Sebastian Lohsse/Reiner Schulze/Dirk Staudenmayer (eds.)

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Münster Colloquia on EU Law and the Digital Economy IV

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Product Liability and Product Security: Present and Future

*Cristina Amato**

I. Introduction

According to Art 6 para 1 Directive 1985/374/EC ('PLD'), an unsafe product is a defective product that may result into producer's liability. In the European legislator's intent, Art 6 seems to implement the following syllogism: defect is an objective notion that refers to safety, not to utility;[1] the identification and qualification of the properties of a product depend on what the public at large expects. Consequently, it is up to the courts to determine the legitimate safety expectations of the public at large. The legitimate expectations of a person concerning safety represent an objective standard, assessed on the public's expectations but not on the injured. It is, therefore, a normative standard, not a factual one.[2] The *nobile officium* of

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1 Directive 1985/374/EC recital 6: 'whereas, to protect the physical well-being and property of the consumer, the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect'. See Hans C Taschner, 'Product Liability: Basic Problems in a Comparative Law Perspective' in Duncan Fairgrieve (ed), *Product Liability in Comparative Perspective* (Cambridge University Press 2006) 159: 'Whether a product is serviceable or not does not apply here. Serviceability is a term which is appropriate to be used for the law of sales. But the question here is not whether the product worked or not (...). The goal is to protect life and limb, and to a certain extent the property, of the product user. The corresponding notion to this requirement is safety, not utility'. See more recently the Commission Notice of 5 April 2016, the 'Blue Guide' on the implementation of EU product rules 2016 C(2016) 1958 final ('the Blue Guide'), 12: 'The fact that a product is not fit for the use expected is not enough. The Directive only applies if a product lacks safety'.

2 *A v National Blood Authority* [2001] 3 All ER 289: it was a very well-known English case concerning recovery of damages arising out of the patients' infection with Hepatitis C; the blood was considered defective under Article 6 PLD and the defendants had no escape within Article 7(e). See also Cees C van Dam, 'Dutch Case Law on the EU Directive', in Duncan Fairgrieve (ed), *Product Liability in Comparative Perspective* (Cambridge University Press 2006) 129: in a case concerning transfused blood containing the hepatitis C virus, it was held that, even though one

judges in determining the legitimacy of the public's expectations is a delicate and a hard one.

To sum up: there are only three conditions for a product liability claim, enumerated in Article 4 of the PLD: damage, defect and causation. The producer's conduct is entirely unimportant. The producer's liability is 'defect' based, not 'fault' based. Foreseeability or avoidability is irrelevant. 'Defect' is an objective notion. It refers to safety, and to nothing else. The identification and qualification of the properties of a product depend on what the public at large, not the consumers, believes. It is up to the courts to decide what the public at large believes.[3]

The safety or the degree or level of safety depends on what persons generally are entitled to expect, that is, on what their legitimate expectations are.[4] The test is not that of an absolute level of safety: the degree of safety is reduced to a question of social acceptance.

In this reasoning, safety is reduced to a discretionary, though objective, notion hold tight to social circumstances: a) the presentation of the product; b) the use to which it could reasonably be expected that the product would be put; c) the time when the product was put into circulation (art 6 para 1 PLD). The argument is that once the mass and large-scale production gets the better of the market, the crucial test for defectiveness rests on the relationship between safety and liability. Defectiveness does not neces-

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could argue that *the actual expectations* of the public probably were that some transfused blood was infected with viruses, a recipient could legitimately expect that the blood he got would be perfectly safe. In a similar case where a patient received HIV-infected blood during heart surgery, the district court of Amsterdam reached the same conclusion. The court held that, taking into account the importance of blood products and the lack of an alternative, the general public is entitled to expect that blood products in the Netherlands have been 100% HIV-free for some time. Even if there was a small statistical chance of infection, this does not relate to the legitimate expectations of the public (Rb Amsterdam 3 February 1999, NJ 1999, 621).

3 Hans C Taschner, 'Product Liability: Basic Problems in a Comparative Law Perspective' in Duncan Fairgrieve (ed), *Product Liability in Comparative Perspective* (Cambridge University Press 2006) 161. See also: Daily Wuyts, 'The Product Liability Directive – More than Two Decades of Defective Products in Europe': 'The standard of liability is the defectiveness of the product at hand and not the negligence or fault of the producer' JETL 1 (2014) 8.

4 *A v National Blood Authority* [2001] 3 All ER at 31, where Burton J ruled that '"legitimate expectations" rather than "entitled expectations" appeared to all of us to be a [happier] formulation'.

sarily refer to safety, and safety cannot be limited to a social perception: it can provide judges with an objective criterion to determine the expectations that the public at large is entitled to demand. My argument is that, the harmonised technical standards should represent the fundamental link[5] between safety and defectiveness: judges should rely on them in order to assess the level of risk that the public is legitimately entitled to accept. The final goal, on the one hand, is to design an *idealtypus* of the product (in any market sectors) that may reduce – though not eliminate – judges' discretionary power; on the other hand, the goal is also to provide a better balance between users' protection and producer's liability.

II. At the Roots of the Problem: National Courts and the Burden of Proof of Defectiveness

European and national courts apparently do not pay the necessary attention to the relationship between product's liability and general product safety. Concerning the burden of proof, the distance from general product safety is demonstrated by the uncertainty in the national courts. In particular, the first condition to assess producer's liability (ie, defect), as enumerated in Art 4 of the PLD, deserves some considerations in regard to the burden of proof. The PLD does not define the standard of proof, it simply states that: 'The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage' (Art 4 PLD). According to European reports,[6] courts should facilitate the burden of proof on claimants. In some situations, proof of the defect poses difficulties for the consumer because of the technical complexity of certain products, the high costs of expert evidence, the parties' unequal access to information (particularly about the production process) and the fact that some products are not retrievable after they have been used (eg, defective fireworks). Therefore, there is much liberty for Member States' courts and courts' discretion in assessing the defectiveness of a product.

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5 U Carnevali, 'Prevenzione e risarcimento nelle direttive comunitarie sulla sicurezza dei prodotti' (2005) 1 Responsabilità civile e previdenza 3–20.

6 COM (1999) 396 final [20]–[22] (Green Paper on liability for defective products) and COM (2000) 893 final, [13]–[15] (Report from the Commission on the Application of Directive 85/374 on Liability for Defective Products).

Although courts have to take into account other possible explanations of the damage, one cannot lose sight of the fact that the claimant has sufficiently proved the defect if he gives evidence that the product did not provide the safety he was legitimately entitled to expect. It would infringe the purpose of the PLD and the definition of 'defect' to expect the claimant to prove the exact cause or nature of the defect. Thus, in cases concerning the defectiveness of breast implants that prematurely ruptured, the Italian High Court affirmed that the products' defect is a binding evidence of the producer's liability.[7] Contrary to that, an English court refused to infer the defectiveness of the breast implants merely from the fact that they had malfunctioned and in the absence of probable proof of what exactly went wrong.[8] In one more well-known case, the English Court of Appeal ruled that the mere fact that a product deviates from the production standards does not prove the existence of a defect.[9] Moreover, usually High Courts take into account the target group (ie, children) and the legitimate safety expectations of the public on the target group.

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7 Cass. civ. (3) No 20985 of 8 October 2007 (2008) 2 Responsabilità civile e previdenza 354ff, note U Carnevali, 'Prodotto difettoso e oneri probatori del danneggiato'.

8 *Foster v Biosil* [2000] 59 BMLR 178, where the Plaintiff alleged that the breast implants, manufactured by the defendant, were defective in that the left implant ruptured prematurely, and the right implant leaked silicone. Consequently, both implants had to be removed.

9 *Tesco Stores Ltd v Pollard* [2006] CA, Civil Division (EWCA Civ) 393: it was held that, even though a manufacturing glitch made a container of dishwasher powder less childproof than it was intended (the child ate the powder), the container was still safe enough to live up to the public's legitimate expectations and, therefore, not defective. On the facts, the Judge held that the legitimate expectations of the public only extended so far as it could expect a child-resistant cap to open with more difficulty than a regular one and ruled by this standard that the product was not defective. See also *Richardson v LRC Products Ltd* [2000] Lloyd's Rep Med 280, where it was alleged that a condom burst during a sexual intercourse and that the claimant conceived as a result. Nevertheless, the court held that the condom was not defective and rejected the claim. One interpretation of this judgment is that, even if it could be proved that the rubber was damaged before it left the factory, the condom was not defective because the public knows and accepts the risk that a small proportion of condoms will burst in the course of use, and it does not matter whether this is by way of a large rupture or a small invisible tear. Therefore, the legitimate safety expectation is not that a condom provides 100% protection from the risk of conception.

A consolidated judicial technique comprises the use of presumptions. In the case of bursting bottles, in particular, the *res ipsa loquitur* reasoning has been largely used by Member States' courts.[10] In one important Italian case,[11] a surgeon suffered damages in using forceps that provoked him with a paraesthesia of two of the right hands' fingers. The surgeon alleged the producer's liability for the defectiveness of the forceps, but the Italian High Court ruled that the injured asking for damages shall give evidence of the foundations of the affirmed right. To this purpose, it is not sufficient for the injured person to infer the defect from the very causality relationship between the use of the product (the forceps) and the personal injury suffered (the paraesthesia), thus transferring on the producer the burden of proving that the product was not defective, or the burden of proving the exemptions (listed at Art 7 PLD). Nevertheless – the Italian High Court continues – this argument does not exclude presumptions: they can be still used, provided that they are serious, specific and consistent.

Seeking help from presumptions, this approach has recently been affirmed by the European Court of Justice,[12] according to which such rules do not require the victim to produce, in all circumstances, certain and irrefutable evidence of a defect in the product and of a causal link between the defect and the damage suffered, but authorise the court, where applica-

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10 SAP Cadiz of 16 March 2002, JUR 2002, 140327; Trib Rome of 17 March 1998, Foro It 1998, 3060; Rb Namen of 21 November 1996, JLMB 1997, 104; Antwerpen of 10 January 2000, RW 2004–2005, 794 and HR 24 of December 1993, NJ 1994, 214. In all these cases, national courts applied the *res ipsa loquitur* rule in establishing the evidence of the defect.

11 Cass. civ. (3) No 13458 of 29 May 2013 (2013) I Foro italiano 2118, overruling the previous approach of the 'Corte di Cassazione' No 20985/2007 (n 7). In Germany, most influential are the cases of the exploding sparkling water bottles, close to the tripartite American approach distinguishing manufacturing, design and warning defects: Bundesgerichtshof (Federal Court of Justice, BGH) Neue Juristische Wochenschrift (NJW) 1995, 2162. See: S Lenze, 'German Product Liability Law: Between European Directives, American Restatements and Common Sense', in Duncan Fairgrieve (ed), *Product Liability in Comparative Perspective* (Cambridge University Press 2006) 107–113. cf also in Belgium: Rb Namen of 21 November 1996, Revue de Jurisprudence de Liège, Mons et Bruxelles (JLMB) 1997, 104. In this case the producer argued that the consumer had exposed the bottle to extreme changes in temperature, making it more fragile. However, the Belgian court held that it was foreseeable to the producer that consumers might chill their soda bottles, especially during the summer.

12 European Court of Justice of 21 June 2017, Case C–621/15 *W and Others v Sanofi Pasteur MSD and Others*, paras 28–29.

ble, to conclude that such a defect has been proven to exist, on the basis of a set of evidence the seriousness, specificity and consistency of which allows it to consider, with a sufficiently high degree of probability, that such a conclusion corresponds to the reality of the situation. However, such evidentiary rules do not bring about a reversal of the burden of proof which, as provided for in Article 4 of Directive 85/374. It is for the victim to discharge, since that system places the burden on the victim to prove the various elements of his case which, where applicable, taken together will provide the court hearing the case with a basis for its conclusion as to the existence of a defect in the vaccine and a causal link between that defect and the damage suffered.

This recent approach on presumptions confirms that the standard of liability is based on defect and not on fault, provided that the injured shall be able to produce evidence of the defect, in the form of serious, specific and consistent presumptions.

III. The EU Quality Chain

1. Social State of Art v Technical Standards

In the EU, quality chain technical regulations represent the transfer of rules of art into standardised data: they should, therefore, be considered as the crucial link that provides a unique, objective standard on which judges from different national legal systems can identify defectiveness and release harmonised decisions. Apparently, the reason why product safety law is concerned with generally accepted rules of the art, or with justified safety expectations that manufacturers have to comply with, instead of threshold values, lays on the fact that nuclear powers or pharmaceutical products require specific standards related to their risks, which can be legally assessed in terms of defectiveness. On the other hand, 'product' is a very general category that includes sophisticated technological devices as well as simple tools.[13] Nevertheless, the issue at stake is the legal assessment of defect, which should be connected to the level of risk that any product implies. Standardisation of production, mass products and large

13 C Joerges, 'Product Safety, Product Safety Policy and Product Safety Law' (2010) 6 Hanse L Rev 115, 117–118.

scale production[14] (eg, cars, pharmaceutical products, electronic components, mobiles, 3D printers, etc) have changed the relationship between consumers/users and producers and, in particular, the legitimate safety the public at large is entitled to expect. In fact, any defectiveness of products may potentially affect a large number of users/consumers because of their large scale of production. This is the reason why in Europe the old liability regime, based on producer's fault, was abandoned in favour of the new regime of strict liability, as such happened in the 'seventies of last century in the United States'.[15]

The goal of these legislations was clear: to match users' protection with the enhancement of competition in a free market. Most mass products, as well as high technological products, distributed on large scale are required to comply with technical standards; while others – usually outside the large-scale market or free from technological complexity: shoes, clothes, furniture and stationery – are not. For the second category of products, it is correct to refer to legitimate consumer's expectations that can be interpreted by judges with reference to a social state of art. The most complex issue on liability concerns the first category of products, mass products distributed on a large scale and large-scale technology. Until now, pharmaceutical products and chemicals represented the most quoted examples of policy treatment of their risks, and the same can be said today of high-tech projects and Artificial Intelligence ('AI') in particular. Anyone who does not wish to leave safety decisions to market forces, but also does not wish to abide by the average level or the state of the art and sees the guaranteeing of safety as a political task will assign this task to either State authorities (as this is the case in Europe) or independent agencies (as this is the case in the United States of America). 'The alignment of corresponding decisions to technical standards specifying general safety duties is equivalent to setting a threshold value establishing the extent of permissible risks in general terms'[16].

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14 E Al Mureden, 'La responsabilità del fabbricante nella prospettiva della standardizzazione delle regole sulla sicurezza dei prodotti' in E Al Mureden (ed), *La sicurezza dei prodotti e la responsabilità del produttore* (Giappichelli 2017) 6.

15 The reference is to the well-known Restatement (Second) of Torts (American Law Institute, 1965) § 402A and now to Restatement (Third) of Torts, Products Liablity (American Law Institute, 1998).

16 C Joerges, 'Product Safety, Product Safety Policy and Product Safety Law' (2010) 6 Hanse L Rev 118.

2. *The European Layout of the New Approach and the New Legislative Framework*

Since Directive 73/23/EEC[17] ('low voltage'), a cross-reference method to harmonised technical standards has been enhanced within the Union. Since then, following the *Cassis de Dijon* case[18] and the European Commission Communication of 31 January 1985, the Council of Ministers on 7 May 1985 indicated the regulatory technique that products placed on the EU market must meet if they are to benefit from free movement within the EU (the 'New Approach').[19] The New Legislative Framework ('NLF')[20]

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17 Council Directive of 19 February 1973 on the harmonisation of the laws of Member States, relating to electrical equipment designed for use within certain voltage limits. Article 5, in particular, referred to safety provisions of harmonised standards, 'drawn up by common agreement between the bodies notified by the Member States' (para 2). Later on, the cross-reference method was pursued by the Council Directive 83/189/EEC of 28 March 1983, laying down a procedure for the provision of information in the field of technical standards and regulation.

18 European Court of Justice of 20 February 1979,– Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein*, [1979] ECR I–649.

19 Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards (85/C 136/01). The 'New Approach' is grounded on Four Principles (Annex II): (1) legislative harmonisation is limited to the adoption of the *essential safety requirements*; (2) the task of drawing up the technical specifications needed for the production and placing on the market of products conforming to the essential requirements established by the Directives, while taking into account the current stage of technology, is entrusted to organisations competent in the standardisation area; (3) *these technical specifications are not mandatory* and maintain their status of voluntary standards; (4) at the same time, national authorities are obliged to recognise that products manufactured in conformity with harmonised standards (or, provisionally, with national standards) are presumed to conform to the 'essential requirements' established by the Directive. This signifies that the producer has the choice of not manufacturing in conformity with the standards but that in this event he has an obligation to prove that his products conform to the essential requirements of the Directive.

20 The NLF (<https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en> accessed 8 August 2018) consists essentially of a package of measures aiming at setting clear rules for the accreditation of conformity assessment bodies; providing stronger and clearer rules on the requirements for the notification of conformity assessment bodies; providing a toolbox of measures for use in future legislation (including definitions of terms commonly used in product legislation, procedures to allow future sectorial legislation to become more consistent and easier to implement); and improving the market surveillance rule, through the RAPEX alert system for the rapid exchange of information among EU countries

was adopted in 2008 in order to promote the quality of conformity assessment. It represents:

'a complete system bringing together all the different elements that need to be dealt with in product safety legislation in a coherent, comprehensive legislative instrument that can be used across the board in all industrial sectors, and even beyond (environmental and health policies also have recourse to a number of these elements), whenever EU legislation is required'.[21]

The result is a complex, multilevel layout:[22] at the first stage, technical harmonisation is achieved through *general* regulatory rules concerning specific products, categories, market sectors and/or types of risks, implemented by European[23] and national standards institutions.[24]

There is a mandatory general standard of safety (Directive 92/59/EC of 29 June 1992, now superseded by Directive 2001/95/EC of 3 December 2001, on general product safety: 'GPSD') intended to ensure a high level of product safety throughout the EU for consumer products that are not covered by sector-specific EU harmonisation legislation, and mandatory

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and the European Commission. These measures are: Regulation (EC) 765/2008 (setting out the requirements for accreditation and the market surveillance of products); Decision 768/2008 on a common framework for the marketing of products; Regulation (EC) 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another EU country.

21 Commission Notice of 05.04.2016, The 'Blue Guide" on the implementation of EU product rules 2016 ('Blue Guide'), 11. The *Transatlantic Trade and Investment Partnership* (TTIP), aiming at harmonising Europe and the American safety standards and imposing a new and deeper reflection on this relationship: RW Parker and A Alemanno, 'A Comparative Overview of EU and US Legislative and Regulatory System: Implications for Domestic Governance & the Translatlantic Trade and Investment Partnership' (2015) 22 Colum. J. Eur. L. 61ff.

22 E Al Mureden, 'La responsabilità del fabbricante nella prospettiva della standardizzazione delle regole sulla sicurezza dei prodotti' in E Al Mureden (ed), *La sicurezza dei prodotti e la responsabilità del produttore* (Giappichelli 2017) 2ff.

23 In Europe: European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC), European Telecommunication Standards institute (ETSI). See Annex I of Regulation (EU) No 1025/2012.

24 In Italy: Ente Nazionale di unificazione (UNI); Comitato Elettrotecnico Italiano (CEI).

specific safety standards contained into vertical directives.[25] GPSD complements the existing sector-specific (vertical) legislation, and it also provides for market surveillance provisions.[26] The wide range of products covered has to be sufficiently homogeneous for common essential requirements to be applicable, and the product area or hazards also have to be suitable for standardisation (see the First Principle of the Council Resolution 7 May 1985, fn 19).

In both horizontal and vertical legislation, the producers' duties to comply with standardised rules are still general (ie, they provide the goal of safety to be achieved and the type of risks to be avoided). The wording of the essential requirements contained in the sections of the acts or in their annexes[27] is intended to:

'facilitate the setting up of standardisation requests by the Commission to the European standardisation organisations to produce harmonised standards. They are also formulated so to enable the assessment of conformity with those requirements, even in the absence of harmonised standards or in case the manufacturer chooses not to apply them'.[28]

Consequently, in most cases, the essential requirements of different harmonisation acts need to be applied simultaneously in order to cover all relevant public interests.

Harmonised technical standards are focused on a second level of intervention.[29] They are European standards adopted by recognised standardisation organisations, upon requests made by the European Commission

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25 See the list of specific Directives and Regulations at <https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en> accessed 30 September 2018.

26 RAPEX, Rapid Alert System set up between Member States and the Commission; to certain conditions, Rapid Alert System notifications can also be exchanged with non-EU countries.

27 As an example, see Directive 2009/48/EC on the safety of toys: art 10, § 2 runs: 'Toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children'. In Annex II, particular safety requirements are then listed: Physical and Mechanical Properties, Flammability, etc. The same can be said on directives and regulations on cosmetics, machinery, medical devices, etc.: < https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en> accessed 30 September 2018.

28 The 'Blue Guide' (n 1) 37–38.

29 There are several instruments to promote safety: preventive approval regulations, performance standards, certification procedures, voluntary standards and safety

for the correct implementation of the harmonisation legislation. Such organisations have a private nature: they operate on a mutual agreement, maintaining their status of voluntary application, and their technical standards never replace the legally binding essential requirements. Regulation (EU) No 1025/2012 on European standardisation defines the role and responsibilities of the standardisation organisations, and it gives the Commission the possibility of inviting, after consultation with the Member States, the European standardisation organisations to draw up harmonised standards. It also establishes procedures to assess and to object to harmonised standards. More deeply, the Commission (assisted by a committee, consisting of representatives of national states: Art 22 of Regulation (EU) No 1025/2012) issues standardisation mandates[30] (ie, after consulting sectoral authorities at the national level), addressing the European standardisation organisations that will formally take a position on the request and finally start up the standardisation work.[31] Harmonised technical standards can also step in absence of vertical legislation, and in compliance with Directive 2001/95/EC on general safety. This is the case, in particular, for furniture, ladders/staircases. At the end of this complex process, standards are published on the European Official Journal. From publication, the standards shall mandatorily be applied by national standards institutions or by national notified bodies that are authorised to issue marks or certificates of conformity. Moreover, publication of references of harmonised standards sets the date from which the presumption of conformity (to the essential requirements) takes place.

The essential feature of this layout is to limit legislative safety harmonisation to the essential requirements that are of public interest, such as

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symbols, warnings, safety campaigns, follow-up market controls (recalls and bans) and rules on liability. Nevertheless, positive regulation of all safety aspect is impracticable, although in principle the justification for preventive safety regulations is undisputed.

30 See the *Vademecum* on European standardization: SWD(2015) 205 final, 27 October 2015 available at <http://ec.europa.eu/growth/single-market/european-standards/vademecum/index_en.htm> accessed 8 August 2018.

31 About the content of the harmonised standards and their relationship with the essential requirements of the harmonised legislation, see more extensively the Blue Guide (n 1) 4.1.2.2., 39ff. 'A specification given in a harmonized standard is not an alternative to a relevant essential or other legal requirement but only a possible technical means to comply with it', 40.

health and safety of users, sometimes even including property, scarce resources or the environment.

Essential requirements define the results to be attained, or the hazards to be dealt with, but do not specify the technical solutions for doing so. The precise technical solution may be provided by a standard or by other technical specifications or be developed in accordance with general engineering or scientific knowledge laid down in engineering and scientific literature at the discretion of the manufacturer.[32]

It is up to a manufacturer to implement a risk analysis of its product and to identify all possible risks inherent to the product. Then, the manufacturer shall be able to assess what the essential requirements are in relation to the risks inherently raised by the product, as well as the harmonised technical standards necessary to ensure that the product complies with the essential requirements. It may happen that only part of the harmonised standard is applied, or it may be that the harmonised standard does not cover all applicable essential requirements, nor does it cover all risks of the product. In these cases, the manufacturer should be able to provide sufficient documents illustrating the way applicable essential requirements not covered by harmonised technical standards are dealt with.

The cross-reference method illustrated hereabove is preferred to vertical, specific legislation (the 'Old Approach'), at least for two reasons. First, it encourages flexibility: safety assessment procedures must be flexible, above all, because the hazards to be assessed vary tremendously in nature and intensity. Secondly, it provides sustainability of the imposed standards, that involves transparency and the participation of relevant stakeholders, including SMEs, consumers, environmental organisations and social stakeholders (see Regulation (EU) No 1025/2012, Art 5 ch II, in particular). This dialogue between public entities, private standardisation organisations and relevant stakeholders provides sufficient guarantees[33] that the standardisation requests are well understood in order to satisfy the es-

32 The 'Blue Guide' 38.

33 For a different view: C Joerges and HW Micklitz, 'Completing the New Approach Through a European Product Safety Policy, (2010) 6 Hanse L. Rev. 381; C Joerges and HW Micklitz, 'The need to Supplement the New Approach to Technical Harmonization and Standards By a Coherent European Product Safety Policy' (2010) 6 Hanse L. Rev. 349 – Special issue. The Authors consider the Union product safety policy as a barrier to trade and plead for a Standing Committee on Product Safety (that includes private parties like CEN/CENELEC) before setting the special standards. On the ineffectiveness of several EU instrument to ensure and control

sential requirements, on the one hand. On the other hand, the public interests are taken into account in the process, without completely delegating technical standards to industry representatives. What safety law is about is social protection, which no manufacturer nor single judge can determine unilaterally by laying down what 'safety' is.

IV. The Relationship between Safety and the Compliance Defence (Art 7 let (d) of the PLD)

1. Safety and Defectiveness

Safety laws and product liability laws respond to different assumptions and requests, but, nevertheless, they are part of a complex and united system. Product liability should be considered a complementary safety-instrument: a modern construction of the PLD that can adapt it to new technologies would create a link between the product liability system created by the PLD and the safety legislation. The occasion is provided by Art 7 let (d) of PLD: 'The producer shall not be liable as a result of this Directive if he proves: (d) that the defect is due to compliance of the product with mandatory regulations issued by the public authorities'. According to the Fourth Principle affirmed in the Council of Ministers resolution of 7 May 1985 (fn 19), there is a presumption of conformity:

'[N]ational authorities are obliged to recognize that products manufactured in conformity with harmonized standards (or, provisionally, with national standards) *are presumed to conform to the 'essential requirements' established by the Directive*. (This signifies that the producer has the choice of not manufacturing in conformity with the standards but that in this event he has an obligation to prove that his products conform to the essential requirements of the Directive)'.

The PLD does not take into account the relevant distinction between unsafe and defective products. Nevertheless, it should be recalled that one

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the safety of products see: C Joerges, 'Product Safety, Product Safety Policy and Product Safety Law' (2010) 6 Hanse L. Rev. 115. RW Parker and A Alemanno, 'A Comparative Overview of EU and US Legislative and Regulatory System: Implications for Domestic Governance & the Translatlantic Trade and Investment Partnership' (2015) 22 Colum. J. Eur. L. 89ff, where the Authors argue for a more procedural approach of the EU consultation practices.

product is unsafe if it does not comply with technical standards or with the state of art, although it may not necessarily turn into a defective product. On the other hand, a defective product may cause damage or injury to users, even though it is perfectly 'safe' (ie, compliant) because of: a) misuse or b) it is an unavoidable unsafe product (eg, cars, mobiles, cigarettes, pharmaceutical products, etc). It is, therefore, crucial to establish what compliance means within the PLD and safety system, as it is the logical medium between safety and defectiveness. In particular, the question here is: does *any* compliance exclude producer's liability?

Once an injury has occurred, and there is evidence that the product has caused the injury, the two categories of products (ie, unsafe and defective) may eventually overlap. In order to assess the producer's liability, we can envisage two situations.

2. *Non-Compliance with Harmonised Standards and Exclusion of the Presumption of Compliance*

There may be cases where producer complied with general and special (mandatory) harmonised legislation but did not comply with harmonised technical standards (the latter being not mandatory: see para III.2. above). Applying the Fourth Principle of the Council of Ministers Resolution, courts can presume that the product is not compliant with the essential requirements of the GPSD, and, therefore, it is defective; thus, the producer has the burden to prove compliance, misuse or an unavoidable risk. In such a situation, although the GPSD had been respected, the producer cannot rely on the compliance defence. In essence, it was the producer's choice of not manufacturing in conformity with the standards; therefore, consequently, the producer has an obligation to prove that the products conform to the essential requirements of the GPSD. It is worth noting that detailed procedures as for conformity and quality management assessment prior to marketing of products came with the Council Resolution on the Global Approach (issued in 1990) and Decision 90/683/EEC (updated and replaced by Decision 93/465/EEC and, at present, by Decision No 768/2008/EC of 9 July 2008 on a common framework for the marketing of products).[34] These decisions developed consolidated conformity assess-

34 OJEU L 218/218 of 13 August 2008.

ment procedures and the rules for their selection and use in special (vertical) directives (the modules), involving both the Commission and private entities (the conformity assessment bodies). The modules are set up from simplest products presenting minimum risks, to very complex products and technologies presenting high risks. This presentation favours their selection and their final use into specific directives, leaving the legislator free to decide which standards are the most appropriate in each sector.

In the aforementioned situation, courts may assume the delicate *officium* of controlling that the plaintiff's claim not only is on line with a social acceptability test, but that harmonised technical standards have been ignored;[35] therefore, the use of presumptions of defectiveness (see para II above) prove to be serious, specific and consistent. Nevertheless, it should be underlined that judges remain free to rule that the respect of essential requirements – given the peculiarities of the case – proves to be a sufficient defence for the producer. They may use their discretionary power and consider the product as reasonably safe, having regard to all the circumstances listed in Art 6 of the PLD (ie, the presentation of the product, the use to which it could reasonably be expected that the product would be put and the time when the product was put into circulation). Harmonised standards, although voluntary, represent the objective transformation of the state of art for mass products distributed on a large scale into the level of safety that the public is entitled to expect. In this perspective, they represent the crucial link between safety and producer's liability: the objective test that reduces social expectations to a sustainable and shared notion of safety. Harmonised technical standards represent, therefore, the convergence of legitimate expectations of the public at large.

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35 Cass. civ. (3) No 3258 of 19 February 2016 (2016) 17 Guida al diritto 2016 51 'The level of safety imposed by the law, beyond which a product shall be therefore considered as defective, does not correspond to its total harmlessness. It rather corresponds to the level of safety requirements generally expected by users with reference to the circumstances listed at Art 5 [of the Italian law implementing PDL] or with reference to other requirements to be evaluated by the ground court, *within which, in particular, we can and must include safety standards possibly imposed by the technical rules within the specialised area*'.

3. *Compliance with Harmonised Standards and Presumption of Conformity*

In a second situation, if the producer complied with harmonised regulations and/or with harmonised technical standards,[36] the Fourth Principle stated by the Council Resolution 7 May 1985 would then apply. Accordingly, applying the presumption of conformity/safety, the compliance defence of Art 7 let (d) is triggered, and the producer is not liable.[37] Therefore, a rare allergic reaction to a detergent or to a perfume that can objectively be considered safe – according to harmonised standards – does not make the producer liable under the Directive.[38] Nevertheless, a damage occurred, although provoked by a 'safe' product. In the situation at stake, if harmonised technical standards are considered as 'floors' (ie, minimum standards) and not 'ceilings' (ie, maximum standards), the injured party can rebut the presumption of conformity and provide the court sufficient social expectation that a product should reach nearly 100% of safety before reaching the market. Or, he/she can give evidence that the particular circumstances of the case rendered the safe product defective. On their side, provided that harmonised technical standards are deemed as floors and not ceilings, judges have a limited discretionary power in eventually considering the producer liable, valuing more the gap of safety in-between the (respected) harmonised technical standards and higher technical standards or higher social expectations, given the peculiarities of the case. Regarding unavoidable unsafe products, in particular, judges still maintain a limited discretionary power to either considering the producer liable, thus

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36 The 'Blue Guide' ([4.1.3.], 48ff) specifies that the presumption of conformity can also be attained through other ways, such as 'technical specifications' consisting of national standards, European standards non-harmonised (that is: not published on the OJEU), manufacturer's own specifications.

37 Cass. civ. (3) No 6007 of 15 March 2007 (2007) 7–8 Responsabilita' Civile e Previdenza 1592, note M Gorgoni, 'Responsabilità per prodotto difettoso: alla ricerca della (prova della) causa del danno': an allergic reaction to a dyeing hair product considered safe according to harmonised standards excludes the producer's liability; Cass. civ. (3) No 25116 of 13 December 2010 (2012) I 2 Foro italiano 576: this was a case involving a tanning cosmetic product causing injury. The Italian High Court has ruled against the plaintiff's claim on the ground of misuse of the product.

38 Daily Wuyts, 'The Product Liability Directive – More than Two Decades of Defective Products in Europe', 5 JETL 1 (2014) 8. See the Italian High Court: Cass. civ. (3) No 6007 of 15 March 2007 (n 36).

discouraging enterprises from placing on the market dangerous products, or excluding producer's liability in cases of socially accepted goods (as it is the case for pharmaceutical products). The challenge for the future, in regard to high-tech products, consists of finding criteria to assess which risks must be eliminated at all costs, which risks should be reduced through design requirements and which risks are unavoidable. Even in this situation, it is not necessary to adopt the tripartite American distinction among design, manufacturing and warning defects, as the assessment of defectiveness is measured on a multi-level notion of safety.[39]

V. Final Remarks

In the era of AI and IoT, judges should adopt an approach aiming at coordinating safety rules and liability rules. If it is the judges' *nobile officium*[40] to qualify a product as defective or not, and to establish what the public's expectations are, then judgements should be grounded on evidence of compliance or non-compliance with harmonised technical standards, as objective connectors to the entitled expectations of the public at large. Provided that harmonised standards are considered as minimum requirements, thus leaving to the judge the delicate task to control that technical rules were correctly drafted within the cross-reference method, and that the dialogue among public entities, private standardisations organisations and the relevant stakeholders had taken place within the NLF system.

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39 This is not the approach of the Italian legislator: in implementing the PLD, Art 117, para 3 Italian Consumer Code runs: 'A product is to be considered defective when it does not provide the same degree of safety as that normally offered by any other product of the same series'. The Italian vision of PLD goes in the direction of cutting short any argument on the degree of expected safety by adopting the manufacturing defect reasoning. See Daily Wuyts, 'The Product Liability Directive – More than Two Decades of Defective Products in Europe' (2014) 5 JETL 13: 'However, it has already been noted that this detracts from the normative character of Art 6 of the Directive. The standard of liability imposed by Art 6 cannot be reduced to a mere finding that the specific product deviates from the production line. In doing so the Italian interpretation violates the maximum harmonisation intended by Art 6 of the Directive, which clearly states that the only standard of liability is that of the legitimate safety expectations of the public'.

40 Hans C Taschner, 'Product Liability: Basic Problems in a Comparative Law Perspective' in Duncan Fairgrieve (ed), *Product Liability in Comparative Perspective* (Cambridge University Press 2006) 160.

Assuming harmonised technical standards as fundamental parameters on which the defectiveness of products can be objectively assessed, may represent an optimal solution to the question concerning the relationship between safety and defectiveness for the following reasons. a) Assessing defectiveness through harmonised technical standards may help in reducing the judges' discretion, thus, reaching a better harmonisation of judgments within Europe and a higher certainty. b) In the AI and IoT technology era, users' protection cannot be completely achieved, mainly because the applications of PLD to new technologies involve public or collective interests.[41] Thus, the state of art, as accepted by the public at large, implies a discretion of judgments that are not sustainable in the new era of high technology. Instead, the recourse to harmonised standards, as evidence of compliance, would represent a balanced way to coordinate the (still) actual provisions of PLD with safety regulations. c) The implementation of the safety legislation through the PLD would also reduce in the long run the placing on the market of unavoidable unsafe products. The judicial respect and support of the dialogue between public European institutions and private organisations (and stakeholders) would contribute to solve ethical questions, concerning the correct edge between promoting technology and making useless technological risks unavailable in the market. d) A better coordination between harmonised safety regulations and liability rules would enhance free competition in a free market. It should be recalled that the history of the connection between the free market movement of goods and harmonised safety regulations started with the CJEU case *Cassis de Dijon*.[42] This ruling is important not only because of the mutual recogni-

41 Piotr Machnikowsky, 'Introduction' in Piotr Machnikowsky (ed), *European Product Liability. An Analysis of the State of the Art in the Era of New Technologies* (Intersentia 2016) 9.

42 Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* (n 18). The case concerned the sale (through a retailer, Rewe) in Germany of a type of *crème de cassis*, a blackcurrant liqueur produced in France. Because the German legislation required the fruit liqueur to contain at least 25% of alcohol, whereas the cassis de Dijon contained 10-20%, the *Bundesmonopolverwaltung für Branntwein* (a section of the German Federal Ministry of Finance) ruled that the product could be imported in Germany, but not marketed. According to the Plaintiff and to the CJEU this measure resulted into a substantial restriction of quantitative imports, against the meaning of Art 34 TFEU.

tion principle,[43] but also because the Court had the opportunity of clarifying the role of technical regulations and opening a debate on future harmonisation legislation that ended in the New Approach. According to the CJEU, Member States could only restrict or forbid the marketing of products from other Member States if they did not comply with 'essential requirements'. Consequently, non-essential requirements could not figure in the EU harmonised legislation. The voluntary nature of harmonised technical standards, as set out later by the EU Commission in the New Approach, forbids the creation of a barrier in importing and marketing Member States' products. However, at the same time, harmonised standards represent appropriate means for demonstrating conformity in a proportionate manner. e) Compliance with harmonised standards would guarantee a fairer apportionment of the risks inherent in modern technological production between the injured person and the producer, in compliance with recital 2 of the PLD. This is especially true in cases of misuse[44] of high technological products or professional machines that are intended for use of skilled and trained workers, but rented to unskilled and unsupervised end-users. f) As described at III.2., standardisation organisations are private entities in the industrial sector, but the mandates asking for specific technical standards come from the European Commission after consultation with sectoral national authorities. This procedure provides sufficient elements of expectations of public authorities, representing an objective, authoritative and competent expression of the 'safety which a person is entitled to expect' (Art 6 para 1 of the PLD).

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43 Enhancing the free movement of goods is the purpose of Arts 34-36 TFEU, which prohibit quantitative restrictions. The CJEU, in the case Cassis de Dijon, with reference to the free movement of goods, has established the mutual recognition principle, according to which products lawfully manufactured or marketed in one Member State should in principle move freely throughout the Union where such products meet equivalent levels of protection to those imposed by the Member State of destination.

44 European Court of Justice of 5 March 2015, Joined Cases C-503/13 and C-504/13, *Boston Scientific Medizintechnik*,, OJ C138/9, EU:C:2015:148, para 37.