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Some remarks on nanotechnologies, safety and product liability

Alcune osservazioni su nanotecnologie, sicurezza e responsabilità da prodotto

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Abstract

This paper examines the legal implications of nanotechnology, focusing on consumer protection and product liability. It highlights how the precautionary principle guides regulatory and civil liability frameworks in managing scientific uncertainty and emerging risks. Emphasis is placed on transparency, labelling, and information disclosure as essential tools for informed consent and risk prevention taking into account the recent EU reforms, including the General Product Safety Regulation (EU) and the new Product Liability Directive (EU) 2024/2853. The study argues that precaution operates as a bridge between product safety regulation and civil liability, ensuring a dynamic balance between technological innovation and the protection of health, safety, and consumer trust in the nanotechnology era.

Il contributo analizza le implicazioni giuridiche delle nanotecnologie, con particolare attenzione alla tutela dei consumatori e alla responsabilità da prodotto. Si evidenzia come il principio di precauzione orienti i sistemi normativi e i modelli di responsabilità civile nella gestione dell'incertezza scientifica e dei rischi emergenti. L'analisi pone l'accento su trasparenza, etichettatura e divulgazione delle informazioni, considerate strumenti fondamentali per garantire il consenso informato e la prevenzione dei rischi, anche alla luce delle recenti riforme europee, tra cui il Regolamento (UE) sulla sicurezza generale dei prodotti e la nuova Direttiva (UE) 2024/2853 sulla responsabilità da prodotto. Lo studio sostiene che il principio di precauzione funge da ponte tra la regolamentazione della sicurezza dei prodotti e la responsabilità civile, assicurando un equilibrio dinamico tra innovazione tecnologica e tutela della salute, della sicurezza e della fiducia dei consumatori nell'era della nanotecnologia.

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Keywords: Nanotechnology; Precautionary Principle; Consumer Protection; Product Liability; Safety

Summary: 1. Benefits and Risks of Nanotechnologies. – 2. Consumer information in the Context of Nanotechnology Products. – 3. Producer Liability and the "Development Risk Defense" Clause. – 4. Burden of Proof (New Directive (EU) 2024/2853). – 5. Conclusion.

1. Benefits and Risks of Nanotechnologies.

The integration of nanotechnology into diverse sectors, including medicine, engineering, and consumer products,[1] has generated significant advancements and opportunities. At the same time, this rapid development raises important legal concerns, particularly with regard to liability and consumer protection.

A proper analysis must begin with a definition. Nanotechnology refers to the engineering, manipulation, and application of materials at the nanoscale (1–100 nm). It broadly encompasses any technology that incorporates engineered nanomaterials.[2]

Although these particles are exceedingly small, they pose substantial questions, as many of their interactions with the human body and the

[1] For example, it is possible to find nanotechnologies in refrigerator linings, in the house, in transport of food from producer to grocery store, in bicycle tires and cosmetics; other example in Swiss Nanocube, Nanorama: The World of Nanotechnology (Swiss Nanocube) http://www.swissnanocube.ch/nanorama/?L=3, accessed 6 October 2025, in which there is an interactive photos identify over fifty household items using nanotechnology and therefore representing potential exposure to engineered or manufactured nanoparticles in daily life.
A definition in European Chemicals Agency (ECHA), Nanomaterials https://echa.europa.eu/regulations/nanomaterials, accessed 6 October 2025: "Nanomaterials are chemical substances or materials with particle sizes between 1 to 100 nanometres in at least one dimension. Due to an increased specific surface area by volume, nanomaterials may have different characteristics compared to the same material without nanoscale features. As a result, the physicochemical properties of nanomaterials may differ from those of bulk substances or particles of a larger size. Many everyday products containing nanomaterials are already on the European market such as batteries, coatings, anti-bacterial clothing and cosmetics. While nanomaterials may offer technical and commercial opportunities, they may also pose risks to our health and the environment. Just like any other substance on the EU market, it is important to ensure that their uses are properly assessed and that any risks are adequately controlled"; see also Commission Recommendation of 10 June 2022 on the definition of nanomaterial: 'Nanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions:
(a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm;
(b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm;
(c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.
In the determination of the particle number-based size distribution, particles with at least two orthogonal external dimensions larger than 100 µm need not be considered.

[2] PC Binsfeld and JM Granjeiro, 'Nanotecnologias: regulação baseada em evidências' (2024) 12 Vigilância Sanitária em Debate https://doi.org/10.22239/2317-269X.02260, accessed 6 October 2025; JV McHale, 'Nanomedicine—Small Particles, Big Issues: A New Regulatory Dawn for Health Care Law and Bioethics?' in M Freeman (ed), *Law and Bioethics: Current Legal Issues*, vol 11 (Oxford University Press 2008; online edn, Oxford Academic, 1 Jan 2009) https://doi.org/10.1093/oso:acprof/9780199545520.003.0020, accessed 4 July 2025.

environment remain insufficiently understood.[3] Despite these uncertainties, products derived from nanomaterials – including food items[4] and packaging – are increasingly entering the consumer market.[5]

This situation brings to the forefront ethical, environmental, and safety challenges. Nanotechnologies and nanomaterials are not without risk. Indeed, the very characteristics that make nanoparticles valuable – such as their diminutive size, large surface-area-to-volume ratio, and high reactivity – may also generate unique and potentially hazardous effects on human health.

This paper examines the regulatory framework governing the use of nanotechnology with particular reference to the consumer protection and product liability.

This domain is strongly shaped by the precautionary principle, which requires proactive measures to prevent harm to public health and the environment even in the absence of complete scientific certainty. The principle highlights the importance of stringent regulatory standards and rigorous risk management practices in the development and deployment of nanotechnologies.

Moreover, this analysis emphasizes the essential role of information disclosure and product labelling in safeguarding consumers. Transparent and comprehensive labelling practices are vital for informing consumers about the presence and potential risks of nanomaterials in products. Proper labelling not only facilitates risk management but also strengthens consumer trust and supports informed decision-making.

Given the broad range of applications for nanotechnologies, attention must be directed towards the specific regulatory frameworks applicable to different product categories.[6] This requires harmonization with general principles of product liability, thereby ensuring consistent and comprehensive legal coverage. The jurist's role is pivotal in navigating this complex regulatory landscape while aligning specialized provisions with overarching liability principles in order to address the distinctive issues raised by nanotechnology.

A particularly significant development is the adoption of the new General Product Safety Regulation (EU) 2023/988,[7] which strengthens consumer

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[3] GBB Nhani and others, 'High-Tech Sustainable Beauty: Exploring Nanotechnology for the Development of Cosmetics Using Plant and Animal By-Products' (2024) 11 Cosmetics 112 <https://doi.org/10.3390/cosmetics11040112>, accessed 6 October 2025.

[4] With reference food see: Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 [2015] OJ L327/1; EFSA Scientific Committee, More S and others, 'Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health' (2021) 19(8) EFSA Journal 6768 <https://doi.org/10.2903/j.efsa.2021.6768>, accessed 6 October 2025.

[5] More information in: European Commission, Opinion on Nanomaterials <https://ec.europa.eu/health/scientific_committees/opinions_layman/nanomaterials/en/l-2/1.html>, accessed 6 October 2025 "Current applications include healthcare (in targeted drug delivery, regenerative medicine, and diagnostics), electronics, cosmetics, textiles, information technology and environmental protection. For example, nanosilver is appearing in a range of products, including washing machines, socks, food packaging, wound dressings and food supplements".

[6] Cosmetics Regulation: Imposes specific safety requirements for nanoparticles in cosmetics. Main legislation: European Commission, Cosmetics Legislation Overview <https://single-market-economy.ec.europa.eu/sectors/cosmetics/legislation_en>, accessed 6 October 2025

[7] P Steindl, 'Consumer Neuro Devices within EU Product Safety Law: Are We Prepared for Big Tech ante Portas?' (2024) 52 Computer Law & Security Review 105945 <https://doi.org/10.1016/j.clsr.2024.105945>, accessed 6 October 2025.

protection by introducing enhanced mechanisms for identifying and managing emerging risks, including those arising from nanoscale substances. Legal professionals must critically assess how this Regulation interacts with existing legal frameworks and embodies the precautionary principle, thereby contributing to a more comprehensive and adaptive model of product safety.

In light of the transversal, disruptive, and pervasive nature of nanotechnologies, their regulation requires not only specialized scientific expertise but also a legal architecture capable of addressing their specific risk profiles. The nanoscale dimension of materials generates unprecedented challenges that demand tailored regulatory solutions, proactive governance strategies, and oversight mechanisms grounded in transparency, accountability, and risk prevention. The evolving character of nanotechnologies therefore calls for a dynamic and responsive legal framework that balances innovation with the protection of public health and the environment.

2. Consumer information in the Context of Nanotechnology Products.

Consumer information constitutes a fundamental component of health and safety protection, particularly in the context of emerging technologies such as nanotechnology. The principle of the "right to know" is a cornerstone of informed consent and plays a crucial role in safeguarding both public and consumer health. Furthermore, it serves to mitigate potential legal liability for businesses engaged in the development and application of nanotechnology. [8]

A major legal and regulatory challenge in this domain lies in the persistent scientific uncertainty and the absence of reliable, reproducible data concerning potential risks. [9] These deficiencies directly hinder the application of two core components of informed consent: (i) the obligation to disclose known risks in a manner that enables the consumer or end-user to make an informed choice; and (ii) the subsequent acceptance of such risks – i.e., the provision of consent despite awareness of those risks – based on robust and validated scientific evidence.

In the case of nanotechnology, these requirements cannot presently be fulfilled due to the limited state of scientific knowledge, particularly with respect to cumulative, long-term, and unquantifiable risks arising from prolonged exposure. This evidentiary gap raises significant concerns in several areas of legal and ethical significance, including consumer protection (especially in biomedical and nanomedical applications), patient safety, nanosafety, and potential corporate liability. In the absence of sufficient data,

[8] Committee on Social Affairs, Health and Sustainable Development, Nanotechnology: Balancing Benefits and Risks to Public Health and the Environment, Rapporteur: Valeriy Sudarenkov, Russian Federation, SOCAS/Soc/Inf (2013) 03.

[9] B Pastore, 'Tecnologie emergenti, incertezze della scienza, regolamentazione giuridica' (2020) 2(17) Teoria e Critica della Regolazione Sociale / Theory and Criticism of Social Regulation 97 <https://mimesisjournals.com/ojs/index.php/tcrs/article/view/63>, accessed 18 July 2025.

ensuring regulatory compliance and mitigating liability for manufacturers and healthcare providers remain highly problematic. [10]

Traditional mechanisms of informed consent - such as those embedded in REACH and the Prior Informed Consent (PIC) procedure - [11] prove difficult to implement effectively. [12]

These frameworks presume that producers disclose known risks, thereby enabling consumers, including corporate actors, to make informed choices. Such disclosure functions as a liability shield, based on the assumption that risk is knowingly accepted by the informed party. Yet, in the context of nanotechnology, the paucity of validated scientific data undermines both the adequacy and comprehensibility of disclosures, raising serious bioethical and legal concerns.

Key issues include: (1) the consumer's capacity to comprehend technical risk disclosures; (2) the sufficiency and quality of such disclosures to support meaningful consent; and (3) the scientific reliability of the underlying data. Within REACH, consumers have the "right to know" (see article 33) whether the products they purchase contain hazardous chemicals. However, in this field the precautionary principle becomes essential to bridging the gap between scientific uncertainty and the legal requirement of informed consent, pending the establishment of a robust evidentiary baseline.

The precautionary principle operates as a legal tool for managing risks that remain unidentified or insufficiently characterised.[13]

The precautionary approach – distinct from the notion of anticipatory preventive action – requires that, in conditions of scientific uncertainty, the conduct of the entrepreneur or producer be guided by prudence, with a view to prioritizing safety over risk. From a legal standpoint, a further consideration warrants closer examination.

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[10] Committee on Social Affairs, Health and Sustainable Development, Nanotechnology: Balancing Benefits and Risks to Public Health and the Environment, Rapporteur: Valeriy Sudarenkov, Russian Federation, SOCAS/Soc/Inf (2013) 03.

[11] More information at European Commission, REACH Regulation – Chemicals and Nanomaterials <https://environment.ec.europa.eu/topics/chemicals/reach-regulation_en>, accessed 6 October 2025 in which it can read: Nanomaterials are chemical substances or materials comprising very small particles of different shapes and sizes no larger than 100 nm. Many occur in nature, but most have been engineered to exhibit novel characteristics such as increased strength, chemical reactivity or conductivity compared to their non-nano counterparts. The REACH Regulation initially made no specific provision for nanomaterials. In 2018 the Commission adopted Commission Regulation (EU) 2018/1881 to modify REACH technical Annexes I, III and VI-XII, introducing nano-specific clarifications and provisions. In 2020 the Commission also updated Annex II with Commission Regulation (EU) 2020/878, introducing new provisions on Safety Data Sheets to complement the new registration requirements for nanomaterials. In 2011 the Commission adopted the Recommendation on the definition of a nanomaterial. This definition has informed many EU directives and regulations and has been supported by implementation guidance. The Recommendation was reviewed and revised in 2022 retaining its principal features. Supplemental information about the revised Recommendation has been provided by the Industrial Minerals Association (IMA) and the Germany Federal Institute for Risk Assessment (BfR).

[12] AskREACH, Art. 33 REACH: A Right to Know, Not a Right to Ask – Final Conference <https://www.askreach.eu/art-33-reach-a-right-to-know-not-a-right-to-ask-final-conference-takes-stock-after-more-than-5-years/> accessed 6 October 2025

[13] G Capilli, 'Gli obblighi di precauzione dell'impresa' in G Alpa and G Conte (eds), *La responsabilità di impresa* (Giuffrè 2015) 149–189; E Al Mureden, *Principio di precauzione, tutela della salute e responsabilità civile*, (Libreria Bonomo 2008); G Alpa, 'Responsabilità d'impresa', in *Digesto delle discipline privatistiche – Sezione Civile*, aggiornamento (UTET 2014) 560 ff.; G Comandè, 'La responsabilità civile per danno da prodotto difettoso… assunta con "precauzione"' (2013) 1 Danno e Responsabilità 107.

The assessment of product safety is therefore intrinsically linked to the nature of the product itself. This interplay between regulatory measures and consumer rights underscores the need for a nuanced approach to balancing innovation with safety. Particularly in the field of nanotechnology, the precautionary principle provides a critical framework for addressing the "unknown unknowns" inherent to nanoscale substances.

Equally, transparency and effective communication are indispensable. Labelling and information practices, as integral elements of informed consent, must be strengthened to ensure clarity and accessibility. This requires a collaborative effort among regulators, producers, and scientific communities to develop standardised guidelines capable of translating complex technical data into forms comprehensible to consumers. Such measures not only enable consumers to make informed choices but also mitigate liability risks for manufacturers by fostering trust and compliance in the marketplace.

Consequently, the precautionary conduct of producers must be calibrated in accordance with the specific category of product and the intended users or recipients.

This calls for a re-examination of the foundations of civil liability in light of the precautionary principle. Liability attribution rules play an evolving role in incentivizing virtuous conduct in risk management and accident prevention, adapting to technological and organisational developments within the relevant sector.[14]

Against this background, the revised Classification, Labelling and Packaging (CLP) Regulation, which entered into force on 10 December 2024, represents a significant step forward in protecting human health and the environment. At the same time, it strengthens the EU's internal market for chemicals, fostering a more competitive, transparent, and sustainable chemical industry.

Key improvements include clearer communication of chemical hazards – especially in online sales – through simplified and modernised labelling requirements. The new rules introduce flexible formats (such as fold-out and digital labels) and stricter standards of legibility. These changes are designed to make safety information more accessible and user-friendly for everyone. Another important feature is the requirement that advertisements and online product listings include clear hazard information. This will enable consumers to make more informed choices and support the growth of a market for sustainable chemical products. For the first time, the Regulation clarifies how household chemicals can be safely sold via refill stations, thereby reducing packaging waste and supporting environmentally sustainable consumption. Small and medium-sized enterprises (SMEs) will benefit from a streamlined and more user-friendly notification system. Overall, the revised CLP Regulation demonstrates a strong commitment to improving safety, enhancing transparency, and supporting innovation in the chemical sector, while keeping pace with new technologies and sustainability goals.[15]

[14] G Capilli, 'Gli obblighi di precauzione dell'impresa' in G Alpa and G Conte (eds), *La responsabilità di impresa* (Giuffrè 2015) 149–189.

[15] <https://environment.ec.europa.eu/news/revised-chemical-labelling-regulation-enters-force-2024-12-10_en>.

Labelling remains a fundamental instrument for communicating risks to consumers and thereby addressing the bioethical concern of informed consent. It functions as a well-established regulatory mechanism to provide essential hazard information to a broad range of stakeholders, including purchasers, workers, downstream users, and the public. Once adequate disclosure is achieved through labelling, these regulations also serve a protective function, limiting the liability exposure of producers and suppliers.

Typically, labels contain critical information about a product's composition, thereby enabling consumers and end-users to make informed decisions and consciously weigh risks against benefits. However, in the case of nanotechnology, the persistent lack of comprehensive scientific data complicates the determination of appropriate and sufficient labelling requirements for products containing nanoscale materials.

3. Producer Liability and the "Development Risk Defense" Clause.

The issue concerns the concept of development risk, which departs from simplified models of product defectiveness and may be understood as a latent defect. It refers to a defect whose identification depends on circumstances and facts that were unforeseeable at the time the product was placed on the market.

The central issue lies in determining the conditions for exemption from liability, which requires evaluating whether the producer discharged a duty of investigation and testing prior to commercialization. The precautionary principle introduces a new dimension of liability, incorporating anticipatory and preventive elements in light of an uncertain and potentially harmful future. The focus thereby shifts from repairing actual damage to addressing risk itself, to the extent that even the mere creation of risk may constitute a sufficient basis for compensation, implying a conscious acceptance of risk.

This gives rise to a significant concern: the producer – who frequently acts both as the primary researcher and financial sponsor of scientific and technical research – may find themselves in the paradoxical position of being both actor and judge of their own responsibility.

The development risk clause (DRC), already included in Directive 85/374/EEC, provides for an exemption from liability where the producer could not have known of the defect at the time the product was placed on the market, given the state of scientific and technical knowledge then available.

The case law of the Court of Justice of the European Union has reinforced the importance of development risk. In Case C-300/95, the Court held that, to invoke the exemption under Article 7(e) of the Directive, the producer must prove that, at the time the product was placed on the market, the state of scientific and technical knowledge – objectively assessed at the highest available level – did not allow the defect to be detected. The Court further clarified that the exemption is not based on the actual knowledge of the specific producer but on the objective state of knowledge presumed to be accessible at that time.

The legal significance of development risk lies in the need to strike a balance: on the one hand, fostering and encouraging corporate innovation; on the other, meeting the legitimate expectations of consumers, particularly in relation to product safety. [16]

Development risk thus derives from a defect inherent in the product, rendering it dangerous from the moment of its commercialization – a defect that was neither visible nor detectable given the state of scientific or technical knowledge available at the time.

The notion of objective knowledge of the defect is of central importance, as it provides the benchmark for assessing the producer's conduct. This evaluation must consider the scientific and technical knowledge available at the relevant time, and the fact that, once doubts were raised concerning a potential danger, the producer may have had the opportunity to contain or mitigate the progression of future harm.

It is evident that the development risk exemption primarily seeks to balance the need to promote and incentivize innovation with the legitimate expectations of consumers regarding product safety. [17]

Development risk stems from a defect inherent in the product, which must be regarded as dangerous at the time of its placement on the market, even if such danger could not have been detected on the basis of the scientific and technical knowledge then available. Precisely because of this intrinsic hazardous character, the producer, consistent with the precautionary principle, has a duty to adopt appropriate safety measures.

In this context, the notion of objective knowledge at the time of market placement is critical. It serves as the benchmark for determining whether the producer acted negligently by failing to identify scientific or technical information that could have revealed the defect, and whether precautionary measures should have been adopted to prevent or mitigate the resulting harm.

Accordingly, the availability and accessibility of objective knowledge at the relevant time become decisive factors in determining whether the producer fulfilled their duty of care and may legitimately invoke the development risk exemption as a defence against liability.

The new proposal for a Directive on liability for defective products (Product Liability Directive – PLD) [18] introduces a significant reform of the so-called "development risk defence," thereby reshaping the traditional balance between producer protection and consumer and end-user safeguards.

Article 10, entitled "Exemption from liability", reiterates the defence whereby a producer may be exempted from liability if he proves that "the objective state of scientific and technical knowledge at the time when the product was placed on the market, put into service, or within the

[16] G Capilli, 'Principe de précaution et responsabilité civil', *Le Consommateur*, vol 57, (Bruylant Paris 2007) 395–406.

[17] For a comparative analysis on the development risk defence: L Di Donna, 'I regimi di responsabilità applicabili ai danni derivanti dai prodotti farmaceutici – Liability regimes applicable to damages arising from pharmaceutical products' (2024) 1–2 Rivista Italiana di Medicina Legale (e del Diritto in campo sanitario) 117.

[18] G Afferni, 'La nuova direttiva sulla responsabilità per danno da prodotti difettosi: una analisi economica' (2025) 2 Responsabilità Civile e Previdenza 351; A Cioni, 'Nuovi pregi e vecchi difetti della proposta di direttiva sulla responsabilità da prodotto difettoso, con particolare riferimento all'onere della prova' (2023) 2 Responsabilità Civile e Previdenza 656.

manufacturer's control was not such that the defect could be discovered" (Art. 10(e)). This provision echoes the classical formulation of the development risk clause, originally codified in Directive 85/374/EEC, but is reinterpreted in light of the contemporary technological landscape, including digital products and artificial intelligence systems.

The most remarkable innovation, however, lies in Article 18, devoted explicitly to "Derogation from development risk defence", which empowers Member States to restrict or even abolish the availability of such an exemption. This legislative choice signals a profound shift of perspective: no longer a generalised immunity for producers in the name of technological progress, but rather an exceptional and derogable defence, to be balanced against the overriding requirement of ensuring a high level of protection for injured parties (Art. 18).

This orientation is further supported by the recitals. Recital 34 provides that national courts should presume either the defectiveness of a product, the causal link between defectiveness and damage, or both, where, notwithstanding the defendant's duty of disclosure, it would be excessively difficult for the claimant to discharge the burden of proof due to the scientific or technical complexity of the case. To impose strict proof in such circumstances would undermine the very effectiveness of the right to compensation. Consequently, since manufacturers possess expert knowledge and privileged access to information, it falls upon them to rebut the presumption (Recital 34).

At the same time, Recital 39 reiterates the need for a fair allocation of risks, clarifying that the development risk defence applies only where the producer can demonstrate that the state of scientific and technical knowledge – assessed with reference to the most advanced level of objective knowledge accessible, rather than the actual knowledge of the producer – was such that the defect could not have been discovered while the product was under the producer's control (Recital 39).

In conclusion, the new PLD reshapes and circumscribes the scope of the development risk defence, transforming it into a limited and potentially inapplicable clause, in order to reinforce the position of consumers and end-users.[19] This normative choice is consistent with the overarching objective of European product liability law: to provide more effective protection to victims of defective products in contexts of heightened technological complexity, including innovative medical devices, artificial intelligence systems, and connected digital products.

[19] G Afferni, 'La nuova direttiva sulla responsabilità per danno da prodotti difettosi: una analisi economica': "*Come regola generale sembra quindi corretto escludere che il fabbricante possa essere tenuto oggettivamente responsabile anche per i difetti del prodotto che non potevano essere considerati tali in base alle conoscenze scientifiche e tecniche del tempo in cui il prodotto è stato messo in circolazione. Ciò non esclude ovviamente l'operare della responsabilità per colpa. In particolare, il fabbricante può essere tenuto responsabile per il danno causato qualora il consumatore dimostri, eventualmente anche solo per presunzioni, alla luce di tutte le circostanze del caso (tipo di prodotto, dimensioni del fabbricante, tipo di informazioni disponibili, ecc.), che il fabbricante ha colpevolmente omesso di svolgere attività di ricerca e sviluppo al fine di far avanzare, avendone le possibilità, lo stato delle conoscenze scientifiche o tecniche del tempo*".

4. Burden of Proof (New Directive (EU) 2024/2853).

Another significant aspect of analysis in this context concerns the allocation of the burden of proof in product liability cases. Consumers are often placed in a position of structural disadvantage: they generally lack the technical expertise necessary to establish the hazardous nature of a product and are simultaneously deprived of the informational resources that remain predominantly under the control of producers. Such asymmetries create a fundamental imbalance in the evidentiary process, which has historically hindered the effective exercise of consumer rights.

It is precisely against this backdrop that the new PLD represents a notable advancement in consumer protection. Article 10, in this context, introduces an innovative approach specifically designed to mitigate disparities between claimants and producers in technologically complex domains. By adapting evidentiary rules to the realities of contemporary technological markets, the Directive seeks to reconcile the promotion of innovation with the protection of those potentially harmed by emerging products. [20]

The practical implications of Article 10 can be illustrated through a hypothetical scenario. Consider a consumer, Mrs X, who purchases and regularly uses an anti-aging cosmetic cream produced by the Y company, which contains zinc oxide nanoparticles coated with novel polymers. After several months of application, she develops chronic dermatitis with permanent skin lesions and initiates proceedings under the product liability regime. Under the traditional legal framework, such a claim would likely fail: the requirement to establish with scientific certainty a causal link between exposure to nanoparticles and the resulting medical condition imposes an evidentiary burden that is, in practice, insurmountable for the consumer, thereby limiting access to justice.

In response to such challenges, Article 10 functions as a mechanism for evidentiary rebalancing. Paragraph 1 reiterates the general principle that the claimant bears the burden of proving the defectiveness of the product, the harm suffered, and the causal nexus between the two. This principle, however, is substantially qualified by the presumptions introduced in the subsequent paragraphs. Paragraph 2 establishes a presumption of defectiveness where the product fails to comply with mandatory safety requirements. In the hypothetical scenario, the omission of the mandatory label indication regarding the presence of nanoparticles, in violation of EU cosmetics regulations, triggers the presumption of defectiveness. Paragraph 3 further provides for a presumption of causation where the type of harm suffered is typically consistent with the alleged defect: chronic dermatitis constitutes a harm inherently compatible with exposure to undisclosed chemical or nano-ingredients.

The most innovative element is found in paragraph 4, which recognises that, in cases characterised by significant scientific or technical complexity, it is

[20] Moritz Becker, Anita Bell, Hannah Meyer, 'Product Risks Today: How the new Product Liability Directive facilitates private enforcement' (*Freshfields*, 1 April 2025) <https://riskandcompliance.freshfields.com/post/102k71h/product-risks-today-how-the-new-product-liability-directive-facilitates-private>.

unreasonable to expect the consumer to discharge an excessive evidentiary burden. Where the claimant adduces sufficient evidence to render defectiveness or causation plausible, the court may presume their existence. This provision is particularly well-suited to nanotechnological products, where scientific knowledge remains in development and critical information continues to be largely controlled by producers. Paragraph 5 safeguards the producer's right to rebut such presumptions; yet the underlying principle is unambiguous: the burden of scientific uncertainty can no longer rest exclusively on the consumer.

Viewed in light of the hypothetical scenario, Article 10 underscores a considerable enhancement of consumer protection under the new regime. Whereas under the previous framework the absence of conclusive scientific evidence would have almost certainly precluded redress, the revised provisions enable the activation of legal presumptions, thereby facilitating consumer access to justice. The Directive effectively redistributes the risks associated with evidentiary uncertainty, requiring producers to provide convincing counter-evidence in order to rebut the presumptions.

In conclusion, Article 10 of the Directive constitutes a decisive step forward in the protection of consumers exposed to risks arising from emerging technologies, such as nanomaterials. It signifies a paradigm shift: scientific uncertainty, which previously served to deny redress, is now employed as a criterion to strengthen consumer protection. By aligning evidentiary rules with the realities of technologically sophisticated markets, the Directive ensures that the advancement of innovation does not occur at the expense of justice for individuals harmed by unsafe products.

5. Conclusion.

The legal treatment of nanotechnologies within the framework of product liability requires a dual perspective: one grounded in regulatory precaution and another rooted in civil liability doctrines. While regulation provides ex ante safeguards by restricting or banning certain nanomaterials, civil liability continues to operate ex post, ensuring redress for harms not prevented by regulatory standards. The dynamic interplay between these two dimensions is particularly evident in light of the most recent amendments introduced by Commission Regulation (EU) 2024/858 to Regulation (EC) No 1223/2009 on cosmetic products.[21]

The regulatory prohibition of specific nanomaterials – such as styrene/acrylates copolymer (nano) and sodium styrene/acrylates copolymer (nano) – and the restrictions imposed on colloidal silver (nano) and hydroxyapatite (nano) are not predicated upon conclusive causal evidence of

[21] European Commission, Official Journal L_202400858 <https://eur-lex.europa.eu/legal-content/IT/TXT/HTML/?uri=OJ:L_202400858>, accessed 6 October 2025; Scientific Committee on Consumer Safety (SCCS), Opinion on Titanium Dioxide (Nano Form), SCCS/1617/20 (2022) <https://health.ec.europa.eu/system/files/2022-08/sccs_o_239.pdf>, accessed 6 October 2025; Normachem, Nuove restrizioni dell'uso di nanomateriali: la cosmetica perde 9 ingredienti (2024) <https://www.normachem.com/it/normachem-informa/nuove-restrizioni-delluso-di-nanomateriali-la-cosmetica-perde-9-ingredienti> accessed 6 October 2025.

harm. Rather, they are grounded in the precautionary principle, reflecting the recognition that preliminary toxicological data on genotoxicity, cytotoxicity, organ toxicity, and nanoparticle bioaccumulation are sufficient to justify preventive measures. This regulatory choice carries significant implications for the assessment of liability in civil law.

First, the definition of "defect" under the EU Product Liability Directive and corresponding national regimes must be read in light of evolving regulatory standards. A product incorporating a nanomaterial that is later banned or restricted by regulation may retrospectively be considered "defective," even if it complied with standards at the time of placing on the market, insofar as consumer expectations of safety are objectively shaped by the regulatory context. Second, the duty to warn – long recognised as a cornerstone of product safety law – acquires heightened relevance in the field of nanotechnologies. The persistent scarcity of toxicological data implies that producers have a positive obligation to continuously monitor emerging scientific knowledge, to update risk assessments, and to provide transparent warnings to consumers and intermediaries. Omission or insufficiency in this regard may constitute a basis for liability, independent of regulatory compliance.

Third, the burden of proof in toxic torts – traditionally placed on the injured party – becomes problematic in the context of nanomaterials, where causation is difficult to establish due to the novelty and complexity of exposure pathways. The application of the precautionary principle at the regulatory level strengthens the argument for a more flexible evidentiary approach in civil proceedings, whether through presumptions of causation, a reversal of the burden of proof, or an expansive interpretation of strict liability. Such adaptations would better reflect the structural epistemic uncertainty inherent to nanotechnologies, while aligning liability doctrines with the preventive rationale underlying EU regulatory action.

In conclusion, the regulation of cosmetic nanomaterials under Regulation (EU) 2024/858 provides a paradigmatic example of how precaution operates as a bridge between product safety regulation and civil liability. It demonstrates that, in a field marked by continuous scientific evolution, liability doctrines must not merely react to proven harm, but must integrate precaution as a guiding interpretative principle. This evolution ensures that producers remain vigilant and proactive in addressing potential risks, thereby aligning civil liability with the broader constitutional objective of safeguarding health and consumer protection in the era of nanotechnology.