

EUROPEAN UNION DIRECTIVES ON PRODUCT LIABILITY AND PRODUCT SAFETY: NOTABLE INNOVATIONS IN THE PRODUCT LIABILITY REGIME*

Abstract

The Product Liability Directive (PLD) and the General Product Safety Directive (GPSD) are essential legislative instruments designed to safeguard consumer health and safety within the European Union. The PLD established a framework of strict liability for producers of defective products, thereby enhancing consumer protection and facilitating the seamless movement of goods across member states. This article provided a comprehensive analysis of the EU's directives regarding product liability and safety, by focusing on the redress mechanisms available to address sellers' misconduct and ensuring consumer compensation. By employing a doctrinal research methodology, the findings of this study revealed that case law from the European Court of Justice (CJEU) tends to favour plaintiffs by reducing the evidentiary burden in product liability cases. The EU has implemented significant innovations to remain responsive to the evolving nature of product specifications, and the increasing interconnectivity of markets. These adaptations reflect shifting consumer behaviour and changes in social norms. The PLD, also ensured that consumers harmed by unfair trade practices were granted the right to individual remedies. Finally, it was recommended that there is a need for uniformity and harmonisation regarding the issue of defects in product designs, as all member countries have different approaches to the issue.

Keywords: European Union, Product Liability, Product Safety, Consumer, Customer

1. Introduction

Product liability has become a fundamental component of consumer protection law across European Union (EU) member states. The EU's product liability and safety framework has been revised to enhance consumer protection while ensuring manufacturer stability. This framework aims to balance consumers' rights to safe products and producers' interests in mitigating the risks of costly litigation stemming from varying national standards. Notable EU directives that safeguard the health and safety of consumers include the Product Liability Directive (PLD), the General Product Safety Directive (GPSD), and the Product Warranty Directive.¹ However, the focus will primarily be on the directives related to product liability and safety. The EU directives undergo a review every five years to assess their effectiveness in achieving their core objective; which is, ensuring that producers are strictly liable for damage caused by defective products while facilitating the free movement of goods, and providing robust protection for consumers across the EU.²

2. Product Liability Directive

The PLD³ establishes a unified framework governing liability for defective products within the European Union (EU). It imposes strict liability on producers for damages sustained due to defects in their products. Under the provisions of the PLD, producers are held liable for any harm caused by defective products, thereby facilitating the free movement of goods while ensuring a high level of protection for consumers across the EU.⁴ Furthermore, all EU Member States are mandated to submit to the European Commission the texts of their national laws that pertain to the key provisions governed by the PLD.⁵ Prior to the implementation of the PLD, EU Member States employed varying approaches to product liability. Some countries operated under a fault-based system, while others utilised a strict liability framework. The PLD aims to standardise the approach by imposing strict liability on all economic operators involved in the manufacturing of defective products. The term 'producer' encompasses a broad range of entities, including manufacturers of raw materials, finished products or components, individuals who place their name or trademark on products, importers who distribute products within the EU, and suppliers, unless they can identify the actual producer to the injured consumer.⁶ In situations where the producer cannot be identified, each supplier of the product will be treated as the producer unless they can inform the injured party of the producer's identity or the identity of the party that supplied them with the product within a reasonable timeframe. This stipulation also applies to imported products lacking clear identification of the importer.⁷ The person who is injured due to the product must prove the defect, damage, and the causal relationship between defect and damage.⁸ To establish liability, the injured party must demonstrate the existence of a defect, the occurrence of damage, and a causal link between the defect and the damage. If multiple parties are held liable for the same harm, they will be jointly and severally liable without prejudice to national law concerning the rights of contribution or recourse.⁹ A product is deemed defective if it fails to meet the safety expectations that a user is entitled to, considering the

*By Jane Chinelo EBUBEDIKE, PhD, LLM (RSU), BL (Nig Law Sch), LLB (Hons) (Benin), Lecturer, Faculty of Law, Nigerian British University, Asa, Abia State Nigeria; Email: ebubedike.jane@nbu.edu.ng; Phone No: 07030474566; and

*Solomon Chituru EBEKU, PhD, LLM, LLB (RSU), BL (Nig Law Sch), BSc (Econs) (USA), Lecturer, Faculty of Law, University of Port Harcourt, Choba, Rivers State Nigeria; Email: solomonebeku@yahoo.com; Phone No: 08036746199.

¹The European General Product Safety, Product Liability & Product Warranty Directives, Emergo

Group<<http://www.emergogroup.com/resources/articles/other-european-directives>> accessed 2 November 2024.

²Council Directive 85/374/EEC of 25 July 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products <<https://www.legislation.gov.uk/eudr/1985/374#>> accessed 2 November 2024.

³Product Liability Directive (85/374/EEC) the Council of the European Communities Article 1.

⁴Article 18(2).

⁵Article 20.

⁶Article 3(1).

⁷Article 3(3).

⁸Article 4.

⁹Article 5.

product's presentation, the time it was placed in circulation, and the reasonable use of the product¹⁰ The liability of the producer shall not be reduced when the damage is caused both by a defect in product and by the act or omission of a third party.¹¹ Liability of the producer may only be reduced when based on 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.¹²

3. European General Product Safety Directive

The European General Product Safety Directive (GPSD) is designed to ensure the safety of all products available in the market.¹³ Every producer is under an obligation to place only safe products in the market.¹⁴ A product is classified as safe when it complies with voluntary national standards that align with European standards.¹⁵ Producers are required to provide consumers with essential information regarding the inherent risks associated with the product during its normal or reasonably foreseeable use. In instances where risks are not immediately identifiable or are not readily apparent, producers must ensure that adequate warnings are provided. This allows consumers to take necessary precautions against any potential hazards inherent in the product.¹⁶ All member states are to ensure that producers and suppliers comply with their obligations under the GPSD, in order to ensure that the products they place in the market are safe.¹⁷ Member states are responsible for ensuring that producers and suppliers adhere to their obligations under the GPSD, thereby guaranteeing the safety of products available in the market. To this end, member states must conduct regular sampling and testing of products. They have the authority to take necessary actions, such as banning products that are found to be dangerous or pose a risk to consumers. Additionally, they may impose restrictions on such products through procedures for withdrawal and recall.¹⁸ When a product is withdrawn or recalled, the reasons for this action must be communicated to the affected parties. Furthermore, member states are obligated to inform these parties about the remedies available under their respective national laws, along with any applicable time limits for seeking these remedies.¹⁹

4. Product Safety, Quality, and Adequate Warning

The EU Product Safety Directive²⁰ was established to ensure that products entering the EU market meet rigorous safety and quality standards. Producers are compelled to market only products that are deemed safe.²¹ A product is considered safe if it complies with the national laws of the Member State where it is sold, and in the absence of specific EU regulations governing the product, aligns with established national standards related to safety. A presumption of safety exists when a product conforms to the relevant national standards regarding potential risks, as outlined in standards that harmonise with EU legislation. The European Commission has published relevant references in the Official Journal of the European Communities in accordance with Article 4 of the General Product Safety Directive (GPSD). Regarding product warnings, the GPSD mandates that producers provide consumers with essential information within the scope of their operations, enabling consumers to assess any risks associated with the product during its normal or reasonably foreseeable use. If a risk is not immediately apparent without a warning, producers are required to inform consumers of necessary precautions to mitigate those risks.²² It is important to note that the existence of adequate warnings does not absolve producers from fulfilling other requirements set forth in the GPSD. Producers must take all necessary measures pertinent to the nature of the products they offer, within the limits of their operations. Over the years, the regulatory framework governing product safety in Europe has become increasingly stringent, reinforcing the commitment to consumer protection across the EU.

5. Product Recall

The GPSD²³ governs product recall procedures within the European Union (EU) and establishes the obligations of both producers and distributors to address product safety risks. According to Article 5(1) of the GPSD, producers are required to implement measures that align with the characteristics of their products. This enables them to be promptly informed about potential risks and take appropriate actions, which may include issuing consumer warnings, withdrawing products from the market, and recalling products from consumers when necessary. Product recalls within the EU are typically regarded as a last resort, employed only when other measures are insufficient to mitigate associated risks. Under Articles 6 and 8 of the GPSD, Member States are mandated to establish a national legal framework that allows for the implementation of necessary actions, including the recall of consumer products. Many EU Member States have empowered enforcement authorities to compel companies to initiate recalls or to execute recalls themselves. Consequently, much of the procedural governance surrounding product recalls is defined by national legislation.²⁴ The European Commission's Guidelines set forth the criteria for determining the level of risk that necessitates a recall, as specified in Article 5(3) of the GPSD. Additionally, the EU has developed a more

¹⁰ Article 6(1)(a)-(c).

¹¹ Article 8(1).

¹² Article 8(2).

¹³ European General Product Safety Directive 2001/95/EC Article 1.

¹⁴ Article 3(1).

¹⁵ Article 3(2).

¹⁶ Article 5(1).

¹⁷ Article 6(1).

¹⁸ Article 8.

¹⁹ Article 18.

²⁰ EU Product Safety Directive (GPSD) 2001/95/EC, Article 1.

²¹ *Ibid*, Article 3(1).

²² GPSD Article 5(1).

²³ General Product Safety Directive 'GPSD' (2001/95/EC).

²⁴ H Lovells, 'Product Recalls in the EU' September 2018<www.lexology.com> accessed 6 November 2024.

comprehensive risk assessment methodology, which was introduced in January 2010 through Decision 2010/15/EU. This decision provides guidance for Member State authorities in evaluating product risks within their jurisdictions and assists them in determining whether a risk is serious enough to warrant notification to the Rapid Alert System for Non-Food Products.²⁵ Certain products, particularly medicinal products and medical devices, are subject to specific recall rules and guidelines. In 2012, the European Commission published a resource titled 'Corrective Action Guide: Guidelines for Businesses to Manage Product Recalls & Other Corrective Actions.' This guide was developed by the Product Safety Enforcement Forum of Europe in collaboration with various stakeholders. Furthermore, the European Commission now offers an online risk assessment application to assist businesses in conducting risk assessments in accordance with the established methodology.²⁶

6. Standardisation of Products in the European Union

The European Union (EU) has adopted a stringent approach to mandatory product safety standards through the establishment of Directives that provide a comprehensive framework for integrating voluntary standards.²⁷ This integration is aimed at achieving acceptable safety levels deemed politically favourable while accommodating the manufacturing industry's preferences. By incorporating these standards into the EU's legal framework on product regulation, the EU has facilitated enhanced public participation in the development of acceptable safety standards. The European Council Resolution of 1985 on the New Approach to Technical Harmonisation and Standards signified a pivotal transition from previously detailed, product-specific regulations to more broadly defined Directives. These EU Directives outline essential safety requirements, leaving the specific implementation details to be further refined by European standards. The fundamental components that underpin the product ecosystem are governed by EU standards.²⁸ Furthermore, the EU standards have embraced a global perspective on issues related to product certification and testing. This innovative framework encompasses three primary dimensions; an enhanced role for standardisation, the introduction of more flexible regulations, and the establishment of reliance on conformity assessment procedures. This approach was formulated to be adaptable, placing significant responsibilities for standardisation upon European organisations and ensuring comprehensive harmonisation of safety aspects. This, in turn, provides member states with confidence in allowing the free movement of compliant consumer goods across their borders.²⁹ In the EU, the bodies responsible for standardisation are tasked with ensuring that technical specifications meet the necessary criteria for production and market distribution. These technical specifications are voluntary, with national authorities tasked with recognising products that conform to the EU harmonised standards. There exists an assumption that these products meet the requisite requirements for standardisation. Producers may opt not to conform to these harmonised standards; however, they must demonstrate that their products comply with the essential requirements.³⁰ Consequently, the safety requirements for products subject to EU standards hinge on national voluntary standards that implement EU regulations, ensuring that products adhere to community technical specifications established in the member states where they are marketed.

7. Enforcement of European Union Directives

The European Union's product liability and safety framework has been revised to enhance consumer protection while providing greater stability for producers. This legal structure aims to balance the interests of consumers, who seek access to safe products, with those of producers, who aim to avoid costly litigation arising from varying national standards. The Product Liability Directive (PLD) mandates strict liability for producers of defective products concerning damages resulting from such defects. Specifically, producers bear strict liability for any harm caused by defective products they manufacture, thereby facilitating the free movement of goods within the EU while offering a robust level of consumer protection.³¹ The PLD applies to all economic operators involved in the manufacture of defective products, encompassing a broad definition of 'producer.' This definition includes manufacturers of raw materials, producers of finished goods or components, those who affix their name or trademark to products, importers of products into the EU for distribution or sale, and suppliers of products, unless they can identify the actual producer to the harmed consumer.³² Despite the PLD's expansive framework, there remains a pressing need for uniformity and harmonisation concerning product design defects, as member states adopt differing approaches. For instance, French law requires consumers to establish that a product failed and caused harm, whereas courts in other jurisdictions may demand identification of the specific defect responsible for the harm. The PLD is designed to contribute to an overarching liability framework that protects consumers adequately without stifling innovation or escalating costs for manufacturers.³³

A critical assessment reveals that the PLD offers broad definitions and applications, often deferring to national courts for specific interpretations and implementations. Notably, the PLD lacks precise definitions of design, manufacturing, and warning defects, leading to situations where national courts may grant compensation to consumers to mitigate the challenges of proving a product defect. Moreover, the Directive allows member states to set a liability cap of 70 million euros per defect and imposes strict liability solely on manufacturers or importers, excluding domestic distributors or retailers. The European Commission plays a crucial role in regulating and enforcing the PLD, continually adapting to technological advancements to meet the EU's

²⁵ *Ibid.*

²⁶ *Ibid.*

²⁷ *Ibid.*

²⁸ *Ibid.*

²⁹ W.D. Howells, 'The Relationship between Product Liability and Product Safety – Understanding a Necessary Element in European Product Liability through a Comparison with the US Position (2000) *Western Law Journal*.

³⁰ General Product Safety Directive Article 4.

³¹ *Ibid.*

³² Product Liability Directive (PLD) Article 3.

³³ T Verheyen, 'Modern Theories of Product Warnings and European Product Liability Law' (2019) (15) *Utrecht Law Review*.

evolving needs. Recognising the rapid pace of innovation, the Commission favours developing non-binding guidelines rather than altering legislation to clarify issues related to product innovations and the standards for determining product defects. The International Consumer Protection and Enforcement Network (ICPEN) consists of law enforcement and trade practices authorities from over thirty countries, many of which are Organisation for Economic Cooperation and Development (OECD) members. ICPEN's mission is to share information regarding cross-border commercial activities affecting consumer interests and to foster international cooperation among law enforcement agencies, thereby enhancing the development of community policies.³⁴

The European Commission spearheads initiatives to bolster public authority networks addressing the rise in cross-border consumer complaints within the single market, facilitated by the Consumer Protection Cooperation (CPC) Network. This network regulates cooperation among national authorities responsible for enforcing consumer protection laws.³⁵ The EU's regulatory framework also encompasses the European Consumer Centre Network (ECC-Net), the FIN-Net, and the Enforcements Network. Established in 2005, ECC-Net aims to enhance consumer confidence by informing citizens of their rights and providing streamlined access to redress, particularly in cross-border purchases. The ECC-Net operates across all EU member states, offering a range of services, including consumer rights information and assistance with complaint resolution.³⁶ The aim of the ECC-Net is to provide consumers with a wide range of services, which covers information on their rights, giving of advice and assistance with their complaints, and also dispute resolution. The ECC-Net is present in all the member States of the EU, and has the role of advising on out of court settlement procedures for consumers throughout Europe and on cooperating with each other and with other European networks. The CPC Network effectively brings together national authorities responsible for enforcing EU consumer laws, preventing harmful cross-border business practices and establishing a cohesive framework for cooperation and minimum investigative and enforcement powers among these authorities. It facilitates the exchange of pertinent information, enhancing collective enforcement efforts.³⁷ The CPC also partially brings together the authorities' investigative and enforcement powers and lays down the mechanisms for exchanging relevant information.

In 2018, the European Commission proposed 'A New Deal for Consumers,' targeting EU countries, including Austria, Belgium, Germany, Greece, Italy, Poland, Portugal, Spain, and Sweden. This initiative modernised consumer protection measures, and reinforced equal treatment for consumers across the European single market. Acknowledging the divergence in consumer protection policy and enforcement frameworks among member states due to differing legal and cultural contexts, the proposals aimed to establish a more consistent approach.³⁸ Utilizing collective redress mechanisms, the EU has strengthened the enforcement of consumer rights by enabling qualified organisations to advocate on behalf of consumers and seek compensation for wronged parties. The proposals also augmented the sanctioning powers of national enforcement authorities, allowing fines of up to 4% of a trader's annual turnover for violations of EU consumer laws, ensuring consistent enforcement across borders.

Dispute resolution frameworks, including Alternative Dispute Resolution (ADR) and Online Dispute Resolution (ODR) mechanisms, are also established under EU directives to handle domestic and cross-border disputes between consumers and traders. Ongoing efforts to educate and empower consumers and traders regarding their rights, responsibilities, and obligations continue, although full compliance with EU consumer law has faced challenges.³⁹ The European Commission is authorised to propose revisions and submit reports to the Council of European Communities every five years for the review of the PLD.⁴⁰ In 1999, the Commission released a green paper examining various liability issues, including burden of proof, development risks, suppliers' liability, types of goods and damages, and access to justice.⁴¹ Subsequent reviews in 2006⁴² and 2011 concluded that no significant changes to the PLD were necessary; rather, an emphasis on monitoring and maintaining the balance between consumer protection and producer interests was warranted. These findings affirmed the PLD's continued efficacy as a stabilising legal framework for the single market, and for harmonising consumer protection across the EU.⁴³

8. European Union Court of Justice Decisions on Product liability

The European Union Court of Justice (CJEU) has rendered significant rulings concerning product liability, particularly in cases where ambiguities exist within the national laws of EU member states. The CJEU has established important guidelines on the conditions under which a product may be deemed defective. Notably, in the *Boston Scientific Cases*,⁴⁴ the CJEU determined that if a product, as part of a product group, presents a notably higher risk of failure, it qualifies as defective, irrespective of

³⁴P Craig, 'Shared Administration and Networks: Global and EU Perspectives', Paper Presented at the Workshop on Comparative Administrative Law (Yale Law School May 2009).

³⁵ Council Regulation (EC) NO. 2006/2004 of 27 October 2004 OJ L 364/1.

³⁶ C Bergstrom, *Comitology: Delegation of Powers in the European Union and the Committee System* (Oxford University Press, 2005) 56.

³⁷ J Davies, *The European Consumer Citizen in Law and Policy* (Palgrave MacMillan 2011) 26.

³⁸RO Ugbe and Others, 'Consumer Redress Channels under Nigerian Laws: A Comparative Analysis' (2020) (104) *Journal of Law Policy and Globalization*.

³⁹ EU Directive 2013/11/EU.

⁴⁰ *Ibid*, Article 21.

⁴¹ Directive 1999/34 Amending Council Directive 85/374 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States concerning Liability for Defective Products (1999) OJ L141/20.

⁴² European Commission, Third Report on the Application of Council Directive on the Approximation of laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products (September 2006: COM (2006) 496 final).

⁴³ European Commission, Fifth report on the Application of Council Directive on the Approximation of Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products (85/374/EEC) COM/2018/246 final).

⁴⁴ C-503/13 and C-504/13.

whether any defect has been identified in each individual product. These proceedings arose from claims made by health insurers of patients seeking reimbursement for costs associated with defective devices, which were destroyed post-removal, thus lacking direct evidence of malfunction. In its decisions, the CJEU provided clarity on the definition of 'defect' in the context of the Directive, which stipulates that a product is considered defective if it fails to provide the safety that consumers are entitled to expect. This assessment involves considering various factors, including the 'consumer expectation test' based on the product's intended use, its characteristics, the time it was made available in the market, and its marketing presentation. The Court emphasized the necessity to evaluate the general expectations of the public while also addressing the specific needs of the intended user group. Furthermore, the CJEU concluded that when products from the same production series exhibit a potential defect, it is justifiable to classify all products in that series as defective without requiring evidence of a defect in any specific item.⁴⁵ In construing this provision, the Court made reference to the sixth recital to the Directive, and stated that the effect of that recital was that the appraisal must be carried out having regard to the reasonable expectations of the public at large. Taking these factors into account, the Court concluded that the consumer expectations test must be assessed by taking into account various factors, including; the intended purpose of the product, its objective characteristics and properties, and the specific requirements of the group of users for whom the product is intended. Although the test is, therefore, said to take into account the general expectations of the public at large, in practice, the test encompasses the specific requirements and expectations of the group of users for whom the product is intended. The CJEU concluded that, in situation products belong to the same production series and show a potential defect, it will be fair to classify all those products in that production series as defective, without the need to prove that any specific product was, in fact, defective.

In *W X Y v Sanofi Pasteur MSD SNC and Others*,⁴⁶ the claimant alleged that the onset of multiple sclerosis was linked to a Hepatitis C vaccine produced by Sanofi Pasteur. Under French law, a presumption of causation arises when a disease manifests shortly after the administration of an allegedly defective product, provided there are no relevant personal or family medical histories. The CJEU indicated that national laws should govern the determination of causation, adhering to the EU principle that procedural matters fall within the jurisdiction of member states. The French Cour de Cassation sought the CJEU's guidance on the evidential standards required to establish causation under the Directive. In the *Vaccine Liability Case*,⁴⁷ the CJEU determined that, in the absence of scientific consensus on a vaccine's defectiveness, the existence of a causal link may be established through 'serious, specific, and consistent' evidence. National courts must ensure that the implementation of this evidentiary standard does not undermine the claimant's burden of proof as outlined in Article 4 of the Product Liability Directive (PLD), which places the onus on the claimant to demonstrate damage, defect, and the necessary causal relationship. Thus, while the use of evidentiary presumptions is permissible to establish a *prima facie* causal link, the claimant remains responsible for proving causation with evidence.⁴⁸

The EU's framework imposes strict liability on producers for damages stemming from defective products. In *Fiorasi v Soc. Crino*,⁴⁹ an Italian case, which aligned with the European approach, a medicine containing an infected blood product was deemed significantly defective and harmful, resulting in the manufacturer being held strictly liable for failing to take adequate precautions to avoid damage resulting from the product. Recently, the burden of proof in product liability claims within the EU has been notably relaxed, reflecting a shift by the CJEU towards a more claimant-friendly approach.⁵⁰ Plaintiffs are now required merely to demonstrate that a product does not conform to established standards, irrespective of the origins of the substandard quality, and without the need to establish negligence.⁵¹ The CJEU has had occasion to rule on proof-related issues quite a few times in recent years. The CJEU's readiness to support member states' efforts to lessen the plaintiff's burden of proof is exemplified in the case of *Novo Nordisk Pharma*,⁵² this case examined whether Germany could modify its liability regulations to allow victims the right to obtain information from pharmaceutical companies regarding products. The CJEU ruled that this right to information fell outside the scope of harmonisation, affirming national legislation aimed at rectifying imbalances between manufacturers and consumers regarding product information, as this does not interfere with the evidentiary burden imposed on plaintiffs. This special liability rule for pharmaceutical companies was adopted prior to the Directive, and therefore was under the control of Article 13 of the Directive. The amendment on the issue of the consumers' right to obtain information from the manufacturer was made afterwards. However, the CJEU ruled that this right to information fell outside the scope of harmonisation. More so, national legislation is only for the purpose of removing significant imbalances which are in existence between the manufacturers and consumers in relation to any needed information on the product. This information is not in contrast to the burden of proof between the plaintiff and defendant; therefore, the right of information was allowed by the CJEU. The CJEU in one breathe addressed the issues of the acceptability of a right to information under a special liability law, and also determined that the right was admissible under the reign of the Directive.

⁴⁵ European Union Directive, Article 6.

⁴⁶ Case C-621/15.

⁴⁷ J Leadley and L Oakley, 'The Vaccine Liability Case – ECJ Lowers the Standard of Proof,' <<https://globalcompliancenews.com/ecj-liability-standard-proof-vaccine-20170817/>> accessed 14 December 2024.

⁴⁸ Product Liability Directive (PLD) Article 4.

⁴⁹ Cass. Civ. 15-7-1987 n. 6241, in Foro, 1998, I.

⁵⁰ *Declan O'Byrne v Sanofi Pasteur MSD Ltd & Sanofi Pasteur SA*, ECLI: EU: C: 2006:93; Case C-358/08, *Aventis Pasteur v O'Byrne*, ECLI: EU: C: 2009:744.

⁵¹ T Verheyen, 'Modern Theories of Product Warnings and European Product Liability Law' (2019) (15) *Utrecht Law Review*; 44.

⁵² *Novo Nordisk Pharma GmbH v S.*, ECLI: EU: C: 2014:2385.

Additionally in *Boston Scientific Medizintechnik*,⁵³ the CJEU further alleviated the plaintiff's evidentiary requirements concerning specific causation. It redefined the notion of defect and diminished the necessity of proving causation. In the *Sanofi Pasteur* case,⁵⁴ the CJEU upheld the French evidentiary rule that permits plaintiffs to establish defectiveness and a causal link based on serious, specific, and consistent presumptions. Critically, the CJEU delineated three limitations on member states' discretion to regulate burden of proof: first, national rules cannot reverse the burden of proof as established in Article 4 of the Directive; second, presumptions must not be automatic; and third, scientific proof of causal links is not a requisite. The CJEU has repeatedly adopted interpretations of the Product Liability Directive that favour consumers/victims, often through a narrow reading of harmonisation parameters. The CJEU has also interpreted the PLD in a manner that has been shown to frequently favour the consumer/victim. This is through the CJEU's restrictive interpretation of the scope of harmonisation. For example, in the case of *CHU Besançon*,⁵⁵ the CJEU endorsed a French liability provision that holds service providers liable for defective products they did not manufacture, reflecting a consistent commitment to minimizing the burden of proof placed on plaintiffs. The CJEU has also shown readiness to the strict interpretation of grounds for exemption enumerated under Article 7 of the Directive.

9. Notable Innovations under the EU Directives

The case law established by the Court of Justice of the European Union (CJEU) typically adopts a plaintiff-friendly stance concerning the burden of proof in product liability cases. The CJEU has interpreted the relevant Directive to enhance consumer protection, simplifying the evidential requirements for plaintiffs. The preamble of the Directive further underscores its pro-consumer orientation, reflecting a comprehensive commitment to safeguarding consumer rights. Recent developments in EU legislation include the introduction of new Directives that enable consumers within the EU to initiate class actions against traders, effective from December 25, 2022, and applicable from June 2023.⁵⁶ The Representative Actions Directive (EU) 2020/1828 represents a significant transformation in the European class action framework, establishing mechanisms for group litigation across all 27 EU Member States and introducing a new cross-border class action process. This Directive targets an array of EU legislation encompassing consumer rights, product liability, product safety, medical devices, and medicinal products. Notably, the losing party in class action cases will be responsible for reimbursing the winning party's costs, including legal fees, a measure intended to deter frivolous claims. However, individual consumers will generally not be liable for costs unless they are found to have intentionally or negligently increased such costs in exceptional cases.

The Consumer Protection Directive (PLD) also strengthens the rights of consumers⁵⁷ by enhancing transparency in online sales and digital services. It mandates that marketing websites and marketplaces clearly identify whether the seller is a professional trader or a private individual, given the potential bias in digital search results due to sellers' payments for higher rankings.⁵⁸ Furthermore, the PLD ensures that consumers harmed by unfair trade practices have access to individual remedies. These remedies may be both contractual and non-contractual, encompassing rights such as rescission or termination of contracts and compensation for damages. Ultimately, the PLD is compensation-driven, a characteristic mirrored in the rulings of the CJEU. The primary focus of the PLD is on compensation rather than factors such as prevention, efficiency, or procedural fairness. This emphasis aims to promote the establishment of safer products rather than merely less expensive ones within the EU. As a result, this regulatory approach may prioritize consumer interests over those of manufacturers, imposing a greater financial burden on the latter. An increase in liability for manufacturers might lead to heightened product prices, inadvertently discouraging consumer purchases.⁵⁹

10. Conclusion and Recommendations

In summary, the European Union (EU) adopts a strategy that involves selecting between safer products and their more affordable alternatives. The EU stands at the forefront of innovation, driven by ongoing modifications to product specifications and the necessity for market interconnectivity. Additionally, the EU's practice of reviewing its directives every five years acknowledges the evolution of human behaviour and social conduct, necessitating the continuous enactment and revision of laws to address emerging issues and prevent gaps or ambiguities in legal frameworks. The Product Liability Directive (PLD) has been instrumental in ensuring that consumers adversely affected by unfair trade practices are provided with the right to seek individual remedies. Furthermore, recent directives released in 2023 include unequivocal provisions for group litigation across all 27 EU Member States, complemented by a new cross-border mechanism for class actions. Finally, the following recommendations are proffered: It is essential to emphasize the need for uniformity and harmonisation concerning defects in product designs, as Member States currently employ diverse approaches to this issue. The broad definitions and applications encompassed by the EU PLD may result in interpretative ambiguities. Therefore, it is advisable for the EU PLD to adopt a more precise approach, particularly regarding the definitions of design defects, manufacturing defects, and warning defects.

⁵³ C-503/13.

⁵⁴ Case C-621/15; ECLI: EU: C: 2017:484.

⁵⁵ Case C-495-10; CLI: EU: C: 2011:869.

⁵⁶ E Turtle, 'New EU Class Action Mechanisms to be implemented by Christmas' October 11 2022 <<https://www.lexology.com/library/detail.aspx?g=2cb98167-b8ca-4477-b93b-0dae698c2dc6>> accessed 14 December 2024.

⁵⁷ Directive 2011/83/EU.

⁵⁸ Directive 2005/29/EC.

⁵⁹ A. Polinsky and S. Shavell, 'The Uneasy Case for Product Liability', (2010) (123) *Harvard Law Review*; 1472.