dk, vera.vallone@lenzstaehelin.com, sekretariat.zech@rewi.hu-berlin.de.

du fait du pouvoir discrétionnaire donné aux juridictions nationales dans la mise en œuvre de la responsabilité. Deuxièmement, l'article cherche à déterminer le niveau et la portée réels de l'harmonization du droit de la responsabilité du fait des produits dans l'UE en mettant en lumière les différences qui subsistent encore dans l'interprétation de règles apparemment harmonisées. Troisièmement, il vise à contribuer au débat sur le point de savoir si le bilan bénéfiques/risques est conforme à l'esprit de la directive, afin d'éclairer les décideurs politiques au moment où des lignes directrices d'interprétation de la directive sont en cours d'élaboration.

Zusammenfassung: Nach der Richtlinie 85/374/EWG des Rates hängt die Haftung eines Herstellers entscheidend vom Nachweis der Fehlerhaftigkeit eines Produkts ab. Dieser zentrale Begriff der Richtlinie war jedoch lange Zeit die Ursache der Debatte darüber, inwiefern die Fehlerhaftigkeit *des Produkts* auf einem ausschließlich sicherheitsrelevanten Ansatz beruht oder ob ein Risiko-Nutzen-Ansatz zugelassen werden kann. Das Konzept der Fehlerhaftigkeit unterliegt nun einer wachsenden Rechtsprechung. In diesem Artikel wird untersucht, wie die Gerichte in einer Auswahl von Mitgliedstaaten (MS) mit dem Begriff des Fehlers umgehen und ob sie bei der Feststellung, ob ein Produkt fehlerhaft ist, Risiko-Nutzen-Überlegungen berücksichtigen. Ziel ist es zunächst, die Komplexität, die der Definition von Produktfehlern in der Richtlinie durch das Ermessen der nationalen Gerichte in Bezug auf den geltenden Haftungsstandard hinzugefügt wurde, zu *verringern*. Zweitens bedeutet dies, den tatsächlichen Grad und Umfang der Harmonisierung des Produkthaftungsrechts in der EU aufzuzeigen, indem Unterschiede aufgedeckt werden, die bei der Auslegung scheinbar harmonisierter Gesetze noch bestehen. Drittens soll dazu beigetragen werden, zu klären, ob der Nutzen-Risiko-Test dem Zweck (oder «dem Geiste») der Richtlinie entspricht, und damit die politischen Entscheidungsträger zu einem Zeitpunkt zu informieren, an dem die Leitlinien für die Auslegung der Richtlinie erstellt werden.

1. Introduction

1. The Product Liability Directive¹ was designed to remove divergences in MS' laws concerning producer's liability for damage caused by defectiveness of a product in order to facilitate an efficient operation of the internal market.² At the same time, the Directive sought to protect consumers against product-related risks.³

Internal market considerations were a major argument behind a series of Court of Justice decisions which confirmed that the Directive is a maximum harmonization measure.⁴ Thus, within the scope of the Directive and with the

1 Council Directive 85/374/EEC on the approximation of the laws, regulations and administration provisions of the MS concerning liability for defective products.

2 Directive 85/374/EEC, Recital 1.

3 Directive 85/374/EEC, Recital 2.

4 Case C-52/00, *Commission v. France* [2002] ECR I-3827, paras 17-20; Case C-154/00, *Commission v. Greece* [2002] ECR I-3879 [13-16]; Case C-183/00, *González Sanchez v. Medicina Asturiana SA* [2002] ECR I-3901 [26-29]. See generally Thomas VERHEYEN, 'Full

exception of several specific options, the MS were not allowed to adopt either more stringent or more lenient standards of producers' liability.

2. One of the crucial elements of the liability regime devised in the Directive is the notion of defect, as the liability in question, although commonly described as a strict liability, is based on the existence of a defect in the product that has caused harm, and of a causal link between the defect and the harm. Therefore, the precise meaning of defect determines the scope of application of the liability regime and thus the scale of the producers' burden and the scope of consumer protection offered by the Directive.

Article 6 of the Directive states that a product is defective when it does not provide the safety which a person is entitled to expect, taking all the circumstances into account. The first paragraph mentions three specific circumstances as examples: the presentation of the product, its reasonably expected use, and the time when the product was put into circulation. The second paragraph of Article 6 also points out that a product may not be considered defective for the sole reason that a better product is subsequently put into circulation. It follows from this provision that the authors of the Directive decided to use the consumer expectation test as a criterion for determining the defectiveness of the product, and rejected possible alternatives based on comparing either the additional safety of the product and the cost at which it could be achieved or the risk associated with the product and the benefit that society gets from its availability on the market.⁵ What is also clear from this provision is that the Directive does not differentiate between various possible categories or types of defects.

3. The European lawmaker's decision on employing the consumer expectation test as the sole criterion for assessing defects might have been influenced by the shape of the US product liability law at the time, as the US court practice and the Second Restatement of Torts (1965) were its sources of inspiration. Section 402A of the Second Restatement uses the phrase 'defective condition unreasonably dangerous to the user or consumer or to his property' and the comment to it explains that a product is 'unreasonably dangerous' when it is 'dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community of its characteristics'. This phrase is read as introducing the consumer expectation test. Under this test, a product is deemed defective if it contains a danger that an ordinary consumer would not expect to find in such a product. During the

Harmonisation, Consumer Protection and Products Liability: A Fresh Reading of the Case Law of the ECJ', *ERPL (European Review of Private Law)* 2018(1), p 119.

5 Franz WERRO & VERNON Valentine PALMER (eds), *The Boundaries of Strict Liability in European Tort Law* (Durham: Caroline Academic Press 2004), p 438 and Thomas VERHEYEN, *ERPL* 2018, p 122.

development of American product liability law, however, and contrary to what happened in the Directive, a distinction was made between manufacturing, design and informational defects. Regarding design defects, the consumer expectations standard raised considerable criticism. On the one hand, it was considered too open and allowed juries to stretch the notion of defect beyond the limits of reasonableness, while, on the other hand, it led to unwanted results when obvious dangers connected to the product were concerned – since they were obvious, consumers could not have any safety expectations with regard to them. Therefore, the Third Restatement of Torts (1998) introduced a different standard for assessing design defects which was adopted by several state courts and is based on the observation that most goods can be made safer by adding safety features or by reducing risk, thus raising the manufacturing cost or lowering product utility. The new standard called *risk-utility test* uses a cost-benefit methodology to compare the additional safety brought by an alternative safer design with the cost of such a design. The risk-utility test is much closer to a negligence standard than to strict liability and does not apply to pharmaceuticals nor to medical devices. In its place either the general comparison of the drug's overall benefits with its overall risks is employed or the issue of defectiveness is solved solely on the basis of adequacy of warnings.⁶ However, the comparison with American law should not go too far, because the consumer expectation test in Article 6 of the Directive is not a copy of the section 402A of the Second Restatement. As it has been rightly mentioned in the literature, the test in Article 6 is in fact not a subjective test, but an objective and normative criterion.⁷ The courts thus retain a certain amount of discretion in establishing the level of safety that the product must keep in order not to be found defective. As this study will show, the MS courts, to various extents, make use of this discretion to the point where the claim that the Directive has fully harmonized the notion of defect may become dubious. One of the possible interpretations of Article 6, sometimes advocated for in the legal writing and adopted by some national courts, is to employ various kinds of risk-utility or risk-benefit reasoning to decide on the legitimacy of safety expectations.

4. This paper examines how courts in a selection of MS approach the notion of defect and take account of risk-benefit considerations in determining whether a product is defective. The analysis, apart from offering a better understanding of the definition of defect in the Directive, allows to verify the claim that the product liability law in the EU has been fully harmonized and to recognize the scale of differences that still exist in the interpretation of the law. It also contributes to the

6 For a more detailed description of the US product liability law and its evolution D. GREEN & Jonathan CARDI, 'United States of America', in P. Machnikowski (ed.), *European Product Liability: An Analysis of the State of the Art in the Era of New Technologies* (2016), p (50 et sqq.), at 575 et sqq.

7 WUYTS, 'The Product Liability Directive - More Than Two Decades of Defective Products in Europe', 5. *JETL (Journal of European Tort Law)* 2014(1), p 8.

debate about the compliance of the risk-benefit test with the spirit of the Directive, which may be useful to policy makers at a time when the interpretation and future development of the European product liability law is being discussed.

2. Austria

5. The Austrian Product Liability Act (*Produkthaftungsgesetz* – PHG⁸) was adopted in 1988. Inspired by the Product Liability Directive (PLD) and later partly amended because of it – Austria joined the EU as part of the 1995 enlargement – the PHG caused a shift from fault-based criteria for liability to uniform objective criteria and safety and compensation-oriented values.

6. A product is legally defined by §4 PHG as any movable *tangible*⁹ property even if it is part of another movable property or combined with an immovable property, including energy. It is debatable whether or to what extent intellectual products or digital content products fall under the Product Liability Act.¹⁰

7. The PHG closely follows the German language version of the PLD for the definition of a defect: §5(1) PHG states that a product is defective when it does not provide the safety which, taking all circumstances into account, may be reasonably expected, in particular with respect to (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; and (c) the time when the product was put into circulation. Paragraph 2 reiterates Article 6(2) PLD by clarifying that a product should not be considered defective for the sole reason that a better product is subsequently put into circulation.

8. The yardstick for the expectation-test is the normative-typological figure of the *ideal type of the average product user*.¹¹ An objective assessment that considers both the type of product and the target group of persons who might be exposed to the relevant product risks is therefore required. The opinion of a reasonable person as well as justified expectations based on certain social experiences will be considered for this analysis. Where there are various target groups of persons, the least informed and therefore most vulnerable group will be relevant for assessing the way

8 Bundesgesetz vom 21. Jänner 1988 über die Haftung für ein fehlerhaftes Produkt 1988/99 [Federal Act Governing the Liability for a Defective Product, Federal Law Gazette No. 99/1988].

9 Austrian civil law follows a broad understanding of property (§285 ABGB [Civil Law Code]), covering tangible items as well as intangibles. It is argued that the narrow definition under the PHG corresponds to the PLD.

10 KOCH, 'Product Liability in Austria', in P. Machnikowski (ed.), *European Product Liability*, p 122. For an interpretation about the legal status of software under the PLD, SCHMON, 'Product Liability of Emerging Digital Technologies', *IWRZ (Zeitschrift für Internationales Wirtschaftsrecht)* 2018(6), p 254.

11 For an overview about Supreme Court jurisprudence, RABL, *Produkthaftungsgesetz* (2017), p 136.

a product was marketed and the appropriateness of instructions for the product's use.¹² Expectations may also vary among regions.

9. Austrian jurisprudence and scholarship distinguish between design, manufacturing, and instruction defects¹³ without assigning interpretative consequences to this classification. These concepts are of descriptive nature only and have no normative value. Design defects relate to frustrations of safety expectations as regards the technical concept of a product, and hence flaws that relate to the planning, developing, or construction of products. In case of manufacturing defects, the ideal-typical design may correspond to the expectations, but the manufactured product may not. A manufacturing defect may occur due to the ignorance of scientific-technical rules in the production process, the failure of product means, or errors of the employed staff. Finally, the concept of instruction defects relates to the lack of guidance about the proper product use or warnings about associated risks.

10. The reasonableness of expectations undoubtedly covers product safety features prescribed by law and other technical standards. However, there is broad consensus that expectations may go well beyond such requirements, which is why regulatory compliance may suggest the absence, but cannot exclude the existence of a defect. It is also commonly accepted that the safety-test cannot be equated with whatever is technically possible to increase the safety of a product. To strive for the highest-possible standard is undesirable as it diminishes consumers' choice and excludes many of them from the market.¹⁴ It might lead to safety features not being added to a product for the sake of ensuring its marketability.¹⁵ It can therefore be concluded that not only technical feasibility, but, at the same time, questions of economic affordability must be considered under Austrian law.¹⁶ In this respect – and considering that *all* circumstances must be taken into account – the price of a product may be relevant for the safety expectations of buyers. Nevertheless, even relatively cheap products cannot fall short of a minimum standard of safety. For example, low-end vehicles¹⁷ or conventional step ladders¹⁸ must be safe to operate and provide the essential functions.¹⁹

12 OGH [Austrian Supreme Court], 30 March 2001, 7 Ob 49/01h.

13 *Ibid.*, pp 164-174; KOLMASCH, 'Judikaturübersicht: Konstruktions-, Produktions- und Instruktionsfehler in der Produkthaftung', *Zak* 2018, p 734.

14 Alexander GRAU, *Produktfehler* (Wien: NWV Verlag 2002) p 115.

15 KOCH, in *European Product Liability*, p 125.

16 Helmut KOZIOL, Peter APATHY & Bernhard A. KOCH, *Österreichisches Haftpflichtrecht III* (Wien: Jan Sramek Verlag 3d ed., 2014) B/169.

17 OLG Innsbruck [Higher Regional Court of Innsbruck], 31 January 1992, 4 R 331/91 (a bicycle must be safe to operate).

18 OGH, 5 December 2002, 2 Ob 249/02k (even where the minimum construction standard is fulfilled, liability arises in absence of a warning about foreseeable risks associated with non-optimal use).

19 POSCH & TERLITZA, in Schwimann & Kodek (eds), *ABGB: Praxiskommentar VII* (Wien: LexisNexis 4th ed. 2016) p 697; RABL, *Produkthaftungsgesetz* 2017, p 146.

11. A risk-utility test is largely considered alien to Austrian liability law and therefore either not thoroughly discussed or bluntly rejected by legal scholarship. It is submitted that a lack of safety cannot be justified by the fact that the creation of a safe product was not economically viable.²⁰ It was also not a critical factor whether a safe-to-use product is on the market at all. Nor will it be relevant that market competitors have not produced safe products after the marketing of such products turned out to be a failure. Although economical reasonableness is not considered a decisive criterion for giving shape to the concept of defect under the PHG, some observe that certain cost-benefit considerations may be evidently necessary – at least from the perspective of the producer. As regards products’ risks that can only be avoided with high financial outlay or not avoided at all, entrepreneurs would only have the choice of accepting the costs of product liability or taking the products off the market. Although a proper warning about product hazards might potentially suffice to escape liability,²¹ a cost-benefit analysis will be needed to compare the costs of consumer information with the financial risk of consumer frustration.²² Austrian courts, too, have abstained from resolving product liability questions by using risk-utility considerations. The Supreme Court clarified that the risk of competitive harm was not relevant for the assessment of defectiveness.²³ Producers must ensure the necessary product safety and take all measures during the design and planning stage that are objectively necessary to avoid product risks. When the specific product risks are *unavoidable* according to state-of-the-art science and technology, it must be assessed whether that risk-prone product can be placed on the market at all. For this assessment, risk type and magnitude should be considered as well as the *likelihood of their realization* and the *benefit* associated with the product.²⁴

12. As for procedural matters, the claimant bears the burden of proof on the elements of the product liability claim, including the existence of a defect, causation, and damage. As regards the defect, the claimant must prove its origin in the defendant’s sphere. The onus of providing satisfactory evidence for the nexus between defect and damage may be alleviated by prima facie evidence related to a typical course of events. The general evidentiary standard of proof under Austrian civil law is a high degree of probability.

20 RABL, *Produkthaftungsgesetz* 2017, p 146; WELSER *Produkthaftungsgesetz Kurzkomentar* (Wien: ZVAB 1988) §5 at 109.

21 Andreas EUSTACCHIO, *Produkthaftung: Eine systematische Darstellung für die Praxis* (Wien: NWB 2002) p 103.

22 Martin PRESLMAYR, *Handbuch der Produkthaftung* (Lexis Nexis 2d ed. 2002) p 67.

23 OGH, 30 September 2002, 1Ob 169/02 (dismissing the defendant’s argument that a warning sign would have negatively impacted the aesthetic design). Cf. also OGH, 6 September 2000, 9 Ob 20/009 (technical control was omitted for financial reasons).

24 OGH, 19 May 2010, 8 Ob 126/09a.

3. The Netherlands

13. Directive 85/374/EEC was implemented in Dutch law in 1990 by the introduction of a separate section of the Civil Code²⁵: Title 6.3.3 of the current Dutch Civil Code (DCC), Articles 6:185–193 DCC, provides a separate product liability regime. Prior to this implementation, there was no specific legal regime for product liability in Dutch legislation that had to be abrogated. Bespoke rules on product liability had been developed in case law based on the general tort law clause. This case law is still relevant since the general liability regimes can substantiate claims for damages against producers, whereas the Directive product liability regime is admittedly based on maximum harmonization but is not exclusive (Article 13 of the Directive).

14. Nevertheless, the product liability regime has an effect on tortious liability of producers and possessors of dangerous products for damage caused by these products; and contractual liability of the seller for selling a defective, and therefore non-conforming, product to a consumer. First, the principle of maximum harmonization has been complied with by channelling liability towards the producer in cases where several grounds of liability of different actors for defective products exist. To be more concrete, a second limb was added to the provision concerning the liability of possessors of dangerous equipment (Article 6:173 DCC), stipulating that liability of the possessor shall not ensue if the possession has a safety defect as stipulated in the Directive and Article 6:186 DCC. Liability of the possessor will then resurface, the second limb further stipulates, if it is likely that the defect did not exist when the product was put into circulation or the defect arose at a later date or that the damage does not exceed EUR 500 (considering the franchise stipulated in the Directive). Similarly, the provision regarding the seller's liability in a consumer sale was amended. Generally, a seller of a product that does not meet the standards that were reasonably to be expected based on the contract shall be liable for damage caused by that product. But in the case of a consumer sale the second limb of Article 7:24 DCC stipulates that where the failure in performance comes about because of a defect which causes a safety risk as meant in Article 6:185 DCC, the seller will not be liable for damage as referred to in Article 6:190 DCC, unless the seller was aware or ought to have been aware of the defect, he guaranteed the absence of the defect, or the damage would not be recoverable under the product liability regime either.

Furthermore, case law has to a large extent created convergence between the Directive product liability regime and the product liability under the general tort law clause (Article 6:162 DCC). Admittedly, the latter tort law standard is one of fault-based liability, whereas the Directive product liability regime is so-called qualitative liability, a form of strict liability. But the *Hoge Raad der Nederlanden* (Dutch Supreme Court) has moulded the standard for liability of the producer under general

25 At the time of implementation, in 1990, in Arts 1407a–1407j BW (old). These provisions were replaced by Arts 6:185–193 in the new BW, which entered into force in 1992.

tort law according to the standard of product liability under the regime of Article 6:185 DCC. The Dutch Supreme Court ruled that it is wrongful to put a product into circulation that, when used in a normal fashion and for the intended purpose, causes damage.²⁶ The criterion used to determine the defectiveness of a product under Article 6:185 ff DCC is also used to determine the unlawfulness under Article 6:162 DCC. As a rule, the act of putting a defective product on the market will be attributable to the producer because generally accepted principles justify such attribution. In the *Koolhaas/Rockwool* case the Dutch Supreme Court establishes a general duty of care on the basis of Article 6:162 DCC for producers to instate safety measures so as to prevent the supply of defective products as well as to keep end-users/consumers informed about potential applications of the product.²⁷ Therefore, the relationship between the European product liability regime and the domestic product liability under the general tort law is considered to have converged.²⁸ Consequently, the question whether the product is defective is essential, and more important than whether the producer has acted negligently.

15. Pursuant to Article 6:186(1) DCC a product is defective when it does not provide the safety that a person is entitled to expect, considering all the circumstances of the case at hand. In Dutch case law, the same standard is used for establishing product liability based on general tort law, as mentioned above. As to the level of safety that a person is entitled to expect, it is not the subjective safety standard of the individual that is relevant, but rather the objective standard of the general public.²⁹ The statutory provision mentions three elements to be taken into consideration, but this is not an exhaustive list of relevant factors.

16. Firstly, the presentation of the product can give rise to liability. The product must be assessed as a whole, including aspects as advertising, packaging and manual, to the extent that they may be relevant for a safe use of the product. A product will be considered defective if the producer has refrained from providing necessary instructions or has neglected to warn adequately of the potential dangers.³⁰ However, it must be noted that a proper warning does not prevent a

26 HR, 22 October 1999, NJ 2000, 159 (*Koolhaas/Rockwool*). Compare also HR, 6 December 1996, NJ 1997, 219 (*DuPont/Hermans*); HR, 6 December 1996, NJ 1997, 219 (*DuPont/Hermans*).

27 HR, 22 October 1999, NJ 2000, 159 (*Koolhaas/Rockwool*).

28 KEIRSE, 'The Netherlands', in P. Machnikowski (ed.), *European Product Liability*, p 324; I. GIESEN, E.R. de JONG & Tarik MUSLAT, 'The State of the Art of Product Liability in the Netherlands', in H-J. Kullmann, B. Pfister, K. Stohr & G. Spindler (eds), *Produzentenhaftung* (Berlin: Erich Schmidt Verlag GmbH and Co 2017), p 69 ff.

29 E. BAUW, *Onrechtmatige daad: aansprakelijkheid voor zaken* (Wolters Kluwer 2015), no 74; Court of Appeal The Hague, 18 September 2012, JA 2012/212; Hoge Raad, 6 September 2013, RvdW 2013/1253.

30 *Kamerstukken II* Mvt 1985/86, 19 636, no 3, 9; Hoge Raad, 30 June 1989, NJ 1990/652 (*Halcion*).

defect from being qualified as such, if the defectiveness could have been prevented in some other way.³¹ Furthermore, a seal of quality does not automatically imply that a product is without defect.³²

17. Secondly, the reasonably expected use of the product is relevant. The producer cannot automatically be held liable for a defect which arises due to the extensive misuse by the user. He is in principle only liable if the product has been used in a reasonable way and the product nevertheless shows signs of having a defect. However, this does not mean that the producer is freed from any kind of liability if the user has neglected to take the necessary precautionary measures when using the product in question. The producer should always know some users will not be as cautious as they should be. Therefore, when designing a product, the producer should not focus on the individuals who always take the necessary precautions, but instead have in mind the general public, some of whom will be imprudent and will neglect taking safety measures.³³

18. Thirdly, the time the product was put into circulation and the regulations in force at the time must be considered when deciding whether the product is defective. It is important to examine the defectiveness according to the safety norms existing when the product was marketed. Otherwise the product can be deemed to be defective for the sole reason that new safety norms have entered into force.³⁴ This situation is closely related to the situation in which a better product is marketed. According to Article 6:186(2), a product is not deemed to be defective for the sole reason that a better product has been put on the market afterwards. In this regard, the notion of *better* must be understood as *safer*.

19. The time the product was put into circulation also plays a role within the context of used objects. It has been argued that one cannot expect the same level of safety from a used product as from a product that has been purchased recently. Such a situation is also closely related to Article 186(1)(b), since a used object might show signs of wear arising from normal usage of the product. However, if a product shows signs of excessive wear, despite normal usage, liability of the producer might be invoked.

20. Although no explicit distinction between manufacturing, design or presentation defects can be found in national law, such a distinction has been used in legal doctrine. However, it does not have any normative meaning, or any legal

31 L. DOMMERING-VAN RONGEN, *Productenaansprakelijkheid. Een nieuwe privaatrechtelijke regeling vergeleken met de productenaansprakelijkheid in de Verenigde Staten* (Deventer: Kluwer 1991), p 96.

32 C.J.J. STOLKER (ed.), *Onrechtmatige Daad* (Deventer: Kluwer 2011) Art. 6:187, n. 5.1 (online resource).

33 Hoge Raad, 2 February 1973, NJ 1973/315 (*Lekkende Kruik I*).

34 *Kamerstukken II Mvt 1985/86*, 19 636, no 3, 9-10.

consequence, and must solely be treated as a means to categorize or establish the defectiveness.³⁵

4. England & Wales

21. In English law, the Directive is faithfully implemented by the Consumer Protection Act 1987. Perhaps surprisingly, there has not been a great deal of litigation on this topic in the English courts since the adoption of the Act, though there has been an upturn more recently with two important decisions at first instance on product liability, as we shall see, which have touched also upon the notion of defect.

22. Under English law, it is for the claimant to prove the existence of a defect which has caused damage,³⁶ consistently with the scheme set out in the Directive. It has been accepted however that the claimant is not required to prove the precise cause of the lack of safety that amounts to a defect, or why the product had failed.³⁷

23. A handful of English cases have dealt with the notion of defect. An extensive treatment of this concept is found in the English High Court in *A v. National Blood Authority*.³⁸ In that case, a successful claim was brought against the UK blood authority by patients who had been infected with Hepatitis C during blood transfusions. The court heard detailed argument on the history of the Directive, the academic commentaries and comparative law. In his judgment, Mr Justice Burton examined the test of defect in some detail. His conclusions may be summarized as follows:

- (a). Liability under the Directive is defect-based and not fault-based, i.e., that a producer's liability is irrespective of fault.
- (b). Avoiding the traditional categorization of defects, Mr Justice Burton drew a distinction between standard and non-standard products. In respect of non-standard products (such as, in the instant case, blood), it was held that a judge, taking a jury-like view of the relevant circumstances, should compare the safety of the product in question with that of other similar products. The court has to decide the question what the legitimate expectation is as to safety of the product, and that might indeed be higher or lower than the public expectation.
- (c). It was also held by the judge that 'all the circumstances' referred to in Article 6 of the Directive, which are to be taken into account during the defectiveness test (such as presentation of the product, and time when it was put into

35 DOMMERING-van RONGEN, *Producentenaansprakelijkheid*, p 144; I. GIESEN, E.R. de JONG & Tarik MUSLAT, *Product Liability*, pp 69 et sqq.

36 For example, *Gee v. DePuy International* [2018] EWHC 1208, at [81.]

37 *Ide v. ATB Sales Limited* [2008] EWCA Civ 424, [19]-[22], per Thomas LJ; [2016] EWHC 3096 (QB).

38 [2001] 3 All ER 289; [2001] Lloyd's Rep Med 187.

circulation), are not exclusive. On the contrary, the specific examples given in Article 6 are intended to be the most significant circumstances. All the circumstances are to be construed as all *relevant* circumstances.

- (d). Avoidability of harm is not one of the circumstances to be considered within Article 6. It was not a relevant circumstance, because it was outwith the purpose of the Directive, which was inter alia to relieve consumers of having to prove fault or negligence.

24. A series of subsequent English cases touched upon the notion of defect but left the status of the analysis in *A v. National Blood Authority* as somewhat unclear.³⁹ Two recent High Court decisions have however looked at this issue in detail, and it is necessary to look at these further, as follows.

25. In the decision of *Wilkes v. DePuy International Limited*,⁴⁰ Mr Justice Hickinbottom (as he then was) took a very different approach to that adopted in *A v. National Blood Authority*. In this case, which concerned an allegedly defective artificial hip, the judge substantially departed from that of Burton J as regards defect, and held that a test of what persons are generally ‘entitled to expect’ required no additional explanation over that in the Act and did not benefit from being re-defined by Burton J as a *legitimate expectation* test.⁴¹ The test for safety required an objective approach, taking into account the information and circumstances before it, whether or not members of the public would have considered each of the factors and all of the relevant information.⁴²

26. This shift away from the legitimate expectation test was followed by Mrs Justice Andrews in the recent decision of *Gee v. DePuy International*.⁴³ In this case, the judge considered that there were pitfalls in adopting Burton J’s reformulation of the test and omitting the essential word *entitled*. She also viewed it as problematic to adopt a phrase which was used as a term of art in a very different (administrative law) context.⁴⁴ Andrews J also rejected drawing any specific distinction between different types of defect ‘such as a manufacturing defect, a design defect or a warning defect, as in the US system’.⁴⁵ Instead, the flexible holistic approach of Hickinbottom J in *Wilkes* was reaffirmed by Mrs Justice Andrews. In her view, all the relevant circumstances noted by Hickinbottom J could be factored

39 For example, *Pollard v. Tesco Stores Ltd* [2006] EWCA Civ 393; *Piper v. JRI (Manufacturing) Ltd* [2006] EWCA Civ 1344; *Palmer v. Palmer* [2006] EWHC 1284.

40 [2016] EWHC 3096 (QB). Cited with approval in the recent case of *Bailey v. GlaxoSmithKline* [2019] EWCA Civ 1924 at [8].

41 *Ibid.*, at 71. *A v. National Blood Authority* [2001] 3 All ER 289 [31(vi)].

42 *Ibid.*, at 69, 72.

43 [2018] EWHC 1208, at 95.

44 *Ibid.*

45 *Ibid.*, at 93.

into determining defectiveness, including potential avoidability, risk-benefit and cost, thus taking a very different approach to that of Burton J.⁴⁶

27. In terms of the notion of risk-benefit, this topic has been the focus of much discussion and of some controversy in the UK literature.⁴⁷ As we have noted above, it was ultimately accepted in the *Gee* case that risk-benefit may be relevant, with Mrs Justice Andrews holding that ‘such factors *may* sometimes play a legitimate part in the evaluation of the degree of safety risk that the public would be expected to tolerate, because there may be cases in which one cannot fairly or sensibly evaluate the latter without looking at the former’.⁴⁸

28. As for the timeframe for determining defect, it is well-known that the point in time for deciding whether a product is defective is as at the time it was put into circulation. In *Gee v. DePuy*, the judge noted that in so determining, the Court may take into account all information available as at the date of legal proceedings: ‘*in determining whether the product met that level of safety, the Court is entitled to have regard to everything now known about it that is relevant to that enquiry, irrespective of whether that information was available at the time it was put on the market or has come to light subsequently*’.⁴⁹

5. France

29. Article 6 of the Product Liability Directive was implemented without any modification in Article 1245-3 of the French *code civil* (hereinafter *cc*). As is well known, however, the definition of defect in Article 6 is quite vague. And, until very recently, French courts have done very little by way of substantiating it. One of the reasons for this is that French judges are notoriously reluctant to draw precise, hard and fast rules, which would unduly restrict their discretion in future cases. Despite the significant number of product liability cases that have been brought before French courts, including the *Cour de cassation* (the highest court in civil matters, hereinafter *Cour*), over the last decade, only very few of them have directly raised the issue of defectiveness.

30. French authors generally agree that the legitimate expectations standard set out at Article 1245-3 *cc* requires an objective assessment of the safety that could be expected (as opposed to an assessment of the safety that the plaintiff personally expected). A majority also accepts that this standard in essence boils down to a

46 *Ibid.*, at 144-167.

47 For example, HOWELLS (ed.), *The Law of Product Liability* (Oxford: Butterworths 2d edn 2007), paras 1.74-1.79 and 4.150; D. FAIRGRIEVE and R. GOLDBERG, *Product Liability* (Oxford: OUP 3d edn 2020), paras 10.41 - 10.46.

48 *Gee v. Depuy* [2018] EWHC 1208 at 152.

49 *Ibid.*, at 84.

normal danger requirement: a product is defective in the sense of the special product liability regime if it is abnormally dangerous⁵⁰ – a position which was confirmed by the ECJ in the *Boston Scientific Medizintechnik* case.⁵¹ How abnormal dangerousness should be assessed is where things get less clear, however.

31. Except in the field of pharmaceutical liability, risk-benefit analysis as a way of assessing defectiveness has hardly been discussed⁵² and seems never to have been used deliberately by the courts. This should hardly come as a surprise, given that French lawyers generally have not been receptive to the *law and economics* approach, and are even often openly hostile to it. Cases can be cited, however, where the courts have in effect implemented the reasonable alternative design standard to assess defectiveness.⁵³

32. On the other hand, and perhaps surprisingly, risk-benefit considerations are often discussed in the specific context of pharmaceutical liability. Several authors have expressed the opinion that risk-benefit analysis should be used to assess defectiveness in that field,⁵⁴ if only because it is difficult to think of another test for pharmaceuticals. Some appellate courts have also endorsed this test,⁵⁵ especially in the context of hepatitis B vaccine litigation.⁵⁶ They concluded that this vaccine cannot be regarded as defective since, even if it might in certain cases cause demyelinating diseases, its benefits to the community greatly outweigh its potential negative side effects.⁵⁷

33. In two cases decided in 2012 and 2013, however, the *Cour* quashed appellate courts decisions, which had used the risk-benefit test to assess defectiveness in the context of hepatitis B vaccine litigation.⁵⁸ In both cases, the supreme court ruled

50 For example, the leading textbooks by BRUN, *Responsabilité civile extracontractuelle* (Lexis Nexis 5th ed 2018), no. 759, and Suzanne CARVAL ET AL., *Les Régimes spéciaux et l'assurance* (Paris: LGDJ 4th ed. 2017), no. 21.

51 ECJ, 5 March 2015, *Boston Scientific Medizintechnik GmbH v. AOK Sachsen-Anhalt – Die Gesundheitskasse* (C-503/13), Betriebskrankenkasse RWE (C-504/13), § 40.

52 However, Jean-Sébastien BORGHETTI, *La Responsabilité du fait des produits. Étude de droit comparé* (Paris: LGDJ 2004) no. 461.

53 *Ibid.*, no. 331.

54 For example, VINEY, 'Observations on Cass. 1 civ., 23 September 2003', *Semaine Juridique (JCP) G* 2004(23), I, p 101; CLERC-RENAUD 'Quelle responsabilité en cas de dommages causés par des produits de santé?', *Revue Lamy droit civil* (RLDC) 2007(14), p 34; BORGHETTI, 'Quelles responsabilités pour les laboratoires fabricants de médicaments dangereux?', *BNDS (Revue générale de droit médical)* special issue 'Les responsabilités du fait des médicaments dangereux. Perspectives nationales et transfrontalières', 2012, p (19), at 25.

55 For example, CA Versailles, 17 March 2006, no. 04/08435; CA Paris, 19 June 2009, no. 06/13741.

56 For example, CA Versailles, 16 March 2007, no. 05/09525; 29 March 2007, no. 06/00496; 5 November 2007, no. 06/06435.

57 For example, CA Versailles, 5 April 2012, no. 09/05661.

58 Cass civ 1, 26 September 2012, no. 11-17738; 10 July 2013, no. 12-21314.

that the lower courts could not rely only on the risk-benefit ratio to rule out defectiveness and that they should have considered if the elements that had been used to presume causation (proximity in time between the vaccination and the first symptoms of the disease; lack of personal or family antecedents)⁵⁹ could not also justify a presumption that the vaccine doses used by the claimant were defective. The *Cour* did not say that a negative risk-benefit ratio could not be proof of defectiveness; but it held that risk-benefit should not be the *only* test to assess defectiveness. Unfortunately, while the *Cour* indicated what elements the lower judges should have considered in order to assess the existence of defect, it did not explain how these elements should be used and what was the precise test underlying the judges' reliance on them.

34. That the *Cour* does not prohibit altogether the use of the risk-benefit test to assess defectiveness was confirmed in a 2018 case.⁶⁰ A young woman had died from pulmonary embolism, allegedly caused by her oral contraceptive. In a preliminary ruling, the appellate court decided that making the contraceptive's producer liable for the harm was out of the question, since the product's leaflet mentioned pulmonary embolism as a possible side effect, and this was enough to rule out the product's defectiveness. The *Cour* quashed this ruling on the ground that Article 1245-3 *cc* had not been correctly applied: to rule out defectiveness, the appellate court should not have had regard only to the information provided, but should also have enquired whether, notwithstanding the information in the leaflet, the seriousness of the thrombosis risk and the frequency of its materialization did not exceed the benefits expected from the contraceptive.

35. The judgment is interesting first as it states that information on the risks associated with a product is not always enough to rule out that product's defectiveness. Even more importantly, the judgment makes it clear that a risk-benefit analysis can be used to assess a pharmaceutical's intrinsic defectiveness.⁶¹ Under French law, a negative risk-benefit balance therefore makes a pharmaceutical defective.

36. Exactly how this 2018 case should be reconciled with the 2012 and 2013 cases is open to debate, as the *Cour*'s judgment does not cite these precedents. The most convincing view seems to be the following: when they have to rule on a pharmaceutical's intrinsic defectiveness, lower judges should check if the product has a positive risk-benefit balance (2018 decision); if so, the existence of a defect is not automatically

59 On the assessment of causation in hepatitis B vaccine cases under French law, BORGHETTI, 'Causation in Hepatitis B Vaccination Litigation in France: Breaking Through Scientific Uncertainty?', 91. *Chicago-Kent Law Review (Chi. -Kent. L.)* 2016(2), p 543.

60 Cass. civ. 1, 26 September 2018, no. 17-21.271.

61 As opposed to the product's 'extrinsic' defectiveness, which consists in a failure to warn of the product's risks or to give indications as to how to use the product safely.

excluded, however, and the judges should also check if other elements, such as those which may have been used to assess the existence of a causal link between the use of the product and the harm, do not point to the existence of such a defect (2012 & 2013 decisions). It is suggested that the first test is enough and that the second test is not only too vague, but also has no justification (at least when the claimant alleges that the pharmaceutical was defectively designed).

37. A further question is whether the risk-benefit analysis should be conducted for the claimant only or based on the whole community of the users of the product.⁶² The formulation of the 2018 judgment suggests that the *Cour* has endorsed the latter view, as it mentions the frequency of the side effects occurring, which can only be measured if one considers the whole community of users. This is the most sensible approach, as the individual approach to risk-utility would result in a pharmaceutical being regarded as defective vis-à-vis a patient as soon as it causes her a serious side effect, however exceptional. Besides, the individual approach would result in the same product being regarded as defective in some cases and not defective in others, depending on the patient's idiosyncrasy.

6. Germany

38. Under German Law, the burden of proof for a defect is attributed to the claimant. This applies both to Civil Law matters (§ 823 (1) *Bürgerlicher Gesetzbuch*; German Civil Code) and Product Liability Law, which has been embodied in § 1 (4) *Produkthaftungsgesetz* (ProdHaftG; Product Liability Act). Article 4 of the Directive 85/374/CEE (the Directive) is implemented in § 1 (4) ProdHaftG.

39. Within the framework of product liability under tort law, a distinction has developed between design defects, manufacturing defects and instruction/warning defects, which serves to categorize the manufacturer's conduct obligations. Thus, also under § 3 ProdHaftG, the safety deficit of the product which triggers liability can be based on a design, a manufacturing or an instruction/warning defect.⁶³ Therefore, there is no reason to abandon the usual differentiation of the individual types of defect in favour of a uniform concept.⁶⁴

A manufacturing defect occurs if the product is of a different nature and therefore reacts differently than the manufacturer had planned.⁶⁵ The standard test is to compare the product showing a defect with the standard product of the

62 For example, BORGHETTI, *BNDS* 2012, p 26.

63 SPRAU, 'Produkthaftungsgesetz', in Palandt (ed.), *Bürgerliches Gesetzbuch (Palandt ProdHaftG)* (Munich: C.H. Beck 2019) § 3 marginal number (mn.) 2.

64 WAGNER, Münchener Kommentar zum Bürgerlichen Gesetzbuch: *Produkthaftungsgesetz MüKoBGB ProdHaftG* § 3 mn. 36.

65 WAGNER, 'Produktehaftung für autonome Systeme', *AcP (Archiv für die civilistische Praxis)* 2017, p (707), at 725.

manufacturer and thus arguably does not comply with the expected safety rules from an objective point of view (*Consumer expectation test*).⁶⁶ Regarding design defects, the BGH (*Bundesgerichtshof*) has supported the *risk-utility*-test in principle.⁶⁷ According to the court's decision, a product shows a design defect, if the manufacturer could have chosen an alternative design that would ensure a security benefit that outweighs the additional manufacturing costs. The security benefit is measured by the rank of the legal good and the probability of its violation.⁶⁸ However, if there is no technically possible alternative design, the question would arise whether the utility of the product outweighs the unavoidable risks of damage. For instruction/warning defects the manufacturer has to warn of a potential danger if the product is used in accordance with its intended purpose as a foreseeable misuse.⁶⁹ Regarding new technologies and their almost completely automated execution, the current duty to warn consumers is too restrictive. The duty to instruct should be extended to e.g., the warning not to interfere with the technology and to inform about higher insurance premiums.⁷⁰

40. The defect is assessed objectively.⁷¹ Relevant factors are the safety expectations of the group of people to whom the manufacturer turns with its product. However, since the scope of protection of liability under the Product Liability Act is not limited to the purchasers or users of products, but also includes uninvolved third parties, not only the security expectations of the target group must be taken into account, but also the level of protection that third parties can legitimately expect if they get into contact with the product.⁷²

41. Whether the consumer is entitled to have certain safety expectations is decided by the judge, based on the objective standards according to Article 6 of the Directive and § 1 (1) ProdHaftG.⁷³ Regarding design defects, the manufacturer has to provide safety within all reasonable efforts. That means that the manufacturer is responsible for avoiding risks from which consumers cannot protect themselves.⁷⁴ The assessment of a design defect in individual cases is a difficult task, which can hardly be accomplished without experts. The public product safety law can be an indication, but it is not binding.⁷⁵ For manufacturing defects, the

66 SPRAU, in *Palandt ProdHaftG*, § 3 mn. 3; BGH *NJW* 2009, 1669, 1670; BGH *NJW* 2014, 2106, 2106.

67 BGH *NJW* 2952, 2954.

68 Ibid.

69 SPRAU, in *Palandt ProdHaftG*, § 3 mn. 11.

70 WAGNER, *AcP* 2017, p 748.

71 SPRAU, in *Palandt ProdHaftG*, § 3 mn. 3.

72 BGH *NJW* 2009, 1669, 1670.

73 SPRAU, in *Palandt ProdHaftG*, § 3 mn. 3; BGH *NJW* 2009, 1669, 1670.

74 Hein KÖTZ & Gerhard WAGNER, *Deliktsrecht* (Munich: Vahlen 13th edn 2016) 245 mn. 619.

75 BGH *NJW* 1987, 372, 373.

BGH stated that consumer expectations are analysed independently of the technical possibilities, so that a manufacturing defect may also exist if the defect cannot be determined technically and thus not be repaired.⁷⁶ In a further decision, the BGH relativizes its case law: manufacturer cannot be held liable for any defect, it depends on the danger, the possibility and reasonableness of security measures.⁷⁷ As for the instruction/warning defect, a manufacturer has to expect any ‘foreseeable misuse’.⁷⁸ The risk-benefit analysis is only considered when dealing with design defects.⁷⁹ Regulatory and industry safety standards can be an indication for the assessment of a defect.⁸⁰ However, the regulatory and safety standards do not determine the safety standard under Private Law, they merely mark the minimum standards.⁸¹ With regard to design and instruction defects, the BGH assumes that the manufacturer may have to do more than the authorities (Regulatory Law) require and cannot rely on their approval.⁸² However, if the manufacturer has violated the administrative standard, the existence of a defect shall be presumed.⁸³

42. The following considerations regard new technologies: A manufacturing defect occurs if the product is of a different nature and therefore reacts differently than the manufacturer had planned. This can be applied to new technologies, such as automated systems. In this case, a manufacturing defect would exist, if the system reacted differently than the manufacturer had planned. As for software, a manufacturing defect could exist in a defective transfer of the software from the servers of the manufacturer to the processor of the autonomous system, before the system is put into circulation.⁸⁴ As for design defects, it is more difficult, because new technology could *per se* be defective.⁸⁵ Nevertheless, there is no guarantee for absolute safety in product liability. Therefore, there is a need to define a safety standard, on the basis of which the product’s defectiveness is assessed.⁸⁶ The risk-utility test serves this procedure and thus leads to a clearly defined responsibility of the manufacturer. Regarding instruction/warning defects, there is no need to adapt the current definition. The system will

76 BGH *NJW* 1995, 2162, 2163 et sq.

77 BGH *NJW* 2009, 1669, 1670.

78 BGH *NJW* 1989, 1542, 1544; KÖTZ & WAGNER, *Deliktsrecht*, 253 mn. 639.

79 KÖTZ & WAGNER, *Deliktsrecht*, 246, mn. 621.

80 KÖTZ & WAGNER, *Deliktsrecht*, 246, mn. 622.

81 WAGNER, *AcP* 2017, p 730.

82 BGH *NJW* 1987, 372, 373, with further comments.

83 KÖTZ & WAGNER, *Deliktsrecht*, 247 mn. 622.

84 WAGNER, *AcP* 2017, p 725.

85 ZECH, ‘Zivilrechtliche Haftung für den Einsatz von Robotern - Zuweisung von Automatisierungs - und Autonomierisiken’, in Gless & Imann (eds), *Intelligente Agenten und das Recht* (2016), p (163), at 192.

86 WAGNER, *AcP* 2017, p 729.

run anyway. The warning might focus more on not to interfere with the system.⁸⁷ Development risks (only regarding instruction and design defects) are excluded from product liability under German Law (§ 1 (2) (5) ProdHaftG).⁸⁸ However, in the case of many new technologies like automated hardware controls the associated risks are foreseeable in general. Even if the potential dangers may not be known *ex ante* in detail, there is no room for the application of the development risk exclusion. Therefore, in many cases there will be no application for the development risk exclusion.⁸⁹ Determining expectations in respect of new/emerging product classes depends on the individual product class. It may be difficult to determine expectations if no normal use can be determined *ex ante*.

7. Italy

43. In order to analyse systematically the case law interpreting the notion of defectiveness of a product, I have gathered them into three different categories. These are not explicitly recognized by judges but are consistent with the specific reasoning justifying the decisions in each category.

7.1. Case Law on Damages Foreseeable and Avoidable

44. The first decision issued by the *Corte di Cassazione* (hereinafter *Corte*) on the notion of defectiveness under Directive 85/374/EEC⁹⁰ was in 2007 and it was about the injuries following an allergic reaction caused by a hair dye.⁹¹

In this case the *Corte* considered that the product was not defective, indicating that there are injuries, although causally related to the use of the product, for which the producer escapes liability because they should be better attributed to self-liability of the victim who could have avoided them more easily than the producer.⁹² Otherwise said, when the damage was foreseeable and avoidable by both parties, the *Corte* implicitly refers to the well-known theory of the cheapest cost-avoider devised by Guido Calabresi, considering which of the two parties was in the best position to avoid that damage at the

87 WAGNER, *AcP* 2017, p 748.

88 § 3 ProdHaftG; SPRAU, *Palandt ProdHaftG*, Einleitung zu § 1 mn. 5.

89 Wagner, *AcP* 2017, p 750.

90 Implemented in Italy by Presidential Decree n. 224/88 and subsequently incorporated into Title II of the CoC).

91 C. Cass. no. 6007/2007.

92 The instructions for use of the dye warned of the possibility that it might cause an allergic reaction and specifically recommended users to conduct a sensitivity test whenever suffering of allergies.

lower cost or the lower sacrifice.⁹³ This way of reasoning seems to be consistent with the definition of defectiveness given by the lawmaker, which distinguishes two different kinds of circumstances to be considered in order to ascertain when an expectation of safety is legitimate or illegitimate. On one side, ‘the presentation of the product’ (i.e., the information available for the user enabling him to avoid the damage), on the other side, ‘the use to which it could reasonably be expected that the product would be put’ (i.e., the information available for the producer).

7.2. Case Law on Damages Unforeseeable and Unavoidable

45. When, instead, the damage was unforeseeable and unavoidable by both parties, the producer is not liable following the development risk defence that in Italy applies to any kind of products. This exemption clause has been interestingly applied by the *Tribunale di Sassari* on a pharmaceutical product case. With explicit reference to the decision given 29 May 1997 (C-300/95) by the ECJ, the Tribunal considers that in the specific case, despite the publication of a couple of accessible scientific works, acknowledging the risk of damage, the state-of-the-art defence is applicable because the information was not yet generally accepted by the scientific community. Therefore, the producer is not held liable as it was normal that he did not warn about a risk still uncertain at the relevant time.

Briefly, when the damage was unforeseeable and unavoidable by both parties, its cost is left on the victim.

7.3. Case Law on Damages Statistically Foreseeable in Advance, Though Unavoidable

46. As the Directive is premised upon a strict liability rule on the producer, it is argued that the producer should be held liable even though he has taken all possible precautions to avoid the damage. The strict liability rule is explicit in Italian law for manufacturing defect (although the legislator does not mention explicitly the three categories of defects elaborated by the American scholars). Article 117 paragraph 3 of the consumer code (CoC) states that: ‘a product is defective if it does not offer the same safety offered by the other products of same series’. In these cases, a warning for consumers alerting to dangers along the lines of ‘be careful, the soda bottle might explode’ would not exempt the producer from liability (otherwise the Directive would become totally ineffective).⁹⁴

93 Guido CALABRESI, *The Cost of Accidents, A Legal and Economic Analysis* (London: Yale University Press 1970).

94 Warning and instruction presenting the product may shift the liability from the producer to the user just if they enable the latter to avoid the damage. Cases on hedonistic products, such as cigarettes and alcohol represent an exception because here the damage is causally related to the

47. The strict liability rule is explained because in manufacturing defect cases the damage is statistically foreseeable in advance, i.e., it is measurable, and thus can be managed by the producer through insurance or increase in product price. On the contrary, it would be inefficient to ask all the consumers to get insured for the remote eventuality of being one of the few unlucky victims of the inherent danger of the product. This reasoning refers to the Management Risk Approach (MRA), that is more and more frequently mentioned in the documents of the European Parliament.⁹⁵

48. Nevertheless, there are cases on damages statistically foreseeable in advance where the strict liability rule is paralysed through the application of a cost/benefit analysis of the product under a global perspective, rather than a marginal perspective related to the individual interests in conflict. Briefly, because the product is beneficial to the entire community, the product is not defective and the manufacturer is immune from liability in the individual case where the product is the cause of the damage, provided that he has warned the user (though the user cannot avoid the damage anyhow). Otherwise said, the public interest comes into play in a trial among individual interests, so that the judge duplicates the role of the Regulator, despite their respective different functions. This rule is applied in particular to pharmaceutical products,⁹⁶ and introduces an exemption clause which is not included in the list of Article 7 of the Directive (though it is intended to be a closed list).

49. In Italy the cost/benefit analysis from a global perspective has not been explicitly applied so far in the decisions assessing the defectiveness of a product. However, there is a recent decision of the *Corte* which implicitly refers to it.⁹⁷ The case law is about a pharmaceutical product which was intended to treat stomach ulcers, that has been later found to be the cause of serious hepatologies in several cases. The risk of hepatologies was known when the product was put into circulation with the authorization of the Italian authority (AIFA) that considered that this risk was acceptable.⁹⁸ However, a few years later, a much higher number of hepatologies than originally foreseen was reported. Therefore

self-responsibility of the user who has consciously and freely abused of the product, been aware of the inherent risk of damage (the most recent decision: Cass. Civ. n. 11272/2018).

95 As an example, Resolution 16 February 2017 on Civil Law Rules on Robotics, where the risk management is defined as the liability of ‘*the person who’s able to minimize the risk and deal with negative impact*’.

96 Eleonora RAJNERI ET AL., ‘Remedies for Damage Caused by Vaccines: A Comparative Study of Four European Legal Systems’, *ERPL* 2018, p. 57.

97 Corte di Cassazione 28 July 2015 n. 15851.

98 Therefore, the fact that the product has been authorized, does not exclude its defectiveness. See Ugo CARNEVALI, ‘Farmaci difettosi e autorizzazione ministeriale’, 77. *Responsabilità civile e previdenza* 2012(1), p. 158.

in 1995 the producer put the drug off the market. In the case brought before courts by one of the victims, the *Corte* considers that the producer is not liable because the state of scientific and technical knowledge at the time when the claimant was assuming the drug (i.e., 1994) was not such as to consider the product as defective, since at that time the higher frequency of the known collateral effects was not yet reported. Therefore, according to this decision, the magnitude of the risk is what makes the product defective, i.e., the fact that the cost of the product outweighs its benefits under a global perspective. On the contrary, the fact that the product has been proven to have caused the hepatology in a single case is not enough to make it defective.

50. As I have explained elsewhere in detail, I believe that the application of the cost/benefit analysis represents a divergence from the aim of the Directive since it exempts the producer from liability in cases presenting the very same factor that justifies the application of the strict liability rule in manufacturing defect cases.⁹⁹ This factor is the foreseeability of the risk of damage in advance in statistics terms, which enable the producer to manage its cost through insurance or a proportional price increase. In decision 21 June 2017 (C-621/15), the ECJ appears to confirm the opinion here advocated when it affirms at point n. 41 that a vaccine is defective ‘because it causes abnormal and particularly serious damage to the patient who, in the light of the nature and function of the product, is entitled to expect a particularly high level of safety’. Though point n. 41 is just an *obiter dictum*, it is remarkable that the Court of Justice do not take into any account the cost/benefit analysis in order to ascertain whether the product ‘does not provide the safety which a person is entitled to expect’.

8. Poland

51. Directive 374/85 has been transposed to Polish law in 2000, that is four years before Poland’s accession to the European Union, by adding to the Polish Civil Code (PCC¹⁰⁰) book on obligations a new chapter consisting of eleven articles (Articles 449¹ to 449¹¹ PCC).¹⁰¹ PCC provisions transposing Directive 374/85, instead of following

99 RAJNERI, ‘Prodotto difettoso’, in R. Sacco (ed.), *Digesto delle Discipline Privatistiche, Sezione Civile* (Turin: Wolters Kluwer 4th ed. 2016) *ad vocem*; Eleonora RAJNERI ET AL., *ERPL* 2018, pp 67-69.

100 *Ustawa* (act) of 23 April 1964 Kodeks cywilny, *Dziennik Ustaw* (Journal of Laws) 1964, No 16, item 93 as amended.

101 *Ustawa* (act) of 2 March 2000 o ochronie niektórych praw konsumentów oraz o odpowiedzialności za szkodę wyrządzoną przez produkt niebezpieczny (on protection of certain rights of consumers and on liability for damage caused by an unsafe product), *Dziennik Ustaw* (Journal of Laws) 2000, No. 22, item 271. For a general discussion of the liability regime see BACIŃSKA, ‘Product Liability in Poland’, in P. Machnikowski (ed.), *European Product Liability*, pp 377 et sqq.; Ewa BACIŃSKA & Magdalena TULIBACKA, *International Encyclopaedia of Laws: Tort Law in Poland* (Wolters Kluwer Law 2014), pp 279 et sqq.

the Directive's terminology ('defect', 'defective product'), use the phrase *produkt niebezpieczny*, an unsafe/dangerous product, in order to avoid confusion with the notion of defect which is the central point of the regime of implied warranty in the contract law, especially sales law.¹⁰² This, however, influenced the discussion on interpretation of the product liability law by focusing it on the relationship between liability law and safety regulations. Another controversial decision of the lawmaker was to replace the criterion of 'the safety which a person is entitled to expect' with the criterion of 'safety which one may expect considering the ordinary use'.

There is no specific provision with regard to the burden of proof of defect (lack of safety), the general provision of Article 6 PCC applies to the effect that the claimant has to prove it. The practical application of this rule is, however, more nuanced, which will be discussed further.

52. For a relatively long period of time Polish case law on product liability was scarce, yet in the last few years a few dozen judgments have been handed issued. It is still not enough to speak about established views of the judiciary, the cases show what kinds of problems arise when it comes to interpretation of the product liability law.

The legislator's decision to define an unsafe product as one that 'does not ensure safety which one may expect considering the ordinary use of the product' called first for an explanation, what an *ordinary use* is. The dominant view of commentators is that ordinary use encompasses not only the kind of use the product is intended for, but also those improper ways of using it which were known to have happened before or were predictable (foreseeable misuse).¹⁰³

There is no doubt that the safety of the product should be assessed as of the moment it has been put into circulation¹⁰⁴ (although little consideration in the

102 Although 'defective design of the product' is mentioned in Art. 4495 §1 PCC. Regardless of the wording of Art. 4491 § 3 PCC, importance of the defect of the product is sometimes stressed, see e.g., RUCHAŁA & SIKORSKI, in GUTOWSKI (ed.), *Kodeks cywilny: Komentarz*, vol. I (C.H. Beck 2016), Art. 4491 No. 49 et seq.; Gnela in FRAS & HABDAS (eds), *Kodeks cywilny: Komentarz*, vol. III (2018), Art. 4491 No. 26; judgment of the Court of Appeal ('CA') in Szczecin of 29 May 2014, I ACa 377/13.

103 For example, GNELA, 'Odpowiedzialność za produkt (uwagi o polskiej regulacji)' 2009(9), p 38; JAGIELSKA, in OLEJNICZAK (ed.), *System Prawa Prywatnego*, vol. 6, *Prawo zobowiązań – część ogólna* (2018), p 1017 et seq.; GNELA, *Kodeks cywilny: Komentarz*, No. 28; BIELSKA-SOBKOWICZ, in GUDOWSKI (ed.), *Kodeks cywilny. Komentarz* vol. III, part 1 (2018), Art. 4491 No. 13; DUBIS, in GNIEWEK & MACHNIKOWSKI (eds), in *Kodeks cywilny: Komentarz* (2017), Art. 4491 No. 14; RUCHAŁA & SIKORSKI, *Kodeks cywilny: Komentarz*, No. 54; BANASZCZYK, in Pietrzykowski (ed.) *Kodeks cywilny: Komentarz* vol. I (2018), Art. 4491 No. 28; judgment of CA in Warsaw of 4 November 2008, I ACa 526/08; judgment of CA in Szczecin of 29 May 2014, I ACa 377/13; judgment of the Regional Court (RC) in Łódź of 7 September 2017, I C 1991/13; judgment of RC in Sieradz of 22 February 2017, I Ca 21/17.

104 Also, development risk defence is available to the producer (Art. 4493 §2 PCC).

legal writing has been given to modern, software-driven products and to cybersecurity¹⁰⁵).

53. As to the relationship between the notion of an *unsafe product* and product safety regulations, it is commonly accepted that the product which does not offer safety required by the administrative law can be deemed unsafe for the purpose of Article 449¹ § 3 PCC, whereas compliance with the safety requirements does not of itself exclude liability.¹⁰⁶

Emphasis put by the legislator on safety expectations and particular mention of ‘the information on the product’s features provided to the consumer’¹⁰⁷ led most commentators to discuss, which model of consumers’ expectations should be applied to assess the product’s safety. The majority view is that the test should be objective, based on a model of an *average consumer*, taking into account, however, features that are relevant for the social group or environment the addressee of the product belongs to, such as availability of information, level of knowledge and technical development.¹⁰⁸ Some authors argue that by referring explicitly to information provided to the consumer, the law allows to differentiate between the damage suffered by the user of the product and that suffered by a bystander. In the former case, the information attached to the product would shape the consumers’ expectations while in the latter case they could be disregarded.¹⁰⁹

Relying by the Polish law on the notion of an ‘unsafe product’ resulted in a disproportional amount of effort put into discussing the liability for things which are dangerous by their nature (products dangerous *per se*, such as knives, toxic substances, fireworks). The dominant view is that such products are not ‘unsafe products’ for the purpose of Article 4491 §3 PCC, unless they are defective – their dangerous characteristics are different from what could be

105 BARANOWSKA & MACHNIKOWSKI, ‘Odpowiedzialność za produkt wobec rozwoju nowych technologii’, *Studia Prawa Prywatnego* 2017(2), p 44 et sq.

106 For example, BIELSKA-SOBKOWICZ, in *Kodeks cywilny: Komentarz*, No 13; BANASZCZYK, in *Kodeks cywilny: Komentarz*, No. 31. To the contrary, however, judgment of the CA in Szczecin of 29 May 2014, I Aca 377/13.

107 It is clear that this formulation does not exclude liability for information defects to a non-buyer or a non-consumer; JAGIELSKA, *System Prawa Prywatnego*, vol. 6, *Prawo zobowiązań – część ogólna*, p 1017; GNELA, *Kodeks cywilny: Komentarz*, No. 30.

108 JAGIELSKA, *System Prawa Prywatnego*, vol. 6, *Prawo zobowiązań – część ogólna*, p 1016 et sqq.; GAWLIK, in KIDYBA (ed.), *Kodeks cywilny: Komentarz* vol. III (2014), Art. 4491 No. 9; DUBIS, in *Kodeks cywilny*, No. 15; RUCHAŁA & SIKORSKI, in *Kodeks cywilny: Komentarz*, No. 53; BANASZCZYK, in *Kodeks cywilny: Komentarz*, No. 28; judgment of the CA in Warsaw of 4 November 2008, I A Ca 526/08 and judgment of the CA in Szczecin of 29 May 2014, I A Ca 377/13.

109 RUCHAŁA & SIKORSKI, *Kodeks cywilny: Komentarz*, No. 53; BIELSKA-SOBKOWICZ, in *Kodeks cywilny: Komentarz*, No. 13; BANASZCZYK, in *Kodeks cywilny: Komentarz*, No. 29.

expected or there is inadequate warning or information about risks connected with the product.¹¹⁰

54. Various categories of defects (design, manufacturing and information defects) are sporadically mentioned in the literature, although the division is generally considered irrelevant under Article 449¹ §3 PCC.¹¹¹ However, as will be explained below, insufficient or lacking information about dangerous qualities of the product is sometimes given special treatment.

55. The risk/benefit test is rarely discussed in the legal writing and sometimes it is only presented as an alternative which has been rejected by the legislator, who opted for the consumer expectation test.¹¹² Nonetheless the risk/utility analysis is sometimes applied. This is related to the issue of avoiding liability by placing warnings and giving information about the danger. Although as a rule, information or warning about risks connected with the product do not exclude liability,¹¹³ it is held that the producer can avoid liability by placing a warning on the product, when the unsafe features of the product cannot be avoided and putting the product on the market is necessary because its benefits outweigh its risks¹¹⁴ or also when dangerous qualities of the product could be eliminated only at a cost so high that manufacturing and purchasing such a product would become uneconomic.¹¹⁵ This reasoning seems to be based on the assumption that inherently dangerous products lead to liability if benefits of their use do not outweigh risks.

110 See GAWLIK, in *Kodeks cywilny: Komentarz*, No. 11; BIELSKA-SOBKOWICZ, in *Kodeks cywilny: Komentarz*, No. 13; DUBIS, in *Kodeks cywilny: Komentarz*, No. 13; RUCHAŁA; SIKORSKI, *Kodeks cywilny: Komentarz*, No. 49; BANASZCZYK, in *Kodeks cywilny: Komentarz*, No. 36; judgment of CA in Białystok of 29 April 2016, I ACa 20/16; judgment of CA in Szczecin of 29 May 2014, I ACa 377/13.

111 JAGIELSKA, *System Prawa Prywatnego*, vol. 6, *Prawo zobowiązań – część ogólna*, p 1014 et sqq.

112 JAGIELSKA, *System Prawa Prywatnego*, vol. 6, *Prawo zobowiązań – część ogólna*, p 1016 et sqq.

113 For example, GAWLIK, in *Kodeks cywilny: Komentarz*, No. 9; judgment of CA in Szczecin of 29 May 2014, I ACa 377/13.

114 RUCHAŁA & SIKORSKI, *Kodeks cywilny: Komentarz*, No. 58; CA in Kraków in its judgment of 9 June 2015, I ACa 1469/14. In this case a patient leaned against the door of a cryogenic chamber during the treatment and broke her leg because the magnetic lock didn't prevent her from falling out. The court held that the chamber was properly designed, because the magnetic lock was necessary to enable patients to leave the chamber quickly (which was essential for security reasons), yet the lack of warning about the risk of falling out constituted its defect. Similarly RC in Łódź in its judgment of 7 September 2017, I C 1991/13 held the producer of a car battery liable for damage resulting from the explosion of a battery during its charging, caused by the user's failure to open the cells (which is a case of foreseeable misuse of the product), because the information of the proper way of charging was deemed insufficient and cell lids were covered with a sticker.

115 JAGIELSKA, *System Prawa Prywatnego*, vol. 6, *Prawo zobowiązań – część ogólna*, p 1018 et sqq.

56. The victim has to prove the existence of the defect, but not its cause.¹¹⁶ There is a tendency in the legal writing to exempt the victim from the duty of proving a defect when she has proven that the damage resulted from the ordinary use of the product,¹¹⁷ although this view is controversial.¹¹⁸

9. Portugal

57. The regime of civil liability of the producer is provided for in Decree-law¹¹⁹ no. 383/89,¹²⁰ which implemented the Directive 85/374/CEE¹²¹ into the Portuguese legal system.¹²²

There are few cases where the producer liability regime is applied in Portuguese case law.¹²³ The notion of defect, however, is the object of plenty of case law on contractual non-performance,¹²⁴ when the plaintiff claims a defect in the sold good, or *a propos* the rendering of a service by the builder within a building contract.

116 GNELA, 2009, p 39.

117 NESTEROWICZ, 'Odpowiedzialność za produkt' (*Kwartalnik Prawa Prywatnego*) 2003(4), p 479; Gawlik, in *Kodeks cywilny: Komentarz*, No. 14; BANASZCZYK, in *Kodeks cywilny: Komentarz*, No. 37. See also judgment of CA in Warsaw of 4 November 2008, I ACa 526/08, where an argument was made that the proof of defect is often impossible (e.g., if the product in question has been destroyed) or very difficult. Similarly in the judgment of RC in Lublin of 25 January 2018, II Ca 852/17 and the judgment of RC in Poznań of 30 May 2017, XVIII C 606/15 (the judgment itself is highly controversial, as the court – two years after the CJEU decision in the *Boston Scientific* case – did not hold defective the cardiac defibrillator which repeatedly generated inadequate discharges, because it has established that the most likely cause of those discharges was not a defect in the material or manufacturing, but the damage to the defibrillator which resulted from its 'standard operation').

118 It has been rejected e.g., in RUCHAŁA & SIKORSKI, in *Kodeks cywilny: Komentarz*, No. 80. In the case law strict adherence to the rule on distribution of burden of proof as designed by Art. 4 PLD was advocated in the judgment of CA in Szczecin of 29 May 2014, I ACa 377/13. Supreme Court in its judgment of 2 October 2015, II CSK 816/14 also did not depart from the wording of Art. 4 PLD and Art. 6 PCC. This approach was taken to the extreme by RC in Białystok in its judgment of 14 February 2013, II Ca 12/13, where the court expected the victim to prove the defect of the glass bottle of mineral water even though it has been indisputable that she has hurt her hand when the bottle cracked during opening and its remains has been disposed of.

119 Hereinafter, 'DL'.

120 *Decreto-lei* 383/89, from 6 November 1989, in *Diário da República* no. 255/1989, Series I of 6 November 1989, which implemented the Directive 85/374/CEE in liability arising out of defective products.

121 Hereinafter, 'the Directive'.

122 The Directive 85/374/CEE was revised by Directive 1999/34/CE, which was in turn implemented into the Portuguese legal system by *Decreto-lei* 131/2001, from 14 April 2001, in *Diário da República* 96/2001, Series IA of 24 April 2001.

123 MORAIS CARVALHO, *Manual de Direito do Consumo* (2020), p 359.

124 For example, 24 March 2017, 14 December 2016, 4 October 2016, 15 September 2016, 2 June 2016, 26 February 2015 and 9 September 2016.

Portuguese Civil law has been significantly influenced by German Civil Law, and this may justify the fact that the distinction between design defect, manufacturing defect and instruction defect can be found in Portuguese law as well.¹²⁵

58. Most of the Portuguese legal scholarship qualifies producer liability as objective liability. Authors consider that the exclusion of liability does not result from the absence of fault, but from objective unenforceability (*inexigibilidade objetiva*): throughout the Decree-Law, liability depends only upon the circumstances inherent to the product (namely, the absolute impossibility of science and technique to find out the existence of the defect) and not of circumstances inherent to the producer.¹²⁶ The latter can only be exempted from liability if he or she proves that he adopted the standard of care of an ideal (not a standard) producer. However, once the liability for development risks may be excluded, it is considered that the objective liability of the producer does not encompass the whole business risks¹²⁷ and thereby is considered limited¹²⁸ and closer to a liability with fault.¹²⁹

59. Product liability is premised upon damage caused by a defective product.

Article 4(1) provides on the circumstances where a product is defective, and it exactly mirrors Article 6(1) of the Directive. According to DL no. 383/89, a defective product is, thus, equivalent to an unsafe product,¹³⁰ and is (at least exclusively) unrelated to the lack of qualities to realize the purpose that it is aimed at,¹³¹ which is

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- 125 MOTA PINTO & CALVÃO DA SILVA, 'Garantia de bom funcionamento e vícios do produto. Responsabilidade do produtor e do distribuidor', *Coletânea de Jurisprudência* 1985, III, pp 19-29, at 20; CALVÃO DA SILVA, *Compra e venda de coisas defeituosas: conformidade e segurança* (2002) p 655 et sqq.; D MONTENEGRO DA SILVEIRA, *Responsabilidade civil por danos causados por medicamentos defeituosos* (2010), p 148. In case law, STJ 2 June 2016 (proc. 2213/108TVLS13.L1S1, rep. Orlando Afonso), last retrieved from, www.dgsi.pt (12 October 2018) and STJ 8 November 2001, *Coletânea de Jurisprudência*, IX, III, p 108.
- 126 CALVÃO DA SILVA, *Responsabilidade civil do produtor* (1990), p 513; SILVA CAMPOS, 'A responsabilidade objectiva do produtor pelos danos causados por produtos defeituosos', *Tribuna da Justiça*, 39, Mar. 1988 (1990), p 7-9, at 16.
- 127 TRIGO, *Responsabilidade civil do produtor: o estado da arte na jurisprudência nacional e a natureza da responsabilidade*, in J. Lobo Moutinho, S. Vicente, P. Garcia Marques & E. Vaz de Sequeira (coords) *Homenagem ao Professor Doutor Germano Marques da Silva, Vol. III* (Lisboa: Universidade Católica Editora 2020), p 1690.
- 128 CALVÃO DA SILVA, *Responsabilidade civil do produtor*, p 517.
- 129 CALVÃO DA SILVA, *Compra e venda de coisas defeituosas: conformidade e segurança*, pp 503 et sqq.; MONTENEGRO DA SILVEIRA, *Responsabilidade civil por danos causados por medicamentos defeituosos*, p 250.
- 130 TRIGO, in *Homenagem*, p 1673.
- 131 SILVA CAMPOS, *Tribuna da Justiça*, 39, Mar. 1988 1990, p 8; MONTENEGRO DA SILVEIRA, *Responsabilidade civil por danos causados por medicamentos defeituosos*, pp 139-140; M FROTA, 'Sobre a responsabilidade civil do produtor e a garantia do seguro', 413. (*Boletim do Ministério da Justiça*) 1992, pp 5-28, at 21; MONTENEGRO DA SILVEIRA, *Responsabilidade civil por danos causados por medicamentos defeituosos*, p 232; N COSTA MAURÍCIO, 'A responsabilidade do produtor pelos danos causados por produtos

the decisive concept to apply the guarantee and contractual liability). Intrinsically unsafe products (such as tobacco) are not considered defective.¹³²

60. The law does not require that the product offers an absolute safety, but only the safety one can legitimately count upon.

According to some scholars, the safety which the article refers to is the one which the *consumer* may expect; according to others, it is instead the safety that the *public at large* may expect,¹³³ i.e., the safety which is normally expected in regular transactions in a given consumer sector.¹³⁴ Courts have attended to the expectations of the public at large in several cases,¹³⁵ but more recent jurisprudence of the Supreme Court of Justice gives relevance to both the expectations of the consumer and the public at large.¹³⁶

In either case, such safety is understood as having to be assessed on a case-by-case basis, taking into account the peculiarity of the product at hand and all circumstances of the case, such as the presentation of the product, the use to which one could reasonably expect the product would be put to and the moment when it was put in circulation.

61. Other relevant factors which, according to case law and legal scholarship, may be taken into account in such assessment are: the technical rules in force at the time of commercialization¹³⁷; the nature of the product; its price; its importance and utility for humankind; the viability of a safer, substitute or alternative product; the probability of the damage and the possibility of avoiding the defect by the user¹³⁸ and, finally, the possibility of eliminating the defect,¹³⁹

defeituosos: regime legal e implemento na prática forense', *Revista Portuguesa de Direito do Consumo*, 25, March 2011, Coimbra, pp 9-49, at 24. STJ 2 June 2016 (proc. 2213/108TVLS13.L1S1, rep. Orlando Afonso), last retrieved from, www.dgsi.pt (12 October 2018).

132 SOUSA ANTUNES, 'Apontamentos sobre a responsabilidade civil do fabricante de tabaco', *Direito e Justiça*, Ano XVII 2003, pp 171-204, at 191-192.

133 MONTENEGRO DA SILVEIRA, *Responsabilidade civil por danos causados por medicamentos defeituosos*, pp 140-141. Decision of the Court of Appeal of Lisbon of 27 February 2007 (proc. 9460/2006-7, rep. Roque Nogueira) and STJ 8 November 2001, *Colectânea de Jurisprudência*, IX, III, p 108.

134 CALVÃO DA SILVA, *Responsabilidade civil do produtor*, pp 633 et sqq.

135 STJ 6 May 2003 (proc. 03A1132, rel. Afonso de Melo), last retrieved from, www.dgsi.pt (12 October 2018); STJ 8 November 2001, in *Colectânea de Jurisprudência*, Year IX, book III, p 108; Court of Appeal of Lisbon of 27 February 2007 (proc. 9460/2006, rep. Roque Nogueira).

136 STJ 9 September 2016 (proc. 63/10.0YFLSB, rep. Serra Baptista), last retrieved from, www.dgsi.pt (12 October 2018) and STJ 2 June 2016 (proc. 2213/108TVLS13.L1S1, rep. Orlando Afonso), last retrieved from, www.dgsi.pt (12 October 2018).

137 CALVÃO DA SILVA, *Responsabilidade civil do produtor*, p 633 et sqq.

138 Decision of the Court of Appeal of Lisbon of 27 February 2007 (proc. 9460/2006-7, rep. Roque Nogueira).

139 STJ 2 June 2016 (proc. 2213/108TVLS13.L1S1, rep. Orlando Afonso), last retrieved from, www.dgsi.pt (12 October 2018).

namely without prejudice to the utility of the product.¹⁴⁰ We may thus consider that courts have been using the relatively open-textured rule in the DL to remain open to risk-benefit considerations, thereby following the example of other European MSs.

62. Risk-benefit considerations are particularly relevant as regards to medicines, even though the DL does not expressly refer to them.¹⁴¹ The law regulating safety of medicines relies on a risk/benefit assessment.¹⁴² Every time the benefit of a given medicine is higher than the risk it poses, the patient must tolerate its secondary effects¹⁴³ that he or she should be previously made aware of. In a case decided by the Supreme Court of Justice in June 2016,¹⁴⁴ it was decided that a medical device aimed at detecting prostatic pathologies that have a false negative, thereby leading to a mistaken diagnosis of a cancer patient, was defective.

63. In a nutshell, the national legal community has not yet fully interiorized the regime established by Directive 85/374/CEE and implemented by DL 383/89, as can be shown by the fact that in the last 20 years there were few cases where that regime was (rightly) invoked.¹⁴⁵

10. Denmark, Norway and Sweden

10.1. Deconstructing Defect

64. Categories of defects, i.e., manufacturing, design and warning defects, are sometimes identified in doctrinal writings.¹⁴⁶ The categorization is mainly done for pedagogical reasons. Case law does not reflect different rules applying to the different categories and the definition of a defect in Article 6 of the Directive has not been supplemented in other ways by the courts. Legal literature emphasizes that the concept of a defect is to be assessed objectively.¹⁴⁷ At the same time, the evaluation must be concrete, i.e., take into consideration all of the relevant

140 CALVÃO DA SILVA, *Compra e venda de coisas defeituosas: conformidade e segurança*, p 191.

141 Montenegro da Silveira, *Responsabilidade civil por danos causados por medicamentos defeituosos*, pp 145-147.

142 Montenegro da Silveira, *Responsabilidade civil por danos causados por medicamentos defeituosos*, p 147.

143 Montenegro da Silveira, *Responsabilidade civil por danos causados por medicamentos defeituosos*, pp 145-146.

144 STJ 2 June 2016 (proc. 2213/108TVLS13.L1S1, rep. Orlando Afonso), last retrieved from, www.dgsi.pt (12 October 2018).

145 TRIGO, *supra*, n. 127, p 20.

146 Vibe ULFBECK, *Erstatningsretlige grænseområder* (Copenhagen, DJOEF 2010), p 181.

147 Vibe ULFBECK, *Erstatningsretlige*, p 193; HAGSTRØM & STENVIK (*supra*, n. 175) p 309 with reference to Rt. 2004.122, BLOMSTRAND & BROQVIST & LUNDSTRÖM, *supra*, n. 146.

circumstances in the situation where the damage was caused.¹⁴⁸ Case law concerning the criteria that may be taken into account mainly concern the impact of information on the product or instructions provided by the producer¹⁴⁹ and marketing efforts.¹⁵⁰ As to the criterion of avoidability, this is dealt with under the heading of system errors (see further below) and the overall theme of risk/benefit analysis.

Legal literature does not explicitly address the question whether risk-benefit considerations are relevant in determining whether a product is defective or not. However, the Scandinavian legal systems have since long recognized the concept of *system errors* which seems to contain some basic risk/benefit considerations.¹⁵¹ The concept deals with situations in which a product has a necessary, negative side effect that is generally accepted in society because the advantages of the product outweigh the disadvantages. A manufacturer cannot be held liable for this type of damage. Typical examples include damage caused by tobacco and alcohol.¹⁵² In order for the manufacturer to be exempted from liability for system errors, three conditions must be fulfilled: 1) the risk of damage must be unavoidable, 2) the risk must be generally known, 3) the risk must be generally accepted in society. A risk is considered unavoidable if it is not possible to produce the product with its desired main characteristics without at the same time generating undesired side effects. It can be discussed to what extent economic considerations can be taken into account when evaluating whether a risk is unavoidable.¹⁵³ For a risk to be generally known it must be generally known to the public.¹⁵⁴ With regard to the requirement that the risk must be generally accepted, public law regulation prohibiting or allowing the marketing of the product can be taken into account.¹⁵⁵

148 HAGSTRØM & STENVIK, *supra*, n. 147, p 309.

149 FED 2004.554 Ø an FED 2008.20 Ø.

150 FED 1994.604 Ø, FED 2000.2856 Ø.

151 On the concept of system errors, for Danish law: Børge DAHL, *Produktansvar*, 1973, 31, Vibe ULFBECK, *Erstatningsretlige*, Ch. 12, Norwegian law: HAGSTRØM & STENVIK, *supra*, n. 147, p 309, Swedish law: BLOMSTRAND, BROQUIST & LUNDSTÖM, *supra*, n. 146, p 80.

152 BLOMSTRAND, BROQUIST & LUNDSTÖM, *supra*, n. 146. Special liability and insurance schemes apply to pharmaceuticals, further below.

153 Vibe ULFBECK, *Erstatningsretlige*, p 229, pointing out that the fact that a manufacturer can increase profits by disregarding the risk of side effects does not make the risk ‘unavoidable’. On the other hand, a risk may be regarded as unavoidable if a risk-free product can only be produced at a loss for the manufacturer.

154 In the Norwegian case Rt 2003.1546, concerning the possible product liability for tobacco, the Norwegian Supreme Court found that after 1964 it had been generally known to the public that smoking entails a risk of negative impacts on health. For that reason, there could be no product liability for deaths caused by smoking that had been initiated after 1964.

155 Vibe ULFBECK, *Erstatningsretlige*, p 231.

65. The concept of system errors was originally viewed as an exception to the general rule on product liability. Today, the concept is regarded as embedded in the concept of a defect under the Directive. In other words, if a risk is unavoidable, generally known and generally accepted then the product will most often have ‘the safety which a person is entitled to expect’.¹⁵⁶

66. The system error concept has been relevant in several cases in Scandinavian law. Examples include the Norwegian Supreme Court decision Rt. 2004.122.¹⁵⁷ In this case, a dentist developed an allergy from working with a specific material for restoring teeth. The Supreme Court found that there was no product liability since the risk had been known to the plaintiff and ‘the damage causing ability of the product – with today’s technology – could be said to be a necessary side effect of the material’.¹⁵⁸ However, the court makes the reservation that it might be possible to impose liability even for system errors if the risk of damage is very small but the consequences very serious.¹⁵⁹ In legal literature it has also been argued that it is not possible to invoke the system error defence in case of manufacturing defects even if in a series of products – from an economic perspective – a certain number of defective products are unavoidable.¹⁶⁰

Arguably, the concept of the system error defence could become relevant for handling damages caused by various autonomous products with certain unavoidable side-effects.

67. Another area in which the concept is relevant is the pharmaceutical area. In pharma cases, the system error defence will most often have as consequence that there is no liability for the manufacturer for negative side effects of pharmaceuticals. For this reason, a special, state funded compensation scheme covers these situations in Danish law.¹⁶¹ The scheme allows the patient to obtain compensation for side effects that go beyond ‘what the patient can reasonably be expected to

156 Vibe ULFBECK, *Erstatningsretlige*, p 228.

157 On this case in general, HAGSTRØM & STENVIK, *supra*, n. 147, p 309, ASKELAND ‘Norway’ in P. Machnikowski (ed.), *European Product Liability - An Analysis of the State of the Art in the Era of New Technologies* (I2016), p 365.

158 Paragraph 34 in the decision.

159 This line of thought has not been further pursued in other cases or in legal literature. From Danish case law e.g., FED 2009.15 Ø concerning a weight loss product which had the negative side effect of causing heart disorder (no exemption from liability) and Ø 2003 2288 V concerning salmonella infected eggs (no exemption from liability).

160 Vibe ULFBECK, *Erstatningsretlige*, p 229. This corresponds with the fact that liability for fabrication errors is quite strict under Danish law, U 1999.255 H, FED 2004.1783 V.

161 Consolidated act no. 995 of 14 June 2018 on access to complaints and compensation in the healthcare system (the complaints and compensation act), Ch. 4. Similar systems exist in the other Scandinavian countries.

accept'.¹⁶² The scheme effectively pulls the cases out of the product liability domain. It has been in force since the mid 90s.

10.2. Defect and Standards

68. It is generally recognized that regulatory standards found in public law are relevant for the assessment of whether a product is to be regarded defective or not.¹⁶³ A product that does not live up to such standards is often presumed to be defective. However, the fact that a product lives up to such standards is no guarantee that the product is not defective. For example, private standards may supplement the public ones, and it may be necessary for the producer also to live up to such private standards.¹⁶⁴ If the defect is due to its living up to mandatory¹⁶⁵ public law standards, the manufacturer is exempted from liability (§7, sections 1, no 3.)

10.3. Time Frame

69. It is generally assumed that the point in time for determining whether a product is defective is at the time when it was put into circulation.¹⁶⁶ This rule seems to leave it to the injured party to prove that the product was defective at that time. However, part of Danish legal literature assumes that the relevant point in time is the time of the injury but combines this rule with the rule found in the Directive Article 7 b) that the producer may be exempted from liability if he can prove that the defect likely was not present at the time when the product was put into circulation.¹⁶⁷ For practical purposes, the difference between these two approaches may be limited. There is no case law concerning the question whether information relevant for determining whether the product was defective at the time when it was put into circulation can be used if this information has only become available subsequently.

11. Spain

70. The concept of defect in the Spanish regime of liability for defective products (Article 137 of the Ley General de Defensa de Consumidores y Usuarios) does not mention the classification of three different kinds of defect that is normally used by

162 § 43 in the complaints and compensation act.

163 ROSTOCK-JENSEN & KVIST-KRISTENSEN, *Produktansvar* (Copenhagen: DJOEF 2014), p 135, BLOMSTRAND, BROQVIST & LUNDSTRÖM, *supra*, n. 146, p 125, Hogström & Stenvik (*supra*, n. 175) p 311.

164 ROSTOCK-JENSEN & KVIST-KRISTENSEN, *Produktansvar*, 2004, p 135.

165 It has been discussed whether a public law regulation can be considered mandatory if it is possible to apply for an exemption, Hogström & Stenvik, *supra*, n. 163, p 311.

166 ROSTOCK-JENSEN & KVIST-KRISTENSEN, *Produktansvar*, 2004, p 142, Hogström & Stenvik, *supra*, n. 163, p 312, BLOMSTRAND, BROQVIST & LUNDSTRÖM, *supra*, n. 146, p 93.

167 Børge DAHL et al., *Produktansvar* (Juristen 1990), p 161.

scholarly writing.¹⁶⁸ Nevertheless, some Spanish legal writers have underscored that the LGDCU itself does know the classification – in manufacturing defect, design defects and defects of information – in its own wording.¹⁶⁹ On the other hand, the aforementioned classification is also known in the case law, although it has not been conclusive so far.¹⁷⁰

71. While dealing with design defects, it is also normal among Spanish authors to mention the risk-utility test. Some have put forward a position in favour of setting aside the consumer's expectation test and directly applying the risk-utility test in design defect cases.¹⁷¹ Some others, the majority I would say, suggest that the current test contained in Article 137 LGDCU (which refers to 'all circumstances...') is wide enough to encompass the use of the risk-utility test.¹⁷² It has been also said that complying with safety standards, the product's price and its manufacturing costs, are the circumstances that can be considered to ascertain whether the product is defective in its design.¹⁷³

72. The risk-utility test has been scarcely mentioned – not really used – in case law. After some years of hesitation, the courts have eventually begun to consider the defective products regime in some recent decisions than can be briefly mentioned.

73. (a) The Spanish Supreme Court decision (hereinafter, STS) 9 December 2010 (RJ 2011/1408) compensates the claimants that had to undertake an operation to remove breast implants that had been put into circulation by a manufacturer without making the appropriate tests to check whether or not it was safe to use a specific kind of oil as the filling for the implants. The *Tribunal Supremo* (Supreme Court, hereinafter SC) did not have any problem deciding that the product was defective – without even mentioning the risk-utility test – because the whole production of the implants did not provide the safety that it could legitimately be expected to provide. In the decision, it was immaterial that the toxicity of the product had not

168 As pointed out in legal doctrine., PARRA, 'Responsabilidad civil por productos defectuosos' in F REGLERO CAMPOS (ed.), *Tratado de responsabilidad civil* (5th ed., 2014), p 254; SALVADOR & RAMOS, 'Defectos de producto', in Salvador & Gómez-Pomar (eds), *Tratado de responsabilidad civil del fabricante* (2008), p 136. LGDCU is the Spanish acronym for the General Act on the Protection of Consumers and Users.

169 Gutiérrez Santiago, 'Aporías y distorsiones en el carácter «objetivo» de la responsabilidad civil por productos defectuosos', *Revista Doctrinal Aranzadi Civil-Mercantil* num 2014(1), p 12.

170 As highlighted by Martín-Casals & Solé, 'Product Liability in Spain', in Machnikowski (ed.), *European Product Liability* (2016), p 419. In case law, Supreme Court decision (hereinafter, STS) of 7 November 2008 (RJ 2009/137), STS 27 July 2005 (RJ 5101) and STS 19 February 2007 (RJ 1895).

171 RAMOS, *Responsabilidad civil por medicamento* (2004), pp 186 and 202.

172 SOLÉ, El concepto de defecto del producto en la responsabilidad civil del fabricante (1997), pp 163–164 and 401. PARRA, in *Tratado de responsabilidad civil*, p 250 highlighting the flexible character of the test in Art. 137 LGDCU.

173 As suggested by SALVADOR & RAMOS, *Tratado de responsabilidad civil del fabricante*, p 173 et sqq.

been ascertained. What made the product defective, in the eyes of the SC, was the fact that the product was put into circulation without previously checking its toxicity.

That STS is loosely based on the defective products regime. In it, the claimants were compensated for being temporarily unable to perform their normal activities during the treatment (I guess that they would have been compensated for loss of earnings, if they had suffered this kind of harm) and for the moral damage that represented the fear and anguish they suffered, the aesthetic harm that some of the claimants had sustained and, for one of the claimants, the moral damage represented by being unable to become pregnant for some time because of the surgical operation and the associated treatment. The cost of the operation in itself was not claimed because the operation was performed at a public hospital that had come to an agreement with the producer.

This STS bears some resemblance to the 5 March 2015 Boston Scientific decision of the Court of Justice of the EU, as some legal writers have pointed out.¹⁷⁴

74. (b) In the STS 28 May 2012 (RJ 3765), the SC found for the claimant that had been neurologically affected by a medicine called *Agreal* prescribed for women during menopause. The decision is based on an information defect, as the leaflet did not contain any references to the neurological side effects that the drug might entail, but Professor Parra has suggested that it should have been decided on the risk-utility test.¹⁷⁵

STS 10 July 2014 (RJ 2014) decided another case of the aforementioned *Agreal* medicine. In this occasion, the SC compensated the victims that had suffered neurological harm, but it did not consider that the claimants had been able to prove the link of causation between *Agreal* and the psychiatric or psychological harm that they have allegedly suffered.

In that 2014 STS, another issue was the role of the safety regulations from the point of view of products liability. Among the authors dealing with defective products, it has been said that, on the one hand, compliance with all applicable safety standards amounts to a presumption that the product is not defective; and, on the other hand, not complying with these standards gives rise to a design and/or information defect.¹⁷⁶

Commenting on this 2014 STS it has been said that the balancing of the medicine's benefits and risks that the public administration has to complete in order to decide whether or not to authorize it onto the market does not necessarily entail that the product is not defective when it causes disproportionate damage to a

174 PARRA, 'Sobre si un producto es defectuoso por los riesgos que presenta', *Revista CESCO de Derecho de Consumo* 13/2015, p 152 and RAMOS & GILI, 'El producto sanitario implantable que presenta un riesgo anormal de', *Revista CESCO de Derecho de Consumo* 13/2015, p 200. PAZOS, 'Un caso de responsabilidad por productos defectuosos', *Boletín do CEDE da USC*, p 30.

175 PARRA, in *Tratado de responsabilidad civil*, p 257.

176 SALVADOR & RAMOS, *Tratado de responsabilidad civil del fabricante*, pp 138 and 171.

concrete victim. The LGDCU does not use the risk-utility test to decide if the defendant should be liable but, instead, it uses the test of safety that can be legitimately expected and a medicine that causes *disproportionate* damage clearly does not comply with the required level of safety.¹⁷⁷

75. (c) According to Article 139 LGDCU, it is for the plaintiff to prove the link of causation between defect and damage. Thus, the rule coincides with the general rule on the burden of proof contained in Article 217 LECi for all kind of trials.¹⁷⁸

76. However, it has been said in Spanish case law that if the victim is able to prove that the product was defective, it suffices to consider that it has caused the harm. It is true that there must be a proof of a connection between the defective product and the harm,¹⁷⁹ but it is not necessary to prove what exactly went wrong with the product and where the defect came from.¹⁸⁰

12. Comparative Analysis and Concluding Remarks

12.1. *The Expert Group on Liability and New Technologies and the Topicality of Defect Within the Product Liability Directive*

77. For more than three decades, the Product Liability Directive 85/374/EEC¹⁸¹ (the Directive) has ensured that producers take responsibility for defective products towards consumers who suffer damage because of the use of such products.

The European Commission¹⁸² considered that, more than thirty years after the Directive came into force, many economic and technological developments had taken place and so it was necessary to reflect how the concepts of the Directive could be interpreted and applied today.

For such purpose, it created the Expert Group on Liability and New Technologies, which operates in the New Technologies formation and the Product Liability Directive formation.

78. The Product Liability Directive formation has two main tasks: to provide advice and expertise on the implementation of the Directive, and to assist the

177 PARRA, 'Comentario a la STS 10 julio 2014', p 97, *Cuadernos Civitas de Jurisprudencia Civil*, 2015, p 23.

178 *LECi* is the Spanish acronym for the Civil Procedural Act (Ley de Enjuiciamiento Civil).

179 As can be seen in STS 16 March 2007 (RJ 1859).

180 GUTIÉRREZ SANTIAGO, *supra*, n. 202, p 16; M A PARRA, *supra*, n. 207, p 5; PARRA, in *Tratado de responsabilidad civil*, p 18. In case law, STS 19 February 2007 (RJ 1895); STS 23 November 2007 (RJ 8122); STS 30 April 2008 (RJ 2686).

181 Council Directive 85/374/EEC of 25 July 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the MS Concerning Liability for Defective Products.

182 More specifically, the Commission's Directorate-General Internal Market, Industry, Entrepreneurship and SMEs ('DG GROW'), Justice and Consumers ('DG JUST') and Communications, Networks, Content and Technology ('DG CNECT').

Commission in drawing up guidance on the implementation of the Directive, attending to the jurisprudence of the Court of Justice and of national courts and to developments in new and emerging technologies and in product liability.

79. Several themes were discussed which revolved around the main concepts of the Directive and were based on the recurrent issues that have been stressed in the consultations and evaluation.

One such theme was the concept of defect. Indeed, in times where the industry is increasingly integrated into dispersed multi-actor and global value chains with strong service components, it is of the essence that both producers, who are strictly liable for defective products, and consumers, who must prove such defects, can rely on a clear regulatory framework.

The discussions on the topic of defect centred around the question of how to determine what a defect is, and, by extension, what are the levels of safety that a consumer is entitled to expect. Several points were brought for discussion, such as whether the concept of defect is a subjective or objective one, to what extent the notion of potential defect as accepted by the Court of Justice for medical devices can be of use for other types of products, whether unforeseen behaviour of autonomous agents can be considered a defect, and how to determine a defect when a product is connected to other products or services (smart products).

12.2. The Safety Standard and the Notion and Classification of Defects

80. Article 6 of the Directive provides for the definition of defective product, by focusing on ‘the safety which a person is entitled to expect’. After the Court of Justice’s *Boston Scientific* case,¹⁸³ such standard shall be understood as the one which ‘the public at large is entitled to expect’.

81. As has been mentioned earlier, the EU legislature showed an intention to leave some discretion to the courts in the application of the liability standard, which is also possible due to the open-textured nature of defect. The safety test is thus assessed on a case-by-case basis (see Portuguese report). The safety that the public is entitled to expect will differ according to the Member State where the case was brought before courts¹⁸⁴ thus potentially compromising the maximum harmonization the Directive purported to achieve.

82. As far as the expectation test is concerned, it has an objective nature both in Austria, Germany, Poland and The Netherlands while in Norway, Denmark and

183 ECJ 5 March 2015, *Boston Scientific Medizintechnik GmbH / AOK Sachsen-Anhalt*, <http://curia.europa.eu/juris/documents.jsf?num=C-503/13>.

184 *Schmon*, ‘Product liability of Emerging Digital Technologies: A Fitness Check of the 1985 Product Liability Directive’, *IWRZ* 6/2018, p 256.

Sweden expectations are assessed concretely. Along the European jurisprudence on this matter, in Portugal and in The Netherlands, it is stressed that this test relates to the expectations of the *general public* while in Poland it refers to what can be expected from the ordinary use of a product. Most importantly, and in the context of freedom, which is given to the courts by the provision, it is the court which decides to which expectations the general public is *entitled*.

83. In order to clarify the standard of safety, one of the issues which has also been considered is whether there should be a distinction between *design, manufacturing* and *instruction/warning* defects, such as there is in the US.

84. The Product Liability Directive does not contain such a distinction and neither do any of the legal systems analysed in this contribution except for Germany. Notwithstanding, this distinction is referred to by legal scholarship in all legal systems. Additionally, courts of several MS, particularly France, Poland, Spain and Portugal have referred to this distinction in their cases, albeit sometimes unknowingly as is the case of France.¹⁸⁵ This is in spite of the fact that there are still few court cases on defectiveness (as in France and in England and Wales) – perhaps because most cases are decided out of court (as in The Netherlands) – and also because the ones that do decide on defectiveness usually do so with regards to transactions of defective goods, so within contractual relationships (as in Portugal). Within this context, it is interesting to note the Polish solution, where the legislature referred to ‘unsafe’ instead of ‘defective’ products to distinguish the supervening defects in things which were the objects of contracts, particularly sale contracts.

85. In a nutshell, despite the fact that most European statutes on product liability do not provide for the classification of defects, European courts do distinguish between manufacturing defects (to which the consumer expectation test is applied) and design and instruction defects (to which they also apply other tests, such as the risk-benefit test).¹⁸⁶

12.3. The Risk-Benefit Test in the Context of the Assessment of Defect

86. The risk-benefit test is used in US law for design defects, where a product is considered defective if the costs of taking precautions are lower than the benefits provided by the product using a global perspective.

In Europe, where there is still a shy support of the Law & Economics approach as compared to the US, this test is less used.

185 BORGHETTI, ‘Product Liability in France’, in MACHNIKOWSKI (ed.), *European Product Liability Directive. An Analysis of the State of the Art in the Era of New Technologies* (2016) p 216.

186 FAIRGRIEVE et al., ‘Product Liability Directive’, in MACHNIKOWSKI (ed.), *European Product Liability Directive. An Analysis of the State of the Art in the Era of New Technologies* (2016) p 53.

87. The Product Liability Directive does not explicitly include risk-benefit considerations, but it does not explicitly exclude them either. Therefore, whether these considerations can be included in the Directive's scope is controversial.¹⁸⁷

Several arguments speak against the inclusion of risk-benefit considerations in the Directive.

88. Firstly, the Directive does not refer to such considerations but to the 'safety which a person is entitled to expect' and in recitals 2 and 7 it reads that 'liability without fault (...) is the sole means of (...) solving the problem (...) of *a fair apportionment of the risks* inherent in modern technological production' which seems to be made prevail over a mere weighting of costs and benefits.

89. Secondly, the risk-benefit test evokes a fault-based system, which is at odds with the no-fault regime created by the Directive as shown in Articles 1 and 6 and its recitals (as stated also in the *A v. National Blood Authority* case referred to in England and Wales¹⁸⁸).

90. Thirdly, the risk-benefit test introduces an exemption clause which is not included in the - intended to be closed - list contained in Article 7 of the Directive. Indeed, it can be argued that the option for the MS to allow for the development risk defence, in Article 7 lit e) - including the inability to notice a design defect given the current state of knowledge - excludes the possibility for a risk-benefit assessment as the defence is a sort of negligence consideration but employs a much higher standard of due diligence.

91. Further, one view is that the use of this test would hamper compensation claims by victims of pharmaceutical product-related damage.

92. Finally, the cases where the global risk-benefit analysis is applied presents the very same factor that justifies the application of a strict liability rule in manufacturing defect cases. This factor is the foreseeability of the risk of damage in advance in statistical terms, which enables the producer to manage its cost through insurance or a proportional price increase.¹⁸⁹ Therefore, the balance between the interests of the injured parties and those of the producers settled by the Directive is not altered.

187 MACHNIKOWSKI, 'Conclusions', in MACHNIKOWSKI (ed.), *European Product Liability Directive: An Analysis of the State of the Art in the Era of New Technologies*, 2016, p 695.

188 *A v. The National Blood Authority* [2001] 3 All ER 289, at 57-63 apud OLIPHANT & WILCOX, 'Product Liability in England and Wales', in MACHNIKOWSKI (ed.), *European Product Liability Directive: An Analysis of the State of the Art in the Era of New Technologies*, 2016, p 189.

189 RAJNERI, 'La notion de défectuosité du produit dans les jurisprudences des pays européens', *La Revue Internationale de Droit Comparé* 2015, pp 185-205.

93. On the other hand, one could argue that these considerations should have a place in judicial practice particularly for three main reasons.

Firstly, *design defects* seem to imply some of these considerations.

Secondly, risk-benefit considerations can feed into the assessment of whether the lack of safety is socially acceptable and should thus not amount to a defect. In Austria economic affordability seems to be considered one of the circumstances to be assessed, even though it should not be decisive.

Finally, the placement in the market of pharmaceuticals and medical products is preceded by the application of such a risk-benefit test and there is a general agreement¹⁹⁰ for the possibility of applying it while assessing whether such products should or should not be considered defective. Curiously, this same argument has been used to reach the opposite conclusion. Because the Regulator has already applied the risk-benefit test, there is no reason why the judge should duplicate the same test in a trial among individual interests.¹⁹¹

94. In either case, despite some doctrinal discussion (see England and Wales, Austria, Spain and France), in many MS there is little academic discussion on whether the risk-benefit test should be accepted.

In Poland, Spain, England and Wales it is often presented as the rejected alternative to the consumer expectation test and in Sweden, Norway and Denmark the concept of system errors is used as a functional equivalent to the risk-benefit test.

95. As far as the judicial practise is concerned, and except for England and Wales (and France in the context of pharmaceuticals), references to this test in case law are almost always implicit (see Italy, Norway, Spain, Sweden, Denmark, Poland and Austria).

96. There is a relatively widespread practical relevance which has been given to the test in specific contexts (see England and Wales), albeit not decisively (see France). Some legal scholars in France and courts in France, England and Wales have recognized that this test can play a role in the assessment of the degree of safety risk that the public would be expected to tolerate.¹⁹² Those specific instances are, namely, the cases of design defects (see Germany, France¹⁹³ and Spain), pharmaceuticals and medical products (see France, The Netherlands,¹⁹⁴

190 It should be noted that despite this agreement there is no consensus, as can be shown by the strong opposition of patients' organizations.

191 VISCUSI, *Reforming Products Liability* (1991), p 2.

192 See however, RAJNERI, 'La notion de défectuosité du produit dans les jurisprudences des pays européens', *La Revue Internationale de Droit Comparé* 2015, pp 185-205.

193 BORGHETTI, in *European Product Liability Directive. An Analysis of the State of the Art in the Era of New Technologies*, p 216.

194 KEIRSE, 'Product liability in The Netherlands', in MACHNIKOWSKI (ed.), *European Product Liability Directive. An Analysis of the State of the Art in the Era of New Technologies*, 2016, p 323.

Germany, Spain and England & Wales) or when the risk is unavoidable and has been brought to users' attention in the product description, instructions, etc. (see Poland and Spain). In the latter case, this means that if the product's side effects are not substantial enough when compared to the advantages of the medicine, the product might not be seen as defective, provided the producer has warned of these potential side effects.¹⁹⁵

97. Undoubtedly, only the CJEU can make a binding decision on whether the risk-benefit criterion is permitted or not. This is such an important problem of interpretation of Article 6 of the directive that it should not be left to the national courts. Divergent concepts of defect mean that the burden on businesses and the level of consumer protection varies between Member States.

98. If the Court were to face this problem, it would first have to determine whether the consumer expectation test applied in Article 6 is of a subjective (empirical) nature, i.e., it refers to the real expectations of safety that consumers have, or whether it is an objective (normative) test and involves a certain abstract (and, in fact, court-determined) level of safety to be achieved by products.

99. Adopting the first view would no longer leave room for examining the risks and benefits associated with putting a product on the market. However, this view has at least three important disadvantages. It takes away the meaning of the word 'entitled' in Article 6. It raises procedural problems linked to the need to establish the content of the expectations of a given consumer community – these are, according to this approach, a fact that needs to be established in the process. Finally, it leads to a situation in which the duties and responsibilities of entrepreneurs depend directly on the ideas that exist in a given community about what qualities products are supposed to have, regardless of whether these ideas are realistic at all. The latter must be seen in the context of technological progress and, in particular, the development of artificial intelligence and automation of devices. It seems (although we do not know any research on the subject) that, as this progress is made, the gap between common expectations about the safety of devices and their actual safety is growing. Social reactions towards accidents involving autonomous vehicles are an example of this phenomenon. The number of these accidents in relation to the number of kilometres travelled is not significant, and yet they are perceived as evidence of the lack of sufficient safety of these devices. This may indicate that there are expectations in society of 100% safety of digital technologies, which any expert would consider unrealistic. If producers' liability were to be based on failure to meet such expectations, it would be

195 KEIRSE, in *European Product Liability Directive. An Analysis of the State of the Art in the Era of New Technologies*, p 323.

excessive. This would result in a slowdown in technological development or, more likely, worse access to modern products for consumers from EU countries.

100. If, instead, consumer expectations were to be understood objectively (normatively), and such a view seems to dominate, then it is necessary to formulate a normative model of these expectations. It is therefore necessary to indicate what criteria determine whether a given expectation of safety is reasonable or justified, and therefore to what level of safety the society is entitled. Various cost-benefit analyses could be such a criterion if they are consistent with the axiological foundation of the liability system provided for in the directive. This foundation is the fair apportionment of risks inherent in production between the injured person and the producer. It is doubtful whether the risk-benefit test in its basic US variant, namely comparing the additional safety brought by an alternative safer design with the cost of such a design, corresponds to this principle. However, another version of the test which is a general comparison of the product's overall benefits with its overall risks can be assessed differently. In this case, account is taken of the benefits that the public (and therefore, at least potentially, also the victim) derives from the presence of the product on the market with its overall risks. This does not seem to contradict the philosophy of the directive in the opinion of most.¹⁹⁶ The use of this test as a criterion for assessing the legitimacy of consumers' expectations as regards product safety would probably lead to a distinction being made between different categories of product, for which the required level of safety would be different. Medicines and medical devices and similar products that meet important social needs, for example, would therefore be treated differently from objects that are purely for entertainment or pleasure. As far as the former are concerned, the social benefit of their existence would perhaps make it necessary to tolerate a certain risk associated with them, if that risk were unavoidable (although the need for social solidarity for the victims cannot be neglected). As for the others, it might be reasonable to expect complete safety.

¹⁹⁶ See however, RAJNERI, 'La notion de défectuosité du produit dans les jurisprudences des pays européens', *La Revue Internationale de Droit Comparé* 2015, pp 185-205.

