Tort law is mainly national law. No provision in the EU Treaties grants the EU unlimited competence in the field of tort law. There are, however, specific provisions for breach of EU law by Member States, such as Article 260(1) TFEU, and for the extracontractual liability of EU institutions, such as Article 340(1) TFEU.

Article 260 TFEU: "If the Court of Justice of the European Union finds that a Member State has failed to fulfil an obligation under the Treaties, the State shall be required to take the necessary measures to comply with the judgment of the Court."

Article 340 TFEU: "1. [...] In the case of non-contractual liability, the Union shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its institutions or by its servants in the performance of their duties."

Directive 73/239/EEC on the coordination of laws, regulations, and administrative provisions relating to the taking-up and pursuit of the business of direct insurance other than life assurance, now replaced by the Directive 2009/138/EU on the taking-up and pursuit of the business of insurance and reinsurance

Directive 85/374/EEC on the approximation of the laws, regulations, and administrative provisions of Member States concerning liability for defective products

Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, now replaced by Regulation 2016/679/EU on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR)

Directive 2014/104/EU on certain rules governing actions for damages under national law for infringements of the competition law provisions of Member States and the European Union

Directive (EU) 2020/1828 on representative actions for the protection of the collective interests of consumers obliged Member States to adopt rules allowing consumers' associations and organizations to pursue in court representative actions against traders

Regulation (EC) 44/2001 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (Brussels I), now replaced by Regulation (EU) 1215/2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (Brussels I bis)

Regulation (EC) 864/2007 on the law applicable to non-contractual obligations (Rome II)

Some of the abovementioned reforms have apparently enjoyed a remarkable success, both within and outside the EU borders.

As EU contract law, EU tort law is fragmented and only partially harmonized. EU legislation on tort law largely rely on underlying national (and diverging) notions, rules and remedies. The use of directives as the main means of harmonization is another reason allowing for the persistence of divergences.

Similar observations also apply to the harmonization results achieved so far by the other supra-national organization at work in the European region – the Council of Europe.

The enforcement of the European Convention on Human Rights by the ECtHRs empowers victims of a breach of the ECHR to claim compensation against the State before national courts, and has thus transformed the breach of an international human rights treaty into an actionable domestic tort. Yet, the requirements and technicalities of ECHR-based torts are governed by the law of each national legal system and therefore subject to a variety of regimes and interpretations following divergent paths.

Works for a directive on products liability started in the 1970s, after the talinomide scandal.

National laws were already developing their own rules in this regard, but, under the influence of developments under US law (as enshrined in the Second Restatement on Torts of 1965), the idea of drafting common rules was raised with the aim of ensuring adequate levels of protection for consumers, of limiting legal divergences within the internal market and of reassuring states willing to enact strict liability rules that other states would have adopted the same rules.

Article 1 Directive 85/374/EEC: "The producer shall be liable for damage caused by a defect in his product."

Article 4 Directive 85/374/EEC: "The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage."

Article 2 Directive 85/374/EEC: "For the purpose of this Directive 'product' means all movables, with the exception of primary agricultural products and game, even though incorporated into another movable or into an immovable. 'Primary agricultural products' means the products of the soil, of stock-farming and of fisheries, excluding products which have undergone initial processing. 'Product' includes electricity."

The notion of product includes pharmaceuticals, medical devices, and vaccines (*NW* et al v. Sanofi Pasteur MSD, C-621/15 [2017]; Boston Scientific Medizintechnik v. AOK Sachsen-Anhalt, C-503/13 [2015]).

National case-law also established that the notion of product includes parts of human body (livers, kidneys, hearts, sperms, eggs, blood) that are processed and stored in banks for consumers' use (*A v. National Blood Authority* [2001] 3 All ER 289; *Rb Amsterdam*, 3 February 1999, NJB 1999, 621).

Article 3 Directive 85/374/EEC: "Producer' means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer.

- 2. Without prejudice to the liability of the producer, any person who imports into the Community a product [...] in the course of his business shall be deemed to be a producer within the meaning of this Directive and shall be responsible as a producer.
- 3. Where the producer of the product cannot be identified, each supplier of the product shall be treated as its producer unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product. [...]."

Aventis Pasteur SA v. OB, C- 358/08 [2009]

Under US law all participants in the distribution chain are liable

Article 5 Directive 85/374/EEC: "Where, as a result of the provisions of this Directive, two or more persons are liable for the same damage, they shall be liable jointly and severally, without prejudice to the provisions of national law concerning the rights of contribution or recourse."

Article 6 Directive 85/374/EEC: "1. A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (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. 2. A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation."

consumerexpectation test US law embraces the risk-utility test and applies different rules to manufacturing, design and warning defects

Article 9 Directive 85/374/EEC: "For the purpose of Article 1, 'damage' means: (a) damage caused by death or by personal injuries;

(b) damage to, or destruction of, any item of property other than the defective product itself, with a lower threshold of 500 ECU, provided that the item of property: (i) is of a type ordinarily intended for private use or consumption, and (ii) was used by the injured person mainly for his own private use or consumption. This Article shall be without prejudice to national provisions relating to non-material damage."

The explantation of an allegedly defective pace maker and of re-implantation of a non-defective one is a damage to the body: *Joined cases Boston Scientific Medizintechnik Gmbh v. AOK Sachsen-Anhalt*, C-503/13 and *Boston Scientific Medizintechnik Gmbh v. Betriebskrankenkasse RWE*, C-504/13 [2015].

Injury to a kidney to be transplanted is damage: *Veedfald v. Århus Amtskommune*, C-203/99 [2001].

Article 7 Directive 85/374/EEC: "The producer shall not be liable as a result of this Directive if he proves:

- (a) that he did not put the product into circulation; or
- (b) that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards; or
- (c) that the product was neither manufactured by him for sale [...]; or
- (d) that the defect is due to compliance of the product with mandatory regulations issued by the public authorities; or
- (e) 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; or
- (f) in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product."

For the purpose of the exemption under Article 7, lit (e), Directive 85/374/EEC, only the "objective state of scientific and technical knowledge, including the most advanced level of such knowledge, without any restriction as to the industrial sector concerned" counts (*Commission v. United Kingdom*, C-300/95 [1997]).

Article 8 Directive 85/374/EEC: "2. The liability of the producer may be reduced or disallowed when, having regard to all the circumstances, the damage is caused both by a defect in the product and by the fault of the injured person or any person for whom the injured person is responsible."

Article 10 Directive 85/374/EEC: "1. Member States shall provide in their legislation that a limitation period of three years shall apply to proceedings for the recovery of damages as provided for in this Directive. The limitation period shall begin to run from the day on which the plaintiff became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer."

Article 11 Directive 85/374/EEC: "Member States shall provide in their legislation that the rights conferred upon the injured person pursuant to this Directive shall be extinguished upon the expiry of a period of 10 years from the date on which the producer put into circulation the actual product which caused the damage, unless the injured person has in the meantime instituted proceedings against the producer."

O'Byrne I v. Sanofi Pasteur MSD Ltd and Sanofi SA (O'Byrne I) C-127/04 [2006] O'Byrne v. Sanofi Pasteur MSD Ltd (O'Byrne II) C-358/08 [2009]

Article 12 Directive 85/374/EEC: "The liability of the producer arising from this Directive may not, in relation to the injured person, be limited or excluded by a provision limiting his liability or exempting him from liability."

Directive 85/374/EEC is a maximal harmonization directive: *Commission v. France*, C-52/00 [2002]; *Commission v. Greece*, C-154/00 [2002]; *González Sanchez v. Medicina Asturiana SA*, C-183/00 [2002].

Article 15 Directive 85/374/EEC: "1. Each Member State may [...] by way of derogation from Article 7 (e), maintain or [...] provide in this legislation that the producer shall be liable even if he proves 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 a defect to be discovered."

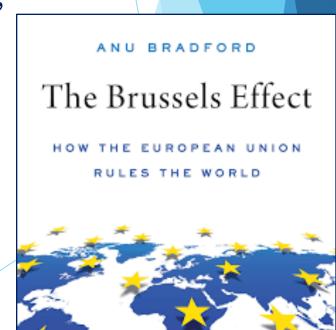
Article 16 Directive 85/374/EEC: "1. Any Member State may provide that a producer's total liability for damage resulting from a death or personal injury [...] shall be limited to an amount which may not be less than 70 million ECU."

Directive 85/374/EEC is a maximal harmonization directive (*Commission v. France*, C-52/00 [2002]; *Commission v. Greece*, C-154/00 [2002]; *González Sanchez v. Medicina Asturiana SA*, C-183/00 [2002]), but national legislation can provide stronger information rights for consumers in case of pharmaceutical products: *Novo Nordisk Pharma GmbH v. S*, C-310/2013 [2015].

Article 13 Directive 85/374/EEC: "This Directive shall not affect any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive is notified."

The intra-European success of the Directive 85/374/EEC is usually described as limited. Between the 2000 and the 2016, only 798 cases under the EU-based regime were brought before European courts, in the whole Europe.

By contrast, the Directive has inspired the adoption of similarly minded legislation in Latin America, Africa and Asia. However, is it the Brussels effect or a hollow victory of the European model?



European Commission, Evaluation of the Directive 85/374/EEC concerning liability for defective products [2016]

European Commission, Proposal for a Directive on liability for defective products [2022], COM(2022) 495 final

Article 4, Proposal for a Directive on liability for defective products [2022]: "For the purpose of this Directive [...] (1) 'product' [...] includes electricity, digital manufacturing files and software."

Article 8, Proposal for a Directive on liability for defective products [2022]: "1. Member States shall ensure that national courts are empowered, upon request of an injured person claiming compensation for damage caused by a defective product [...] who has presented facts and evidence sufficient to support the plausibility of the claim for compensation, to order the defendant to disclose relevant evidence that is at its disposal."