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Directive 85/374/EEC concerning liability for defective products: in the name of harmonisation, the internal market and consumer protection

Fidelma White*

INTRODUCTION

Directive 85/374/EEC concerning liability for defect products has been part of the European Union legal order for over 30 years now.[1] At the time of its adoption, Directive 85/374 was notable for a number of reasons, including that it was an early example of European legislative intervention in the area of private law.[2] It was also notable for introducing 'strict liability' in relation to defective product claims in Europe.[3] Accordingly, the producer is

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* Senior Lecturer in Law, School of Law, University College Cork. This Chapter was subsequently published as Chapter 5: "Directive 85/374/EEC concerning liability for defective products: in the name of harmonisation, the internal market and consumer protection," for Edward Elgar's ***Research Handbook on EU Law***, edited by Professor Paula Giliker (Cheltenham: Edward Elgar, 2017) pp.128-153.

[1] [1985] OJ L 210/29: Art 19 provided that the Directive was to be transposed by member states not later than 30 July 1988. However, transposition of Dir 85/374 was problematic: some states were slow to transpose the Directive (eg in Ireland, the Directive was transposed late by the Liability for Defective Products Act 1991); while the Commission took infringement proceedings against a number of member states for late or incorrect transposition, including unsuccessfully against the UK (in the UK, the Directive was transposed by Part I of the Consumer Protection Act 1987) and successfully against France; Greece; and Denmark: see C-293/91 *Commission v France* [1993] ECR I-1; C-300/95 *Commission v United Kingdom* [1997] ECR I-2649*;* C-52/00, *Commission v France* [2002] ECR I-3827; C-154/00 *Commission v Greece,* [2002] ECR I-3879; C-177/04, *Commission v France* [2006] ECR I-2461; C-327/05 *Commission v Denmark* [2007] ECR I-93.

[2] Subsequent initiatives have focused more on contract law, than tort law: see further Christian Twigg-Flesner, *The Europeanisation of Contract Law* (2nd edn, Routledge, London 2013); Paula Giliker, *The Europeanisation of English Tort Law* (Hart, Oxford 2014).

[3] Dir 85/374 was clearly influenced by the development of strict liability in the United States: see eg *Greenman v Yuba Power Products* 377 P 2d 897 (1963) Supreme Court of California, and s 402A Restatement (Second) of Torts (1965); see further Wolfgang Wiegand,

liable for damage caused by a defect in his product, without the proof of fault.[4] Instead, the injured person must prove the damage, the defect and the causal relationship between defect and damage.[5] Moreover, the Directive includes a number of exonerating circumstances, or defences, which may relieve the producer of liability including where he did not put the product into circulation,[6] the defect is due to compliance with mandatory regulations,[7] or the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered (the development risk defence).[8]

At first sight, Directive 85/374 has all the appearances of a consumer protection measure, designed to improve the position of consumers. It was adopted in the wake of the thalidomide tragedy, which illustrated the difficulty for injured parties in securing compensation for defective products under fault based systems.[9] Recital 2 of the Directive states that liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production. However, 30 years later, Directive 85/374 has turned out to be somewhat disappointing from a consumer protection perspective. Case law from member states on Directive 85/374 has been slow to develop throughout the

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'Reception of American law in Europe' (1991) 39 *American Journal of Comparative Law* 229. In turn, Dir 85/374 has itself influenced developments in product liability law in Australia and a number of countries in Asia and South America: see Mathias Reimann, 'Product liability in a global context: the hallow victory of the European model' (2003) 11 *European Review of Private Law* (ERPL) 128.

[4] Art 1.

[5] Art 4.

[6] Art 7(a).

[7] Art 7(d).

[8] Art 7(e): an optional provision.

[9] See generally Harvey Teff and Colin R Munro, *Thalidomide: The Legal Aftermath* (Saxon House, Farnborough1976).

European Union (EU), and in particular in the United Kingdom (UK) and Ireland (although consumer disputes rarely find their way to the law reports in the UK and Ireland, and it is difficult to estimate accurately the impact of Directive 85/374 on the out-of-court settlement of consumer disputes[10]). In addition, important questions about the exact boundaries of producer liability remain to be answered, in light of the paucity of rulings from the European Court of Justice.[11] Key to understanding Directive 85/374 and its stunted development in terms of consumer protection is the fact that it is a harmonising measure adopted in the context of the internal market. Therefore, in this short chapter, we focus on the harmonising nature of Directive 95/374 and its impact on consumer protection.

HARMONISATION: MAXIMUM OR MINIMUM?

Directive 85/374 is an internal market directive having been adopted pursuant to Article 100 of the European Economic Community (EEC) Treaty (now Article 115 Treaty on the Functioning of the European Union, TFEU).[12] The first Recital makes clear that the approximation, or harmonisation, of national laws concerning liability for defective products was considered necessary because the existing divergences in national laws undermined the functioning of the internal market by distorting competition, affecting the free movement of goods and entailing differing degrees of consumer protection. However, the Directive is silent

[10] One estimate, by German and Dutch insurers, is that 90 per cent of product liability claims are settled out-of-court: the Second Commission Report on the Application of Directive 85/374, COM(2000)893 final p.10.

[11] See eg Simon Whittaker, 'The EEC Directive on Product Liability' (1985) 5 *Yearbook of European Law* 233; Christopher Newdick, 'The future of negligence in product liability' (1987) 104 LQR 288; Jane Stapleton, 'Products liability reform real or illusory? (2006) 6 OJLS 392; Jane Stapleton, *Product Liability* (Butterworths, London 1994).

[12] It is worth noting that Dir 85/374 was born out of Directorate General (DG) Internal Market and not DG SANCO, the directorate with responsibility for consumer protection, at that time.

as to the exact nature of harmonisation. Other consumer directives from this period, such as Directive 85/577/EEC concerning contracts negotiated away from business premises,[13] expressly provided for minimum harmonisation, that is, Directive 85/577/ECC did not prevent member states from adopting or maintaining more favourable provisions to protect consumers in the field covered by the Directive.[14] In fact, the vast bulk of Directives from this early phase in the development of the *consumer acquis* were minimum harmonising measures. However, by the turn of the millennium, minimum harmonisation fell out of favour with the European institutions which were seeking to bring a greater level of coherence to European consumer law as part of a 'more aggressive internal market strategy'.[15] This led to a shift in the European legislative agenda towards the introduction of 'full' or 'maximum' harmonising measures.[16] As described in the *Green Paper on the Review of the Consumer Acquis*, maximum harmonisation means that 'no Member State could apply stricter rules than the ones laid down at Community level'.[17] Indeed, maximum harmonisation subsumes within it minimum harmonisation, such that, member states cannot deviate from the uniform

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[13] [1985] OJ L 372/31.

[14] Art 8. See also eg Dir 84/450/EEC concerning misleading and comparative advertising [1984] OJ L250/17, Art 7; Dir 93/13/EEC on unfair terms in consumer contracts [1993] OJ L95/29, Art 8; Dir 97/7/EC on the protection of consumer in respect of distance contracts [1997] OJ L144/19, Art 14; and Dir 99/44/EC on certain aspects of the sale of consumer goods and associated guarantees [1999] OJ L171/12, Art 8.

[15] Norbert Reich, 'From minimal to full to "half" harmonisation' in James Devenney and Mel Kenny (eds), *European Consumer Protection: Theory and Practice* (CUP, Cambridge 2012) 3.

[16] See *Green Paper on the Review of the Consumer Acquis* COM (2006) 744 final. Accordingly, see eg Dir 2002/65 on the distance marketing of financial services [2002] OJ L271/16, Recital 13; Dir 2005/29 on unfair business-to-consumer commercial practices [2005] 149/22, Art 4 (Recitals 5 and 6); Dir 2008/48 on credit agreements for consumers [2008] OJ L 133/66, Art 22; and Dir 2008/122 on the protection of consumers of certain aspects of timeshare, long-term holiday product, resale and exchange contracts [2009] OJ L33/10, Recital 3.

[17] COM (2006) 744 final, p 10.

standard with either greater or lesser levels of consumer protection: a 'one size fits all' approach to harmonisation. However, importantly, maximum harmonisation is limited to the subject-matter of the particular directive or as Mak describes 'the degree of harmonisation can only be seen within the context, or indeed *within the scope* of regulation set down by the directive'.[18]

The nature of the harmonisation in Directive 85/374 remained unsettled until the matter was resolved by the Court of Justice in a series of cases dating from 2002: a time when maximum harmonisation was in the ascendency. In the first of these cases, *Commission v France*[19] proceedings were brought against France for failure to properly transpose Directive 85/374, in particular Articles 3(3), 7 and 9.[20] French law transposing the Directive included three particular features whereby: (1) suppliers were made liable to the same extent as producers; (2) some of the defences available to producers were made conditional on the producer taking appropriate steps to avert the harmful consequence of a defective product; and (3) compensation for damage under the €500 threshold was allowed. The initial issue before the Court was whether the Directive was a minimum harmonising directive, allowing more generous protection to consumers at national level than that provided for in the Directive or a maximum harmonising directive prohibiting such measures.

Taking a purposive approach to interpretation, the Court found that Directive 85/374 was a maximum harmonising directive. In particular, the Court stated: 'the purpose of the Directive in establishing a harmonised system of civil liability on the part of producers in respect of damage caused by defective products is to ensure undistorted competition between

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[18] Vanessa Mak, 'Review of the consumer acquis: towards maximum harmonisation' (2009) 17 ERPL 55.
[19] Case C-52/00 [2002] ECR I-3827.
[20] This case followed earlier proceedings of a similar nature: Case C-293/91 *Commission v France* [1993] ECR I-1.

traders, to facilitate the free movement of goods and to avoid differences in levels of consumer protection'.[21] Moreover, the lack of a minimum harmonisation clause reinforced the court finding: hence, maximum harmonisation by default. There is a broader ongoing debate around minimum or maximum harmonisation and its impact on consumer protection,[22] and it is arguable that the court's finding that Directive 85/374 is a maximum harmonisation directive was an inevitable but retrograde step for consumer protection.

As noted above, maximum harmonisation is based on the premise that 'one size fits all' – nothing more; nothing less. While the judgment in *Commission v France* may have been justifiable in term of the internal market imperative, it was clearly not good for French consumers or indeed any consumers whose national levels of protection were higher than that set by the Directive. Maximum harmonisation (which tends to be favoured by business interests) is designed to address issues which distort competition, raise barriers to trade for business and/or deter consumers from buying cross-border, leading to greater competition, productivity, and choice for consumers. However, critics of maximum harmonisation have identified various arguments which challenge this premise.[23]

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[21] *Commission v France*, Case C-52/00, [2002] ECR I-3827, para. 17.
[22] Alexandre Duterque, 'Do we really want a *ius commune* for EU consumer protection?' (2012) 35 *Dublin University Law Journal* (NS) 72.
[23] See eg Jan M Smits, 'Full harmonization of consumer law? A critique of the draft directive on consumer rights' (2010) 18 ERPL 5; Gary Low, 'The (ir)relevance of harmonisation and legal diversity in European contract law: a perspective from psychology' (2010) 18 ERPL 285; Simon Whittaker, 'Unfair contract terms and consumer guarantees: the proposal for a directive on consumer rights and the significance of "full harmonization"' (2009) 5 *European Review of Contract Law* 223; Thomas Wilhelmsson, 'The abuse of the "confident consumer" as justification for EC consumer law' (2004) 27 *Journal of Consumer Policy* 317; Geraint Howells and Thomas Wilhelmsson, 'EC consumer law: has it come of age?' (2003) 28 EL Rev 370, 376.

First, it is claimed that maximum harmonisation lacks a sufficiently strong empirical basis. The 'Better Regulation' agenda[24] introduced in the early 2000s had a direct impact on the development of consumer policy and the move to maximum harmonisation.[25] Accordingly, greater emphasis was placed on developing policies that were 'more evidence based' and 'outcome-oriented', followed by 'better monitoring and evaluation of outcomes'. Eurobarometer studies and reports, public and stakeholder consultations, impact assessments of legislative proposals with greater reliance on economic analysis, and market scoreboards[26] are now commonly used to identify problems in the market and assess the most appropriate solution to the problem. Directive 85/374 pre-dated this emphasis on data and outcomes and so it was not evidence-based. Even today, many question the rigour of such studies which are commonly attitudinal in nature rather than reflecting actual business and consumer behaviour.[27] Moreover, the necessity of a fully harmonised EU system can be further questioned in light of the US experience where differing state product liability regimes work within a single market.

Second, even within a fully harmonised context, member states can have different ways of giving effect to the law and different interpretations of legal concepts. Thus, divergences in national systems may remain. Some of these divergences are a feature of

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[24] See Communication from the Commission – Action Plan 'Simplifying and Improving the Regulatory Environment', COM (2002) 278; Commission, Action Programme for Reducing Administrative Burdens in the European Union, COM (2007) 23; and Parliament, Council and Commission, Inter-institutional Agreement on Better Law-Making, [2003] OJ C 321/01.
[25] See Commission, Consumer Policy Strategy 2002–2006, COM (2002) 208 final.
[26] For latest consumer scoreboards see http://ec.europa.eu/consumers/consumer_evidence/consumer_scoreboards/index_en.htm (accessed 15 November 2016).
[27] Iain Ramsey, 'Regulation and the constitution of the EU Single Market: the contribution of consumer law' (2011) 50 *Canadian Business Law Journal* 322, 334.

harmonisation by directive and hence unavoidable.[28] So, for example, harmonisation by directive while binding as to the result to be achieved, allows member states freedom as to the form and method of transposition into the national legal system.[29] Other divergences, such as those relating to matters of interpretation, are however an unwelcome reality. The preliminary ruling procedure in Article 267 (TFEU) whereby national courts or tribunals can refer a question or questions of interpretation of EU law to the Court of Justice is designed to ensure a uniform interpretation of EU law. However, the system only works where cases are referred in the first place. In relation to the UK and Ireland, for example, case law concerning Directive 85/374 has been slow to develop. The first UK cases started to emerge around the turn of the millennium[30] while Irish case law is still very sparse.[31] Since Directive 85/374 was adopted, there have been two references from a UK court (concerning the same matter[32]) and none from an Irish court. Further, and despite a reported increase in some member states in the number of cases brought under national laws transposing Directive 85/374, preliminary references from other member states are also a rare occurrence.[33] A search of the Curia website, shows that the total number of preliminary rulings directly concerning Directive 85/374, to date, is nine.

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[28] One way to limit this divergence would be to utilise regulations which have general application and are binding in their entirety and directly applicable in all member states (Art 288 TFEU) rather than directives.
[29] Art. 288 TFEU.
[30] See Elspeth Deards and Christian Twigg-Flesner, 'The Consumer Protection Act 1987: proof at last that it is protecting consumers' (2001) 10 *Nottingham Law Journal* 1; Geraint Howells and Mark Mildred, 'Infected blood: defect and discoverability a first exposition of the E.C. Product Liability Directive' (2002) 65 MLR 95; Peter Shears, 'The EU Product Liability Directive – twenty years on' [2007] JBL 884.
[31] Mary Donnelly and Fidelma White, *Consumer Law: Rights and Regulation* (Thomson Round Hall, Dublin 2014), 208–19.
[32] Case C-127/04 *O'Byrne v Sanofi Pasteur MSD Ltd* [2006] ECR I-1313; Case C-358/08 *Aventis Pasteur SA v OB,* [2009] ECR I-11305: see further below.
[33] In the period 2006–10, increases were reported in Austria, France, Germany, Italy, Poland and Spain: COM(2011) 547 final p.4.

In additional to the preliminary reference procedure before the Court of Justice, the Commission has developed a number of other means which seek to facilitate a uniform interpretation and application of EU law at national level. For example, the Commission has supported the development of databases which bring together information, including transposing measures and case law from member states, in relation to a number of directives. One of the earliest such databases was the CLAP Europa database, a publicly accessible electronic database of national case law (and more) on the unfair contract terms directive.[34] This was superseded by the Consumer Compendium, an online database of national laws relating to eight consumer directives but not Directive 85/374.[35] More recently, the practice has developed that when a directive is adopted, the Commission may also publish Guidance on the directive. So, for example the Commission has published *Guidance on the Consumer Rights Directive*, Directive 2011/83.[36] This guidance is available online and is described as a living document which will be supplemented and updated as is necessary in the light of experience of its practical application in member states. Importantly, this guidance information from the Commission is not legally binding; rather it represents the considered views of the Commission on a range of matters. It remains for the Court of Justice of the EU to determine definitively the interpretation of EU law. However, no such database or

[34] The database covered the period 1997–2004/5.
[35] The *Consumer Compendium* covered the period 2005–12. See also website and database on the Unfair Commercial Practice Directive, accessed 15 November 2016 at https://webgate.ec.europa.eu/ucp/public/index.cfm?event=public.home.show&CFID=2020474&CFTOKEN=f649faa2fd6b9f4e-084C46EB-9CE5-3643-AA61E9C7A8BE56C2&jsessionid=a5035bd5f68e2a61e50a601d538204fc457aTR.
[36] DG Justice Guidance document concerning Directive 2011/83/EU, accessed 15 November 2016 at http://ec.europa.eu/justice/consumer-marketing/files/crd_guidance_en.pdf. See also 2016 Commission Guidance on the Unfair Commercial Practices Directive SWD(2016) 163 final at http://ec.europa.eu/justice/consumer-marketing/files/ucp_guidance_en.pdf.

guidance document on Directive 85/374 exists and so the potential for divergences in national interpretation and application remain.[37]

Third, critics of maximum harmonisation argue that the 'one size fits all' approach does not respond to the heterogeneity of consumer society and the growth in membership of the EU exacerbates this issue. When Directive 85/374 was adopted there were 10 member states in the then EEC; today there are 28 member states with different consumer cultures and legal traditions.[38] Difference exists between those member states with a well-developed consumer society and a strong consumer voice, and those with less well-developed consumer society and a weaker consumer voice; between older member states and newer member states; between civil law systems and common law systems. Maximum harmonisation does not engage positively with these difference but instead promotes uniformity. So, for example, in the case of consumers in member states with higher levels of consumer protection, the effect of maximum harmonisation has been to lower consumer protection standards, and any arguments that the overall gain is greater than any national losses remains to be empirically proven. This has been the experience in a number of member states including France, Greece, Spain and Denmark.

Fourth, it is claimed that maximum harmonisation stifles experimentation and innovation at a national level. Prior to Directive 85/374, some states had already moved towards strict liability (for example, France and Denmark) or were considering such a move (for example, the UK). Infringement proceedings relating to Directive 85/374 taken by the Commission against various member states evidence this stifling effect, which is of particular

[37] An online database on Dir 85/374 is operated by the Product Liability Forum of the British Institute of International and Comparative Law but it is not publically accessible.
[38] This figure will reduce to 27, in due course, following the Brexit referendum in the UK.

concern when the relevant EU measure has, for whatever reasons, failed to have a significant impact at national level.

The decision in *Commission v France* surprised and disappointed many and though there is no formal doctrine of precedent in EU law, this position has prevailed in subsequent case law.[39] It is clear from this line of case law, that the Court has prioritised the internal market rationale of the Directive, as espoused in Recital 1, over any consumer protection agenda. Nevertheless, the Directive is subject to interpretation by the Court of Justice and to periodic review by the Commission and thus in the following sections we explore the extent to which, in these regards, the consumer interest has been to the fore.

MAXIMUM HARMONISATION: TARGETED BUT NOT TOTAL

Although Directive 85/374 is classed as a maximum harmonisation measure, this must be understood in light of the scope or application of the Directive, including the built-in exclusions and options. Maximum harmonisation therefore should not be overestimated; in spite of the nomenclature, maximum harmonisation has its limits. This point is noted in Recital 18 when it states that the harmonisation resulting from Directive 85/374 'cannot be total at the present stage'. In a similar vein, Howells refers to harmonisation under Directive 85/374 as 'non-exhaustive'.[40] The phrase preferred by the Commission today is maximum 'targeted' harmonisation, that is, maximum harmonisation is targeted or focused on those

[39] See Case C-154/00 *Commission v Greece* [2002] ECR I-3879; Case C-183/00 *Gonzalez Sanchez v Medicina Asturia SA* [2001] ECR I-3901; Case C-177/04 *Commission v France* [2006] ECR I-2461; Case C-402/03 *Skov Ægv Bilka Lavprisvarehus A/S* [2006] ECR I-199; Case C-310/13 *Novo Nordisk Pharma GmbH v S* ECLI:EU:C:2014:2385.

[40] Geraint Howells, 'Product liability: a history of harmonisation' in Arthur S Hartkamp et al, *Towards a European Civil Code* (4th edn, Kluwer, Alphen on the Rhine 2011) 894.

areas which are disruptive to the proper functioning of the internal market, leaving other aspects subject to minimum harmonisation or unaffected by the measure.

The scope of Directive 85/374 can be defined in both positive and negative terms, in the sense that you can examine what comes within the scope of the directive (the positive) and what is excluded (the negative). Unlike more modern consumer protection directives, there is no express provision in the Directive addressing its scope or application, although Article 1 comes closest with the simple statement that the producer shall be liable for damage caused by a defect in his product. When read in conjunction with Article 4 (the injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage) we can positively identify the scope or application of the Directive in relation to the parties concerned (the producer and the injured party) and the subject matter (liability for damage caused by the producer's defective product). However, this is only half the picture because the Directive contains a number of exclusions from its scope. Most importantly, Article 13 provides that Directive 85/374 does not affect any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive is notified to member states.[41]

[41] See also Art 2 which originally excluded primary agricultural products and game from the definition of 'product'; Arts 5 and 8 which provide that the Directive is without prejudice to national laws on contribution and recourse; Art 9 which defines 'damage' and states that the provision is without prejudice to national provision relating to non-material damage; Art 10 provides that national laws concerning suspension and interruption of limitation periods are not affected by Dir 85/274; and Art 14 which provides that Dir 85/374 does not apply to injury or damage arising from nuclear accidents and covered by international conventions ratified by the member states. Other aspects of national law not expressly mentioned in Directive but also left to national rules include rules on causation; rules on the measure of damages; and transferability of the right to compensation, including succession rights.

The scope of Directive 85/374, and the interpretation of Article 13 in particular, has been the subject of a number of cases before the Court of Justice.[42] These cases provide an insight into the exact scope of Directive 85/374 and the degree of discretion left to member states to pursue their own consumer protection policy. So, for example, in *Commission v France*[43] the Court of Justice decided that the maximum harmonising nature of Directive 85/374 precluded France from making suppliers liable to the same extent as producers. In particular, the Court stated that Article 13 cannot be interpreted as giving the member states the possibility of maintaining a general system of product liability different from that provided for in the Directive.[44] Although clearly, as provided in Article 13, this does not preclude the application of other systems of contractual or non-contractual liability based on other grounds, such as fault or a warranty in respect of latent defects, or other special liability systems existing at the time when the Directive was notified to member states. This point was considered further in *Skov v Bilka Lavrishvareus*[45] where the Court ruled that Directive 85/374 must be interpreted as precluding a national rule under which the supplier of a defective product is answerable, beyond the cases listed exhaustively in Article 3(3) of that Directive, for the no-fault liability which the Directive imposes on the producer. Article 3(3) provides for a limited form of supplier liability where the producer cannot be identified and the supplier does not inform the injured person, within a reasonable time, of the identity of the producer or his supplier. However, the Court clarified that the Directive does not preclude a national rule under which the supplier is answerable without restriction for the producer's fault-based liability. Further, in *Moteurs Leroy Somer v Dalkia France*,[46] the Court of Justice

[42] See also Recital 13.
[43] Case C-52/00 [2002] ECR I-3827.
[44] Ibid, para 21.
[45] Case C-402/03 [2006] ECR I-199.
[46] Case C-285/08 [2009] ECR I-4733.

ruled that the Directive does permit domestic laws whereby an injured party may seek compensation for damage to an item of property intended for professional use and employed for that purpose where that injured party simply proves the damage, the defect in the product and the causal link between that defect and the damage. The property damage for which a producer is liable under Directive 85/374 is defined as damage to, or destruction of, any item of property other than the defective product itself, provided that the item of property is of a type ordinarily intended for private use or consumption, and was used by the injured person mainly for his own private use or consumption.[47] Therefore, damage to an item of property used in a professional context is not covered by the term 'damage' for the purposes of Directive 85/374 and, consequently, such damage is outside the scope of the Directive. Also, in *Centre hospitalier universitaire de Besançon v Thomas Dutrueux and ors*[48] the Court of Justice ruled that where a service provider, such as a hospital providing treatment, uses a defective product, of which it is not the producer, and the defective product causes damage to the recipient of the service, Directive 85/374 does not apply. Thus, Directive 85/374 does not prevent a member state from applying rules under which such a provider is liable for damage thus caused, even on a no-fault basis, provided that the injured person and/or the service provider retains the right to raise the issue of producer's liability pursuant to Directive 85/374.

Most recently, in *Novo Nordisk Pharma GmbH v S*[49] the Court had to consider, for the first time, the exclusion of special liability systems in Article 13 and, in particular, whether an amendment to a special liability system post-Directive 85/374 was compatible with Directive 85/374. In Germany, since 1978, a special system of liability has applied when a consumer's

[47] Art 9.
[48] Case C-495/10 [2011] ECR I-14155; [2012] 2 CMLR 1.
[49] Case C-310/13 ECLI:EU:C:2014:2385.

health is damaged due to the use of medicines.[50] This special liability system was, however, amended in 2002, by introducing a presumption of a causal connection between the defective product and the damage and a right for a consumer to request from the producer of the medicinal product information on the adverse effects of that product.[51] The question referred to the Court of Justice concerned only the consumer's right to request information. In reply, having noted that the Germany system of liability for medicinal products was a 'special liability system', the Court ruled that the exclusion of special liability systems under Article 13 was limited to those systems and rights which existed at the time the Directive was notified to member states: a cut-off date interpretation. Thus, any subsequent amendments to a special liability system would have to be compatible with Directive 85/374 in light of its maximum harmonisation character. Given that Directive 85/374 does not regulate the provision of information, the Court further held that Directive 85/374 does not preclude national legislation which imposes on traders information duties not mentioned in the Directive. This judgment is clearly good news for German consumers who can continue to seek information on adverse effects of medicines which may assist in pursuing claims for damage against a producer. In the Court's view, the right to information does not go so far as to reverse the burden of proof which rests with the consumer under Article 4 of Directive 85/374 or to undermine the effectiveness of the general system of liability. Indeed, any member states would be free to introduce legislation along these lines. However, the case leaves open the question as to whether the other aspects of the German system of liability for medicinal products, in particular, the presumption of a causal connection, would be equally

[50] *Arzneimittelgesetz* of 24 August 1976, following the experience of the Thalidomide tragedy.
[51] Zweites Schadensersatzrechtsänderungsgesetz of 19 July 2002.

compatible with Directive 85/374. Article 4 states that the injured person must prove the causal relationship between defect and damage but otherwise the Directive is silent on the matter of causation. Arguably, from a consumer protection perspective, a presumption of a causal connection is not the same as a reversal of a burden of proof, it merely acts to lessen the burden of proof which remains with the injured party. However, ultimately this will be a matter for the Court of Justice to decide.[52]

As well as the areas excluded from the scope of Directive 85/374 in Article 13, Directive 85/374, although a maximum harmonising directive, also includes a number of optional provisions, giving member states further discretion to tailor their national liability systems. Article 15 contains two options for derogation: first, in relation to the definition of 'product' in Article 2, member states may provide that the 'product' includes primary agricultural products and game[53]; and second, in relation to the defences in Article 7, member states may choose not provide a development risk defence for producers, as per Article 7(e).[54]

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[52] A recent reference to the Court of Justice raises such issues: Case C-621/15 *W and Others v Sanofi Pasteur MSD SNC, and Others*, including by asking whether Art 4 of Dir 85/374 precludes a system of presumptions by which the existence of a causal relationship between the defect and the damage will always be considered to be established where certain indications of causation are found; or must Art 4 be interpreted as meaning that proof of the causal relationship must always be established scientifically?. In March 2017 the Advocate General's opinion was issued according to which the AG noted that the standard of proof and what evidence is required to meet that standard are not harmonised by the Directive and are, therefore, matters of national law, subject to the overarching requirement that those national laws must respect the principles of equivalence and effectiveness. Therefore, a factual presumption could, in principle, be relied on to establish causation provided that the national court was convinced it was based on relevant evidence and was sufficiently rigorous such that it did not, in practice, amount to a reversal of the burden of proof. At the time of writing, the Court's judgment is awaited.

[53] Initially, primary agricultural products and game were included in the definition of product by Luxembourg, Greece, Finland and Sweden: see First Commission Report on the Application of Directive 85/374, COM(95)617 final. France subsequently included agricultural products.

[54] Initially, the development risk defence was excluded by two states only, Luxembourg and Finland: see First Commission Report on the Application of Directive 85/374, COM(95)617

A third option is contained in Article 16 whereby member states may limit a producer's total liability to an amount not less than €70 million.[55] The first of these options was removed in 1999 by Directive 1999/34/EC,[56] which amended the definition of 'product' to include primary agricultural products, largely as a result of various 'food scares' in Europe. While the extension of the definition of 'product' was clearly designed to bolster consumer confidence in agricultural products, in reality, evidential obstacles of proving a defect and causation in relation to such any food products renders this development less of a victory for the consumer and more of an exercise in public relations.

Critics of maximum harmonisation often point to exclusions and options contained in maximum harmonising measures as a weakness which undermine the rationale of maximum harmonisation. However, these exclusions and options are usually the result of negotiation and compromise as part of the legislative process and, as such, they can operate to temper the more extreme nature of maximum harmonisation with its 'one size fits all' approach, allowing some scope of national divergences. What can result is a sort of hybrid compromise between total maximum harmonisation and minimum harmonisation (that is, targeted maximum harmonisation or 'half-harmonisation'[57]). For example, when the Consumer Rights Directive, Directive 2011/83[58] was proposed as a maximum harmonising measure, it sought to consolidate and update four existing consumer directives (concerning doorstep selling,

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final. Subsequently, it has been excluded in other states including Spain regarding food and medicinal products; and France for products derived from the human body: see *Green Paper on Liability for Defective Products* COM (1999) 396 final.

[55] Initially, a financial ceiling was introduced by Germany, Portugal and Spain: see First Commission Report on the Application of Directive 85/374, COM(95) 617 final.

[56] [1999] OJ L 141/20; see further the EC Commission *Green Paper on Liability for Defective Products*, COM (1999) 396 final.

[57] See Reich, n 15.

[58] [2011] OJ L 304/64.

unfair terms, distance selling and consumer sales) into one coherent measure.[59] However, it become apparent during the legislative process that a number of member states had concerns about the maximum harmonising nature of the proposal and its potential impact on certain aspects of consumer protection at national level. When the Directive was finally adopted, the end result was a slimmed-down directive (unfair terms and consumer sales were largely excluded from its scope) with more targeted maximum harmonisation. Of course, when Directive 85/374 was proposed and being negotiated, it's maximum harmonising character was not expressly recognised in the text of the Directive and so this tempering function of the exclusions and options was less transparent at that time and so, arguably, not fully utilised. When in *Commission v France*[60] the Court ruled that Directive 85/374 was a maximum harmonising directive, this operated as a form of retrospective maximum harmonisation. Nevertheless, the exclusions and options continue to perform a moderating function subject to the interpretation of the Court of Justice. It is clear from the above case law that the Court guards strictly the scope of Directive 85/374, however, as the case law has developed the room for divergences at national level has been clarified. In particular, the case of *Novo Nordisk Pharma GmbH v S*[61] shows how the inclusion of a right to information may be utilised to assist consumers in pursuing claims against producers of defective products. Also, from a consumer perspective, it is hoped that an up-coming ruling from the Court of Justice, will find that a system of national presumptions of fact relating to the proof of a causal

[59] COM(2008) 614 final.
[60] Case C-52/00, [2002] ECR I-3827.
[61] Case C-310/13 ECLI:EU:C:2014:2385.

connection between the defect and the damage is also compatible with the maximum harmonisation nature of Directive 85/374, although this issue is less clear-cut.[62]

MAXIMUM HARMONISATION: UNDER THE SPOTLIGHT BUT STILL IN THE DARK

As well as limiting the freedom of member states to pursue their own consumer policy within the scope of a particular measure, maximum harmonisation also 'shines a light' on the scope and substance of the EU rules because they are the sole source of consumer protection within the scope of that measure. As a result there is greater pressure on a maximum harmonising measure to 'get it right' than with a minimum harmonisation measure. In the case of minimum harmonisation, member states can supplement the measure at national level and increase its protectionist content, as long as minimum levels of protection are guaranteed. This is not the case with a maximum harmonising measure which must be transposed faithfully: no more, no less. Moreover, any such measure, as well as striking an appropriate balance between different interests, must also bring clarity and certainty to the law so that those subject to the law can react appropriately and those who benefit from the law can utilise it.[63]

Taking the issue of balance first, a reading of the recitals to the Directive and subsequent case law identifies four main interests to be balanced: (1) guaranteeing that

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[62] See Case C-621-15 *W and Others v Sanofi Pasteur MSD SNC, and Others*, lodged with the Court of Justice on 23 November 2015, with AG's Opinion issued 7 March 2017.

[63] EU law recognises the general principle of legal certainty which requires, in particular, that rules of law must be clear and precise and their application must be foreseeable by those subject to them, that requirement being particularly important in the case of rules liable to entail financial consequences, in order that those concerned may know precisely the extent of the obligations which those rules impose on them: Case C-201/08 *Plantanol GmbH & Co v Hauptzollamt Darmstadt* [2009] ECR I-8343, para 46.

competition will not be distorted; (2) facilitating trade within the internal market; (3) consumer protection; and (4) ensuring the sound administration of justice.[64] Other interests may exist, including encouraging innovation and scientific and technological development.[65] Accordingly, it has been noted elsewhere that consumer protection is not the only, or even the principal, objective of Directive 85/374.[66] Nor is it clear what weight these different interests carry: whether they are all of equal weight or whether some interests outweigh others. Without getting into the question of whether an appropriate balance was struck in Directive 85/374, it is notable that little has changed in over 30 years: the inclusion of primary agricultural products being the only amendment to Directive 85/374.[67] This is despite the fact that the Directive makes provision for its review on a number of grounds. There is the standard review clause in Article 21 which requires the Commission to report on the application of the Directive, and make appropriate proposals, every five years.[68] There is also provision to review the application of the development risk defence;[69] the implementation of the financial limit of liability in member states;[70] and the amounts in the Directive.[71] So clearly, the framers of Directive 85/374 envisaged its development in light of its implementation and effect. The Commission has produced a number of periodic reports, to date, the latest being the *Fourth Report on the application of Directive 85/374/EEC*

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[64] Case C-52/00 *Commission* v *France* [2002] ECR I-3827**,** para 29; Case C-154/00 *Commission* v *Greece* [2002] ECR I-3879 para 29.
[65] Dir 1999/34/EC [1999] OJ L 141/20, Recital 2.
[66] AG's opinion at para 20 in C-310/13 *Novo Nordisk Pharma GmbH v S* ECLI:EU:C:2014:2385.
[67] Dir 1999/34/EC [1999] OJ L 141/20.
[68] See also Recital 18.
[69] Art 15(3).
[70] Art 16(2).
[71] Art 18(2).

concerning Liability for Defective Products,[72] with a fifth report due soon. However, all the Commission reports, to date, are united in the conclusion that the status quo should be maintained. Earlier reports did not make any proposals for change largely because transposition of the Directive was slow initially and experience of its application was limited, with little relevant data.[73] Subsequent reports concluded that the Directive contributed to maintaining a balance between producer and consumer interests which did not create significant barriers to trade or distort competition and thus no reform was needed.[74] The different reports have identified numerous aspects of the Directive for monitoring and possible reform although interest in this regard seems to be narrowing. The Commission's *Second Report* identified in excess of 10 different aspects of Directive 85/374 as issues for possible future reform,[75] in contrast, the Commission's *Fourth Report* focused on four particular issues identified as part of the consultation process: the burden of proof; the defence of regulatory compliance; the development risk defence; and the €500 threshold.[76] Based on previous reports, the fifth report seems unlikely to offer much in terms of reform proposals from a consumer protection perspective; while delivering any actual reform is an even more unlikely prospect.

Turning to the issue of clarity of the law, when the spotlight of maximum harmonisation is shone on Directive 85/374, there are more questions than answers. The

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[72] COM(2011) 547 final. See also the *First Report*, COM(1995) 617 final; the *Green Paper on Liability for Defective Products* COM (1999) 396 final; the *Second Report* COM(2000)893 final; the *Third Report* COM(2006) 496 final; and a number of other external commissioned studies referred to therein.
[73] COM(1995) 617 final p 2; COM(2000)893 27–8.
[74] COM(2006) 496 final p 4; COM(2011) 547 final 11.
[75] COM(2000) 893 final 12–27, including the burden of proof; developments risks; financial limits; prescription and limitation periods; insurance requirement; transparency; supplier liability; products covered; damages covered; and access to justice.
[76] COM(2011) 547 final 6–10.

Directive itself is short on definition and detail,[77] being based around a general clause which requires that products are safe, and hence not defective, an assessment which is based on what a person is entitled to expect, taking all circumstances into account. The Directive provides a non-exhaustive list of relevant circumstances[78] and so clearly other unenumerated circumstances may also be relevant. Moreover, the nature of what a person is entitled to expect remains an open question. General clauses are a common feature of European consumer protection measures and are designed to bring a degree of flexibility to the law, but the price for such flexibility is uncertainty.

Furthermore, any clarification that has emerged, as a result of the work of the Court of Justice has been slow, ad hoc and limited, with the same or similar questions frequently being referred more than once in order to achieve clarification. The first preliminary ruling of the Court of Justice providing clarification on the meaning of aspects of Directive 85/374 was made 16 years after the Directive was adopted in *Henning Veedfald v Århus Amtskommune*.[79] The defendant was the owner and manager of two hospitals: one where a flushing liquid used in the transplantation of human organs was produced and another where the kidney was prepared for transplant using the liquid. The kidney was damaged while being prepared for transplantation using a defective flushing liquid. Mr Veedfald, the proposed recipient of the transplant, sued for damages and liability was denied, *inter alia*, on the basis that the fluid had not been 'put into circulation'.[80] The Court first noted that the phrase was not defined in the Directive, although it did state that this exemption from liability was designed, primarily,

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[77] The words 'product', 'producer', and to a lesser extent 'defective product', are defined in Arts 2, 3 and 6 respectively.
[78] Art 6(1)(a)–(c).
[79] Case C-203/99 [2001] ECR I-3569; see further Geraint Howells, '*Henning Veedfald v Århus Amtskommune*, Case-203/99' (2002) 6 ERPL 847.
[80] Art 7(a).

to covers cases where a person other than the producer caused the product to leave the manufacturing process. Further, the Court noted that the exemption should be interpreted strictly. Offering no definition itself, the Court ruled that a defective product is put into circulation when it is used during the provision of a specific medical service, consisting in preparing a human organ for transplantation, and the damage caused to the organ results from that preparatory treatment: a ruling based closely on the facts of the case and hence of limited value for future cases.

The meaning of the phrase 'put into circulation' arose again in *O'Byrne v Sanofi Pasteur MSD Ltd & Sanofi Pasteur SA*[81] in the context of Article 11 which provides that an injured person's rights are extinguished 10 years from the date when the producer put the defective product into circulation. The producer's argument that the action was statute-barred depended on a finding as to when the product – an allegedly defective vaccine – was put into circulation. There were two possibilities on the facts of the case: (1) when the product was transferred by a producer company to a distribution subsidiary, or (2) when the product was sold by that subsidiary to a third party. Having reviewed the *Veedfald case*, the Court of Justice held that a product is put into circulation when it is taken out of the manufacturing process operated by the producer and enters a marketing process in the form in which it is offered to the public in order to be used or consumed. So, despite the Commission's earlier view that the phrase 'put into circulation' was 'self-explanatory' and that there was no need for a definition in the Directive,[82] the above case law illustrates that the devil is in the detail and the lack of a definition added to the uncertainty of the law.

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[81] Case C-127/04 [2006] ECR I-1313.

[82] When the Directive was being drafted, the Commission was of the view that it was unnecessary to define the phrase 'put into circulation' since 'it was considered self-explanatory in the ordinary meaning of the words'. According to the Commission's Explanatory Memorandum, normally a product has been put into circulation where it has

The O'Byrne litigation also illustrates how the same question had to be referred to the Court of Justice twice before clarification was achieved.[83] The case involved an application to substitute a parent company (the manufacturer of the allegedly defective vaccine) as defendant for its English subsidiary against whom an action has been commenced, in error. English procedural law allowed for such a substitution, but the question was whether the substitution could be made after the 10-year period in compliance with Article 11. The question was first referred by the High Court and in *O'Byrne v Sanofi Pasteur MSD Ltd & Sanofi Pasteur SA*,[84] the Court of Justice held that, since matters of procedural law fell outside the scope of Directive 85/374, the substitution of a new party after the 10-year period was a matter for the national court to decide:

<quotation>it is as a rule for national law to determine the conditions in accordance with which one party may be substituted for another in the context of such an action. A national court examining the conditions governing such a substitution must, however, ensure that due regard is had to the personal scope of the Directive, as determined by Articles 1 and 3 thereof.[85]</quotation>

Following the ruling of the Court of Justice, the High Court substituted the parent company, as a new party, which unsuccessfully appealed to the Court of Appeal. On appeal to the House of Lords, a second reference was made which asked directly whether Directive 85/374 must be interpreted as precluding national legislation which allows the substitution of one defendant for another after the expiry of the 10-year period laid down in Article 11,

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been started off on the chain of distribution: Commission's Explanatory Memorandum [1976] II EC Bull Supp L 11/15.

[83] Geraint Howells, '*O'Byrne v Aventis Pasteur SA* – how many trips to Luxembourg are necessary' [2009] JBL 97.

[84] Case C-127/04 [2006] ECR I-1313.

[85] Ibid, paras 34–8.

although the person named as a defendant in those proceedings before the expiry of that period did not fall within the scope of the Directive, as defined in Article 3.

The Court of Justice in *Aventis Pasteur SA v OB*[86] clarified its interpretation of Article 11, ruling that it must be interpreted as precluding national law, which allows the substitution of one defendant for another during proceedings, from being applied in a way which permits a 'producer', within the meaning of Article 3 of that Directive, to be sued, after the expiry of the 10-year period, as defendant in proceedings brought within that period against another person.[87] However, it then made clear that Article 11 must be interpreted as not precluding a national court from holding that, in the proceedings instituted within the period prescribed by Article 11 against the wholly owned subsidiary of the 'producer', that producer can be substituted for that subsidiary if the court finds that the putting into circulation of the product in question was, in fact, determined by that producer.[88] Applying this ruling, the UK Supreme Court held, on the facts, some 18 years after proceedings seeking compensation had originally commenced, that the new party could not be substituted in this case.

The above case law addresses mainly issues which could be described as peripheral to Directive 85/374; case law clarifying core issues (such as, the meaning of 'defect'; 'damage' and the development risk defence) which define the boundaries of producer liability are scarce. For instance, there has been no preliminary reference to the Court of Justice concerning the development risk defence whereby the producer has a defence if he can prove

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[86] Case C-358/08 [2009] ECR I-11305.
[87] Ibid, para 49.
[88] The Court also provided clarification regarding the supplier's liability under Art 3(3). Accordingly, Art 3(3) must be interpreted as meaning that, where the person injured by an allegedly defective product was not reasonably able to identify the producer of that product before exercising his rights against the supplier of that product, that supplier must be treated as a 'producer' for the purposes, in particular, of the application of Art 11 of that Directive, if it did not inform the injured person, on its own initiative and promptly, of the identity of the producer or its own supplier.

'that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered'.[89] At best, we have *Commission v United Kingdom*[90] which considered this defence in the course of infringement proceedings. Following a close reading of the provision, the Court of Justice held that in order to utilise this defence, the producer of a defective product must prove that the objective state of scientific and technical knowledge, including the most advanced level of such knowledge, at the time when the product in question was put into circulation was not such as to enable the existence of the defect to be discovered. Further, in order for the relevant scientific and technical knowledge to be successfully pleaded as against the producer, that knowledge must have been accessible at the time when the product in question was put into circulation. Despite this clarification, divergences at member-state level concerning this defence remain. For example, in the same year, the English High Court (in *A v National Blood Authority*[91] concerning blood infected with hepatitis C) and the Amsterdam District Court (in *Hartman v Stichting Sanquin Bloedvoorziening* concerning blood infected with HIV) reached apparently opposing conclusions.[92] Further clarification, such as what is meant by 'accessible', is needed.

For the first time, most recently, the concept of 'defect' has been considered by the Court of Justice in *Boston Scientific*.[93] In this case, the Court was asked to determine if a product is defective if it forms part of a product group which has a significantly increased risk

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[89] Art 7(e).
[90] Case C-300/95 *Commission v United Kingdom* [1997] ECR I-2649.
[91] [2001] 3 All ER 289.
[92] See COM(2006) 496 final p 6. For further examples of divergences, see further COM(2011) 547 final8–9.
[93] Cases C-503/13 and C-504/13 ECLI:EU:C:2015:148; [2015] 3 CMLR 6 Case Analysis 19CA2AEB03F&C. See further, Barend van Leeuwen and Paul Verbruggen, 'Resuscitating EU product liability law? Contemplating the effect of *Boston Scientific*' (2015) 23 ERPL 899.

of failure, but where a defect has not been detected in the specific product. The case involved two related cases concerning implanted medical devices: a pacemaker[94] and a cardioverter defibrillator,[95] both manufactured by Boston Scientific. The cases related to claims by patients' health insurers who sought reimbursement of the costs of replacing the devices. In addressing the issue of 'defect', the Court noted that Article 6 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, including the presentation of the product, the use to which it could reasonably be expected that it would be put and the time when the product was put into circulation (the consumer expectations test). Moreover, recital 6 provides that the assessment of defectiveness must be carried out having regard to the reasonable expectations of the public at large. Thus, in assessing safety, the Court identified a number of factors which must be taken into account, including the intended purpose, the objective characteristics and properties of the product and the specific requirements of the group of users for whom the product is intended.[96] Applying these factors to medical devices, the Court found that patients are entitled to expect a particularly high level of safety, in light of the abnormal potential for damage which those products might cause to the person concerned. Therefore, the Court found that where products belonging to the same product group have a potential defect, it is possible to classify as defective all the products in that group, without there being any need to show that the product in question is defective. While the case is welcome for identifying, in

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[94] Boston Scientific's quality control system found that a component of the pacemaker could degrade over time causing premature and sudden loss of power: the risk of failure was between 0.3 and 0.9 per cent. Boston Scientific wrote to doctors recommending that they consider replacing the pacemakers in affected patients and agreed to provide new devices free of charge.

[95] Boston Scientific quality control system identified that a certain switch could remain stuck in a closed position inhibiting treatment. The manufacturers advised that the switch should be deactivated inhibiting its functionality.

[96] See n 93, para 38.

general terms, the relevant factors over and above those listed in Article 6(1), including the specific requirements of the group of users for whom the product is intended, the question remains whether this generous view of 'defect' is limited to the particular circumstances of the case (that is, products where a particularly high level of safety can be expected and where the risk of failure has serious consequences) or whether it has a wider application.

The Court in *Boston Scientific* was also asked to rule on the concept of 'damage': a phrase not defined in Directive 85/374. Article 9 sets out the various heads of damage: (a) damage caused by death or personal injuries; and (b) certain property damage; although this provision is without prejudice to national provisions concerning non-material damage. In *Henning Veedfald v Århus Amtskommune*[97] the Court had been asked about the interpretation of the phrase 'damage caused by death and personal injuries': does Community law impose requirements on the definition of this phrase or are member states free to define the phrase; and was the damage incurred, in this case,[98] damage caused by 'personal injury' or 'property damage'? Noting the lack of definition in Directive 85/374, the Court found that it was left to member states to determine the precise content of those two heads of damage, nevertheless, the Court held that full and proper compensation for persons injured by a defective product must be available and thus member states may not restrict the types of material damage which are to be made good.[99] However, taking a strict view of its function under the preliminary reference procedure, the Court refused to categorise the type of damage as personal injury or property damage or non-material damage, leaving the application of the

[97] Case C-203/99, [2001] ECR I-3569.
[98] That is, damage to a human organ which, at the time when the damage occurred, had been removed from a donor's body for immediate transplant to the intended recipient of the organ.
[99] See n 97, paras 27–9.

law to the facts of the case to the national court.[100] The Court was more forthcoming in *Boston Scientific*. There the Court was again asked about the meaning of the phrase 'damage caused by death or personal injuries' and answered that the phrase was to be interpreted as meaning that the damage caused by a surgical operation for the replacement of a defective product, such as a medical device, constitutes 'damage caused by death or personal injuries' for which the producer is liable, if such an operation is necessary to overcome the defect in the product in question. This decision was rationalised on the basis that further to the objective of protecting consumer health and safety,[101] this phrase had to be given a broad interpretation. Producer liability is dependent on a causal relationship between the defect and the damage suffered. Thus, compensation for damage covers all that is necessary to eliminate harmful consequences and to restore the level of safety which a person is entitled to expect, including the cost of replacement surgery.

The above analysis shows that when the spot-light of maximum harmonisation is shone on Directive 85/374, we remain 'in the dark' with regard to many important issues. Given the open-textured nature of key concepts, such as defect and damage, in Directive 85/374, it is clear that decisions will continue to be made on a case-by-case basis. Moreover, the volume of case law, from member states and before the Court of Justice would have to increase significantly before a comprehensive and in-depth interpretation of Directive 85/374 can be achieved.

CONCLUSION

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[100] See n 97, para 33. The Court also held that a national court may, however, not decline to award any damages at all under the Directive on the ground that, where the other conditions of liability are fulfilled, the damage incurred is not such as to fall under any of the foregoing heads.

[101] See Recitals 1 and 6.

The issue of product safety and consumer protection clearly is not limited to the provision of compensation to injured persons as per Directive 85/374. To start with, as recognised in Article 13, other schemes of liability continue to apply. Thus, Directive 85/374 is part of a bigger picture. For example, in a UK context, it has been argued that the tort of negligence continues to dominate, with Directive 85/274 having a lesser impact than might otherwise have been expected, as a result.[102] At the same time, strict liability in relation to goods sold to consumers has been a feature of sale of goods legislation in the UK and Ireland since the Sale of Goods Act 1893,[103] and today, 'safety' is expressly included in the legislative framework as an aspect of merchantable/satisfactory quality.[104] It is notable that the seller's liability in this context is both strict and mandatory (it cannot be limited or excluded against a consumer buyer) and this is despite the fact that the seller rarely has any control over the quality, including the safety, of the goods sold and is typically acting as a conduit between the producers and the consumer. Also relevant is Directive 2001/95, the General Product Safety Directive[105], which is complimented by sector specific legislation.[106] Accordingly, producers and distributors are obliged to place only 'safe' products on the market and to inform consumers of the risks associated with products. Member states, through the appointment of competent authorities, play a key role in monitoring and enforcing these obligations. Central to this system is RAPEX, the Rapid Alert System whereby information about dangerous

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[102] Giliker (n 2), 46–63.
[103] See eg *Lee v York Coach & Marine* [1977] RTR 35; *Bernstein v Pamson Motors (Golders Green) Ltd* [1987] 2 All ER 220; *Clegg and another v Olle Andersson* [2003] EWCA Civ 320; [2003] 1 All ER (Comm) 721.
[104] See UK Sale of Goods Act 1979, s 14(2B)(d) and UK Consumer Rights Act 2015, s 9(3)(d); Irish Sale of Goods and Supply of Services Act 1980, s.13. In contrast, safety does not feature as part of the conformity requirement in Dir 1999/44 on certain aspects of the same of consumer goods and associated guarantees: [1999] OJ L 171/12, Art 2.
[105] [2001] OJ L 11/4.
[106] Sector-specific legislation applies, eg in relation to cosmetics, toys, electrical appliances and construction products.

products is exchanged between member states and the Commission. Notifications[107] about dangerous products under this system have risen from 139 in 2003 to over 2000 in 2010, with 2123 notifications in 2015 (of which 2072 concerned notifications related to products posing risks to consumers' health or safety[108]) a drop on the previous three years.[109] This rise in notifications illustrates the growing impact of these *ex ante* controls in relation to product safety. The general product safety regime is currently under review and the Commission has proposed a package of legislative (and non-legislative) measures to streamline and simplify the system as well as to improve consumer safety, including two new regulations: one on product safety (to replace Directive 2001/95)[110] and another on market surveillance.[111]

Other factors impact on the issue of product liability and consumer protection, not least issues concerning access to justice and the development of alternative dispute resolution[112]; the provision and cost of insurance for both producers and consumers; the

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[107] A notification is defined as an alert received from a member state on measures taken regarding a dangerous product.

[108] The total figure of 2123 includes professional products and products posing risks other than to consumers' health and safety.

[109] Directorate-General for Justice and Consumers, 'Keeping European consumer safe, Rapid Alert System for dangerous non-food products', *Annual Report 2014*, Complete Statistics, accessed 15 November 2016 at http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/reports/docs/rapex_report_2014finalweb_en.pdf; and Directorate-General for Justice and Consumers, 'Rapid Alert System, for dangerous products, *Annual Report 2015*, Results, accessed 15 November 2016 at http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/reports/docs/rapex_annual_report_2015_en.pdf.

[110] COM(2013) 78 final.

[111] COM(2013) 75 final.

[112] Eg in *Gaffney v Dupuy International Ltd* (unreported, 16 December 2015) the Irish High Court, for the first time, approved an ADR process thereby pausing over 70 defective product claims concerning hip replacements on the High Court list, in light of the Mediation Bill 2012 and the Legal Services Regulation Act 2015 on the facilitation of mediation. Reports claim that there may be as many as 1000 similar claims pending: [2016] *Law Society Gazette* 5.

social welfare system; and the role of market forces and reputation.[113] However, Directive 85/374 must be viewed critically within its own terms.

The ruling that Directive 85/374 is a maximum harmonising directive can be seen as having a negative impact on consumer protection, for the reasons outlined above, although outside the strict scope of the Directive, member states retain certain discretion, for example, in relation to rights to information, and perhaps presumptions of fact, to advance the consumer interest. Unlike the Unfair Contract Terms Directive which, more recently, has been revived by a plethora of preliminary reference rulings from the Court of Justice,[114] there is no indication that Directive 85/374 is going to be resuscitated in a similar way.[115] Therefore, attention turns to the Commission. As noted above, it seems unlikely that the Commission will recommend changes to Directive 85/374 in its next periodic review, as this would upset the delicate balance of interests achieved in Directive 85/374. However, the Commission has other options. First, with the reported growth in case law from member states,[116] the time seems appropriate for the development of an online database of national measures and case law, supported by Commission Guidance on Directive 85/374, along the lines of the Unfair Commercial Practices Directive and the Consumer Rights Directive. If developed, such a database would bring greater transparency to the operation of Directive 85/374 and would assist in promoting Directive 85/374. Second, greater coordination within the Commission, between DG Internal Market (GROW) and DG Justice and Consumer

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[113] Juan José Ganuza, Fernando Gomez and Marta Robles, 'Product liability versus reputation' (2016) 32 J Law Econ Organ 213–41; A Mitchell Polinsky and Steven Shavell, 'The uneasy case for product liability' 123 *Harvard Law Review* 1437–92 (2009–10).
[114] Hans-Wolfgang Micklitz and Norbert Reich, 'The Court and Sleeping Beauty: the revival of the Unfair Contract Terms Directive' (2014) 51 CML Rev 117.
[115] Barend (n 93).
[116] COM(2011) 547 final.

(JUST) would be welcome. As the product safety regime[117] and the consumer sales regime[118] are being reviewed and proposals for reform are being put forward by DG JUST, there is a real concern that producer liability for defective products is being left behind, and not for the first time.

[117] COM(2013) 75 final and COM(2013) 78 final.
[118] COM(2015) 634 final and COM(2015) 635 final.